

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Therapy--Incident To  
Scott Goode ATC  
Salve Regina University  
62 Burton Ave  
Riverside RI 02915

August 10, 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  
NATA member  
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 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. 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 physicians 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 patients recovery and/or

increase recovery time, which would ultimately add to the medical expenditures of Medicare.

Curtailling 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 masters degree or higher.

Submitter : Jeffrey S. Monroe Date & Time: 08/11/2004 06:08:41

Organization : Michigan State University

Category : Other Health Care Professional

Issue Areas/Comments

**GENERAL**

GENERAL

please see attached Word File

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Mark A. Mac Aleese MBA, MS, ATC  
Therapy Services Manager  
Special Tree Rehabilitation  
Romulus, MI 48187

August 12, 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.

Currently I am the therapy services manager for a brain injury and spinal cord facility. Part of my responsibilities is overseeing physical therapy, occupation therapy, speech and language, psychology, and social work as well as some other therapies. My responsibilities include making sure the interdisciplinary approach to therapy is seamless. There is a definite role for each therapy and their specialization in the rehabilitation process. I am pleased to report that all 35 therapists believe in this process and understand their role in the team. As an Athletic Trainer overseeing this program with diverse therapeutic backgrounds my professional education has benefited me by have a better overall knowledge of anatomy, physiology, and overall teamwork for one goal.

Having a Master of Business Administration degree has opened my eyes to the need for qualified health care professionals for the patient?s at the most cost effective way. In reviewing this I believe you are being misled in being informed that un-educated persons are providing these services. If that were the case that should be stopped and the physicians should e held accountable. What I believe is being used as an argument of unqualified individual is actually a smoke screen to create a monopoly for the physical therapy association. This would solely benefit this group and create increased billings at a higher rate for the same but delayed services. This would allow physical therapists to control billings and providing more jobs for their profession by elimination other professions.

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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

You are planning to place frequency limitations of one/5 years for many screening tests. How do you expect us to know when to administer and ABN form for these tests when you don't have the billing data available to us "online, real-time". This places a great legal as well as financial burden on providers, working to provide 1st rate care to our patients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Illegal aliens should not receive American taxpayer money for medical treatment, and health care workers should not do the work of ICE and other federal agencies. We do not have enough taxpayer money to pay for health care for American citizens, and the Medicare programs should focus on serving actual citizens. Federal laws and policies should have the responsible agencies deal with their own responsibilities, not deflect an unwillingness to enforce immigration laws onto local hospitals to find and report illegal aliens.

Submitter :  Date & Time:

Organization :

Category :

#### Issue Areas/Comments

#### Issues 11-20

##### Drug Coding and Billing

I am a practicing medical oncologist in Florida. As a private practitioner owning and managing my practice I can without hesitation state that ASP drug reimbursement will cause significant changes in cancer care.

My review of the recently released ASP for oncology drugs reveals a significant percentage of the drugs being reimbursed under the best possible price that I can acquire drugs from my wholesalers. Especially true is the generic drugs for which a major pharmaceutical company is not backing. These are very important drugs for cancer survival and will not be administered as an outpatient nor given in a timely manner in our hospital setting. For example Taxol, which will be at least \$40-70 below my acquisition price per 50mg.(average dose(300mg--deficit of approximately \$200-350) Since, taxotere, a more expensive drug is still reimbursed at cost and in most cases can replace taxol, taxotere usage will increase and cost savings to CMS will be offset.

ASP has not taken in consideration impact on drug costs to the physician when CMS delays reimbursement or denies payment for an incorrect reason. Appeals can take up to one year or longer especially in FLorida. Who will cover the cost when an employee error causes lack of reimbursement for expense oncology drugs, further delaying reimbursement? Will CMS be more receptive?

ASP has not taken in consideration the cost of inventory and maintaining even a few days extra of drugs. This will impact cancer patients in an acute setting. Instead of being simply cared for in the outpatient setting, they will be hospitalized increasing costs to CMS.

ASP nor drug infusion charges have not calculated the escalating toxic waste charges with chemotherapy drugs. The ?margin? on drugs previously covered things such as special IV tubing, special needles for port access and IV access, supplies, extra rent, malpractice costs, extra billing and administrative personnel and nurses who are specialized in oncology. To save cost practices in my area have already started to use less competent individual, such as medical assistance and phlebotomists--- Increasing medical errors with toxic drugs which will increase health care costs i.e. renal failure, neutropenic sepsis, and heart failure.

ASP does not cover the cost of mixing the chemotherapy drugs nor the qualified personnel salaries to perform the mixing.

ASP will not cover a patient's inability to pay the 20% medicare copayments that private physicians can write off in difficult situations. Florida state medicaid as a medigap insurance will no longer be accepted in any out patient oncology center. This will cause a wider gap in quality of care for our under privileged elderly.

As an agency being responsible for the care of the elderly and disabled please do instigate these changes in Jan 2005. Work with the leaders from ACCC and ASCO. Oncology Care in the US is currently superior to the rest of the world. This Care cannot be measured by statistics or cost ratios. Once, these changes are implemented the devastation will not be easily detected nor reversed. Quietly you will see oncologists retiring, and young physicians not being trained for this difficult specialty. This is a fact because with last year's CMS changes this is already occurring. Elderly patients always have comorbid medical conditions that need extra monitor by a physician. With the new changes, they will be monitored by inexperienced personnel or with increasing emergency room visits. This will increase CMS costs.

I ask why would I, as a physician, stay in oncology when as a primary care physician (internist) my income would improve and I would have easier patients to handle???? Or my choice-- (and a lot of other established oncologists) not to be a medicare or blue cross provider, giving care to the wealthy elderly.

HCPCS Codes

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Payment Rate for APCs

The payment rate for reimbursement of the Pharmaceutical used in PET Scanning is already below our costs and the proposed reimbursement rates would represent a dramatic loss for us. The proposed rates that we would be reimbursed for PET Scans would be well below costs as well. We offer PET Scans through a mobile service that visits our hospital. It is an expensive proposition and cuts in reimbursement would mean that we would be donating this service to our patients or discontinuing it and forcing very ill patients to travel clear across the state to have this service. It would probably also shut down providers of this service in rural areas. Please reconsider the efforts to cut reimbursements it would cause great damage to Patient care and the facilities that deliver Patient care.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Payment Rate for APCs

1427-p  
I feel moving to an approved APC rating is a positive move but making sure that the reimbursement covers the cost to do the exam. PET scanners, now PET CT scanners are very expensive, and are not considered high volume machines. Moving to a fixed apc, with a rate of at least 1200 dollars (not including isotope, which is charged separately) would allow for this modality to be adequately compensated and allow for the appropriate staffing to cover the exams.  
This modality is seeing great advances in cancer imaging, finding disease earlier on will save money in the long run by putting patients in a treatment path before their condition becomes more complex and critical.  
Bone imaging is fast becoming the scan of choice and cardiac needs to be moved to the acceptance line as well.  
PET is a valuable patient diagnostic and screening tool, and needs to be supported.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

I would like to comment that I strongly support the idea that Physical Therapy services for Medicare recipients must be provided only by a graduate of an accredited Physical Therapy program. I feel also that no entity should be able to bill for Physical Therapy services unless these services are provided by a Physical Therapist. This will insure that Medicare recipients receive the highest quality care. Thank you. Bruce Langevin

Submitter : Mrs. Ly Gallardo Date & Time: 08/25/2004 12:08:10

Organization : Fresenius HemoCare

Category : Device Industry

**Issue Areas/Comments**

**Issues 1-10**

APC Groups

Under the August 16, 2004 Proposed Changes to the Hospital Outpatient Prospective Payment System Federal Register (Addendum B), CMS has put CPT code 36515 under APC group 0111 instead of 0112. APC group 0111 is for Blood Product Exchange, which is not what CPT 36515 should fall under. CPT code 36515 is Therapeutic Apheresis with extracorporeal Immunoabsorption and plasma reinfusion. This code has always and should still be under APC 0112, which is Apheresis, Photopheresis, and Plasmapheresis. There is a big difference since the payment rates are drastically different between the two APC groups. Please advise on whether this was a mistake or whether there has indeed been a change. Attached are the Final OPPS for 2004 and the proposed OPPS for 2005.

Under the August 16, 2004 Proposed Changes to the Hospital Outpatient Prospective Payment System Federal Register (Addendum B), CMS has put CPT code 36515 under APC group 0111 instead of 0112. APC group 0111 is for Blood Product Exchange, which is not what CPT 36515 should fall under. CPT code 36515 is Therapeutic Apheresis with extracorporeal Immunoabsorption and plasma reinfusion. This code has always and should still be under APC 0112, which is Apheresis, Photopheresis, and Plasmapheresis. There is a big difference since the payment rates are drastically different between the two APC groups. Please advise on whether this was a mistake or whether there has indeed been a change. Below are the Final OPSS for 2004 and the proposed OPSS for 2005.

2004 Payment rates for Hospital Outpatient prospective Payment System; Final Rule (November 7, 2003 Federal Register)

APC	Group Title	Status Indicator	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0111	Blood Product Exchange	S	13.1719	718.67	200.18	143.73
0112	Apheresis, Photopheresis, and Plasmapheresis	S	37.5832	2050.58	612.47	410.12

CPT/ HCPCS	Status Indicator	Condition	Description	APC	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
36511	S		Apheresis wbc	0111	13.1719	718.67	200.18	143.73
36512	S		Apheresis rbc	0111	13.1719	718.67	200.18	143.73
36513	S		Apheresis platelets	0111	13.1719	718.67	200.18	143.73
36514	S		Apheresis plasma	0111	13.1719	718.67	200.18	143.73
36515	S		Apheresis, adsorp/reinfuse	0112	37.5832	2050.58	612.47	410.12
36516	S		Apheresis, selective	0112	37.5832	2050.58	612.47	410.12
36522	S		Photopheresis	0112	37.5832	2050.58	612.47	410.12

2005 -

Under the August 16, 2004/ Proposed Rules Addendum B. – Payment Status by HCPCS Code and Related Information Calendar Year 2005

CPT/ HCPCS	Status Indicator	Comment Indicator	Description	APC	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
36511	S		Apheresis wbc	0111	12.9206	\$737.74	\$200.18	\$147.55
36512	S		Apheresis rbc	0111	12.9206	\$737.74	\$200.18	\$147.55
36513	S		Apheresis platelets	0111	12.9206	\$737.74	\$200.18	\$147.55
36514	S		Apheresis plasma	0111	12.9206	\$737.74	\$200.18	\$147.55
36515	S		Apheresis, adsorp/reinfuse	0111	12.9206	\$737.74	\$200.18	\$147.55
36516	S		Apheresis, selective	0112	37.7298	\$2154.30	\$612.47	\$430.86
36522	S		Photopheresis	0112	37.7298	\$2154.30	\$612.47	\$430.86

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

This legislation is an elitist activity being introduced by physical therapists. It is attempting to involke exclusionary legislation against athletic trainers. With or without this legislation the majority of persons will not be seen by physical therapist. It is limiting our access to the reimursement system and thus preventing an athletic trainers ability to ply a trade, recoginized by the AMA, as an allied health professional and be compensated for thier knowlege, skills and work ethic.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Observation Services

It is not uncommon to admit a patient through the ED to Observation for chest pain and then follow up with a diagnostic heart cath 93510 -93529 cpt codes within a 24 hour period. To restrict Status T to only infusion and injection codes would require hospitals to dismiss from observation and readmit another day to perform the heart catheterization. This is not only unnecessary but is a burden on the Medicare Beneficiary. We would recommend that you a least allow the heart cath in situations when the patient is placed in observation for chest pain.

Submitter : Ms. JoAnn Williams, RKT Date & Time: 08/26/2004 05:08:48

Organization : American Kinesiotherapy Association

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

JoAnn Williams, RKT  
423 E. Mendocino St.  
Altadena, CA 91001-2229

September 15, 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, placing 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 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.

? 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, 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. 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. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient?s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.

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

? CMS, in proposing this change, offers no evidence that there is a problem that is in need of fixing.

In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.

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

Sincerely,

JoAnn Williams, RKT  
VA Greater Los Angeles Healthcare System

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-10**

New Technology APCs

File Code: CMS-1427-P

Issue Identifier: New Technology APCs

Please see attached file (Word Document)

CMS-1427-P-15-Attach-1.wpd



# RITA Medical Systems

August 26, 2004

Sent Via Email to: [www.cms.hhs.gov/regulations/ecomments](http://www.cms.hhs.gov/regulations/ecomments)

**File Code:** CMS-1427-P

**Issue Identifier:** New Technology APCs

Dear Sir or Madam:

RITA® Medical Systems, Inc. develops a unique radio frequency technology used to percutaneously ablate nonresectable liver lesions (CPT code 47382: *Ablation, one or more liver tumor(s), percutaneous, radiofrequency*). We want to take this opportunity to comment on the reconfiguration of the APC to which percutaneous radio frequency ablation of liver lesion is proposed.

Radio frequency ablation of liver tumors is currently included in APC 1557(*New Technology—Level XX*). CMS is proposing to reassign this procedure to a newly created clinical APC 0423 (*Level II Percutaneous Abdominal and Biliary Procedures*). We believe it is premature to assign this procedure to a permanent clinical APC because there is insufficient experience with the procedure and because the clinical data CMS used to make this adjustment understates the actual cost of the procedure. We encourage CMS to leave the procedure in New Technology – Level XX in order for additional claims data to accumulate through 2005. We also recommend that CMS encourage hospitals to resubmit claims that inadvertently omitted the full costs associated with the procedure, including the disposable components.

The following showcase the data CMS analyzed for payment adjustments to OPSS for 2004 and 2005.

### DATA USED TO CALCULATE 2005 REIMBURSEMENT

CPT/HCPCS Code	APC	2005 Proposed Payment	Single Frequency Claims	Minimum Costs	Maximum Costs
<b>Claims Data is 4/1/2002-12/31/2003</b>					
47382	0423	\$1,659.71	269	\$81.27	\$14,259.35

### DATA USED TO CALCULATE 2004 REIMBURSEMENT

CPT/HCPCS Code	APC	2004 Final Payment	Single Frequency Claims	Minimum Costs	Maximum Costs
<b>Claims Data is 4/1/2002-12/31/2002</b>					
47382	1557	\$1,850	136	\$112.96	\$9,903.58

We do not believe that a total of 405 claims in less than two years are sufficient claims data to support moving the procedure from New Technology APC to a permanent clinical APC at this time. Furthermore, the minimum cost data reported for the two years clearly demonstrates that hospitals are not accurately reporting the costs involved with the procedure.

The proposed reimbursement of \$1,687.70, is inadequate and does not even cover the cost of the single-use radio frequency catheter alone, which costs hospitals \$2,195.00 - \$2,495. The StarBurst technology reflects superior treatment including:

- The ability to treat large tumors (7 centimeter ablations)
- Real time temperature monitoring (real cell death determination)
- Infusion Technology (ablates more tissue faster)

Based on the proposed payment for this procedure, Medicare beneficiaries with nonresectable liver tumors may not have radiology outpatient access to this unique technology: a multi-electrode temperature –monitoring device. The system measures complete tumor temperature and includes a staged deployed ablation process to ensure complete cell death, which includes proper margin around the tumor.

Fundamentally, we believe it is inappropriate to base payment adjustments on flawed data. Instead, we believe it is appropriate to carefully monitor claims for another year so that more accurate data can be used to transition the procedure out of New Technology and into a permanent clinical APC assignment. Realizing that this is not unique to the percutaneous radio frequency ablation of liver lesions, we also support a CMS sponsored initiative to educate hospitals on submitting claims that accurately reflect service and charges.

Thank you for the opportunity to present these comments. We appreciate your consideration of this matter as you finalize the 2005 Outpatient Prospective Payment System. Please contact me with any questions you may have concerning this request.

Sincerely,



Lynn Saccoliti  
Rita Medical, Inc.  
Vice President , Reimbursement Affairs  
lsaccoliti@ritamed.com  
650-314-3405  
<http://www.ritamedical.com/>

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

In regards to changing Medicare billing:

CMS-1427-P-16-Attach-1.txt

CMS-1427-P-16-Attach-2.rtf

Carly Manghelli  
292 Fairgrounds Dr.  
Lexington, KY 40516

8/30/04

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

Re: Therapy – Incident To

Dear Sir/Madam:

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

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

- Incident to has, since the inception of the Medicare program in 1965, been utilized by physicians to allow others, under the direct supervision of the physician, to provide services as an adjunct to the physician’s professional services. A physician has the right to delegate the care of his or her patients to trained individuals (including certified athletic trainers) whom the physician deems knowledgeable and trained in the protocols to be administered. The physician’s choice of qualified therapy providers is inherent in the type of practice, medical subspecialty and individual patient.
- There have never been any limitations or restrictions placed upon the physician in terms of who he or she can utilize to provide ANY incident to service. Because the physician accepts legal responsibility for the individual under his or her supervision, Medicare and private payers have always relied upon the professional judgment of the physician to be able to determine who is or is not qualified to provide a particular service. It is imperative that physicians continue to make decisions in the best interests of the patients.
- In many cases, the change to “incident to” services reimbursement would render the physician unable to provide his or her patients with comprehensive, quickly accessible health care. The patient would be forced to see the physician and separately seek therapy treatments elsewhere, causing significant inconvenience and additional expense to the patient.
- This country is experiencing an increasing shortage of credentialed allied and other health care professionals, particularly in rural and outlying areas. If physicians are no longer allowed to utilize a variety of qualified health care professionals working “incident to” the physician, it is likely the patient will suffer delays in health care, greater cost and a lack of local and immediate treatment.
- Patients who would now be referred outside of the physician’s office would incur delays of access. In the case of rural Medicare patients, this could not only involve delays but, as mentioned above, cost the patient in time and travel expense. Delays would hinder the patient’s recovery and/or increase recovery time, which would ultimately add to the medical expenditures of Medicare.
- Curtailing to whom the physician can delegate “incident to” procedures will result in physicians performing more of these routine treatments themselves. Increasing the workload of physicians, who are already too busy, will take away from the physician’s ability to provide the best possible patient care.
- To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide “incident to” services would improperly provide those groups exclusive rights to Medicare reimbursement. To mandate that only those practitioners may provide “incident to” care in physicians’ offices would improperly remove the states’ right to license and regulate the allied health care professions deemed qualified, safe and appropriate to provide health care services.

- CMS, in proposing this change, offers no evidence that there is a problem that is need of fixing. By all appearances, this is being done to appease the interests of a single professional group who would seek to establish themselves as the sole provider of therapy services.
- CMS does not have the statutory authority to restrict who can and cannot provide services “incident to” a physician office visit. In fact, this action could be construed as an unprecedented attempt by CMS, at the behest of a specific type of health professional, to seek exclusivity as a provider of physical therapy services.
- Independent research has demonstrated that the quality of services provided by certified athletic trainers is equal to the quality of services provided by physical therapists.
- Athletic trainers are employed by almost every U.S. post-secondary educational institution with an athletic program and every professional sports team in America to work with athletes to prevent, assess, treat and rehabilitate injuries sustained during athletic competition. In addition, dozens of athletic trainers will be accompanying the U.S. Olympic Team to Athens, Greece this summer to provide these services to the top athletes from the United States. For CMS to even suggest that athletic trainers are unqualified to provide these same services to a Medicare beneficiary who becomes injured as a result of running in a local 5K race and goes to their local physician for treatment of that injury is outrageous and unjustified.
- These issues may lead to more physician practices eliminating or severely limiting the number of Medicare patients they accept.

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

Sincerely,

Carly Manghelli, ATC

292 Fairgrounds Dr.

Lexington, KY 40516



Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

CMS-1427-P - Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates.

Outpatient rehabilitation providing physical therapy will be provided by licensed physical therapists and licensed physical therapy assistants.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Using cost to charge ratios may encourage hospitals to raise retail prices to rates uninsured patients cannot afford.

Add a definitions page in order to make the rule easier to understand.

**Issues 1-10**

2 Times Rule

A variation of 100% may be too large for accurate payment. Please consider a maximum dollar amount parameter as well.

APC Groups

Perhaps the FI statement of work should include additional resources for provider education to promote accurate billing and cost reporting?

APC Relative Weights

The 'pseudo' single claim concept should be validated with randomly sampled claims data and medical record documentation. Perhaps a random sample of claims information that is reviewed in detail and validated for accuracy would allow for more accurate APC pricing, than by using as many claims as possible? Consider setting up an edit system that links a list of revenue codes with a list of APC codes, to help create more accurate billing. The edit, when hit, could prompt a provider education letter, not necessarily a claim denial. The claims that do not pass the edits would not be eligible for APC payment calculations. Consider using external data for device dependent APC pricing in a manner similar to that being developed for ASP pricing. Consider a long term strategy to move away from the need to know hospital charges, since these charges seem generally unreasonable and cause distress among the uninsured. Establish consistent standards to decide whether or not the accurate and verifiable claim data available is sufficient to establish APC payment amounts.

Devices

Establish a full range of C codes for covered devices. Consider the relevance of the requirement of that defines a device by the nature of the opening into which it is placed, or in some cases, associated with its use (i.e. created by a person vs. by God.)

New Technology APCs

CMS seems to apply inconsistent standards with respect to the number of claims reported that CMS considers sufficient in order to allow CMS to move an APC from a new technology APC code to a specific APC code and payment rate.

Physical Examinations

Please include 'anticipatory guidance/risk factor reduction interventions' in the description of the initial preventive physical examination. This will prevent reporting of 99387 additionally, to defeat getting past the limiting charge rules. Assign the APC codes for 99203 and 93005, not a new technology APC code. Allow for the three services to be reported by different providers in different places of service, physical exam, ECG-PC, and ECG-TC. Allow separate payment for and providers to separately perform DRE/preventive pelvic-breast/pap collection. Allow providers to separately report a DRE with an unrelated E/M service. For a beneficiary who receives a preventive care physical, do not allow reporting of 99387 within three years. Allow separate payment for a 99202-99205 for the same day by the same provider for a patient who receives a preventive exam, particularly for a patient who is taking medicine. Require a -25 modifier for the E/M service. Explain in detail how to report the various covered preventive services together with services covered under 1862(a)(1)(A) of the act by the same provider, for the same patient, on the same day. Limit

the number and type of preventive cardiac blood tests to community standards based on outcome data. Explain how to report a service when a preventive service becomes an 1862(a)(1)(A) covered service--consider how this works for mammograms--i.e. when an abnormality is discovered during a screening exam.

**Issues 11-20**

Radiopharmaceuticals

Create individual HCPCS II codes for each radiopharmaceutical so that carriers do not have to accept unlisted codes. This is needed to pay the claims accurately.

**Issues 21-30**

Cost-to-Charge Ratios

Post an explanation on how cost-to-charge ratios work, why these are used, and whether or not this methodology encourages hospitals to raise their retail rates to compensate for Medicare fee reductions. Include some examples. Let the public know how Medicare pays hospitals in detail. Currently, the process is more like making sausage. See <http://www.suttercorporatewatch.com/news/DailyRepublic9-1-04.pdf>

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Submitter :  Date & Time:   
Organization :   
Category :

**Issue Areas/Comments****Issues 1-10**

Devices

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS?1427?P  
P.O. Box 8010  
Baltimore, MD 21244?8018.

Reference: CMS-1427-P Deep Brain Stimulator Pulse Generator Replacement-CPT 61888  
assigned to APC 0688

Lee Memorial Health System is a public hospital located in Southwest Florida. Our facilities include three acute care facilities, a children's hospital, skilled nursing facility, an acute inpatient rehabilitation facility, and physician practices.

Last year, in an ongoing effort to provide medically necessary services to our residents, LMHS developed a Deep Brain Stimulator program for the many area residents with Parkinson's Disease. Additionally, we have a large number of seasonal residents who also require reprogramming and attention to their DBS units that were implanted elsewhere. During our review of the Proposed HOPPS for 2005, we discovered that CPT code 61888 (Revision or removal of cranial neurostimulator pulse generator or receiver) is still assigned to APC 0688 with an unadjusted reimbursement of \$2,429.95. Although we believe this code assignment and reimbursement would be appropriate for a simple revision or removal, this code is also the only one available for use in pulse generator replacement. In most of these cases, despite the fact that there is less surgical intervention, we incur the same expense for the pulse generator replacement as the initial placement of the pulse generator. The initial placement, however, is coded with CPT 61886 (61885) and is assigned to APC 0315 (2005 Proposed) with unadjusted reimbursement of \$20,291.50. Coding the replacement neurostimulator pulse generator device with HCPCS C1767 offers no additional reimbursement, since this device is no longer eligible for pass-through payment. As a result, our total reimbursement is approximately \$2,429.95, while our cost for the pulse generator device alone is in excess of \$8,800.

We failed to recognize this issue in our first year of experience in this service since the pulse generator replacements typically begin several years after insertion. But, as these implanted devices age, the incidence of replacement pulse generators will inevitably rise, shifting over \$6,500 in expenses (excluding any other labor or facility costs associated with this procedure) to the facility.

We believe the appropriate action would be to either make separate reimbursement for the device, or to create a new HCPCS code for the replacement of the pulse generator in an APC with a higher relative weight. It is our sincere hope that CMS will act on this issue in the 2005 Hospital Outpatient Final Rule.

Respectfully,  
Denise E. Adema, RN, MBA  
Sr. Financial Analyst  
Lee Memorial Health System

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE:CMS-1427-P

I feel strongly that mammography reimbursement rates need to be increased. With facilities closing and availability of services decreasing, the demand for mammography increases, while the reimbursement rates have not kept up with the increasing costs of performing the examinations. Soon women will no longer have access to screening mammography services without having to wait many months, if they receive it at all. Mammography has been proven to save lives, and after much research and many years of singing its praises, we will be in a position where the service is obsolete. Hospitals and clinics can no longer afford to upgrade equipment or supply state-of-the-art tools which are so mandatory in a modality that demands no margin for error. There are freezes on budgeting staff and opening positions for mammographers. Mammographers system-wide are being asked to perform more patients with less resources. Newly licensed and certified radiologists out of training have no desire to complete mammography credentialing because of the low reimbursement rates for breast imaging. Even experienced, dedicated, mammography-specialized radiologists are now removing themselves from interpreting mammograms, because it is one of the highest-litigated, lowest-reimbursed modalities in existence. Creating a structure of payment which will allow facilities to provide higher quality, more expedient service to patients will ultimately save the lives of our own mothers, sisters and daughters. Thank you.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-10**

APC Groups

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1429-P  
P.O. Box 8012  
Baltimore, MD 21244-8012

In re: Proposed Rule for the 2005 Outpatient Prospective Payment System  
Section: APC Groups  
Removal of HCPCS Code GO168, Wound Closure By Adhesive, from APC 340

Dear Dr. McClellan:

The purpose of this letter is to provide comment on the removal of HCPCS Code GO168, Wound Closure By Adhesive, from APC 340 in the proposed OPSS rule for 2005.

Since their introduction topical skin adhesives like ETHICON's DERMABOND Topical Skin Adhesive have provided an effective and less invasive method of closing lacerations and operative incisions.

In addition to strong wound closure the use of topical skin adhesives can reduce need for local anesthetic and save time in emergency room as well as operating room settings. Additionally these technologies can eliminate the need for a return visit to remove sutures and their associated costs.

In 2000 the Centers for Medicare & Medicaid Services (then HCFA) placed DERMABOND in a new technology APC. This decision recognized both the significant innovation that this technology represented as well as the additional cost to hospitals providing the product to Medicare Beneficiaries.

In 2003 CMS assigned HCPCS GO168, Wound Closure by Adhesive to APC 340, Minor Ancillary Procedures. Again this decision reflected the value of these technologies and appropriately signaled the acceptance of skin adhesives to the standard of care. At the same time by specifically mentioning this approach to wound closure, the additional cost over traditional forms of closure were reflected in payment when provided for Medicare beneficiaries.

Upon reviewing the proposed OPSS rule for 2005 it has come to our attention that Wound Closure by Adhesive ? (HCPCS GO168) has been removed from APC 340 and will therefore no longer provide hospitals with a mechanism to bill and be paid for the use of closing lacerations and incisions using skin adhesives.

The use of skin adhesives is a notable enhancement to the repair of lacerations and operative incisions and provides many benefits to patients. We want to be sure that Medicare beneficiaries continue to have access to these important technologies.

Medicare, as a national payer and leader in setting reimbursement policy, should retain HCPCS Code GO168, Wound Closure by Adhesive, for payment under APC 340. This decision will continue promote access of these important technologies that benefit Medicare patients.

Please do not hesitate to contact me if you have any questions or if you need any additional information.

Thank you for your consideration.

Sincerely,

Brian B. Vaughn  
Director Health Economics & Reimbursement  
Ethicon Inc.  
A Johnson & Johnson Company  
908)218-3266  
bvaughn@ethus.jnj.com



Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 11-20**

Drug Administration

Drug Administration:

Upon reviewing the "Proposed Coding and Payments for Drug Administration," we were a little concerned when we saw Table 29 and the column for "Maximum units of the APC OCE would assign, regardless of codes billed." We understand the methodology previously employed by CMS and it has functioned well, however this new method fails to address multiple visits on the same day, i.e. a patient is seen at 9:00 am for an infusion and then returns at 3:00 pm for another. Based on Table 29 there would be no reimbursement for the second infusion because of the maximum units assigned.

Multiple visits to the ER/IV Therapy for antibiotic infusions are not uncommon. Failure to acknowledge/consider multiple visits (more than one unit) for infusion therapy would place a heavy burden on these departments/facilities.

Is there a method in place for reimbursing a facility for two infusions on the same date of service? Perhaps modifier '59' or '76'

Your reconsideration would be greatly appreciated.

Thank you,

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear Sir/Madam:

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

During the decision-making process, consider the following:

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

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

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

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

"CMS does not have the statutory authority to restrict who can and cannot provide services "incident to" a physician office visit. This action could be construed as an unprecedented attempt by CMS to seek exclusivity as a provider of physical therapy services.

"To allow only physical therapists and PT assistants, occupational therapists and OT assistants, and speech and language pathologists to provide "incident to" services would improperly provide those groups exclusive rights to Medicare reimbursement.

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

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

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

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

Sincerely,

David W. Stewart, MD

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

AAEM has notified me that these changes are in need of comment.  
Revisions to the Payment Policies Under the Physician Fee Schedule for Calendar Year 2005. As part of that proposal, CMS is asking for comments on its new reassignment provisions. Please be aware that almost all emergency physicians work for a group that does billing in the name of the physician for services provided. The physicians do not have access to the billing information. If the physicians are to be responsible for the accuracy of that billing the groups must be required to give them complete billing information monthly. Giving them "Access" only is fraught with problems for the individual physician, such that such "access" is useless for all practice purposes.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

My name is Jessica White and I am currently a practicing PT in the private sector at an outpatient facility. I feel that I have worked especially hard to gain the knowledge required by a physical therapist academically and clinically to deliver safe, effective and reasonable care. I find it difficult, at times, to be aware of all that may be involved with patient care. And that is why I feel that as a PT, I have been trained to safely, effectively and productively manage patient care, whereas an ATC or exercise physiologist may not. I feel that I have been educated to deliver physical therapy services, whereas athletic trainers are just that. Exercise physiologists are just that. Dental hygenists are just that. Radiology technicians are just that. You get my drift. I would like to support my profession, a well organized and documented field that has done so much for society and medicine. I feel very strongly that ATCs and exercise physiologists are extremely important in the care of patients, but should not take over a responsibility that they are not properly trained for. I feel that I can humbly say that I am not qualified to treat an acute ACL tear on the foot ball field, and they may need to agree that they may not be qualified to treat a patient with a 30 year history of spine pain, status post laminectomy with degeneration of vertebral height and complicating factors including possible orthostatic hypotension, vertebral artery compromise or benign paraxysmal positional vertigo, who also is on extensive medication with a history of depression. Thank you for the opportunity to voice my opinion.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Observation Services

The requirement that "the medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care" is more burdensome to hospitals than the current observation rules. This requirement is more stringent than documentation guidelines for inpatient care for the same conditions.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear CMS,

as a citizen of Santa Cruz county, California. I am greatly concerned by Center for Medicare & Medicaid Services (CMS) designation of Santa Cruz as a "rural" county for terms of medical reimbursement rates.

As you may know, most insurance companies use these designations to determine the reimbursements they pay to our hospitals and doctors. The median price of homes in our county is currently \$630,000.00 ? hardly the price for a home you might find in more rural counties. Yet despite the high cost of living in this county, our hospitals and doctors are still reimbursed as if living expenses in this county were a fraction of what they are.

The net effect of our being designated as a "rural" county is that we are losing medical staff to bordering counties designated as "urban" (these counties can pay their doctors and hospitals higher amounts than we can in Santa Cruz county). And we can not recruit new doctors to move to our county because they can easily bypass Santa Cruz county and work in the San Jose area for much higher wages.

In addition to this, the trauma center that has traditionally served Santa Cruz and Monterey counties (the San Jose Medical clinic) has just decided to shut its doors on December 1, 2005. This leaves citizens of our county in grave danger should they incur trauma injuries. And because our county is incorrectly designated a "rural" county for medical reimbursements, there are no business incentives for new hospitals, trauma centers, or doctors to set up shop in Santa Cruz county.

Please act immediately to update our county's reimbursements status from "rural" to "urban" in order to deliver congress' promise to "fairly and equitably adjust physicians' payments based on local variations in the cost of delivering care.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments****Issues 1-10**

New Technology APCs

ATTN: FILE CODE CMS-1427-P  
New Technology APCs

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

Dear Dr. McClellan:

I am the Medical Director of Nuclear Medicine and PET Services, and I am writing to you regarding Medicare's proposed payment for FDG PET procedures under the Hospital Outpatient Prospective Payment System for Calendar Year 2005. Sunrise Hospital has been providing Positron Emission Tomography (PET) services since 2003. Your proposed changes for PET reimbursement will deleteriously effect our ability to offer this new technology to our patients who desperately need medical help.

I understand that CMS has set forth a number of options that it is considering with respect to the appropriate APC and APC rate for PET and is soliciting public comments on this issue. I would like to urge CMS to retain current Medicare payment for these crucial services in APC 1516 (Option I as set forth in the Federal Register of August 16, 2004.)

I understand that the hospital cost and charge data that CMS uses to establish APC rates appears to suggest that a lower rate would be appropriate, but I believe that either of the two alternatives set forth in the Federal Register would greatly impede access to these crucial diagnostic services. The alternatives proposed by CMS would reduce Medicare payment for FDG PET by about 38% (Option 2) or 21% (Option 3). In addition, CMS is proposing to reduce Medicare payment for the radiopharmaceutical FDG from approximately \$324 to \$220.50 per dose (4-40 mCi/ml), a reduction of about 32%. Our PET program simply cannot sustain such a substantial reduction in Medicare payment in a single year and continue to provide high quality services.

While the clinical benefits of PET are enormous, the costs should not be understated. The establishment of our PET program in 2003 involved the expenditure of approximately \$2,000,000 for the necessary medical equipment, and capital expenditures of approximately \$42,000 to make appropriate renovations to the facility. In addition, the ongoing operational expenditures of the program are high, relative to many other hospital services, requiring highly trained and dedicated staff who are increasingly difficult to recruit.

It is unclear why the cost and charge data accumulated by CMS do not accurately reflect these substantial costs. However, I understand that CMS itself has acknowledged that its methodology may disadvantage highly capital-intensive services, such as PET, since capital costs generally are not specifically allocated to the departments that incur them, thus distorting the cost-to-charge ratio used to impute costs from hospital charges. It does not seem to be appropriate for CMS to reduce Medicare payment for PET services so significantly, when the agency itself has admitted that its methodology disadvantages capital intensive procedures.

While many clinical applications of PET are now established practice, the diagnostic capabilities of this procedure are still being explored: PET fundamentally remains a new technology that should be protected from major year-to-year variations in payment. Our institution's own experience with the technology does not suggest that it is overvalued in light of the costs involved, and I urge CMS not to subject providers of this new service to so significant a reduction in payment on the basis of a methodology that, by CMS's own admission, fails to appropriately weight capital intensive procedures.

Sincerely yours,

Wayne Jacobs, M.D.

Medical Director of Nuclear  
Medicine and PET Services.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

I have an exclusive practice in lymphoma. Radioimmunotherapy (RIT) is now an integral part of therapy for many of the relapsed cases who don't have other options. It is crucial that we are able to continue to offer this treatment to our patients without burdening them with large co-pay. The proposed change in reimbursement for 2005 will exclude large number of patients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please consider reimbursement for patients receiving the drug, Bexxar. Bexxar is a complex therapy where only select hospitals can administer treatment. In consideration of providing state of the art care for patients who have relapsed non-hodgkin's lymphoma where all other treatment options have been exhausted, to deny treatment because reimbursement will not cover the cost of administering the treatment creates a reimbursement barrier that limits leading edge treatment for this disease. The administration of Bexxar requires tailoring the therapeutic dose to each patient and is given over seven to ten days of observation. Thus, hospitals will need to have reimbursement to cover the costs of administration of this newer therapy.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Inpatient Procedures

Regarding proposed rate changes for APC 0659, Hyperbaric Oxygen Therapy, it is my hope that the data and presentation from our professional organization presented by our representatives from HOTA and the Lewin Group will be considered. Please recall that a similar catastrophe some ten years ago concerning reimbursement was not corrected, causing a loss of facilities and thus a loss of availability for patients who require this valuable treatment modality. The data used to make that decision was seriously flawed, as admitted by HCFA officials, just as the data used for the current decision is seriously deficient. The proposed dramatic rate decrease is based on coding errors, but the data are manipulated by CMS in such a way as to indiscriminately decrease future reimbursement for health care, with little to no regard for the patients that we must treat. In addition, using the respiratory center, with its typical low costs not representative of those costs associated with delivering hyperbarics, is arbitrarily manipulating the dollars to provider's disadvantage.

It is my fear that the dramatic decrease in reimbursement for APC 0659 will once again knock the hyperbaric specialty to its knees. We are just recovering from the mistakes CMS made 10 years ago. A 50% reduction does not make sense to anyone familiar with the costs of providing any valuable medical service in the year 2004.

Please objectively re-evaluate your data and consider the presentation by our professional organization. Do not make the same mistake of being arbitrary and unyielding as HCFA did in the past. The specialty can not continue to survive and fight these wars every few years.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 11-20**

Radiopharmaceuticals

I have general concern over the reduction in payment for the isotopes used in PET and PET/CT imaging. I am certain that the manufacturing and distribution network required to meet the imaging service centers needed for that 'cost effective' use of PET is not in place. In other words if the study that was done to establish payment for this modality was correct, then the industry still needs some time to mature and develop in order to provide 'cost effective' algorithms using PET. I think that the reduction proposed for the scan and the radiopharmaceutical will potentially jeopardize the initial intentions of CMS. Please reconsider your proposal, and atleast maintain the payment structure for the next 3 to 5 years until the service network of scanners and cyclotrons are established to provide medicine that will ultimately benefit the Medicare budget. Thank you for your consideration.

Mike Chavez, Nuclear Pharmacist  
Diversified Pharmacy Group 678.416.6053

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 11-20**

New Drugs, Biologicals, and Radiopharmaceuticals Pass-Throughs

The proposed decreased rates of reimbursement for FDG radiopharmaceutical for 2005 is inappropriate, unfair, and out of touch with the current market costs for FDG.

We currently must pay \$450-/dose of FDG for patients undergoing PET scans. The current rate of reimbursement of \$324- is already \$126-less/dose than what we must pay to cover this cost. A proposed reduction of \$112- only adds further insult to injury. Please research REAL market costs for these expenses before considering such changes in reimbursement rates. Thank you.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 21-30**

Payment Rate for APCs

Dear CMS Representative,

Thank you for the opportunity to comment on the CY 2005 HOPPS rate for PET scanning. I am pleased that the CMS recognizes that PET is an important technology and would like to ensure that the technology remains available to Medicare beneficiaries when medically necessary. Further, I would like to recognize the complexity faced by the CMS of ensuring access while balancing provision costs. To this end I would like to offer comment on CMS-1427-P.

Our PET service is located in an urban area associated with higher costs of provision. Our monthly demand for PET is conservative. Our pro forma includes costs associated with; equipment, physical space, service and preventative maintenance, technologists, insurances, office staff, benefits, utilities, specialist education, radiologist education, bad debt, and cancelled studies. Many of these costs are variable and increase annually.

While we support the efforts of the CMS to appropriately expand indications for PET based on evidence-based criteria, we do not support the proposed reduction for PET as detailed in the Federal Register, August 16, 2004, Vol. 69:157. Such a reduction would have a dramatic negative impact on our service as it will not keep pace with our cost to provide services. To this end, we respectfully request that the CMS consider maintaining current reimbursement levels through 2005.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

As Nuclear Medicine PET technologist I see the value of this important diagnostic tool every day. It would be inexcusable to shorten the lives of cancer-stricken patients by denying them the benefits of PET because of reimbursement reduction, which would lead to unnecessary surgeries with even higher pricetags.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-10**

New Technology APCs

In our small, rural hospital setting it would be devastating to have the reimbursement cut to our facility. We are basically at a break even situation for our OP PET services which we provide only every other week. By decreasing reimbursement I truly feel that the hospital will discontinue the service to our patients and referring physicians requiring the patient to drive 1-2 hours to receive this test which has proven vital in their treatment and outcome.

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

if you are increasing the rates and including more payments for these procedures fine.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

HOPPS PET

As a physician in the community I am concerned over the proposed payments for CY 2005 PET reimbursement rates. As a Nuclear Medicine/Radiologist, I strongly feel that these proposed changes will limit the health care of oncology patients. PET scans have been a tremendous addition to medicine. Not only are they improving the treatment of cancer patients, but in the long run are cost effective. I am very worried that decreasing reimbursements for PET scan are going to decrease the number of scanners in the community(which are already too few--we have a 6 week waiting list). The time it takes to read a PET scan is double or triple the time it takes to read a CT or MRI. Also, the time it takes to do a PET scan is approx. one hour as opposed to a CT that takes seconds. The CMS may want to just decrease the reimbursement of the radiopharmaceuticals(as well as chemotherapy reimbursements), but I would strongly recommend that the PET scan reimbursements not be adjusted. The impact of the cuts will ultimately compromise patient care. Thank you for your time,  
Franco Policaro MD

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 1-10**

New Technology APCs

HOPPS PET

As a physician in the community I am concerned over the proposed payments for CY 2005 PET reimbursement rates. As a Nuclear Medicine/Radiologist, I strongly feel that these proposed changes will limit the health care of oncology patients. PET scans have been a tremendous addition to medicine. Not only are they improving the treatment of cancer patients, but in the long run are cost effective. I am very worried that decreasing reimbursements for PET scan are going to decrease the number of scanners in the community(which are already too few-- we have a 6 week waiting list). The time it takes to read a PET scan is double or triple the time it takes to read a CT or MRI. Also, the time it takes to do a PET scan is approx. one hour as opposed to a CT that takes seconds. The CMS may want to just decrease the reimbursement of the radiopharmaceuticals(as well as chemotherapy reimbursements), but I would strongly recommend that the PET scan reimbursements not be adjusted. The impact of the cuts will ultimately compromise patient care. Thank you for your time,  
Franco Policaro MD

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 11-20**

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

It has come to my attention there may be a change in the proposed rule concerning reimbursement issues associated with Bexxar therapy. Bexxar is an effective treatment for relapsed, refractory or transformed CD 20 positive, Non-Hodgkin's Lymphoma. Response rates in these patients may be as high as 80% making it very efficacious and 37% of all patients have durable remissions beyond one year with many responses lasting 6-9 years.

With the proposed reimbursement changes, a barrier may arise for access in these heavily treated patients. Bexxar is a complex therapy requiring unlabeled and radiolabeled antibody administration over a seven to ten day period. Numerous departments participate in the care of these patients, including: hematology/oncology, nuclear medicine, pharmacy, and radiopharmacy. The prescribed dose is tailored based on biologic clearance of the radioisotope allowing for individual dosing.

Under the proposed rule, reimbursement will be significantly below the actual cost of the product, not including multiple other tasks necessary for delivery, including scanning and compounding.

My concern is the shortfall in reimbursement may limit access to this new therapy, requiring patients to receive less effective therapies. This cutting edge treatment may be disallowed due to reimbursement shortfalls.

Please revisit the reimbursement rules for Bexxar and other forms of radioimmunotherapy to ensure the cost of the drug is recovered therefore reducing inaccessibility to patients.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Issues 11-20**

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

Dear Sir or Madam:

One of the significant advances in the past few years in the treatment of patients with relapsed and refractory non-Hodgkin's lymphoma, has been the FDA approval of Bexxar. Bexxar has been indicated for the treatment of patients who have not only failed chemotherapy, but also immunotherapy with rituximab. Basically, these patients are left without any further therapeutic options.

Of significant importance, despite the fact that patients treated to date have failed all other therapeutic maneuvers, data presented at recent national hematology and oncology meetings have shown that a significant percentage of these "failed" patients not only have responded anew, but many are alive and free of disease as long as 8 years following a single treatment with Bexxar. Given that this was a single treatment delivered over a 7-14 day period, these results are nothing short of spectacular. Obviously, the FDA panel that reviewed the dossier thought similarly in recommending approval for this product to be available to the American public.

I stress the fact that a single therapy delivered over 7-14 days is all that has been required to achieve these long term durable remissions. Other options that could be considered in this heavily treated patient population are further rounds of chemotherapy that typically are administered over many months, and not infrequently require expensive supportive care measures. Thus, the cost (both financial and healthwise to the patient) from a single treatment with Bexxar, is modest compared to the repetitive rounds of chemotherapy and required supportive care.

I have become aware that the 2005 CMS re-imburement will be subject to a significant reduction compared to 2004 levels. This re-imburement level will be significantly below the actual cost of the treatment. Although only one treatment is necessary, the Bexxar treatment regimen requires a team approach of medical oncologists, nuclear medicine physicians and technicians, nurses, and radiopharmacists. The patients are treated in specialized outpatient facilities not offered by every hospital. Thus, specialized centers are needed in each community. However, the re-imburement cuts to be initiated by CMS will simply make it impossible for hospitals and physicians to offer this therapy at a financial loss. It would be a devastating situation, indeed, for physicians to have to deny their patients of potential life-saving therapy.

For unknown reasons, the incidence of non-Hodgkin's lymphoma is increasing in the elderly, the population covered by CMS. If hospitals and physicians are not re-imbursed at reasonable levels to cover the cost of the medication and its formulation and administration, the therapy simply will not be made available to patients. This is a serious issue.

I implore CMS to re-consider the proposed re-imburement schedule to cover the costs of the drugs, its handling and administration so that this valuable therapy will be made available to patients.

Should you have any questions in this regard, or if I can be of any assistance in your deliberations, please do not hesitate to contact me.

Thank you for your consideration of this important matter.

Sincerely yours,

Robert L. Capizzi, MD