Submitter : Mrs. Mary Stewart **Date & Time:** 09/23/2004 07:09:01

Organization : Camelback High School-Athletic Trainer Certified

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

CARE PLAN OVERSIGHT

Athletic Trainers set up a plan for prevention & rehabilitaion on every athlete or person we evaluate. The doctor's have the final approval on everything.
Working as a team charts, plans, and concerns are discussed daily.

IMPACT

Not recognizing Athletic Trainers as part of the health care profession, will only delay quality care and the speedy recovery of patients. Possible even increasing the expense to the insurance companies, due to longer rehabilitaion time.

I encourage CMS to take a closer look at Athletic Training. We are highly educated health care providers trained to perform services and duties needed by the public.

THERAPY - INCIDENT TO

My response to the CMS identifing who they feel is qualified to charge for Evaluation and Therapy services.
I am a Certified & Licensed Athletic Trainer, with my MA degree in Kinesiology. I have been employeed for 6 years in Arizona with the Phoenix Union High School district. I am educated & skilled to prevent, evaluate, manage, and rehabilitate injuries sustained by athletes and active individuals. I do not charge for my services, however, I have worked in physical therapy clinics where I performed the same services that were charged and billed.
CMS deciding who is qualified is ABSURD!. If this issues is passed, you will create a BIGGER shortage of qualified health care professionals, the public needs. I feel CMS needs to educate themselves in my world of ATHLETIC TRAINING. We are highly educated. We are responsible for Olympic, Professional and college sports teams, as well as high school teams. We belong and are part of a doctor's medical staff. They wouldn't put their medical license behind an Athletic Trainer if we weren't educated and experienced.

THERAPY STANDARDS AND REQUIREMENTS

Athletic Trainer's Bachelor of Science college courses:
Anatomy,
Physiology,
Kinesiology,
Exercise Physiology,
Biomechanics,
Modalities,
Athletic Training,
Injury Prevention and Evaluation,
Taping and Bracing Techniques,
Rehabilitaion: Acute and Chronic,
Sports Psychology,
Nutrition,
Neurlolgy,
Training Room Hours: 1800 or more experience.

Then upon graduation ATCs must take a national exam: Pracitcal, written, and simulation. They must PASS ALL 3 SECTIONS.

Most ATC even go back to school and get their MASTER's degree. Becoming a Certified Athletic Trainer is not easy. We are very valuable to the

medical field and it would be ashame for CMS to not realize how much we can help them out.

THERAPY TECHNICAL REVISIONS

Athletic Trainers are medical professionals that know there limits. You wouldn't ask a dentist to work on your back, just because he is a doctor. Every health care provider has their education and skills they are trained to perform. Athletic Trainers are no different. All we are asking is that you recognize our profession and allow us to continue our role as an educated, experience, and qualified medical provider.

Submitter : Timothy Stament **Date & Time:** 09/23/2004 07:09:28

Organization : Timothy Stament

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. I have worked on people that did not get relief/improvement from Physical Therapist treatment. If you limit thier care you will eventully pay more in drug therapy.

CMS-1429-P-3402

Submitter : marlene sokol **Date & Time:** 09/23/2004 07:09:28

Organization : marlene sokol

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We strongly encourage 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 physician's prescription or under their supervision.

Thank you for your help!!!

CMS-1429-P-3403

Submitter : Mr. Michael Mohle' **Date & Time:** 09/23/2004 07:09:30

Organization : Mr. Michael 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-3403-Attach-1.pdf

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

The attachment to this document is not provided because:

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

Submitter : Mrs. Wendy Hart **Date & Time:** 09/23/2004 07:09:59

Organization : UPMC Sports Medicine

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3404-Attach-1.doc

Wendy G. Hart, MS, ATC
University of Pittsburgh Medical Center
Center for Sports Medicine
Pittsburgh, PA 15203

September 22, 2004

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

Re: Therapy – Incident to

Dear Sir/Madam:

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

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

> "Incident to" has, since the inception of the Medicare program, 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 judgement 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 interest 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" 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.

Certified 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 and anatomy, kinesiology/biomechanics, nutrition, acute care of injury and illness, statistics and research design, and exercise physiology. Seventy 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 physician's offices would improperly remove the states' right to license and regulate 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 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 the 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 accompanied the U.S.Olympic Teams to Greece 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 5 K 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,

Wendy G. Hart, MS, ATC

Submitter : **Date & Time:** 09/23/2004 07:09:22

Organization : Marshfield Clinic

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Marshfield Clinic, we would like to briefly comment on the August 5, 2004, Federal Register proposed rule 'Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005'. Marshfield Clinic is a 735 physician, tertiary care, physician-lead multi-specialty group practice, serving patients irrespective of their ability to pay from communities in northern and central Wisconsin.

In the rule, CMS states that changes in the rule are proposed to ensure that that our payment systems are updated to reflect changes in medical practice and the relative value of services. The following comments are submitted in the spirit of assisting CMS to adhere to this high standard.

Issues 1-9

GPCI

Please see attachment for our comments on GPCI

SECTION 303

Please see attachment for our comments on Section 303 and additional Excel spreadsheet

SECTION 611

It is commendable for CMS to provide additional preventive coverage for the Medicare population with the new Initial Preventive Physical Examination. However, it would be helpful to have a few areas addressed in regard to this new service.

Payment for Initial Preventive Physical Examination - basis for payment
The proposed 'G' code includes an electrocardiogram while other preventive services performed on the same day may be separately billable.

In many medical clinics, it is common to have the either the professional component or the global EKG service performed by a Cardiologist and not by the physician providing the E/M service for the patient. Other clinic's may send the patient to a separate facility for the EKG. In either case, it would not be appropriate to allocate the fee and work RVU's associated with the EKG solely to the physician or provider performing the preventive physical exam.

We recommend that the electrocardiogram not be included in the fee for the 'G' code but rather allow for separate reporting on the same day. This will allow for proper fee and work RVU allocation of the services provided.

Payment for Initial Preventive Physical Examination - Evaluation and Management (E/M) Service
When a medically necessary E/M service is performed on the same day as the initial preventive physical exam, the proposed language states that the E/M service may be no greater than a level 2.

In our practice, we have found that many Medicare patients have one or more chronic or acute medical conditions that require management. The history, exam and complexity of these problems may result in the E/M service supporting a level 3 or higher.

We recommend that a medically necessary E/M service performed on the same date as the 'G' code not be limited to a level 2. Rather, the policy should indicate that if a medically necessary E/M service is warranted, the documentation should support the level of service charged.

SECTION 613

We appreciate the proposed coverage for diabetic testing, and we fully support the mandate. We agree with the proposed definition of 'pre-diabetes' and coverage of two diabetes screening tests within a twelve-month period.

We suggest that 'family history of diabetes' be defined as: persons with Type 2 diabetes in one or more first or second-degree relatives. We favor this wider definition due to the increased incidence of obesity in recent years.

CMS-1429-P-3405-Attach-1.pdf

CMS-1429-P-3405-Attach-1.pdf

CMS-1429-P-3405-Attach-1.pdf

CMS-1429-P-3405-Attach-1.pdf

CMS-1429-P-3405-Attach-1.pdf

GPCI

Physician Work, Practice Expense, Medical Office Rents, Equipment and Supplies

Medicare's physician fee schedule, which specifies the amount that Medicare will pay for each physician service, includes adjustments to help ensure that the fees paid in a geographic area appropriately reflect the cost of living in that area and the costs associated with the operation of a practice. This geographic adjustment is a critical component of the physician payment system. An adjustment that is too low can impair beneficiary access to physician services, while one that is too high adds unnecessary financial burdens to Medicare. Although much attention has focused on the Sustainable Growth Rate (SGR) formula used to annually update the physician fee schedule, we believe that there is also reason to be concerned about the appropriateness and accuracy of the geographic adjustments.

Small differences between proxy measurements and the real cost of providing services lead to large differences in payment to physicians throughout the country. We believe that the failure of proxy measurements to reflect the actual cost of providing services has undermined the accuracy of payments for services in different localities nationwide.

Physicians in rural localities and states are acutely aware that Medicare does not cover the cost of providing services to Medicare beneficiaries. Access problems are emerging in those localities. Seniors are finding it harder to find a physician who will see them in a reasonable time frame, so patients are gravitating to community-based systems whose losses are accelerating. In contrast, in some urban high payment localities such as California, Florida, New York and New Jersey, Medicare is the best payor, and access is not a problem.

There is also growing evidence that high utilization of discretionary services that are not associated with better outcomes or reduced patient mortality is affecting the distribution of Medicare payments among payment areas and providers. "The additional utilization in high spending regions is largely devoted to discretionary services that have been demonstrated to be associated with the local supply of physicians and hospital resources. More aggressive patterns of practice observed in higher spending regions offer no benefit in terms of their major aim, which is improving survival." (Fisher, Wennberg, "The Implications of Regional Variations in Medicare Spending," *Annals of Internal Medicine*. 18 Feb. 03).

The validity of the geographic adjustment factors in current use has not been established since the fee schedule was implemented in any published research. We believe a payment system relying on such adjustments must have valid and reliable direct or proxy measures that do not systematically under or overpay physicians in different geographic areas either at single points in time or over time.

In the proposed rule, page 47502, CMS states "We are proposing to revise the work and practice expense GPCIs beginning in 2005 based on updated U.S. Census data and Department of Housing and Urban Development fair market rent data." **We strongly request CMS to undertake nationwide studies to refine, validate, and**

continually improve the accuracy of the data upon which CMS bases its relative value calculations.

The Physician Work GPCI

CMS states in the rule on page 47502, (GPCI) "Indices were developed that measured the relative physician resource cost differences among areas compared to the national average in a 'market basket' of goods."

We believe that payment errors are related to and a function of the miscalculation of relative physician resource cost differences among areas compared to the national average.

On page 47503, Table 6.lists the SPECIFIC OCCUPATION CATEGORIES USED IN DEVELOPMENT OF PHYSICIAN WORK GPCI. The work GPCI is based on a national sample of median hourly earnings of workers in six professional categories: Engineers, mathematicians, teachers, social workers, registered nurses, and writers.

Even though the proxies have been utilized for more than 10 years they have never been validated. The proxies result in the redistribution of Medicare payments across the country, using locality based measurements that bear no proven relationship to the salaries of physicians.

Physician earnings were not used in the calculation of the work adjuster, for the stated reason that physicians derive much of their income from Medicare payments, and an index based on physician earnings would be affected by Medicare's geographic adjustments. The problem with this theoretical construct is that the earnings of non-physicians have nothing to do with the earnings of physicians.

CMS defines physician work as the amount of time, skill, and intensity a physician puts into a patient visit. There is no difference in the work of physicians in different locations regardless of where the work occurs.

We believe that the premise underlying the selection of proxies to establish the relative physician resource cost differences among areas compared to the national average in a market basket of goods is fundamentally flawed.

Physician work payments should not vary by geography. Physician work is physician work, no matter where it occurs. Professor William Hsaio, the architect of the RBRVS payment system and the Physician Payment Review Commission, recommended "...the cost of practice index underlying the geographic multiplier should reflect variation only in the prices of non-physician inputs."

One of the basic premises behind the resource based relative value scale as it was originally conceived is that the relative value of physician work should not vary across geographic regions. Marshfield Clinic concurs with this principle. We understand CMS is obligated to implement the provisions of OBRA '89 that called for 25% of the cost of living variation across regions to be incorporated within the fee schedule. While Marshfield Clinic believes the current method for implementing the congressionally mandated adjustment is flawed, we recognize that any alternative proposals will have both strengths and weaknesses. B**ased on the premise that there should be no adjustment of physician work we request CMS to explore alternative methods of**

making the adjustment for cost of living variation and select the method that produces the least amount of variation across payment localities.

The Practice Expense GPCI

The practice expense GPCI for 2005 amounts to 43.7% of the fee schedule payment. The practice expense is composed of non-physician wages, office space costs, and equipment and supplies. The projected 2004 cost share weights for each component is

Employee wages	18.7%
Rents	12.2%
Equipment and Supplies	12.8%

Employee Wages

Aside from physicians' own time, the largest component of physician practice expenses is non-physician, (i.e., employee) wages. Staff wages are based upon US census data and account for about 40 percent of the practice expenses and a similar share of the practice expense GPCI. To calculate an employee price adjuster, CMS uses the median hourly earnings of four occupational classes found in physician offices: Clerical Workers, Registered nurses, Licensed practical nurses, and medical technicians.

While salary data on these four occupational codes are conveniently available nationwide, much has changed in medicine since the four occupational codes were selected. Non physician staff salaries have migrated towards more highly compensated professional staff. As a proxy measure the data does not include or account for the variations in costs related to the most highly compensated employed staff: physician assistants, administrators, managers, IT programmers, attorneys, accountants, coding specialists, interpreters, Medicare benefits specialists, and pharmacists who are recruited and retained not from a local pools of workers, but from the national market of eligible individuals.

On page 47502 of the rule, CMS indicates that they propose to revise both the work and practice expense GPCIs based on updated US Census and other data. While we support such updates and believe regular updates to be important, we believe the base upon which these updates will be made can and should be improved. To that end, **we request CMS to undertake nationwide studies to refine, validate, and continually improve the proxy measures**.

We believe it is also important to go beyond the median hourly earnings of clerical workers, registered nurses, licensed practical nurses and medical technicians in establishing geographic variation in employee wages. The problem with relying on an assumption that higher wage staff will follow the same relative patterns of wages found in the occupational classes utilized, is that higher wage staff are frequently recruited from larger market areas (multi state and national). We believe the realities associated with recruiting in larger markets undermine the premise that higher end jobs will follow the same relative geographic wage pattern observed with jobs recruited from more localized markets.

We recommend that CMS should undertake studies to validate the census data selected as a measure of employee wages.

Office Rents

There has been insufficient commercial rental data for all geographic areas for CMS to employ commercial rather than residential data to calculate medical office rental costs. As a proxy for medical office rental costs, fair market rental data for residential two bedroom Section 8 apartments was used, produced by the Department of Housing and Urban Development. The base year utilized 1987 data, updated at three-year intervals since 1994. We believe that physicians select medical office sites accessible to and in close proximity to the patients they serve whether this is in a medical complex or on major thoroughfares accessible to patients. The cost of the land is a function of the commercial value of the real estate. Residential real estate is usually situated on acreage in close proximity to amenities or employment. The value of residential real estate is not necessarily an accurate predictor of commercial rental values. **We recommend that CMS commission studies to identify commercial measures of medical office rents rather than employing residential data as proxies.**

Medical Equipment and Supplies

We would also encourage CMS to consider the implications for the RBRVS system of the newer and significant costs associated with development or installation of electronic medical records, computerized order entry systems, decision support, and extended care management services. These new practice costs are not only being encouraged by the federal government, but also have the potential to greatly benefit Medicare beneficiaries. Organizations like Marshfield Clinic and others across the country who seek to improve their quality of care and avoid medical errors are making these investments now, in most cases without public payor support.

The cost inputs of Medical equipment and supplies are assumed by CMS to be bought in a national market so Medicare computes this component of cost the same regardless of where physicians practice. Delivery fees and procurement costs are not a function of the national costs of medical equipment and supplies. We urge CMS to develop measures of the added costs of distribution of such materials to remote areas.

Medical equipment and supply costs are higher when operating in a rural service area. The cost drivers are due primarily to added distribution costs that are not as much a factor in an urban environment.

Contract pricing for supplies is often the same for facilities of similar size (rural or urban). However, volume drives price and smaller facilities often don't have volume needs that allow them to access the best level pricing of many contracts. Suppliers frequently utilize contract volume clauses that provide a price advantage for meeting specified volumes. The volume incentives disadvantage rural facilities because of their relative size. To some degree the volume needs of the Marshfield Clinic system have softened this problem for our organization, but we do have to contend with a very real and substantial additional cost burden. The costs are primarily related to the additional infrastructure and distribution costs that we must bear as a result of operating in a rural environment.

Various inventory and distribution strategies can significantly reduce the overhead costs of a healthcare organization by removing unnecessary infrastructure in the supply chain. JIT (just in time) inventory delivery, "stockless" distribution services, and vendor managed inventory strategies can work well when key suppliers are located in close proximity to the healthcare system. Such strategies are much more challenging and often not practical in the rural environment.

Two years ago, Marshfield Clinic restructured its internal supply distribution system to streamline the fragmented internal supply system that had developed as a result of various acquisitions and major expansions. We had four internal supply warehouses located at each of our major regional hubs in Eau Claire, Wausau, Minocqua, and Marshfield, Wisconsin. We are currently in the process of consolidating to a single warehouse/distribution center, and have already closed the warehouse in Eau Claire. Prior to making a final decision on how to best restructure, we investigated the potential of a distributor managing our inventory and direct delivering department shipments to our facilities, thereby eliminating the infrastructure and overhead costs of managing our internal distribution center. The idea just wasn't practical given our rural dispersion. The distributors that helped us investigate the possibilities were not reassuring once they understood the geographic layout of our system. The Midwest distribution centers for the firms involved are Madison, Wisconsin, St. Paul, Minnesota, and Waukegan, Illinois. The distance between Madison and our major facility in Minocqua, Wisconsin (which includes a surgery center) is over 200 miles. At this distance, regular deliveries and a timely response to an immediate medical supply need weren't practical especially given that we are one of many customers that are served by the Distributor.

Our internal centralized distribution center, while more efficient than having four warehouses, still represents a significant cost burden for our rural system. The distribution center occupies about 25,000 sq ft of an industrial building that we lease in Marshfield, Wisconsin. The annual cost of the lease and basic services for the facility is $187,000. Six staff members at a cost of about $193,000 annually are exclusively dedicated to working the internal supply warehouse.

Another example of a major expense is the courier cost we have to transport individual department shipments from our central warehouse to our facilities across the state. At this point, we have transferred support for about one-half of our facilities to the central distribution center and our courier costs are already $133,527 annually.

In summary Marshfield Clinic incurs substantial added costs in our supply chain as a result of operating in a rural environment. These costs are not reflected in the current pricing noted in the proposed rule. **We urge CMS to develop measures of the added costs of distribution of medical equipment and supplies to remote areas.**

SECTION 303

Twenty physicians practice within the medical oncology department of Marshfield Clinic, serving a very large geographic area of rural Wisconsin. Medicare patients make up 51% of the service volume provided by the oncology department. Our oncology physicians are located in six distinct locations and serve a total of ten communities with on-site consultation and chemotherapy services. Several of these sites are relatively low volume but provide considerable convenience for patients that would otherwise have to travel long distances for cancer treatment.

MMA changes for oncology reimbursement. Prior to January 1, 2004, drugs not paid on a cost or prospective payment basis were paid based on the lower of the actual charge or 95 percent of the average wholesale price (AWP). Section 303 of the MMA provides that most such drugs will be paid at 85 percent of AWP during 2004, and, effective January 1, 2005, they will be paid on the basis of the average sales price (ASP) plus 6 percent payment. Section 303 of the MMA requires CMS to evaluate existing drug administration codes for physician services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption. Specifically, Section 303(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended Social Security Act Section 1848(c)(2) to provide for increased work and practice expense Relative Value Units (RVUs) for those drug administration services typically billed by oncologists (procedure codes 90780-90788, 96400, 96408-96425, 96520, and 96530). MMA Section 303(a)(4) also provided that payments for those drug administration services would receive additional temporary increases of 32% for 2004 and 3% for 2005. These changes were in addition to MMA-mandated across-the-board updates to all physician fee schedule services of 1.5% in both 2004 and 2005.

To determine the impact of MMA changes on oncology reimbursement Marshfield Clinic conducted an internal analysis of Medicare revenues derived from drugs and services provided within the Clinic oncology practice. Our estimates of changes in Medicare revenues for drugs and physician fee schedule services compare payment rates for 2005 with payment rates for 2004 using 2003 Medicare utilization for both years. The attached spreadsheet summarizes the Marshfield Clinic findings.

In 2003 net Medicare revenue for the 20 oncologists was $12,059,000. Of this amount, $10,344,000 was reimbursement for drugs provided, and $1,715,000 was reimbursement for Medicare oncology physician services. Drug expenses were $6,442,000, resulting in $3,902,000 in net earnings for drugs. Direct expenses for physician and staff salary and benefits, supplies and occupancy totaled $5,801,000, coupled with indirect expenses of $1,347,000 resulting in net earnings (loss) for Medicare patients treated by the department for 2004 of **($1,531,000)**.

Using FY 2003 drug and services utilization as a baseline, similar calculations were conducted trending forward reimbursement for the oncology department for FY 2004 and FY 2005. In FY 2004, drug reimbursement declined by $1,490,000 resulting in $2,412,000 in net earnings for drugs; while reimbursement for physician services increased by $1,899,000 as a result of the 1.5% conversion factor and GPCI change, the addition of practice expense RVUs and the 32% transitional payment, and the addition of billing for multiple chemotherapy drug administrations resulting in an estimated net earnings (loss) for Medicare patients treated by the department for 2004 of **($1,122,000)**.

In FY 2005, we project drug reimbursement will decline by $2,838,000 resulting in a net (loss) of $426,000 for drugs; while reimbursement for physician services will decrease by $626,000 as a result of the reduction of the chemotherapy drug administration transitional payment from 32% to 3% resulting in an estimated net earnings (loss) for Medicare patients treated by the department for 2003 of **($4,586,000)**.

We calculate the reduction in drug reimbursement for the oncology department from FY 2003 to FY 2005 as $4,328,000/$10,344,000 or a **41.8% reduction. This is substantially greater than CMS' estimate that "Medicare drug revenues for oncologists would decline by less than 8 percent as a result of policies adopted in this proposed rule." (Fed. Reg. Volume 69, No.150, page 47563)**. We calculate the reduction in the net loss for Medicare physician oncology services from FY 2003 ($5,433,000) to FY2005 ($4,160,000) to be a **23.4% increase** in net Medicare oncology physician reimbursement for services. **We calculate the combined net impact of the drug reimbursement and the service reimbursement changes from FY2003 to FY 2005 to be net reduction in overall oncology reimbursement of 25.3%. This is substantially greater than the combined revenue reduction of 2 percent estimated by CMS on page 47564.**

This is just the Medicare portion of the oncology practice, but we suspect that other commercial payers will follow suit with payment reductions. Assuming no change in utilization, we estimate that Medicare drug revenues for oncologists would decline no less than 25 percent as a result of policies adopted in this proposed rule. We are concerned that patient access for Medicaid, Medicare, and commercial patients would be severely disrupted if such preliminary reimbursement levels were implemented on January 1st. Such cuts, particularly if compounded by private payer reductions, could make it difficult if not impossible for many patients to continue to access cancer care in non-hospital community settings. We are aware that CMS is considering further changes to the payments or codes for drug administration once the AMA's CPT Panel review of this issue is complete. **We recommend that CMS establish new billing codes and related payment amounts to fully cover the costs of all services furnished in the care of Medicare patients with cancer.**

MARSHFIELD CLINIC
ONCOLOGY PRACTICE OVERVIEW AND EFFECT OF MEDICARE CHANGES
Based On 12 Months Ended September 30, 2003
In Thousands
SUMMARY

	MEDICARE DRUG	MEDICARE SERVICES	TOTAL
FISCAL YEAR 2003			
GROSS CHARGES	**18,739**	**6,448**	**25,187**
Gross Charge % of Total	74.4%	25.6%	51.0%
Discount %	44.8%	73.4%	52.1%
NET REVENUE	**10,344**	**1,715**	**12,059**
Net Revenue % of Total	85.7%	14.2%	38.5%
TOTAL DIRECT EXPENSES	**6,442**	**5,801**	**12,243**
Direct Expenses % of Total	52.6%	47.4%	43.3%
NET EARNINGS BEFORE INDIRECT EXPENSES	**3,902**	**-4,086**	**-184**
INDIRECT EXPENSES		1,347	1,347
NET EARNINGS (LOSS)	**3,902**	**(5,433)**	**(1,531)**
FISCAL YEAR 2004			
2004 Reimbursement Changes			
Reimbursement/Fees (1)	-1,490	53	-1,437
Chemo Administration (2)		1,700	1,700
Multiple Push Billing - Net (3)		146	146
	-1,490	**1,899**	**409**
NET EARNINGS (LOSS) 2004	**2,412**	**(3,534)**	**(1,122)**
FISCAL YEAR 2005			
Reimbursement Changes 2005			
Chemo Administration (4)		-626	-626
ASP Reimbursement (Acquisition + 6%)	-2,838		-2,838
	-2,838	**-626**	**-3,464**
NET EARNINGS (LOSS) 2005	**(426)**	**(4,160)**	**(4,586)**

Notes:
Fiscal Year 2005 Assumes No CPT Coding Changes or GPCI Adjustments From 2004

(1) Estimated effect of decrease in Oncology drug reimbursement, effect of 1/01/04 conversion factor change of 1.5% and GPCI change. All cost are held constant and no fee increase is applied to Non Medicare charges.
(2) Estimated effect of the addition of practice expense RVUs (with the resultant increased reimbursement) and the 32% transitional payment.
(3) Estimated net effect of billing changes regarding not billing for CPT 99211 and billing for multiple chemotherapy drug administrations.
(4) Estimated effect of decrease in chemo therapy drug administration transitional payment from 32% to 3%

CMS-1429-P-3406

Submitter : Mrs. Irina Shulkin **Date & Time:** 09/23/2004 07:09:27

Organization : Children Hospital Los Angeles

Category : Individual

Issue Areas/Comments

Issues 20-29

IMPACT

Chiropractors adjustment is not in any way complete without improved muscular support and money, time and health might be wasted otherwise. I also see excellent result on HIV patient with energy massage??as it reduces her anxiety and increases her ability to fight HIV with improvement in her immune system and power of will to live ?.mother of three. Commonly known lower back, neck and shoulder pain can not be treated (or should not be treated) with medication only since massage is first thing I do, advocate and apply to my friends, family and coworkers in these cases.

THERAPY - INCIDENT TO

massage therapy

THERAPY STANDARDS AND REQUIREMENTS

Massage therapy is extremely important modality that must be accessible and affordable to USA citizens.

CMS-1429-P-3407

Submitter : Mrs. Pamela Mohle' **Date & Time:** 09/23/2004 07:09:25

Organization : Mrs. Pamela 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-3407-Attach-1.pdf

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

The attachment to this document is not provided because:

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

Submitter : Mrs. JANET YARD **Date & Time:** 09/23/2004 07:09:36

Organization : SINGH

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The list of drugs that CMS posted the first ASP figures, over 80% of those drugs our practice would be by paying more than what we would be reimbursed. No good business would purchase a product for more that what they would get reimbursed for. Also, as far as the practice expense, Chemo regimens given today are far more complex. Special tubing, needles, filters, gloves, gowns, cleansers are needed.
Patients have to be monitored more frequently, IV pumps are needed to administer chemos. Hepatic pumps and cadd pumps are very time consuming. Waste bins and pickup are very costly to a practice. Emergency drugs and oxygen must be kept on hand. The list goes on and on. A lot of items that are needed to administer chemo are not even billable, they are considered supplies.

If these cuts in payment are enacted, we will be forced to send our Medicare patients to the hospital. This will be such an inconvenience to patients. Our staff even helps procure rides for our patients through various sources. We also employ a full time person to help patients apply for assistance for drugs if they have no insurance or limited beneifts. We accept Medcaid and no insurance patients, we will no longer be able to do this. We are not asking CMS to supplement these patients, but with the cuts our practice will be forced to also cut in all areas.

Issues 1-9

PRACTICE EXPENSE

The practice expense for an oncology clinic is astronomical. There are so man items that are needed to administer chemo. OCN nurse, supplies, special tubing, needles, some chemos require special filters, iv pumps. Mixing the drugs alone, special gowns, gloves, hoods (that need to be maintained and inspected), special waste bins need to be ordered, and a toxic waste management service pickup for the bins to be disposed. Blankets, pillows, snacks are offered to patients, sometimes chemo takes up to 8 hours to adminster. Patient teaching and educational materials are made available. Shredders are needed, analyzers for the blood machines, special controls for the blood machine. Special cleansers are need for the chemo hoods and chemo clinic. Spill kits kept on hand, emergency drugs also kept on hand. Not to mention charts to be made a nurse co-ordinator to answer patient calls. Maplpractice to be paid, rent, utilites, taxes the list goes on and on. Health insurance is offered to employees.
If these cuts do take place the office will be forced to drastically modify in all areas.

Submitter : Mr. Jeff Hall **Date & Time:** 09/23/2004 07:09:28

Organization : FSMTA

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please do not pass this policy that allows physical therapists service. Patients often need other health care providers with a physicians prescription.

CMS-1429-P-3410

Submitter : Dr. Kathleen Swanik **Date & Time:** 09/23/2004 07:09:25

Organization : Temple University

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

please see attached document

CMS-1429-P-3410-Attach-1.doc

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

Kathleen Swanik, PhD, ATC
Assistant Professor
Temple University
129 Pearson Hall
Department of Kinesiology
Philadelphia, PA 19122

September 17, 2004

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

For the past 10 years I have worked as an athletic training educator teaching students the knowledge and skills to future certified athletic trainers. During this time I have witnessed the academic and clinical reform our profession has undergone and can say that our curriculum and clinical experiences, even at the Baccalaureate level, employ our students with the tools necessary to be successful with this population. Having worked closely with and in other health care curriculums I would challenge that the foundation on the aging athlete provided to athletic training students would meet or in most cases exceed other curriculums. To imply that as a profession ATC's are not qualified to provide quality health care services to our active, senior population is insulting. By denying our senior population access to qualified health care providers would be unfortunate, and could cause a host of problems.

The United States is experiencing a shortage of qualified health care providers, coupled with a rising physically active population. This proposal would exacerbate this shortage by eliminating quality providers of these important services. In turn, it would reduce the quality of health care for our Medicare patients, increase the costs associated with this service and place an undue burden on the health care system. Most importantly, it would reduce the quality of life for our aging athletes. This alone is a liability to our health care system.

Consider the impact of this decision on rural Medicare patients, who would experience delays in receiving care. These delays could hinder the patient's recovery and/or increase recovery time,

which would ultimately add to the medical expenditures of Medicare. In many cases, physicians would be forced to perform more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician's ability to provide the best possible patient care.

Physicians have utilized "incident to" to provide services to patients since the inception of the Medicare program in 1965. A physician has the right to delegate the care of his or her patients to trained individuals (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.***

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

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

Sincerely,

Kathleen Swanik, PhD, ATC
Assistant Professor

Submitter : Mr. Larry Grollman **Date & Time:** 09/23/2004 07:09:52

Organization : Univ. of Pittsburgh Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

please see attached file

CMS-1429-P-3411-Attach-1.doc

Larry J. Grollman, MBA, ATC
Director
Athletic Training & Development
UPMC Sports Medicine
3200 S. Water Street
Pittsburgh, PA 15203

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,

Larry J. Grollman, MBA, ATC

CMS-1429-P-3412

Submitter : Mr. Kevin Arp **Date & Time:** 09/23/2004 07:09:49

Organization : Healthsouth Rehabilitation

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To whom it may concern,
This comment is in regards to the attempt of Medicare to eliminate to respect, value, and integrity of the Postion of Certified Athletic Trainer. In order to become a Certified Athletic Trainer one must accomplish 4 years of College level education from a National Accredidated Programm, pass a very in-depth national exam, and become liscensed in the state in which they practice. The amount of experience, education, and training of an Athletic Trainer Certified out-weighs any other curriculum of only two years at a Community College (i.e. PTA's). This note is not to bash any other organization or credential. This note is to ask for the respect that the profession of Athletic Trainer Certified so truly deserves. We are Professionals, we are capable, we are willing, and we are real. Let us work with you in allowing for the best and unconditional treatment of patients. Thank you for your time.

Submitter : Ms. Kathleen Downes **Date & Time:** 09/23/2004 07:09:44

Organization : Hellerwork Mt. Shasta

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a Hellerwork Structural Integrationist I do not directly treat diseases, but have provided alignment and relief from structurally distorting tension that has resulted in the body healing itself, often of conditions that have baffled allopathic medicine. For example, one of my clients, blind from birth, had lost feeling in her reading hand. The neurology specialists said there was nothing they could do for her and her life was stopped. She came to me and I worked out the lifelong tension in her neck, arm, shoulder and hand, and feeling returned, allowing her to return to productive life. I have had a doctor report that passing on my exercises allowed her to get patients off chronic pain medications.

Not all conditions are cured by drugs or surgery. It doesn't take a Physical Therapist to do my work with the soft tissues, non-invasive, with little down side or risk associated. It seems the future of health care, not something to take out of play now when we are nearly at the end of resources to provide relief from painful conditions that most people experience at some time in life. This work is very efficient at effecting the source of problems, not just covering up the problem by managing the symptoms with the added risk of side effects from medications.

Please consider allowing qualified massage and Structural Integration professionals to work and be paid along side the medical field that could use our support and skills in their practices.

CMS-1429-P-3414

Submitter : Mrs. Jeanette Phillips **Date & Time:** 09/23/2004 07:09:08

Organization : Mrs. Jeanette Phillips

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly DISAGREE with the proposal to allow only PT's to work with and under physicians. I think this would be detrimental to the clients health and their right to choose what type of therapy works best for them. I believe that there are MANY types of therapies that will help with any given illness or injury and to force a client to receive a type of therapy that may not be in their best interest and to force them not to see a therapist that could help them is very ignorant on your part. We live in a day and age where clients and patients are educated and should have control over their medical treatments. Not only would this bill hurt thousands of patients, but it would also hurt thousands of therapists. There are so many therapaies out there that are less expensive and more effective than physical therapy. Someday you may be in a position where you will want the right to choose which therapy works best for you. After all, you live in your body, only you can experience what works for you. It is ludicrous to believe that one therapy can help every single person and injury. Thank you for your consideration on this very important matter

CMS-1429-P-3415

Submitter : Ms. Lucy Gonzales-Romero **Date & Time:** 09/23/2004 07:09:13

Organization : Upledger Institute

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I oppose limiting health care provision coverage exclusively to Physical Therapists. It is my belief all QUALIFIED, TRAINED AND CERTIFIED alternative health therapists should be allowed to provide health care under a doctor's prescription or care. The Sept. 27th issue of Newsweek highlights the body-mind connection. Throughout this issue there is supporting data of therapies outside the realm of physical therapy which enhance well-being and facilitate recovery. The proven costs to the medical provider are far less than exclusive traditional allopathic treatment.

Submitter : Mr. Matthew Munjoy **Date & Time:** 09/23/2004 07:09:10

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 !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 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.
?h 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.
?h 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.
?h 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 past summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

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

Matthew Munjoy ATC/L
3661 N. Union Street

Decatur, IL 62526

Submitter : Mr. Wayne Hoff **Date & Time:** 09/23/2004 07:09:07

Organization : IAHP

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Don't pass this policy whereby a physician can only refer
"incident to" services to physical therapists.

I work with a number of elderly persons who find my therapy effective and affordable. Please allow all qualified health care providers, like myself, to provide services to patients with a physicians prescription or under their supervision.

Submitter : Miss. Marielle Gatenby **Date & Time:** 09/23/2004 07:09:25

Organization : Ridgeview Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 21, 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 physicians 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.

As an Athletic Trainer, I work closely with physicians and their patients. Because of my skills, training and education, I am able to provide injury care, rehabilitation and prevention. Being able to do this at the same time the patient sees the physician provides continuity to their care. It strengthens the message of self care responsibility because their physician is right there supporting them. If that patient needs further rehabilitation, they are referred on for that service.

Billing incident to allows patients to receive more information and early intervention regarding their health care from qualified allied health providers, (Athletic Trainers). Working with physicians in this matter is not new to athletic trainers. Athletic Trainers provide physicians and their patients with value added services that reduce overall health care costs by treating underlying causes early, thereby reducing unnecessary rehab treatments later. Athletic trainers are able to help patients recognized the benefits of physical therapy and encourage them to continue treatment so that self care prevention measures are followed through.
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.
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,
Marielle Gatenby, MA, ATC/R
4234 90 street- Glencoe, MN 55336

Submitter : Mr. John Smith **Date & Time:** 09/23/2004 07:09:58

Organization : University of Delaware

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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:
? 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.
? 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.
? Curtailing to whom the physician can delegate ?incident to? procedures will result in physicians performing more of these routine treatments themselves.
? 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, 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.
? 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 deterrent.
John J. Smith, Athletic Trainer University of Delaware

Submitter : Mary Rydesky **Date & Time:** 09/23/2004 07:09:52

Organization : Mary Rydesky

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please accept this note of opposition. You are limiting health care access without regard to the range of specialists who might be called upon to see patients. By setting a limitation, you will decrease quality of care and potentially drive up costs (limiting competition.) Today, when we try to control costs by pushing tasks down to the lower levels (such as tasks previously assigned to RNs pushing down to LVNs, and then to PCAs), it does not seem prudent to set policy that prevents matching the appropriate provider and level of care with the needs of the patient.

Submitter : Mrs. Alice Buckendahl **Date & Time:** 09/23/2004 07:09:57

Organization : AMTA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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-3422

Submitter : Ms. Deborah Hendricks **Date & Time:** 09/23/2004 07:09:09

Organization : Oncology Nurses Society

Category : Nurse

Issue Areas/Comments

Issues 1-9

PRACTICE EXPENSE

I have practiced as an RN certified in Oncology for 12 years. It is a constant struggle to provide the care my patients need and help my employer control cost. Frequently we are at risk because of deficits in reimbursement from Medicare for administration of medication and supplies. I understand that the tax payer cannot afford to pay uncontrolled amounts of money and that we are in a crisis but making it even more difficult for patients to get their care is not the answer. Even though the amt paid for adminstration and expense has been increased, the cut in drug reimbursement will literally kill community based cancer centers which in effect will literally kill many patients. Many of my patients are not physically able to make the trip that would be required to go to a cancer center in a larger city. Many could not afford the cost of travel or do not have a way to travel the distance even if they are physically able. Your attention to these issues NOW is essential. We are told that it is not the intent of Congress to limit access to care but in effect that is what will happen. Thank you for your time.

Submitter : Ms. Stephanie Bandy **Date & Time:** 09/23/2004 07:09:47

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 !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 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.
?h 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.
?h 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.
?h 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 past summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.

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

Stephanie Bandy
1135 W. Wood, 908

Decatur, IL 62522

Submitter : Mrs. Renee Baumgartner **Date & Time:** 09/23/2004 07:09:59

Organization : Earth Touch, LLC

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I think other Health Care Providers other than PT's should be allowed to provide care/services related to physician's patients. I provide CranioSacral Therapy and SomatoEmotional Release Therapy as a Certified Massage Therapist. I believe I am as valuable to a patients' care as a PT.

Submitter : Mrs. Tonda Allen **Date & Time:** 09/23/2004 07:09:17

Organization : Licensed Massage Therapist

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I beg you to Not pass this policy whereby a physiciancan 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. Thank you for your consideration, I have almost 700 patients and 95% are referrals from physicians who rely on me and trust in my care. These same patients did not get better with physical therapy. Thanks again, Tonda G. Allen, LMT - Tonda's Healing Hands

CMS-1429-P-3426

Submitter : Mrs. Irene O'Loughlin **Date & Time:** 09/23/2004 07:09:00

Organization : The Women's International Suport Environment

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am writing in reference to the Medicare Post PaymentAusits: Common Sense Doesn't Apply.

I work as the billing and accounts manager at The Women's International Support Environment. The clients we get here come to us to get their mastectomy and lymphedema supplies that they need. Most of them do not have an immediate way to come to us for thier supplies. They have to rely on others to bring them in for their fittings and supplies.

It does not make any sense that Medicare would do an audit on the prescriptions and have us refund the payments back to medicare. After we would supply the items and then have to refund the money this would not be cost effective.

In the meantime the customer wears the items and we are out of the money and our business would most likely go under. We would not be able to stay open with this type of audit being done.

As of now we are to under stand that the prescription is good for one year from when it's written. As I mentioned many of our customers are not able to come into our facility to get their supplies for more than a month or they forget; and then come in much later on.

Please think again about doing these audits or make it known that the prescriptions are not accepted after 30 days. This will make this very confusing to our customers no matter what age they are. This can also lower the quality of life for the patients if they were not able get their supplies as they need.

Submitter : Mr. Daniel Alviso **Date & Time:** 09/23/2004 07:09:24

Organization : Mr. Daniel Alviso

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am in strong support of the $0.05 per unit fee to cover the costs and services related to furnishing blood clotting factor to Medicare hemophilia patients. Although I am only a consumer (a hemophiliac), the fee would definitely help me and other members of the bleeding disorder community in that health care providers (not hospitals) are responsible for a large part of our program funding. Moreover, it is imperative that there be a strong economic incentive to provide the necessary quality of care to people with bleeding disorders.

CMS-1429-P-3428

Submitter : **Date & Time:** 09/23/2004 07:09:05

Organization :

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist working in the NYC area and am strongly in favor of preserving the services provided by physical therapists. Encroachment of our field by non-professionals will severly devalue the credibility of the physical therapy profession. I agree with the position of CMS to limit the services provided in physicians offices concerning physical therapy services only be provided by licensed physical therapy professionals. Thank you for your consideration of my comments in this manner. Thank you, James V. Cooper, Lutheran Medical Center.

Issues 20-29

THERAPY - INCIDENT TO

I am a Physical Therapist practicing for 23 years in New York State. I practice in a Hospital and outpatient setting. I am writng to respond to the "Therapy-Incident To" .The purpose of my comments is to comment on the August 5 proposed rule on "Revisions to Payment Policies Under the physician Fee schedule for 2005".
Cms has proposed that individulas who furnish outpatient physical therapy services in physicians offices should be licensed Physical Therapists or Physical Therapy Assistants under the supervision of Physical Therapists. The above individuals should be graduates of accredited professional Physical Therapist education program.
As a practionier I feel this is so important because I have treated patients in the past who have recived services from "unlicensed people". The patients did not improve, were dissatisified, sought additional treatment, resulting in increased costs to the health care system. There is a reason why professionals are licensed to practice, and that reason is to assure the public that when you seek help you are receiving from a competent individual. In the interest of public safety, cost containment, and ethical practice; I support CMS' proposal.
I thank you in advance for your support and consideration of this issue.

CMS-1429-P-3429

Submitter : Dr. John Buckley **Date & Time:** 09/23/2004 07:09:39

Organization : University Orthopaedic Clinic, P.C.

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.

"Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon the physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter : Mr. Nathan Tellers **Date & Time:** 09/23/2004 07:09:18

Organization : Ridgeview Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

September 21, 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 physicians 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 physicians choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.

As an Athletic Trainer, I work closely with physicians and their patients. Because of my skills, training and education, I am able to provide injury care, rehabilitation and prevention. Being able to do this at the same time the patient sees the physician provides continuity to their care. It strengthens the message of self care responsibility because their physician is right there supporting them. If that patient needs further rehabilitation, they are referred on for that service.

Billing incident to allows patients to receive more information and early intervention regarding their health care from qualified allied health providers, (Athletic Trainers). Working with physicians in this matter is not new to athletic trainers. Athletic Trainers provide physicians and their patients with value added services that reduce overall health care costs by treating underlying causes early, thereby reducing unnecessary rehab treatments later. Athletic trainers are able to help patients recognized the benefits of physical therapy and encourage them to continue treatment so that self care prevention measures are followed through.
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.
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,
Nathan Tellers 8865 Tellers Road Chaska, MN 55318

CMS-1429-P-3431

Submitter : Dr. Mary Pat Moyer **Date & Time:** 09/23/2004 07:09:13

Organization : SanAntonio Austin Life Science Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

We respectfully request that CMS designate San Antonio as a separate payment area (distinct locality), or consider the San Antonio-Austin metroplex as an identified as a state region, and recalculate the artificially low GPCI values for this locality using current statistical and demographic data in order to bring San Antonio to a payment level comparable to the payment levels of other equivalent metropolitan areas in Texas. (please see attachment)

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

The attachment to this document is not provided because:

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

CMS-1429-P-3432

Submitter : **Date & Time:** 09/23/2004 07:09:29

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1429-P-3432-Attach-1.doc

September 23, 2004

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

Re: Therapy – Incident To

To Whom It May Concern:

I am writing to express my concerns about the recent proposal that would limit providers of "incident to" services in physician offices and clinics. There are a number of reasons to keep this from being adopted, which I will elaborate on in the letter to emphasize why it is imperative that this does not become a law.

"Incident to" provides the physician the right to delegate the provision of services to Medicare patients by qualified individuals who are under the "direct supervision" of said physician, and it has been this way since the inception of the Medicare program in 1965. Trusting our physicians to make the choice of qualified providers, such as Certified Athletic Trainers who are fully trained in protocols to be administrated, is not only prudent, but is respectful to their judgment on how to best serve the Medicare patients in the most effective and judicious manner possible. There have never been restrictions placed upon physicians regarding whom he/she can utilize to provide any "incident to" services. The physicians are fully aware that they would be legally responsible for all care ordered, and in every situation are making these decisions to help expedite car to shorten recovery times and lower expenses for the Medicare patients.

If all other providers are eliminated for incident to care, the physicians might be forced to do all the care themselves. In many cases, this would only decrease the quality of care by taking them away from much more needed services for the Medicare population. Athletic trainers alone could easily help by providing immediate, qualifies care while under the supervision of the physicians. Independent research has demonstrated that the quality of services provided by Certified Athletic Trainers is equal to the quality of services provided by the physical therapist. Athletic trainers are highly educated with a Bachelor's Degree and in 70% of all cases, a Master's Degree from an accredited college or university. Foundation courses include: human anatomy and physiology, kinesiology/biomechanics, therapeutic modalities, nutrition, injury recognition, exercise physiology, evaluation and treatment, and rehabilitation of injuries. 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 education programs in Athletic Training (JRC-AT). The great majority of practitioners who hold advanced degrees are comparable to other health care professionals including registered nurses, physical therapists, occupational therapists, speech therapist, and other mid-level health care practitioners.

It is apparent that to only allow physical therapists, occupational therapists, and speech therapists to be providers for “incident to” outpatient services would improperly provide these groups exclusive rights to Medicare reimbursement. Mandating this would improperly remove the States’ rights to license and/or regulate the allied health care professions deemed qualified, safe, and appropriate to provide health care services. The Ohio Physical Therapy, Occupational Therapy, and Athletic Training Boards set our State Practice Act and it does allow for Certified/Licensed Athletic Trainers to provide rehabilitation. Athletic trainers are recognized and reimbursed for their therapy by a number of insurance companies, including The Ohio Bureau of Worker’s Compensation.

CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” the physician’s office visit. It appears that this is being done to appease the interests of a single professional group who wants to establish themselves as the sole providers of therapy services; especially when CMS has offered no evidence that there is a problem with the status quo that would require fixing.

Certified Athletic Trainers are working with physically active populations throughout the United States of America. Athletic Trainers bring the same high quality care to our seniors. Just because they are on Medicare does not mean that they are not active. They still have to function in their home with daily activities, as well as their fitness activities.

Please consider these facts when voting on these proposed changes, because the changes are not necessary, and do not reflect well on the care our elderly deserve and should expect from our government.

Sincerely,

Maureen L. Gurley, ATC/L

Submitter : Ms. Pam Sunderland **Date & Time:** 09/23/2004 07:09:29

Organization : Massage Therapy

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 send/refer "incident to" services to a physical therapist. All qualified health personel should be allowed to provide services under a physicians supervision and/or perscription. We are a very benificial component of the care and healing process of the client /patient in the hospital, clinic, office, & home care facilities. Again, we beg you not to pass this policy. Thank you. :)

CMS-1429-P-3434

Submitter : Mr. brian kane **Date & Time:** 09/23/2004 07:09:53

Organization : NATA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

see attached letter

CMS-1429-P-3434-Attach-1.doc

Brian Kane

Rowan University Student Athletic Trainer

Currently I am an Athletic training student at Rowan University. Recently I was made aware of the "Incident to" conflict. Personally I find it inconceiablely and preposterous to stake a claim that PTs and OT's are the only people with the adequate knowledge to provide outpatient therapy and rehabilitation. To claim and athletic trainer can treat and fully rehabilitate a trimaleolar fracture or dislocated shoulder from the initial trauma until full functional return to competition in the collegiate and professional sports setting, yet they are incapable of doing so for a woman who turned her ankle at work in a rehab clinic is absurd. Athletic trainers proactively earn an education in; safety first aid and prevention, kinesiology, exercise nutrition, exercise prescription, exercise physiology, pathology and evaluation of the spine and extremities, therapeutic modalities, advanced emergency care, therapeutic exercise, anatomy and physiology, chemistry, and biology, not to mention the plethora of clinical experiences and observational experiences daily. Athletic trainers earn an education and scope of practice that ensures they are expert providers of outpatient therapy services.

CMS-1429-P-3435

Submitter : Dr. Barbara Murray **Date & Time:** 09/23/2004 07:09:15

Organization : Medicare Recipient

Category : Individual

Issue Areas/Comments

Issues 1-9

GPCI

PLEASE MODIFY THE SANTA CRUZ COUNTY GPCI LOCALITY (CURRENTLY 99) TO REFLECT THE TRUE PRACTICE COSTS HERE, WHICH ARE OVER THE 5% THRESHOLD OVER THE NATIONAL AVERAGE. The situation in Santa Cruz County, California is in crisis because the RATE for the GPCI is WRONG here! Santa Cruz was assigned to Locality 99, which no longer reflects true medical practice costs in this area. Santa Cruz exceeds the 5% threshold (105% rule) over the national 1.00 average! Doctors are leaving the county or refuse to take Medicare because reimbursement is so far below their costs. I have lost several doctors because of this (they opted out of the system) and I am not able to receive the care I should near where I live. I have to drive an hour and a half to see one of my doctors, who is willing to see me on Medicare. Please help me, as a consumer, to receive the medical care I need in my own community. Neighboring Santa Clara County, Locality 9, receives 25.1% for the same medical services. Their practice expenses are more on a par with those of Santa Cruz County. Please rectify this situation by CHANGING THE GPSI LOCALITY GROUPING FOR SANTA CRUZ COUNTY.
Thank you for considering my concerns. Barbara Murray, Medicare Recipient

CMS-1429-P-3436

Submitter : Ms. stephanie strange **Date & Time:** 09/23/2004 07:09:41

Organization : t.trevor singh md, pc

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

with the proposed changes to the 2005 fee schedule for physician, it would greatly impact oncologist and the reimbursement on oncology drugs. we understand that the cost of chemotherapy drugs are very expensive, but the cost comes from the drug companies. we have to pay the high cost of buying the drugs to administer to the patients. if our fee are cut we could not bear the cost of obtaining the drugs for the patients. this plan would be detremental to all onoclogist office that provide chemotherapy services in there office, along with the employee's and their families

CMS-1429-P-3437

Submitter : Dr. Denise Wise **Date & Time:** 09/23/2004 07:09:21

Organization : The College of St. Scholastica

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly support CMS 's proposed requirement that physical therapists working in a physician's office be graduates of accredited professional physical therapist programs, and most importantly, be licensed to practice physical therapy. In the interest of consumer protection, I believe this is the most prudent and ethical avenue to take. My father, a Medicare beneficiary, recently fractured his ankle and required rehabilitation. Receiving rehabilitation (exercise, instruction with limited weight bearing, edema/swelling reduction, and mobility exercises) by a physical therapist who is knowledgeable about the human body, how it works and functions, and how complicating factors such as hypertension affect his tolerance is a relief to me. Knowing that he received care by the most appropriately educated and licensed provider allowed me to rest easy. As a physical therapist myself, I would expect that anyone receiving physical therapy is truly being seen by an educated, licensed physical therapist. If the person providing the service is not, then I believe there is no truth in advertising. In order to protect consumers, provide accurate information, and accountable and regulated services, it is imperative CMS's proposed requirements that physical therapy services provided in a physician's office incident to a physician's professional services must be furnished by a physical therapist who is a graduate of an accredited program and is licensed to practice physical therapy.

CMS-1429-P-3438

Submitter : Michael Radomski **Date & Time:** 09/23/2004 07:09:12

Organization : Michael Radomski

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am writing in support of CMS-1429-P. The 'Incident To' provision in the proposed regulation ensures that patients recieving physical therapy will be treated by educated, trained and licensed physical therapists. We would never allow an individual without a medical degree to practice medicine, and we should not allow individuals without a physical therapy education to provide physical therapy care to patients.

In todays educational institutions, all accredited physical therapy programs are at a masters degree level with most progressing to a doctoral level. The extent of the schooling and internships require approximately 8 years to complete. After graduating, each individual must pass a state licensing examination prior to practicing in the field of physical therapy. This is the education level that each patient recieving therapy expects and deserves. It is this level of education and understanding that allows physical therapy to be benificial, and most importantly, safe for the patient.

With the passing of this proposal, It will ensure each physical therapy patient will recieve the highest quality care from the most highly trained professionals.

Thank you for your consideration in this matter.
Michael T. Radomski MPT

CMS-1429-P-3439

Submitter : Jon VonderHaar **Date & Time:** 09/23/2004 07:09:17

Organization : Jon VonderHaar

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am writing to express my concern over the recent proposal that would limit the providers of 'incident to' services in physician clinics. This proposal has been interpreted as both a 'clarification' of existing rules and a proposed rule change. The Centers for Medicare and Medicaid Services, in proposing this change, have not offered any basis or justification for this change in policy. Nor does CMS explain why its interpretation of section 1862(a)(20) has changed. The August 5 Federal Register announcement of a 'clarification' does not provide adequate notification of a change in agency policies, and therefore may not comply with the Administrative Procedure Act.

Longstanding CMS policy requires that all 'incident to' services be provided under the supervision of a physician. 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. The guidelines proposed in the August 5, 2004 Federal Register would have therapy services provided 'incident to' physician care be provided or supervised by a therapist. This is inconsistent with the 'incident to' rules that require that the physician supervise the service.

In many cases, the change to 'incident to' services reimbursement would render the physician unable to provide his or her patients with comprehensive, accessible health care. If physicians are no longer allowed to utilize a variety of qualified health care professionals working 'incident to' their services, it is likely the patient will suffer delays in health care, incur greater costs and face a lack of local and immediate treatment options. Many rural Medicare patients would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient. Such delays would also hinder the patient's recovery and/or increase recovery time, which would ultimately increase the cost of care.

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 determine who is or is not qualified to provide a particular service. A physician has the right to delegate the care of his or her patients to trained individuals (including registered kinesiotherapists) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician's choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient. It is imperative that physicians continue to make these determinations in the best interests of their patients.

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. Such a change in policy could be construed as an unprecedented attempt by CMS to grant exclusivity as providers of therapy services. And as practice issues tend to be driven by reimbursement, mandating that only certain practitioners may provide 'incident to' care in physicians' offices could, de facto, improperly remove the states' right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

This CMS recommendation can only serve as a deterrent to health care access. It is neither necessary nor advantageous for CMS to institute the changes proposed.

Submitter : **Date & Time:** 09/23/2004 07:09:46

Organization : Marshfield Clinic

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

On behalf of Marshfield Clinic, I would like to briefly comment on the August 5, 2004, Federal Register proposed rule "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005." Marshfield Clinic is a 735 physician, tertiary care, physician-lead multi-specialty group practice, serving patients irrespective of their ability to pay from communities in northern and central Wisconsin.

In the rule, CMS states that changes in the rule are proposed "to ensure that that our payment systems are updated to reflect changes in medical practice and the relative value of services." The following comments are submitted in the spirit of assisting CMS to adhere to this high standard.

Please see attachment for our comments on Section 305

Issues 20-29

DIAGNOSTIC PSYCHOLOGICAL TESTS

We appreciate this proposed change in supervision requirements for psychology and neuropsychology services, and agree that this change will significantly reduce delays in testing, diagnosis, and treatment of patients.

CMS-1429-P-3440-Attach-1.pdf

CMS-1429-P-3440-Attach-1.pdf

SECTION 305

We appreciate that your proposal includes consideration of a dispensing fee for inhalation drugs. We agree that allowing a pharmacy to provide a 90-day supply of the drugs rather than limiting it to a 30-day supply will reduce the overall amount of time spent in dispensing the drug. The recent change allowing a pharmacy to fill the prescription approximately 5 days prior to the end of the current usage period may also eliminate the need to use an overnight delivery service.

The cost of compounding and handling the drugs varies, but we believe an average cost would be about $15.00. This would include the direct labor costs and the indirect costs associated with drug preparation. The cost of delivering a 90-day supply would be higher than the cost of delivering a 30-day supply. We believe the average mailing cost would be about $5.00. The delivery cost could be as high as $8.00 if we used a shipping service.

Submitter : Vivien Slabe **Date & Time:** 09/23/2004 07:09:23

Organization : American Massage Therapy Association

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY STANDARDS AND REQUIREMENTS

Doctor's should be able to refer patients to Massage Therapists, rather than be restricted to other just medical proffessionals

CMS-1429-P-3442

Submitter : **Date & Time:** 09/23/2004 07:09:01

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

i feel the cuts in medicare are going to cause private practice oncology physicians to send their patients to the hospital for chemotherapy treatment instead of treating them in the office...in the long run medicare is going to be spending more money by paying high costs at the hospital...

Submitter : Dr. Thomas Dreisinger **Date & Time:** 09/23/2004 07:09:03

Organization : Dynamic Back & Neck Clinics

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

GENERAL

GENERAL

Re: ?Therapy-Incident To?

To Whom This Matter Concerns:

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

Dynamic Back & Neck Clinics -- a multidisciplinary practice that employs physical therapists, physical therapy assistants, as well as other health care professionals providing "Therapy-Incident To" -- believes that the physician is best equipped to make such medical decisions, and that such freedom serves the best interests of the patient.

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

CMS-1429-P-3443-Attach-1.doc

September 23, 2004

Re: “Therapy-Incident To”

To Whom This Matter Concerns:

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

Dynamic Back & Neck Clinics -- a multidisciplinary practice that employs physical therapists, physical therapy assistants, as well as other health care professionals providing "Therapy-Incident To" -- believes that the physician is best equipped to make such medical decisions, and that such freedom serves the best interests of the patient.

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

Thomas E. (Ted) Dreisinger, PhD, FACSM
Director of Research and Development
Dynamic Back & Neck Clinics
1800 W. Big Beaver Road - Suite 150
Troy, MI 48084
Phone: 248-649-2323
Fax: 248-649-2324
Email: ted@dynamicrehab.com

CMS-1429-P-3444

Submitter : Mrs. Debra Vierling **Date & Time:** 09/23/2004 07:09:27

Organization : Nat'l Assn of Nurse Mass. Ther., ABMP

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 therpists. All qualified health care providers- whether nurse massage therapists, massage therapists, athletics trainers, physical therapists, or others- should be allowed to provide services to patients with a physician's prescription or under his/her supervision.

Submitter : Mrs. Shannon Scrivner,LMT,CMMMT **Date & Time:** 09/23/2004 07:09:45

Organization : American Medical Massage Therapy Assoc.

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a Certified Master Medical Massage Therapist I ask that you not pass this policy whereby a physician can only refer to "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. I feel that this policy would take the patient's and Physician's right to choose the Therapist or Health Care provider that they feel would be of most benefit. I appreciate your time and consideration in this matter.
Shannon Scrivner, LMT,CMMMT,NCTMB
1st Vice President Colorado State Chapter of the
American Medical Massage Therapy Association

CMS-1429-P-3446

Submitter : Mr. raymond herradura **Date & Time:** 09/23/2004 08:09:04

Organization : self

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I belive this would be totally unfair for people on medicare. Most would have to go without services. There is more and more taken away from this class of population. I thought the president wanted to protect the needs for these people in need of services under medicare.
More and more services are taken away. At the present the cost of medications are rising and if were not for medicare's assistance many would go without, and it is the same situation. It has been proven right down to the micro stimulators that massage is benifical and can have or speed up healing. Please do not let this happen. Do not take away anymore services for medicare recipients. STOP IT .. MASSAGE HELPS!!
MAHALO

Submitter : Mr. Gary Cheney **Date & Time:** 09/23/2004 08:09:36

Organization : American Prosthetics

Category : Other Health Care Professional

Issue Areas/Comments

Issues 10-19

SECTION 302

See attached file

CMS-1429-P-3447-Attach-1.doc

Section 302- *Clinical Conditions for Coverage of Durable Medical Equipment (DME)*

Proposed coverage criteria requiring a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to obtain an order for a prosthesis or orthosis will place a burden on the Medicare beneficiary, in many instances delay care, and the additional examination charge will increase health care costs. Routinely physicians depend upon the orthotist or prosthetist for their clinical opinion when developing appropriate prescription criteria. Mandating this face-to-face encounter for orthotic and prosthetic orders will not in any way accomplish the intended goals of enhancing quality and reducing fraud.

The statutory language contained within the Medicare Modernization Act (MMA) requires CMS to establish standards governing the coverage of Durable Medical Equipment (DME). The MMA instructs CMS to develop types or classes of DME that requires a face-to-face encounter by identifying those areas of DME where there has been "*a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation"*. Orthotic and prosthetic services have not been identified or linked with any recurring or on-going incidents of fraud or abuse.

Currently orthotics and prosthetics are excluded from certain coverage criteria such as CMN's. This exclusion differentiates DME and orthotics and prosthetics. This differentiation acknowledges the professional nature of orthotic and prosthetic services. Further example of this differentiation is the fact that orthotists and prosthetists clinical records may be included as supporting documentation when determining medical necessity. CMS Manual System, Pub.100-8; Medicare Program Integrity Manual, Chapter 5, 5.2 and 5.3.3; and CMS Ruling 93-1 affirms the following when addressing documentation in the patients medical record:

"The patient's medical record is not limited to the physician's records. It may include hospital, nursing home, or home health agency records and records from other professionals including, but not limited to, nurses, physical and occupational therapists, prosthetists, and orthotists."

The orthotic and prosthetic profession has demonstrated the ability to work in partnership with the physician in developing an appropriate treatment plan as well as maintaining appropriate documentation in their clinical records. Taking into consideration the statutory language addresses DME only, as well as the fact that orthotic and prosthetic providers have not been linked to fraud and abuse, and recognizing that current CMS standards distinguish between DME and the orthotic and prosthetic profession, I believe orthotic and prosthetic services should be exempt from this face-to-face examination requirement.

CMS-1429-P-3448

Submitter : Ms. Karen Malinowski **Date & Time:** 09/23/2004 08:09:08

Organization : Lutheran Medical Center

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

My name is Karen Malinowski and I am a Physical Therapist working in Brooklyn, NY. I am also the District Chairperson for the Brooklyn/Staten District of the NY Chapter of the American Physical Therapy Association. I wish to comment on the August 5th proposed rule on "Revisions to Payment Policies Under the Physician Fee Schedule." I strongly feel that there should be requirements for individuals who furnish outpatient physical therapy services in physician's offices. Anyone providing these services should be required to have graduated from an accredited professional physical therapy education programs. Interventions should be represented and reimbursed as physical therapy only when performed by a licensed physical therapist or by a physical therapist assistant under the supervision of a licensed physical therapist. I STRONGLY oppose the use of the unqualified personnel to provide services described and billed as physical therapy services. Lastly, I'd like to thank you for your consideration of my comments.

Sincerely,
Karen V. Malinowski

CMS-1429-P-3449

Submitter : **Date & Time:** 09/23/2004 08:09:37

Organization :

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly DISAGREE with the proposal to allow only PT's to work with and under physician. Not only would this bill affect thousands of patients, but it would also hurt thousands of therapists. There are so many therapies out there that are less expensive and more effective than physical therapy. Massage therapists have an important role in our health care.

Submitter : Mr. Trey O'Brien **Date & Time:** 09/23/2004 08:09:43

Organization : Advanced Rehabilitation

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY STANDARDS AND REQUIREMENTS

I am very much in favor of this measure as it certainly is taking the appropriate steps to ensure that patients are receiving therapeutic/rehabilitative care from professionals that are thoroughly trained to provide said care. While ATC's, rehabilitative nurses, and kinesiologists have their place in the health fields, they do not receive the training that PT's, OT's, and ST's have received in the rehabilitative sense. To be fair, therapists do not receive the same amount of on-the-field training that ATC's do and that should be left to the profession that would provide the best care for the patients/athletes. PT's, OT's, and ST's are able to provide the utmost quality of care for pt's in need of rehabilitation across the wide range of injuries, diseases, deficits, and conditions that occur to all ages. I think that it is very important to rid all ambiguity to give patients a clear understanding as to who is most skilled to provide the best care. Thank you for your consideration in this matter.

Submitter : Mrs. Katherine Warnecke **Date & Time:** 09/23/2004 08:09:07

Organization : Mrs. Katherine Warnecke

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

9/23/2004

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

Katherine L. Warnecke
972 Cliff Brook Lane
Columbus, OH 43228
Warnecke.24@osu.edu

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

Dear Mr. McClellan,

I am a second year student in physical therapy school at The Ohio State University. This is a master?s level degree that requires 2.5 years of classroom and clinical experience after first obtaining an undergraduate degree and multiple prerequisites. Upon my graduation, I plan on working with our aging population in the area of stroke rehabilitation and other brain injuries.

The purpose of my letter is to comment on the ?Incident to? component of the proposed revisions. I feel strongly that physical therapists and physical therapist assistants under the supervision of a physical therapist are the only providers with the education and experience necessary to provide safe and effective physical therapy care. It is imperative that all physical therapists, regardless of practice setting, graduate from an accredited professional physical therapy program and also obtain state licensure.

As a current student, I know firsthand the rigorous education and training that students of physical therapy receive. Allowing unlicensed personnel to provide physical therapy care in a physician?s office or any other practice setting is a dangerous proposition. Thank you for your continued efforts to protect and promote the health and well-being of our nation.

Thank you for your consideration of my comments!

Sincerely,

Katherine L. Warnecke

CMS-1429-P-3452

Submitter : Mr. David Herrington **Date & Time:** 09/23/2004 08:09:44

Organization : Mississippi Physical Therapy Association

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Dear Sir,
I fully support the changes outlined in CMS 1429-P regading physical therapy procedures being perfromed in a physician's office. The educational level should be the same no matter where the patient is receiving the services. Physical therapists and physical therapist assistants under the supervision of physical therapists are the only practitioners who have the education and training to furnish physical therapy services. Unqualified personnel should NOT be providing physical therapy services and certinly our tax dollars should not be spent on services that unqualified personnel provide.
Taking this one step further, Medicare dollars are being spent on "aide" services being provided in a home yet the patient is billed for physical therapy services under the physicians provider number. The physcial therapy service is not being provided by a qualified physical therapist, but someone who " massages or walks" a patient and it is billed as physical therapy procedure using the physician provider number. These are abuses and misleading services to the patients, and money being wasted on nonqualified personnel.
I support these changes and welcome any changes that will assure that services provided to the Medicare patients is of quality and performed by qualified personnel.

Respectfuly,
David Herrington
MPTA

Submitter : Ms. Mia Turpel, LMT **Date & Time:** 09/23/2004 08:09:15

Organization : Hearts of Healing Education

Category : Other Health Care Provider

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

We beg you to NOT pass this policy whereby a physician can only refer"incident to" services to physical therapists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision. I am a licensed massage therapist and I have seen the tremendous benefits in relief of pain, increase in range of movement, and increased quality of life to patients who experience the benefits of massage therapy. Sincerely, Mia Turpel LMT Columbus, Ohio

Submitter : Mr. Jay Zanger **Date & Time:** 09/23/2004 08:09:52

Organization : Mr. Jay Zanger

Category : Health Care Provider/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

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 : Mr. Jay Zanger **Date & Time:** 09/23/2004 08:09:52

Organization : Mr. Jay Zanger

Category : Health Care Provider/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)
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Submitter : Ms. Beth Umba **Date & Time:** 09/23/2004 08:09:31

Organization : Body Maintenance Massage and Bodywork

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Issues 20-29

THERAPY TECHNICAL REVISIONS

I strongly wish to be able to work with or for medical doctors as a massage therapist.

CMS-1429-P-3456

Submitter : Mr. Stephen D. McMillan **Date & Time:** 09/23/2004 08:09:58

Organization : AstraZeneca Pharmaceuticals LP

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1429-P-3456-Attach-1.pdf

Stephen D. McMillan
Director Government Reimbursement
Federal Government Affairs

Tel 202 350 5577
Fax 202 350 5510

September 24, 2004

By Hand Delivery
Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca"), respectfully submits the following comments pertaining to the Medicare Part B payment rates for drugs and biologicals as set forth in the Proposed Rule (the "Proposed Rule") on Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 47488 (August 5, 2004). The Proposed Rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA")[1] that concern the payment of drugs and physician fee schedule payments for the calendar year 2005.

AstraZeneca is one of the world's leading pharmaceutical companies, with a strong commitment to discovering, developing, and delivering innovative pharmaceutical solutions for debilitating diseases and improving patient lives. In keeping with this commitment, AstraZeneca manufactures numerous drugs, including hormonal therapies for women with certain types of

[1] Pub. L. No. 108-173, 117 Stat. 2066 (2003).

breast cancer and men with prostate cancer, antibiotics used to treat infections, and inhalation drugs for people suffering from asthma. Several of AstraZeneca's products are reimbursed under Medicare Part B and, as such, we are keenly interested in the changes to the drug payment methodology mandated by MMA. It is important to AstraZeneca that CMS develop and implement these changes in a manner that ensures patient access to needed therapies, promotes fairness and equity for physicians, and is consistent with the delivery of care in cost-efficient, patient-friendly settings.

As we have in connection with other MMA-related changes, AstraZeneca seeks to work cooperatively with CMS and, towards that end, respectfully submits comments to the Proposed Rule for CMS's consideration. In brief, our comments address the following areas:

1. Issues associated with the reporting and calculation of Average Sales Price ("ASP");
2. Issues associated with the OIG's determination of widely available market price ("WAMP");
3. Payment issues associated with one of AstraZeneca's products, Pulmicort Respules®; and
4. Issues related to physician reimbursement for drug administration services.

I. ASP Calculation and Reporting Obligations

A. Reporting Issues

1. Formal Guidance Regarding ASP Reporting Requirements

AstraZeneca requests that CMS issue further guidance concerning ASP reporting requirements as soon as possible. Additional ASP regulatory guidance will help assure that this system is developed rationally, equitably, consistently, and without significant administrative disruption. We support CMS's recent revision of the 12-month rolling average methodology to require the use of a ratio methodology that promotes maximum "smoothness" in ASP pricing data over time. The final rule addressed our concern, previously expressed in comments and during various Open Door Forums, that the MMA estimation methodology for price concessions would result in ASP "spikes." AstraZeneca applauds CMS for soliciting input from interested parties and proactively addressing this issue before the October 30, 2004 third quarter submission deadline for ASP data.

Despite this important step forward, additional guidance on ASP reporting and calculation requirements is still needed. In addition to requesting that CMS revise the 12-month rolling average methodology, manufacturers, including AstraZeneca, have commented on the need for further clarification on other technical ASP data reporting and calculation requirements, including the following:

- Defining key terms (e.g., "manufacturer");
- Addressing what process manufacturers should follow to revise corrected ASPs;
- The reporting of alternative data when ASP calculations result in zeros or negative ASPs;
- Permitting the inclusion or exclusion of territories based on a manufacturer's normal accounting practices;
- Clarifying ASP reporting requirements under licensing arrangements (e.g., clarifying that the licensee (the entity responsible for all sales arrangements and pricing information) and not the manufacturer (the entity with legal title to and/or possessions of the NDC number) is responsible for ASP reporting);
- Reconsidering CMS's position that returns must be included in the calculation of ASP;
- Clarifying that CMS will set two different payment rates for drugs based on each ASP reported in the case of a product that is available in two strengths, where each has a different billing and payment code;
- Adopting the existing Medicaid nominal price definition for ASP calculations and clarifying what data, if any, manufacturers are required to report on nominal price sales (e.g., limiting the data to aggregate dollar value and units of such sales);
- Providing more information on the treatment of administrative fees in ASP calculations;
- Clarifying how certain Best Price-exempt transactions should be "excluded" for purposes of the ASP calculation; and
- Incorporating into the ASP regulations that manufacturers can use reasonable assumptions in calculating ASP in the absence of specific guidance in the regulations or the MMA.

Our comments to the Interim Final Rule on ASP reporting, 69 Fed. Reg. 17935 (April 6, 2004) [CMS-1380-IFC], contain a full discussion of these issues and AstraZeneca's recommendations.

2. Drugs Subject to ASP Calculation and Reporting

In addition to the issues noted above, AstraZeneca also requests guidance concerning which drugs are subject to ASP calculation and reporting. The ASP reporting requirements apply to "certain drugs and biologicals covered under Part B [of Medicare] that are paid under sections 1842 (o)(1)(D), 1847A and 1881(b)(13)(A)(ii) of the [Social Security] Act."[2] There continues to be some uncertainty regarding the applicability of this requirement. For instance, it is not always clear whether a drug is covered by Medicare Part B (*e.g.*, where products are billed under miscellaneous codes), and manufacturers cannot readily determine whether payment for a covered drug is based on specified sections of the Social Security Act ("SSA" or "the Act"). Manufacturer reporting obligations are also unclear in the case of discontinued products or for those products that have been sold to another manufacturer. In light of these difficulties, we recommend that CMS create a process—similar to that created under the Medicaid drug rebate program—whereby manufacturers can phase out or cease ASP reporting in certain circumstances. Manufacturers could cease reporting, for example, upon the sale of their product to another manufacturer with control over its pricing, or if CMS receives notice of the product's final sale. At the very least, to avoid confusion and to allow manufacturers to meet their ASP reporting obligations, we request that CMS (1) provide a comprehensive list of reimbursable drugs, identified by NDC codes, and (2) a list of drugs, or categories of drugs, that are *not* subject to ASP reporting.[3] CMS also should implement a process whereby manufacturers can appeal CMS's inclusion of certain drugs on a comprehensive list of drugs subject to ASP reporting requirements. In addition, for new drugs, CMS should issue clear instructions that identify the specific events or circumstances that will trigger ASP-reporting obligations for a drug potentially covered by Part B.

II. Public Comment on the Application of WAMP

A. Guidance on WAMP Methodology

AstraZeneca urges CMS to provide further insight into the application of widely available market price ("WAMP") data as it relates to the ASP methodology. As you know, WAMP is

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2 42 C.F.R. § 414.800.

3 CMS provided lists of drugs potentially subject to ASP reporting on its website, but that list included a number of products that clearly are not covered under Medicare Part B, products for which coverage is unclear, and a number of discontinued products. CMS should refine this list based on input from manufacturers, consistent with the principles described in these comments.

defined by MMA as the price that a prudent physician or supplier would pay for a drug or biological. Section 1847A(d)(1) of the Act states that "The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate."[4] Based upon these studies, MMA permits the Office of the Inspector General ("OIG") to make comparisons of WAMP data with the ASP and the Medicaid AMP for a specific item. Significantly, Section 1847A(d)(3) of the Act allows the Secretary to disregard the ASP for a drug or biological to the extent that it exceeds the WAMP or AMP by 5%. In addition, if the OIG finds that the ASP exceeds the WAMP or AMP by the statutory percentage, the OIG must inform the Secretary and the Secretary must substitute a payment amount equal to the lesser of the WAMP or 103 percent of the AMP.

Given the OIG's role in this process, and the impact its involvement could have on Part B reimbursement rates, AstraZeneca urges CMS to solicit comments from affected parties on appropriate data collection efforts. In particular, AstraZeneca urges CMS to follow Congressional mandates and implement appropriate safeguards to ensure the reliability and timeliness of data used to make WAMP determinations.

Moreover, because data from the OIG could be used to support reimbursement below the originally calculated ASP, AstraZeneca urges CMS to provide further guidance on the WAMP methodology. Specifically, we support PhRMA's request for guidance on how the OIG will compare ASP to WAMP, and its discussion of key issues such as whether the OIG will recommend a substitute payment rate of WAMP or 103% of AMP if the ASP exceeds WAMP or AMP in only one quarter and how a drug can qualify for the normal payment rate again once its payment is reduced to the lesser of WAMP or 103% of AMP. This information is particularly necessary since MMA broadly prohibits judicial review of payment determinations under the Medicare statute.

B. WAMP Process for Multiple Drugs Represented by Single J-Code

In addition to general information related to the WAMP survey process, AstraZeneca seeks clear guidance on how WAMP determinations will be made in the case of multiple drugs

4 SSA, § 1847A(d)(1).

represented by a single J-Code. MMA provides that WAMP calculations will be drug-specific.[5] Further, OIG WAMP survey data may show that an adjustment for one drug in a J-Code may be warranted because the ASP for that drug exceeds the WAMP or AMP by the applicable threshold percentage but that the ASPs of other drugs in the J-Code do not warrant adjustments.

It remains unclear how CMS will use the WAMP process in such cases. Consider, for example, Drug A and Drug B, both with an assigned J-code of J1000. Drug A's reported ASP data may warrant a substitute payment rate of WAMP or 103% of AMP based on findings from the OIG's WAMP survey process but Drug B may not. In such case, CMS could adjust the payment rate for the J-Code by taking the weighted average of Drug A's WAMP or 103% of AMP and Drug B's ASP. Alternatively, CMS could adjust the payment rate by substituting WAMP or 103% of AMP for each drug in the J-Code. AstraZeneca urges CMS to carefully evaluate each of these options to ensure that WAMP adjustments are consistently applied in the manner required under MMA.

III. Pulmicort Respules®

One of the products that AstraZeneca manufactures is Pulmicort Respules, a budesonide inhalation suspension used in conjunction with nebulizers. Currently, CMS reimbursement policy does not distinguish between the FDA-approved budesonide inhalation suspension and pharmacy compounded budesonide solution. AstraZeneca requests that CMS reconsider this approach and make a distinction between these two products. Our concern is that patients receiving compounded budesonide solution are not receiving a product with the same quality as the commercially pre-mixed suspension. We recommend that CMS only reimburse for compounded budesonide with documentation showing the medical necessity of this customized product.

Such a policy would ensure that the patient is receiving a safe product. Specifically, if Medicare will only pay for the commercially premixed product, patients will then have access to a product that has been subject to FDA-testing and approval. Patients, therefore, can be more certain of the product's safety, efficacy and quality. A product that is compounded in the pharmacy, in contrast, is more likely to vary from prescription to prescription due to human error and the variance in components used to make the solution. Additionally, this reimbursement policy that AstraZeneca is recommending will take into account the additional costs associated

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5 *See e.g.*, SSA § 1847A ("The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage.")

with the FDA-approval process that the manufacturers of the commercially premixed products have incurred.

IV. Physician Reimbursement for Drug Administration Services

AstraZeneca joins PhRMA in supporting the prompt issuance of any revisions or additional codes for physician administration services to ensure continuity and improved patient access to needed medicines. We further support PhRMA's request that CMS announce and adopt detailed plans to analyze any shift in utilization patterns once the payment changes for drugs and drug administration required by MMA go into effect.

* * * * *

AstraZeneca appreciates this opportunity to comment on the Proposed Rule. We hope our recommendations will be useful to CMS as it seeks to develop and implement the new Medicare Part B reimbursement methodologies. AstraZeneca welcomes any comments or questions you may have on these matters. If you have any questions or need additional information, please contact me at (202) 289-2577.

Sincerely,

Stephen D. McMillan

Submitter : Mr. Mark de Bruin **Date & Time:** 09/23/2004 08:09:58

Organization : Rite Aid Corporation

Category : Other Health Care Provider

Issue Areas/Comments

Issues 10-19

SECTION 302

This section of the proposed regulation would create new standards for coverage of DMEPOS, including drugs and supplies. Because we 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 reducing our costs of participation. As a supplier, we 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.

RITE AID 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.

CMS-1429-P-3457-Attach-1.doc

September 23, 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 to May Concern:

Rite Aid Corporation (RITE AID) 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.

There are currently 3,369 Rite Aid pharmacies operating in twenty-eight (28) states and the District of Columbia. We are providers of Medicare Part B drugs and DME to Medicare beneficiaries.

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 we 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 reducing our costs of participation. As a supplier, we 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.

RITE AID 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.

Section 303 – Payment Reform for Covered Outpatient Drugs and Biologicals

RITE AID 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 our 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

RITE AID continues to be concerned about the use of the ASP methodology to reimburse pharmacies for Part B drugs, and the potential lack of certainly in the reimbursement amounts that will be paid to us for these drugs, many of which are expensive. RITE AID is concerned about the impact of the ASP reimbursement methodology on our ability to provide Part B pharmacy services to Medicare beneficiaries. ASP is an inappropriate reimbursement metric for various reasons. For example:

ASP Represents Manufacturer's Revenues, Not Purchasing Costs: Any changes to the Medicare Part B payment system must ensure that we 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 our 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 us 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 our 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 even account for the fact that we purchase drugs through wholesalers, who provide a valuable service in drug distribution.. However, these costs are additive to the ASP. Because CMS is not collecting data from wholesalers, it cannot calculate the markup that wholesalers add

to the ultimate cost that they charge the providers, including pharmacies. As a result, a significant part of the 6 percent markup that pharmacies are allowed to add onto the ASP is eroded by the costs added by wholesalers, for their services.

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 RITE AID, will have to absorb these manufacturers' price increases because ASP will always lag behind. This further erodes the value of the 6 percent add on over ASP. To mitigate this problem, CMS should allow for an inflation factor on top of the 6 percent amount allowed under the statute. This will at least assure that some of the value of the 6 percent 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 6 percent to the ASP for a drug will not likely even allow us to recoup its purchasing costs for the drug. In fact, given the combination of the lack of accounting for the wholesaler's markup, the outdated data used to calculate ASP, and the class of trade pricing inequalities, it is highly unlikely that we 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 the various purchasers, and the distribution of these purchasers in the marketplace, the addition of six percent to the ASP may not make us 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 may force us 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 us. 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 byus, not the Medicare program, and reflect business decisions that we make regarding the use of our 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:

- We 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, RITE AID urges that these types of transactions be excluded from the calculated 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. RITE AID 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 RITE AID 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 we will have little financial incentive to dispense a generic when we will only be paid the ASP plus 6 percent. Given that generics are generally less expensive than brands, we have 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 us for supplying Part B drugs, such as pharmacist salary increases, rent, utilities, computer expenses, and other increasing overhead costs. We recommend that Medical CPI be the basis for the increase. The agency should publish the updated supplying fee amount for the next year as part of its physician fee schedule rule.

RITE AID will not be in a position to determine whether the proposed $10 supplying fee is an adequate supplying fee, given that we 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 November or December.

Even if we do believe that we can financially participate in the program, the level of uncertainty surrounding future Medicare reimbursement rates – even in 2005 –causes concern. Because some of these Part B products are very expensive, and thus have significant inventory carrying costs, we will have to determine whether the return on investment is worth providing these drugs. We 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.

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.

Issues Relating to Billing Requirements

RITE AID 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.

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 this reason, CMS needs to establish an efficient, on-line 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 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:** RITE AID appreciate 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 be that the prescription can be filled and billed based solely on a verbal order from a physician as well. 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). Encouraging 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):** RITE AID 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:** RITE AID 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:** RITE AID 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 this 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 it has been rejected and/or paid and then crossed over to another payer. However, the remittance advice may fail to indicate the payer to which the claim has been sent. For the purposes of assuring appropriate payment from third party source, Medicare DMERCs must indicate on the remittance advice the identity of the third party payer that received

the claim.

Section 305 – Payment for Inhalation Drugs (Nebulizer Drugs)

RITE AID 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 markup on these products, almost all of which have a lower-cost generic base, may not provide enough margin to allow us 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.

RITE AID 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 on line 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.

While we agree that certain chronic use medications should be provided in larger quantities, we urge caution with the practices of some suppliers that automatically ship additional product (i.e. 90 day supply) to individuals without knowing whether their current supply is exhausted. We might argue that allowances for a smaller renewal quantity (i.e. 60 days supply) might be more cost effective in the long run because it reduces the potential that these large quantities of medications might be wasted.

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

Sincerely,

Mark de Bruin, R.Ph.
Senior Vice President, Pharmacy Services

Submitter : Ms. Jackie Voulgaris **Date & Time:** 09/23/2004 08:09:49

Organization : NCBTMB, FSMTA

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

CMS-1429-P-3459

Submitter : Ms. Lisa Grossman **Date & Time:** 09/23/2004 08:09:44

Organization : Ms. Lisa Grossman

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am in support of not allowing the practice to continue where physicians may bill out physical therapy services under the incident to system. I am also an athletic trainer, and a physical therapist. I do not think it is appropriate that athletic trainers are treating medicare patients. The athletic training profession is designed to treat acute athletic injuries. I believe the "incident to" billing allows physicians to bill for services using personnel that are not qualified to provide the service. Thank you for allowing public input on this very important issue.

CMS-1429-P-3460

Submitter : Mrs. Jennifer Rocco **Date & Time:** 09/23/2004 08:09:38

Organization : Cambridge Physical Therapy Center

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

As a licensed physical therapist, I am appalled at the notion that anyone other than a licensed physical therapist or licensed physical therapist assistant would even be considered to be able to perform physical therapy services, or "rehabilitation" as many physicians and other health care providers like to say to get around physical therapists, and be reimbursed for such services. Most physicians are not physical therapists, and therefore they are not qualified to pass judgment on the needs of physical therapy for patients. That is why there are licensed physical therapists. Even more so, aides, athletic trainers, exercise physiologists, personal trainers, etc., are not qualified to perform physical therapy services, or physical medicine and rehabilitation services as per the AMA CPT Code guidelines. Athletic trainers are educated in assessing immediate injuries limited to athletic competitions. Their education does not cover extensively the rehabilitation of injuries and doesn't cover at all the rehabilitation of neurological, cardiac and other non-athletic related injuries. To allow them the full scope of being reimbursed for performing what is all reality, physical therapy services, no matter what anyone likes to call it, is doing a grave disservice to patients and insurance companies. Insurance costs are on the rise too much as it is already, and to allow unqualified and non-licensed personnel to perform such services will only cost the insurance companies more and even further increase insurance and healthcare costs to patients. To comment on aides, personal trainers, exercise physiologists, etc., being utilized to perform physical therapy services, is a waste of time as they don't have any formal education or training in "rehabilitating" patients that need physical therapy services. I speak from direct knowledge also as my husband was an athletic trainer and he agrees that an athletic trainers place is not in a clinical setting unless under the direct supervision of a licensed physical therapist. He feels patients are at increased risk for further injury or damage when being "rehabilitated" by an athletic trainer that is not supervised by a licensed physical therapist because they do not have the proper training, as he did not have, in rehabilitating patients with physical therapy services.

To allow anyone other than licensed physical therapists and licensed physical therapist assistants under the supervision of a licensed physical therapist, to perform, no matter what phrase or terminology is used, physical therapy services, is a danger to patients. Insurance companies and patient pocket books will also feel the effects as costs will rise due to faulty and increased treatments being performed, and healthcare costs will continue to rise in a day and age when we all need them to lower and become more affordable for all.

Thank you for allowing me to comment on this issue.

Respectfully,

Jennifer L. Rocco, LPT

Submitter : Mrs. Larisa Chapman **Date & Time:** 09/23/2004 08:09:55

Organization : Self-employed Massage Therapist

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 : Mrs. Jamie Kohrn **Date & Time:** 09/23/2004 08:09:44

Organization : Mrs. Jamie Kohrn

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 therpists. All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under their supervision.

Submitter : Ms. Katherine Jones **Date & Time:** 09/23/2004 08:09:03

Organization : Allergy Partners

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The proposed 2005 physician payment rate for IVIG of 106% of the volume-weighted average of the manufacturer's most recently reported average sales prices aggregated across all product brands is unacceptable. IVIG products administered depend on the patient symptoms and may require the infusion of a more costly product in order to achieve the desired effect and prevent a systemic reaction. The costs currently reimbursed allow for the cost of the ancillary items (i.e. IV administration set, sterile water for reconstitution, syringes, etc.) to be included in the charge. If the 106% was implemented, an additional charge would need to be implemented to cover these ancillary items.

Thank you for your consideration

Submitter : Mrs. Carol R. Cauthen **Date & Time:** 09/23/2004 08:09:50

Organization : Touching You, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Mastectomy products should be excluded from the face-to-face prescription requirements. The effects of a mastectomy are permanent. Based on that fact, mastectomy products are necessary throughout the life of recipient. Medicare already has parameters in place for the dispensation of these items. These parameters should be sufficient. The face-to-face prescription requirement would place an undue burden on all affected Medicare beneficiaries, physicians, suppliers and Medicare as well. The face-to-face prescription requirement will require the recipient the inconvenience of a visit to the physician, the physician's time for the visit and Medicare's payment for the visit.

CMS-1429-P-3465

Submitter : Dr. Hugh Boston, Jr. **Date & Time:** 09/23/2004 08:09:21

Organization : University Orthopaedic Clinic, P.C.

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

CMS-1429-P-3466

Submitter : Mr. Jeffrey Dehn **Date & Time:** 09/23/2004 08:09:36

Organization : HealthQuest Physical Therapy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

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

I would like to strongly support the CMS proposal that individuals who provide physical therapy services in physicians? offices must be graduates of an accredited program. As a recent graduate of a professional program, I am very aware of the differential diagnosis, pathology, and contraindications required to practice safely. The educational requirement of a professional program in physical therapy can not be taught ?on the job?.

I appreciate your time in reading this letter and allowing me to voice my concern.

Sincerely,

Jeffrey P. Dehn, MPT

CMS-1429-P-3467

Submitter : Dr. darin bush **Date & Time:** 09/23/2004 08:09:40

Organization : institute for nonsurgical orthopedics

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

As a physician in a busy chronic pain clinic, i see a lot of people who are being treated for pain. some of these patiens only receive meds, some only pt, others only surgery. in our practice, we combine manipulation, injection therapy, massage therapy, and physical therapy modalities, as well as prescription medications for the overall care of these patients. in our practice, it is licensed massage therapists who combine traditional massage therapy with cranial-sacral therapy to care for part of the musculoskelatal, and neuromuscular systems of the patients. they have skills which are beyond that of the physical therapists who have seen these patients...from the neuromusculat reeducation standpoint. it is nurses and licensed medical assistants who provide physical therapy modalities such as ultrasound, stimulation, heat, and vaso to the patients. as medical assistants, their training and expertise is in treating this aspect of the patient. the physicans provide the medication, injection, medical, as well as manipulative treatments to the patient. physical therapists are great at what they do.....they provide therapy, strengthening, retraining, and education to the patients. we send our patients to physical therapists for this reason. the assistants and manual therapists who work in our office provide their services as a physical therapy modality. hands on is a modality, not one that should be limited to a physical therapist. that is like sayiong that only a pulmonologist should be allowed to listen to a patients lungs. that only a pulmonologist should be able to treat coughs, athma, and allergies. this is not only limiting a patients resources, but it is limiting the practitioners ability to best care for their patients. therapy modlaities are a part of all medical assistant training programs, and massage therapy programs. these people are well vesrsed in what they do, and are more than qualitfied to provide hterapy for patients who it is appropriate for. physical therapists are an integral part of the overall treatmnent and care of the aging and injured patient, but they are not the only part of it, nor should it be made a law that they are the only part of it. i welcome anyone to come visit our practice. our patients get the best care possible, they get better the quickest, and have the best quality of life and care.....why.....?...because it is a team approach.....
I encourage you to benefit, not hurt the future of medicine, by vetoing this proposed policy. we are all here for the patient, why should a policy be made which prevents the patient the most avenues of care?

CMS-1429-P-3468

Submitter : **Date & Time:** 09/23/2004 08:09:06

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Physicians who are liable for the actions of third party billers must be dealt with fairly. Those physicians can easily be left out of the loop and face punitive action for investigating an employers/third party billers billing practices. I would request that it be mandated that physicians receive monthly reviews of account billed in their names.

Submitter : Mr. Walt Gainey **Date & Time:** 09/23/2004 08:09:11

Organization : Rock Hill High School

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Walter C. Gainey,A.T.,C.
320 West Springdale Road
Rock Hill, SC 29730

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 addition, I am greatly disturbed by the unfortunate accusations by the APTA regarding the health care of Medicare patients in the United States. The APTA position concerning individuals who provide said healthcare, comes on the heels of a failed attempt to limit certain healthcare practioners, namely certifice athletic trainers, from providing proper physician directed treatment and rehabilitation in the clinical setting. The APTA claims that these individiuals do not have the eductation necessary to provide said services. This accusation is totally inaccurate. Certified athletic trainers have extensive training in Anatomy & Physiology, Kinesiology, Human Kinetics and Motor Learning, as well as Exericise Physiology.

Interestingly enough, A.T.,C.'s are taught proper rehabilitation techniques, by physical therapists in the college curriculum programs. Secondly, many rehabilitation clinces employ physical therapy assistants, which provide much of the treatment and rehabilitation services for patients. This is billed under the guise of an acutal physical therapists.

A.T.,C's are highly qualified people who perform treatment and rehabilitative services for any patient. To regard our profession as uneducated in this field is totally without merit.

Sincerely,

Walter C. Gainey, A.T.,C.
Rock Hill High School

CMS-1429-P-3469-Attach-1.doc

Walter C. Gainey, A.T.,C.
320 West Springdale Road
Rock Hill, SC 29730

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,

Walter C. Gainey, A.T.,C.

Submitter : Dr. Darren Johnson **Date & Time:** 09/23/2004 08:09:21

Organization : University of Kentucky Orthopaedics and Sports Med

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

see attached file

CMS-1429-P-3470-Attach-1.doc

Darren L. Johnson, MD
Chief Orthopaedic Surgery
Director of Sports Medicine
University of Kentucky School of Medicine
The Kentucky Clinic K415
740 S. Limestone
Lexington, KY 40536

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

Re: Therapy-Incident To

Dear Sir/Madam:

I am the Chief of a very large orthopaedic and sports medicine department. Quality of care and patient satisfaction are very high priorities in our department. I am very concerned over the recent proposal that would limit providers of "Therapy-incident to" services in physician offices and clinics. I have 9 certified athletic trainers on my staff. If adopted, this would eliminate our ability to utilize ATC's who are extremely qualified as health care professionals to provide the services our patients need.

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

- Incident to has 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/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. My ATC staff has Master's degrees, is required to submit and present research and obtain CE credits annually. Kentucky PT's are not required to have CE credits ever. There has never been any limitations or restrictions placed on physicians in terms of who they can utilize to provide ANY incident to service. We, as the physicians, accept the legal responsibility for the individual providing these services. Medicare and private payers have always relied upon our professional judgment to determine who is qualified to provide a particular service. It is imperative physicians continue to make decisions in the best interest 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. The wait time to see one of our physical therapists is sometimes an hour or longer.

- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. Many of my patients travel a great distance from these areas to see me. 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.
- I also work with the staff of ATC's working with the University of Kentucky athletic teams. I have total respect for what they do on a daily basis when evaluating, treating and rehabilitating these Division I athletes. Many of whom go on to play professional sports. To think they are not qualified as health care professionals to provide "incident to" services in my clinic is utterly ridiculous. Independent research has demonstrated that the quality of services provided by ATC's is equal to the quality of services provided by physical therapists.
- 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's office visit. This action could be construed as an unprecedented attempt by CMS to seek exclusivity as a provider of physical therapy services.

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:
Darren L. Johnson, MD

Submitter : Ms. DAWN CLARK **Date & Time:** 09/23/2004 08:09:11

Organization : FHN

Category : Hospital

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I feel that this ruling would limit the Physician's right to delegate the case of his or her patients to training individuals whom the physican deems knowledgeable and training in the protocols to be administered.

Submitter : Kellt Emmons **Date & Time:** 09/23/2004 08:09:02

Organization : Kellt Emmons

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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.

Thank you,

Kelly Emmons, RN

CMS-1429-P-3473

Submitter : **Date & Time:** 09/23/2004 08:09:45

Organization : Education Section, American Phys Ther Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The Education Section of the American Physical Therapy Association strongly support CMS?s proposal to replace the requirement that physical therapists provide personal supervision (in the room) of physical therapist assistants in the physical therapist private practice office with a direct supervision requirement. Physical therapist assistants are educated to function within these parameters and are trained to supervise physical therapist assistant students within this capacity. This change will not diminish the quality of physical therapy services.

This change in supervision standard will not cause physical therapists to change staffing patterns. As licensed health care providers in every jurisdiction in which they practice, physical therapists are fully accountable for the proper delegation and direction of services. The majority of states have physical therapist/physical therapist assistant supervision ratio limits in their state laws or Board rules.

Submitter : Mrs. Marilyn Rissmiller **Date & Time:** 09/23/2004 09:09:15

Organization : Colorado Medical Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The following comments are being submitted on behalf of the physician members of the Colorado Medical Society. In addition, we support and would ask that you consider adoption of the comprehensive comments that were submitted by the American Medical Association.

Issues 1-9

MALPRACTICE RVUs

We support the American Medical Association's (AMA) position that CMS should consider implementing the PLI RVUs on an "interim" basis until you have worked more closely with the medical community to ensure that this important (and volatile) component of the physician payment formula accurately reflects what is happening to malpractice insurance rates across the country.

PRACTICE EXPENSE

We appreciate CMS' review and acceptance of the majority of recommendations made by te Practice Exxpense Advisory Committee (PEAC), as well as the consideration given to comments from specialty organizaitons.

SECTION 303

We share the concerns voiced by the AMA regarding the availability of complete information on the proposed average sales price (ASP) for all impacted drugs. This information is vitale in order for physicians to make appropriate business decisions regarding their ability to continue to provide these services in their offices for Medicare beneficaries. It is our fear that the limited preliminary data will only lead physicians to believe that they will not even be able to meet their costs, and therefore cause more of them to send the patients to other locations for the necessary treatment (such as the outpatient department of the hospital). Because of this we would urge you to delay implementation of the ASP rates until physicians have had an opportunity to review all of the proposed drug payments and provide comments on them.

SECTION 413

The proposed rule does not inclue a list of the counties qualifying for the incentive payments under the primary and specialty care shortage area provision. This information is of interest to many areas of our state. Without timely publicaiton of this information the goal of this provision - to help recruit and retain physicians in underserved communities - will not be met.

SECTION 611

We support the AMA's comments concerning the Initial Preventive Physicial Examinations, and in particular we do not agree with the need for a new "G" code for this service. The initial preventive exam and any related testing should be coded under the existing CPT codes, based on the existing definitions and levels of servuce, wth the appropriate "V" diagnosis codes. A complaint many physicians have had concerns the requirement that different codes by used for Medicare billilngs when appropriate CPT codes already exist.

Issues 10-19

DEFINING THERAPY SERVICES

Because of the substantial confusion surrounding the incident to provisions, including those related to physicial therapy we recommend that CMS not implement the changes outlined in this proposed rule. Rather, for the purposes of continuity of care and patient access, we would suggest that changes for incident to physicial therapy services be issued as a separate proposed rule after CMS has had an opportunity to consult with the

physicians and health professional organizations affected.

SECTION 302

We would urge you to accept PPAC's recommendation that the requirement for a face-to-face exam by a physician prior to the DMEPOS order be limited to power operated vehicles.

Issues 20-29

THERAPY - INCIDENT TO

Because of the substantial confusion surrounding the incident to provisions, including those related to physical therapy, we recommend that CMS not implement the changes outlined in this proposed rule. Rather for the ppurposes of continuity of care and patient access, we would suggest that changes for incident to physical therapy services be issued as a separate proposed rule after CMS has had an opportunity to consult with the physician and health professional organizations affected.

Submitter : Mrs. Susan Carlson **Date & Time:** 09/23/2004 08:09:52

Organization : Rocky Mountain School of Massage

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

With health care costs going thru the roof, why should anyone even entertain the idea of limiting access to health care? That is exactly what this bill will do. Many massage therapists do quality bodywork for less money than PTs. This gives the medicare provider more choices and more flexability in the modalities offered to the patient. Massage therapists can and do encourage total body wellness, hence preventing injury or re-injury. No health care provider should be excluded in this age of skyrocketing costs. Giving people access should be first and formost in the minds of lawmakers, not restricting access.

Submitter : Mr. Paul Hadden **Date & Time:** 09/23/2004 08:09:25

Organization : Mr. Paul Hadden

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services September 22, 2004

Department of Health & Human Services

Attention: CMS-1429-P

PO Box 8012

Baltimore, MD 21244-8012

To Whom It May Concern:

I am an Athletic Trainer and a Physical Therapist and I am writing this letter to defend the ATC's on our position about the ability to provide rehabilitative services to to medicare paying individuals. As is stated below there are an abundance of didactic and practical education in which an ATC learns that gives him/her proper preparation to evaluate, assess, and treat these patients.

In going through both curriculums I have seen and experienced the differences and similarities, and I have worked side by side with these individuals and they demonstrate the knowledge to provide the proper care to with the medicare clientele.

?Incident to? has been utilized by physicians to provide services (including therapy/rehabilitation) as an adjunct to the physician?s professional services, since the inception of the Medicare program in 1965. A physician has the right to delegate the care of his/her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered.

Points of concern regarding CMS proposal:

? This proposal would severely limit qualified health care professionals, such as Certified Athletic Trainers, from providing these necessary physical medicine services prescribed by the Medicare beneficiary?s physician. The idea of limiting the ability of qualified health care professionals from providing rehabilitation services at a time when our US Health Care System is in need does not make sense.

? 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. These physicians make decisions that are in the best interest of their patients.

? By proposing this change, CMS, is allowing a specific health care profession to seek exclusivity as the sole provider of therapy/rehabilitation services. This limits the marketplace, the skills applied to patients and their eventual outcomes.

? This action 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.

This is a critical issue and one that will restrict the athletic training profession and decrease the physician?s ability to provide the best possible patient care. For CMS to exclude certified athletic trainers from providing these services (under the direction of a physician) to a Medicare beneficiary is unjustified. Certified Athletic Trainers are qualified to provide injury assessment, treatment and physical medicine services to Medicare beneficiaries.

Sincerely,

Paul Hadden ATC/MPT

Submitter : Mrs. Kelly Smigiel **Date & Time:** 09/23/2004 08:09:50

Organization : Flint School of Therapeutic Massage

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

CMS-1429-P-3478

Submitter : William Gebhards **Date & Time:** 09/23/2004 08:09:19

Organization : William Gebhards

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am opposed to proposed changes to billing regulations and support recognition of Certified Athletic Trainers as providers of rehabilitation services.

CMS-1429-P-3479

Submitter : Mr. Lawrence Johsens **Date & Time:** 09/23/2004 08:09:58

Organization : private

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Dept. of Health & Human Services September 22, 2004
Attention: CMS-1429-P

In an editorial piece in our local paper, The Santa Cruz Sentinel, written by the CEO of Sutter Medical Center, it was pointed out that Santa Cruz is defined as a rural county, a Locality 99, for purposes of Medicare compensation for medical services, which, as was pointed out, many medical insurance companies use to base their compensation to physicians on as well. The news of this was startling, that we are considered a rural county, which apparently has something to do with the cost of living in the county. Let me explain.
A constant complaint voiced throughout the community is the cost of living here. Teachers, construction workers, retail help, you name it, are unable to afford the extremely high cost of housing, to name but the main complaint. We have a university in the community so we have a great pressure on rentals. In our neighborhood, in fact, two houses down from us, a house rents for somewhere between $2500 and $3000 per month, with a number of students living there, in a two bedroom house, at that. Around the corner from us a house sold last week for $765,000, and I can?t tell you how ordinary or modest the place is. We constantly read of how high our real estate is relative to almost everywhere else in the state. It is so high that even physicians are unable to settle here or are leaving because they can?t find housing they can afford.
Others have said our home is easily worth $800,000 given the prices of other houses in the neighborhood, which is ridiculous. It?s a two bedroom house with nothing special about it except that we take very good care of it. It?s a tract home!!
Housing is not the only thing that?s high. Our gas prices are on average $.05 higher than in San Jose, the heart of Silicon Valley, as it?s known. Grocery prices are relatively high as well. We try to wait to fill our car with gas until we drive over the mountain to San Jose, for crying out loud.
I can?t imagine how you can conclude that this is a ?rural? community. There are a few farms to the north and south of the town, but they are gradually being filled in with housing, plus the shopping stuff that follows it. Farmers and those who serve them are a rarity. I know no one in the business, and I can think of no farm equipment suppliers anywhere in the area This town is filled with people who work in computer related businesses, manufacturing and otherwise. To call us rural is nuts, and it does a serious disservice to those whose lives depend on the medical community. I?ve heard of any number of elderly people who have had trouble getting medical service from physicians who will not take medicare patients or who have restricted the number of medicare patients they will serve because they can?t afford to take them.
You folks need to seriously reconsider why you designate this county as rural because it?s just whacky, if you have any commitment to reality.

Sincerely,

Lawrence Johsens
215 Merced Avenue
Santa Cruz, California
95060

CMS-1429-P-3480

Submitter : **Date & Time:** 09/23/2004 08:09:42

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

i strongly support the proposed requirement that personnel working in physician's offices and providing "physical therapy" be graduates of accredited professional physical therapist programs and that unqualified personnel should NOT be providing physical therapy services (commenting on august 5 proposed rule on revisions to payment policies under the physician fee schedule for calendar year 2005-"therapy-incident to". i am concerned that interns, aides, secretarial staff in the physician office may not be familiar adequately with modality precautions / contraindications. if requested by physician to do modality, after instruction on use only, could this lead to patient harm?

Submitter : Mrs. Linda Wilson **Date & Time:** 09/23/2004 08:09:50

Organization : Board of Massage Therapy

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

ASSIGNMENT

Oppose

CARE PLAN OVERSIGHT

Oppose

TECHNICAL REVISION

Oppose

THERAPY - INCIDENT TO

Oppose

THERAPY STANDARDS AND REQUIREMENTS

Oppose

THERAPY TECHNICAL REVISIONS

Oppose

Submitter : Mrs. Glynda Bauman **Date & Time:** 09/23/2004 08:09:36

Organization : Nature Escape Therapeutic Massage

Category : Other Practitioner

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

do not want PT's to be
>the only health care professionals allowed to provide medically related
>care to physician's patients.

CMS-1429-P-3483

Submitter : Dr. Juan Vazquez-Bauza **Date & Time:** 09/23/2004 08:09:34

Organization : MidAmerica Cardiovascular Institute, PC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:
I would like to express my concern with the reduction in the 2005 Proposed Medicare Fees for G0166, External Counterpulsation and its impact on the payment rate for this therapy. Specifically, I wish to express my concern with the reduction in the Practice Expense RVU of 10% from 3.58 in 2004 to the 3.22 proposed for 2005. ECP offers a safe, non-invasive, outpatient based method of alleviating ischemia for patients who have failed usual medical therapies for treatment of diabling angina not amenable to revascularization.
External counterpulsation requires a practice investment in capital equipment and disposable supplies for each treatment. In addition, the capital outlay, the procedure requires a physician to provide direct supervision and a specially trained nurse to evaluate and assess the patient's status before, during and after the one-hour treatment session. Patients spend approximately 90-120 minutes in the practice setting per one-hour treatment session as the staff conducts assessment, patient education and post treatment evaluations. Patients receive a total of 36 one-hour treatment sessions in the usual course of therapy, although the actual amount of staff and physician time may actually be more.
Proven clinical benefits of ECP include reduced chest pain, reduced need for medication, increased exercise tolerance and significantly improved quality of life. ECP is a non-invasive treatment procedure with a low risk of complications. Invasive procedures have a major compication rate of MI's, death, infection of over 3%. Despite these documented and peer reviewed outcomes, a patient must fail multiple angioplasties or bypass procedures at costs of $9,000-$25,000 per procedure vs. less than $5,000 for ECP before qualifying for this therapy.
It has been shown than angioplasty begets. In spite of this there is still a favor toward it, while ECP is criticized if a patient requires more treatments. It is very unfortunate that invasive options still receive so much attention and increased reimbursement given the success of ECP therapy.
Open heart surgeries are being approved for patients with angina class I in which ACBG has not been found to increase survival rate if the patients have normal LV function. If we truly want to decrease the costs, then the more expenseive procedures with a higher risk should be reassessed.
I encourage you to read the article in Cardiology 2003:100:129-135 on the utilization of ECP as initial revascularization treatment in patients with angina are refractory to medical therapy.
The goal of medical therapy option should include ECP as a cornerstone of treatment. This will prove to be a very cost effective treatment and will save millions of dollars in angioplasty and CABG surgeries that are being performed only to alleviate symtoms. ECP will also decrease health care costs by decreasing the risk factor which will overall decease the costs of complications associated with the invasive procedures.
I believe that this 2005 proposed rule for Medicare Physician Fee Schedule for G0166, External Counterpulsation will limit the availability of this therapy for physician's who want to provide this to their patients, and serve no useful purpose in reducing healthcare costs.
Thank you for the opportunity to be on record through the public comment period to voice my concerns with the continued reduction in physician fees for G0166 and a formal request for reconsideration and increase in the rate for G0166. We have sent the above mentioned article along with a signed copy of this letter by mail. This was express mailed from the post office on 9-23-04. It is guaranteed to your office by 12:00 noon on 9-24-04. You may track this at www.usps.com with a tracking #: ER023779765US. Please do not hesitate to call my office with any additional questions or concerns.
Sincerely,
Juan J Vazquez-Bauza, MD FACC

CMS-1429-P-3484

Submitter : Ms. Shirley Adams **Date & Time:** 09/23/2004 08:09:59

Organization : Finger Lakes School of Massage

Category : Academic

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Commenting on proposed rule from Aug. 5, 2004.
As a profession in New York State we realize there is no mandated coverage for Massage Services under Medicaid CMS 1429-P. It appears to be used there as an example of services related incidental to therapy (unlicensed professionals). With 15,000 massage therapists in New York State (13,000 Licensed) we are becoming an integral part of the health care profession, working in many venues, such as Nursing Homes, Hospitals, Hospice settings, Rehabilitation Centers. The profession of massage Therapy is covered by several insurance compannies. I am concerned the example used will deter further inclusion in therapy related health care. Some of the professions listed are unregulated. Massage should not fall into that category. Please revise your docket issue to reflect the NYS Licensed Profession of Massage Therapy accurately.

CMS-1429-P-3485

Submitter : Mrs. Marion Denton **Date & Time:** 09/23/2004 08:09:17

Organization : Senior Citizen

Category : Individual

Issue Areas/Comments

Issues 1-9

GPCI

My doctors are leaving the Medicare system, and some are even leaving Santa Cruz County,California, because of the extremely high costs of maintaining a medical practice. Reimbursement costs from Medicare are not adequate here. I believe the ASSIGNED GPCI LOCALITY 99 is in ERROR here, since this county exceeds the 5% threshold over the national average (105% rule). In fact, if taken separately and not as a part of Locality 99, Santa Cruz reflects 1.125% of the GAF. Can?t you fix this problem so we will not lose well qualified Doctors here and so we can receive the best of care from the Medicare system we paid into for so many years? CHANGE THE LOCALITY ASSIGNMENT FOR SANTA CRUZ COUNTY, CALIFORNIA, TO PROPERLY REFLECT THE HIGH COSTS OF MEDICAL PRACTICE EXPENSES. Thank you for reviewing and considering my comments.

CMS-1429-P-3486

Submitter : Ms. Barbara Harris **Date & Time:** 09/23/2004 08:09:44

Organization : member of AMTA

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Massage therapy is one of the greatest benefits to health and healing that is available to the individual. I am a sports injury neuromuscular therapist and the work I do is different from a physical therapist. I do not believe it is beneficial to limit avenues of improving or regaining better health. This limitation would neither help the patient nor the overall cost since health improvement reduces additional costs.

Submitter : Miss. Rachelle Bowman **Date & Time:** 09/23/2004 09:09:49

Organization : Miss. Rachelle Bowman

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3487-Attach-1.doc

Rachelle Bowman
R-2 Box 2336
Eastanollee, GA 30538

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,

Rachelle Bowman

CMS-1429-P-3488

Submitter : Ms. Abbey Meyers **Date & Time:** 09/23/2004 08:09:45

Organization : National Organization for Rare Disorders

Category : Consumer Group

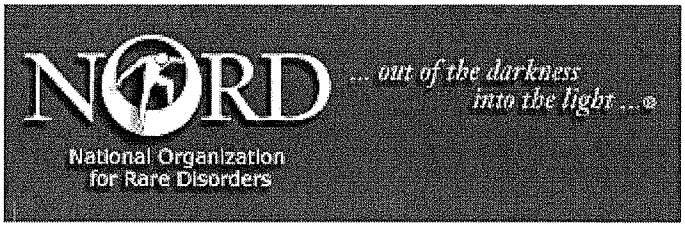
Issue Areas/Comments

Issues 1-9

SECTION 303

Please see attached PDF file.

CMS-1429-P-3488-Attach-1.pdf



September 23, 2004

Via electronic submission at http://www.cms.hhs.gov/regulations/ecomments

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

RE: CMS–1429–P
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Proposed Rule
Comments on Section 303

Dear Dr. McClellan:

On behalf of the National Organization for Rare Disorders (NORD), we are pleased to provide comments on this Proposed Rule. Our guiding principle is that section 303 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), along with the new Part D, are implemented to:

- expand access where there was no coverage, and
- maintain access where there has been coverage.

Specifically, we are concerned about the access of rare disease patients (estimated to be at least 10 percent of the overall Medicare population) to orphan drugs and biologicals provided in physicians offices and free-standing facility settings.

NORD is a federation of approximately 130 voluntary health organizations and approximately 60,000 individual patients, healthcare providers and clinical researchers. We are all committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research and service.

Unique Needs of Rare Disease Patients; Unique Role of Orphan Drugs In Filling this Need

Although rare diseases affect 25 million Americans--none of the 6,000 rare diseases has a service population exceeding 200,000 individuals. Most rare disease populations are much smaller, often numbered in dozens or only hundreds of patients. For many of these diseases, Medicare elderly and adult disabled are a significant portion of those affected by the rare disease.

Orphan drugs are of little value to Medicare beneficiaries—both elderly and adult disabled with rare diseases—if they are not covered by CMS and reimbursed at levels sufficient to insure that providers will stock them. We are committed to making sure that Medicare beneficiaries with rare diseases have and maintain access to orphan drugs and biologicals, which they need to sustain and improve the quality of their lives.

Incentives Seriously Diminished if Access is Limited

The Orphan Drug Act (passed in 1983, amended several times since) represents Congress' continuing support for the development and accessibility of orphan drugs for rare diseases. Incentives under the Act have been enormously effective in stimulating research and development (only 10 orphan drugs were developed in the 10 years prior to 1983; 260 orphan drugs, and biologicals have been approved for marketing by the FDA since enactment, and approximately 1,000 experimental orphan drugs are in various stages of research.

Given a choice, providers will stock lower cost, widely used therapies and ignore the few patients who have a rare disease, and need an expensive medication. The incentives under the Act are likely to be much less effective if a company believes that the Medicare marketplace is relatively closed to them. Since most rare diseases do not yet have a therapy, this is a critical consideration for the future of our constituents.

We are pleased that Congress took action to increase access to orphan drugs and biologicals by creating the new Part D drug benefit, and by making certain changes to payments for drugs and biologicals currently covered under Part B in the physician office and hospital outpatient settings. However, the follow-through in regulations needs to be equally sensitive to the vulnerable position of Medicare beneficiaries with a rare disease, and a need for orphan drugs.

Section 303: Problem Statement and Proposed Resolution

Section 303 of the MMA mandated sweeping changes to payments for drugs and biologicals. In 2004, these changes resulted in reduced payments for most drugs and biologicals. These changes have had an unknown impact on patient access, but we suspect these levels of reduction were high enough not to cause many access problems.

However, further reductions are predicted for most drugs and biologicals in 2005. As a result, we fear that many physicians and free-standing facilities are likely to discontinue providing orphan drugs and biologicals if reimbursement is inadequate to cover the costs of acquiring and providing these drugs. The rare disease community is particularly vulnerable to problems with access. Nearly half of all biologics on the U.S. market are designated orphan drugs.

Orphan drugs and biologicals are generally expensive; physicians are not likely to purchase these drugs if reimbursement revenues fall short of covering their costs. One undesirable current example (provided in the attached article), emphasizes that Medicare will not reimburse for any part of the cost of the drug if it is purchased by the beneficiary and administered by the physician. Physicians may believe there will be

no significant impact to his or her practice if they discontinue offering orphan drugs and biologicals, but those impacted by the decision will feel the loss acutely.

To address these concerns we make the following recommendations—

1. CMS should actively monitor the effect on access of changes in reimbursement for orphan drugs and biologicals. CMS should review the claims databases on a regular basis to see if utilization of orphan drugs and biologicals falls below historical levels (adjusting for expected increases in utilization due to changes in the size of the Medicare population, and in methods for detection of specific conditions). CMS should actively seek input from beneficiaries with rare diseases about any problems they experience with access to orphan drugs and biologicals, such as physicians no longer offering these drugs or referring their Medicare patients to hospitals to receive the drugs they need. CMS should inform beneficiaries about changes in payments to health care providers for certain drugs and biologics, alerting them to the potential impact on access. Beneficiaries should have convenient methods to report any problems with access.

2. When adopting any specific payment policies that may affect access to orphan drugs and biologicals, CMS should follow the policies we outlined in our August 23 letter following up on our July meeting with the Administrator. Specifically—

- For the purposes of identifying drugs and biologicals that are treatments for rare diseases, CMS will adopt the definition of "orphan drugs" used in the Food, Drug and Cosmetics Act;

- For the purpose of determining whether rare disease patients utilizing specific orphan drugs are subject to access problems, CMS will:

- accept orphan products designated by FDA as a valid class,

- develop prospective criteria to determine which orphan drugs should not be part of this class because patients with rare diseases do not experience problems with access to these orphan drugs (e.g. because of high volume use not attributed to a rare disease),

- work with stakeholder organizations, such as the National Organization for Rare Disorders, to identify any access problems that may occur or are likely to occur in the near future and

- provide patients and pharmaceutical companies an opportunity to present data and receive a written explanation with examples before making a final decision that an orphan drug is not subject to access problems.

* * * *

We appreciate the opportunity to provide comments on this Proposed Rule and to continue our dialogue about assuring access to orphan drugs and biologicals under all parts of the Medicare program.

Sincerely,

Abbey S. Meyers

Abbey S. Meyers, President
National Organization for Rare Disorders
55 Kenosia Avenue
Danbury, CT 06813
Phone: (203) 744-0100

Attachment

CMS Pressed To Ensure Cancer Patients Are Not Stuck With Drug Bills

Beneficiary advocates are pushing CMS to prevent cancer patients from getting stuck with un-reimbursable drug bills when physicians shift the responsibility for the purchase of physician-administered drugs onto their patients, a practice they say is increasing and could spike when sharp cuts to drug reimbursement take effect 2005.

The issue first surfaced in an appeal brought by the Medicare Rights Center on behalf of a New York beneficiary who was denied reimbursement for about $13,000 in payments she made for Camptosar, an anti-cancer medication that was used to treat her brain cancer. According to a decision by the administrative law judge (ALJ), the physician prescribed and administered the drug but instructed the patient she would have to purchase the drug herself. In ruling against the beneficiary, who died within a year despite the treatment, the ALJ noted that the Medicare Carriers Manual specifically states that "where a patient purchases a drug and the physician administers it, the drug is not covered."

Faced with that definitive ruling, and with other reports that oncologists were requiring patients to purchase their own drugs, the Medicare Rights Center asked CMS for an administrative fix that would allow patients to be reimbursed or restrict physicians from shifting the purchase of drugs onto their patients. At a minimum, the advocates want CMS to require physicians to tell beneficiaries that they will not be reimbursed by Medicare if they purchase the drug, although that solution still leaves cancer patients in a very vulnerable situation, advocates said.

But so far advocates have received no answer from CMS and are looking at a possible legislative fix next year. According to a CMS official, there is "no way for a patient to be paid if she purchases the drug herself." In addition, there are no restrictions on physician participation in Medicare that would bar the practice, according to the official.

Following the case, the Medicare Rights Center received additional anecdotal reports that the practice of shifting drug purchase onto patients is increasing. With drug reimbursement rates slated to fall sharply in

2005, advocates worry the practice will increase. The case at issue, however, predates the cuts to physician drug reimbursement, and instead centers on the uncertainty of coverage for off-label uses of cancer drugs. The drug at issue, Camptosar, was not approved for treatment of brain cancer by the carrier covering New York, although it is covered by carriers serving other parts of the country. The physician shifted the risk of a non-coverage decision onto the patient although he did not provide her with an Advanced Beneficiary Notice, that would have spelled out the risk of financial liability if Medicare denied coverage.

Date: September 22, 2004

CMS-1429-P-3489

Submitter : Lucy Vallejo-Alviso **Date & Time:** 09/23/2004 08:09:46

Organization : Lucy Vallejo-Alviso

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As a parent who has experienced what it feels like to be told that your baby has a life threating chronic condition such as hemophilia I feel that I am in a position to express my concern for continued quality care for this small community. Hemophilia is one of those conditions that has benefitted in the past recent years due to better medicines and more knowledge. Today we enjoy a good quality of life for our children due to access to care. MediCal has been a big part of this quality. Our medicines are extremely costly. A small child can use $20-70,000 a year in medicine alone.
I am writing to you in support of the increase ($.05) for factor and delivery/support practices. I took a long time to become familiar and knowledgeable enough to feel secure in the care of my son. The providers of factor and support out in the field are called homecare companies. They are the key to us when we are new. They follow our sons into college, like they have with mine. They are part of a team, along with the hemophilia treatment center doctor and staff, that provide all of the medicines and valuable information and support that is needed to produce one independent person with hemophilia. This is a very tight community and when one falls we all feel it. Keep our community strong by continuing to support our guys who use MediCal. Enforce the increase of $.05. Thank you.

CMS-1429-P-3490

Submitter : Mr. Thomas Stueber **Date & Time:** 09/23/2004 08:09:50

Organization : Member at large NATA

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

Please see attached file

CMS-1429-P-3490-Attach-1.doc

Thomas M. Stueber, M.S., ATC, LAT
13101 ACR 9808
Mexico, Mo. 65265
573.581.3692

September 23, 2004

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

Re: 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 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 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 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 interest 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 increased 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 personnel 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. The 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 Commission 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 with 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' rights 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 seek to establish themselves as the sole provider of therapy services.

- CMS does not have 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 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 Medicare beneficiary who becomes injured as a result of walking a 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,

Thomas M. Stueber, M.S., ATC, LAT

Submitter : Miss. Kristin Hosea **Date & Time:** 09/23/2004 09:09:10

Organization : Marquette Physical Therapy

Category : Individual

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

To Whom It May Concern:

Re: ?Therapy-Incident? To

I wish to comment on the August 5 proposed rule on ?Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005.? I am a student physical therapist at Marquette University and will be graduating in May 2005 as a doctor of physical therapy. I have been at Marquette for 6 ? years through undergraduate and graduate school.

I strongly support that therapists working in physician offices be graduates of accredited professional physical therapy programs, any less education would be providing patients substandard care. As a student physical therapist I pride myself in my education, both in the breadth of the knowledge as well as the up-to-date details of individual subject areas. As physical therapists, we are highly skilled in differential diagnosis, pathophysiologies, suitable treatment programs, and we are the most knowledgeable of any health care provider regarding the musculoskeletal system.

In addition to extensive schooling requirements to graduate, physical therapists are expected to keep current with subject material by attending continuing education courses and by being licensed through each individual state of practice to ensure complete observance of a particular state?s practice acts. By allowing non-physical therapists to do similar duties, laws and ethical or legal state regulations may not be met..

In previous clinical affiliations I have worked with physicians and physician?s assistants eager to learn and apply certain ?physical therapy services.? However, regardless of how often they observed, asked questions, or read material they could find, they still were unable to correctly diagnose musculoskeletal impairments in patients, and consequently unable to select appropriate treatment methods for a majority of patients. Physicians, though highly educated, are not as knowledgeable as physical therapists regarding the specifics of the musculoskeletal system and associated pathophysiologies. This experience in itself further confirmed my belief in the importance of physical therapy services to be provided by licensed and educated physical therapists from accredited programs.

In closing, I wish to further state that physicians providing ?physical therapy services? are providing units that are counted as part of the allotted units of physical therapy provided by Medicare/Medicaid. This may result in long term problems for the patient as well as at the time of injury/illness. If the patient received substandard care as result of an unqualified provider of physical therapy, the patient may be denied further treatment due to limited visits or units of covered ?physical therapy services? provided by Medicare/Medicaid. The patient may be unable to afford further therapy to correct their illness/injury and will then be deemed ?out of luck? due to a potentially correctable series of events, involving qualified physical therapists in the patient?s plan of care. I thank you for the consideration of the fore-mentioned comments and hope that these will prove helpful in changing payment policies for 2005.

Sincerely,
Kristin M. Hosea, SPT

Submitter : Catherine Wilson **Date & Time:** 09/23/2004 08:09:15

Organization : Personal

Category : Individual

Issue Areas/Comments

Issues 1-9

GPCI

Medicare needs to correct an egregious error in the GPCI Locality assignment (99) for Santa Cruz County, California. I understand that Medicare wants to save dollars, but it is unfair for a group of recipients to be cheated because doctors in this county are not properly reimbursed. Many Doctors now refuse to accept Medicare or are leaving because of poor reimbursement here. Santa Cruz County exceeds the 5% threshold (105% rule) over the national 1.000 average, and the Medicare pay schedule should reflect that. Santa Clara, a neighboring county, receives 25.1% more for the same service. Santa Cruz, standing alone, would be 112.5%, well above the 105% threshold. Please REVISE THE GPCI LOCALITY FOR SANTA CRUZ COUNTY, CA, to properly reflect the higher costs in this county so we can keep our doctors and receive the medical care we need within our own county.
Thank you for your attention to this matter.

CMS-1429-P-3493

Submitter : **Date & Time:** 09/23/2004 09:09:38

Organization :

Category : Physical Therapist

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I strongly support the proposed revision to only allow liscensed physical therapists from accredited universities provide 'physical therapy' to patients. This proposal is imperative for the wellbeing of our clients and for the future success of our profession.

CMS-1429-P-3494

Submitter : Dr. Stephen Ikard **Date & Time:** 09/23/2004 09:09:51

Organization : University Orthopaedic Clinic, P.C.

Category : Physician

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I am a physician writing to express my concern over the proposal which would limit both the provider group eligible to perform therapy incident to services rendered in physician offices and clinics and the current ability of physicians to exercise judgment in delegation of incident to services. This proposal appears to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services. "Incident to" has traditionally been utilized under the Medicare program to allow physicians to supervise directly services which are provided to patients by other qualified individuals. There have never been any limitations or restrictions placed upon physicians in terms of whom he or she may utilize to provide any incident to service. Medicare and private payers have always relied upon the professional judgment of physicians to determine who is qualified to provide a particular service. It is imperative that physicians be permitted to continue to make decisions regarding who renders services to patients under their supervision and legal responsibility. This proposal sets a precedent which could have far reaching consequences upon the practice of medicine. Please reconsider implementation of this proposal.

Submitter : Karen Hiatt **Date & Time:** 09/23/2004 09:09:02

Organization : Karen Hiatt

Category : Social Worker

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under the supervision of a physician.

Please do not limit the choices that a physician may make in order to provide the right care for the patient.

By limiting payment to physical therapists only ? you are cutting off effective treatment for RSD patients (manual lymph drainage ? MLD; or lymph drainage therapy -- LDT)

Physical therapy is an effective modality ? it is not the ONLY modality that works. Diagnosis for similar conditions may have different prescriptions or referrals ? depending on what ELSE is going on in the patient?s life/medical profile.

I?m a retired government employee ? a bureaucrat, if you will; please do not limit my medical care to the dictate of a bureaucrat. With 30 years experience in social work, I?ve seen very effective treatment through massage therapy, acupuncture, craniosacral therapy, acupressure, lymph drainage, etc.

Have the bureaucrats who wrote this change in payment looked at cost-effective treatment by referral? Again ? I?ve seen less expensive treatment in shorter times (sometimes) ? with modalities OTHER than physical therapy.

I myself have experienced treatment with all modalities above ? and each is effective for DIFFERENT reasons, and each was prescribed for me for different reasons.

Yes, I can pay for my treatment right now ? so I?m not limited except by my bank account. If you change Medicare payments to exclude effective, legal, qualified care ? which might actually be faster and less expensive ? this is not right, and is a form of discrimination.

All qualified health care providers should be allowed to provide services to patients with a physicians prescription or under the supervision of a physician.

Submitter : Ms. Patti Abbott **Date & Time:** 09/23/2004 09:09:32

Organization : LMP

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

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

Submitter : Ms. Lori Sundbom **Date & Time:** 09/23/2004 09:09:03

Organization : First Care Medical Services

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Coding-Telehealth
CMS-1429-P

I am the director of an agency in rural Minnesota that provides home health and hospice services to patients in their home. We have an existing telehealth program that includes an interactive telecommunication system that allows interactive sound and video visits to patients in their home. We have three partnering clinics that also have the ability to use the same equipment and do interactive physician visits to patients in their home. These clinics are Dakota Clinic of Thief River Falls (MN), Dakota Clinic of Fosston (MN), and Altru Clinic of Thief River Falls.

Many times our home care and hospice patients have real difficulty traveling to the clinic to see their physician. Especially the hospice clients toward the end of their lives. These patients must then make the choice of not seeing their physician or relying on expensive ambulance or other services to get them to the clinic. This can cause an increased amount of pain and difficulty for the patients if they choose to travel. By partnering with these clinics, the goal has been to enable the physician to continue to be as involved in the patient's care even when traveling by the patient causes extreme hardships. Telehealth makes this possible. The problem that has been encountered is that the clinics are not able to get reimbursed for the physician telehealth visits because the patient is at their own home. Current statute does not include the patient's home as an approved originating site to enable payment to be made to the physicians.

I am requesting CMS to add the patient's home to the definition of approved originating sites for the purposes of a physician office or other outpatient visit, consultation, or office psychiatry (6/28/2002 Federal Register 67 FR 43862 Category 1). I am also requesting that CMS finish the study on originating sites.

Thank you,

Lori Sundbom, BSN
Director of Home Services
First Care Medical Services
900 Hilligoss Blvd. SE
Fosston, MN 56542
218-435-1103, Ext. 164

CMS-1429-P-3498

Submitter : Ms. Deborah Shields **Date & Time:** 09/23/2004 09:09:20

Organization : FSMTA, AMTA, NANMT

Category : Other Health Care Professional

Issue Areas/Comments

Issues 20-29

THERAPY - INCIDENT TO

I respectfully request you NOT pass regulations so that a physician may refer ONLY to PTs for massage therapy services. There are many qualified and duly licensed health care professionals besides PTs who can administer these services with expertise. The benefits of massage therapy extend to more than moving muscles. The reduction of stress and ensuing decrease in catecholamine brought about by massage therapy is so beneficial to many people. As both a Registered Nurse and a Licensed Massage Therapist, I recommend you allow all qualified professionals to assist our aging population to receive the quality of care they seek, from the professional of their choice, and as recommended by their physician. Our health care system is moving toward a more holistic approach so why not advance this approach by allowing qualified health care professionals to provide services? Thank you for your consideration.

CMS-1429-P-3499

Submitter : Ms. Marcia Nusgart **Date & Time:** 09/23/2004 09:09:49

Organization : Coalitions/Wound Care/Resp Care Manufacturers

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

COALITION OF RESPIRATORY CARE MANUFACTURERS
COALITION OF SEATING & POSITIONING MANUFACTURERS
COALITION OF ENTERAL NUTRITION MANUFACTURERS
COALITION OF WOUND CARE MANUFACTURERS
5225 POOKS HILL ROAD SUITE 1626 NORTH
BETHESDA, MARYLAND 20814

TELEPHONE: (301) 530-7846
FAX: (301) 530-7946
E-MAIL: marcia@nusgartconsulting.com

September 23, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attn: CMS-1429-P ? Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Federal Register 47488 (August 5, 2004) Section 302

Dear Dr. McClellan:

Four distinct coalitions of medical device companies who manufacture durable medical equipment orthotic and prosthetic supplies, The Coalition of Respiratory Care Manufacturers, the Coalition of Seating and Positioning Manufacturers, the Coalition of Enteral Nutrition Manufacturers and the Coalition of Wound Care Manufacturers (hereby known in the rest of these comments as ?The Coalitions?) are pleased to submit these comments in response to Section 302 of the proposed final rule for the Physician Fee Schedule Update for Calendar Year 2005. The Coalitions are comprised of the leading medical device manufacturers of innovative respiratory, seating and positioning, enteral nutrition and wound care products.

The Medicare Modernization and Prescription Drug Act of 2003 (?MMA?) requires the Secretary of Health and Human Services (?HHS?) to establish types or classes of Durable Medical Equipment (?DME?) that require not only a prescription but also a face-to-face evaluation by a physician or other prescribing practitioner. The MMA specifically required this type of evaluation for patients receiving power wheelchairs, based on Congressional concerns about overuse and/or misuse of this specific type of product. In addition, Congress directed CMS to establish clinical criteria for coverage of other types of DME, as appropriate. We believe that Congress intended for CMS to add the new coverage criteria and evaluation requirements when and if there was evidence that these requirements were needed to ensure appropriate utilization of a specific type of product.

However, in Section 302, Clinical Conditions for Coverage of Durable Medical Equipment (DME), CMS now proposes to expand the requirements for clinical conditions for coverage and face-to-face evaluations to all items of durable medical equipment, prosthetics, orthotics and supplies (?DMEPOS?) defined in 42 CFR 410.36. We would like to comment on two of the proposed clinical conditions:

1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;

2. Provide that we would promulgate through the national coverage determination process or through the local coverage determination process additional clinical conditions for items of DMEPOS.

1. Establishing a requirement for a face-to-face examination by a physician, physician assistant, clinical nurse specialist, or nurse practitioner to determine the medical necessity of all DMEPOS items;

In regards to the first two proposed clinical conditions, CMS states the reason for requiring it is because the Agency believes that DMEPOS items should be ordered in the context of routine medical care. While the Coalitions agree that DMEPOS should be ordered in the context of routine medical care, we submit that the vast majority of DMEPOS are currently ordered in an appropriate medical context and that CMS may not be aware of the practical reality of how some items of DMEPOS may be ordered. For example, many items of DMEPOS are ordered in the hospital for the beneficiary?s use at home. In this situation, the item is ordered based on a physician?s evaluation of the b