Submitter : scott goode **Date & Time:** 08/10/2004 02:08:00

Organization : salve regina

Category : Other Health Care Professional

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.

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 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

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.

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:

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Submitter : Mr. Mark Mac Aleese **Date & Time:** 08/12/2004 04:08:45

Organization : Special Tree Rehabilitation System

Category : Other Health Care Professional

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 my 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 : Ms. Mary Eileen Bezman **Date & Time:** 08/13/2004 01:08:11

Organization : NY Presbyterian Hospital

Category : Health Care Provider/Association

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 : David Pritchett **Date & Time:** 08/15/2004 04:08:59

Organization : David Pritchett

Category : Consumer Group

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 : Dr. D Anda Norbergs **Date & Time:** 08/19/2004 09:08:25

Organization : Dr. D Anda Norbergs

Category : Physician

Issue Areas/Comments

Issues 11-20

Drug Coding and Billing

I am a practicing medical oncologist in Florida. As a private practioner 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 useage 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 denials 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 inexperience 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 : Mr. Scott Lucas **Date & Time:** 08/20/2004 01:08:59

Organization : Great Plains Regional Medical Center

Category : Health Care Industry

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

The payment rate for reimbersement of the Pharmaceutical used in PET Scanning is altready below our costs and the proposed reimbersement rates would represent a dramatic loss for us. The proposed rates that we would be reimbersed 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 reimbersement would mean that we would be donating this service to our patients or discontinuing it and forcing very ill patients to travel clear accross 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 reimbersements it would cause great damage to Patient care and the facilities that deliver Patient care.

Submitter : Ms. Paula Lenane **Date & Time:** 08/23/2004 10:08:18

Organization : Pottstown Memorial Medical Center

Category : Hospital

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 : Mr. Bruce Langevin **Date & Time:** 08/24/2004 01:08:09

Organization : Bolton Physical Therapy

Category : Physical Therapist

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

CMS-1427-P-11

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 Immunoadsorption and plasma reinfusion. This code has always and should still be under APC 0112, which is Apheresis, Photophoresis, and Plamapheresis. 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.

CMS-1427-P-11-Attach-1.doc

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 Immunoadsorption and plasma reinfusion. This code has always and should still be under APC 0112, which is Apheresis, Photophoresis, and Plamapheresis. 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 OPPS for 2004 and the proposed OPPS for 2005.

2004 Payment rates for Hospital Outpatient prospective Payment System; Final Rule (Novemeber 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 : Mr. John Heusman **Date & Time:** 08/25/2004 04:08:14

Organization : St. Anthony North SportSciences

Category : Other Health Care Professional

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, recoginzed by the AMA, as an allied health professional and be compensated for thier knowlege, skills and work ethic.

Submitter : Mr. Mike Metro **Date & Time:** 08/26/2004 05:08:52

Organization : Salina Regional Health Center

Category : Nurse

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 : Ms. Lynn Saccoliti **Date & Time:** 08/29/2004 09:08:15

Organization : Rita Medical Systems

Category : Device Industry

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

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 OPPS for 2004 and 2005.

DATA USED TO CALCULATE 2005 REIMBURSEMENT

CPT/HCPCS Code	APC	2005 Proposed Payment	Single Frequency Claims	Minimum Costs	Maximum Costs
Claims Data is 4/1/2002-12/31/2003					
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
Claims Data is 4/1/2002-12/31/2002					
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 : Ms. Carly Manghelli **Date & Time:** 08/30/2004 01:08:37

Organization : National Athletic Trainers' Association

Category : Health Care Professional or Association

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 : Mr. Gil Uy **Date & Time:** 08/31/2004 11:08:52

Organization : American Therapy Services

Category : Other Health Care Provider

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 : Dr. gerald Rogan, MD **Date & Time:** 09/05/2004 10:09:21

Organization : Rogan Consulting

Category : Individual

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 elible 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 moves 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 intial 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

Submitter : Ms. Denise Adema **Date & Time:** 09/07/2004 06:09:53

Organization : Lee Memorial Health System

Category : Hospital

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

CMS-1427-P-20

Submitter : Mrs. Pamela Whitaker **Date & Time:** 09/10/2004 12:09:00

Organization :

Category : Health Care Professional or Association

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.

CMS-1427-P-21

Submitter : Mr. Brian Vaughn **Date & Time:** 09/14/2004 03:09:50

Organization : Ethicon Inc.

Category : Device Industry

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 OPPS 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 OPPS 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

CMS-1427-P-22

Submitter : Mr. Paul Jackson **Date & Time:** 09/14/2004 10:09:51

Organization : Intermountain Health Care

Category : Health Care Provider/Association

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 : Dr. David Stewart **Date & Time:** 09/15/2004 02:09:13

Organization : Chester Family MedCare

Category : Physician

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 : Dr. EARL JOHNSON **Date & Time:** 09/15/2004 09:09:22

Organization : Dr. EARL JOHNSON

Category : Physician

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 practicle purposes.

Submitter : Miss. Jessica White **Date & Time:** 09/16/2004 04:09:40

Organization : Guenthner Physical Therapy

Category : Physical Therapist

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 : Ms. S. Oprsal **Date & Time:** 09/17/2004 01:09:03

Organization : Ingham Regional Medical Center

Category : Other Practitioner

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.

CMS-1427-P-27

Submitter : **Date & Time:** 09/20/2004 01:09:49

Organization :

Category : Individual

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 : Dr. Wayne Jacobs **Date & Time:** 09/20/2004 01:09:10

Organization : Sunrise Hospital, Las Vegas, Nevada

Category : Physician

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.

CMS-1427-P-29

Submitter : Dr. Ayad Al-Katib **Date & Time:** 09/20/2004 02:09:58

Organization : Van Elslander Cancer Center/St John hosptial

Category : Physician

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 : Dr. Rafat Ansari **Date & Time:** 09/20/2004 07:09:59

Organization : Michiana Hematology-Oncology, P.C.

Category : Physician

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 bee exhausted, to deny treatment because reimbursement will not cover the cost of administrating 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.

CMS-1427-P-30-Attach-1.doc

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

The attachment to this document is not provided because:

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

CMS-1427-P-31

Submitter : Dr. Greg Robicheaux **Date & Time:** 09/20/2004 08:09:09

Organization : Our Lady of Lourdes

Category : Physician

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 avilability 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 indiscrimately 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 it's typical low costs not representative of those costs asociated 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 it's 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 tha 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 : Mr. Michael Chavez **Date & Time:** 09/21/2004 01:09:29

Organization : Diversified Pharmacy Group

Category : Health Care Professional or Association

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 develope in order to provide 'cost effective' algorithams 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 : Dr. Stephen Gerard **Date & Time:** 09/21/2004 02:09:30

Organization : Seton Medical Center (Daly City, CA)

Category : Physician

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 : Mr. Robert Popilock **Date & Time:** 09/21/2004 01:09:12

Organization : Arlington Medical Imaging

Category : Other Technician

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 : Mr. Richard Perez **Date & Time:** 09/21/2004 03:09:27

Organization : jSan Diego Regional PET Center

Category : Health Care Professional or Association

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:** 09/21/2004 06:09:35

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

New Technology APCs

In our small, rural hospital setting it would be devestating 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 : Ms. cassandra carter **Date & Time:** 09/21/2004 08:09:41

Organization : Ms. cassandra carter

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. Franco Policaro **Date & Time:** 09/21/2004 10:09:10

Organization : Dr. Franco Policaro

Category : Physician

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 decreaseing 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 : Dr. Franco Policaro **Date & Time:** 09/21/2004 10:09:54

Organization : Dr. Franco Policaro

Category : Physician

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 decreaseing 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

CMS-1427-P-40

Submitter : Dr. Stephanie Gregory **Date & Time:** 09/22/2004 04:09:21

Organization : Rush University Medical Center

Category : Physician

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.

CMS-1427-P-40-Attach-1.doc

September 20, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1427-P
P.O. Box 8010
Baltimore, Maryland 21244

RE: Bexxar and Other Forms of Radioimmunotherapy

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.

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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.

Sincerely,

Stephanie A. Gregory, MD
The Elodia Kehm Professor of Medicine
Director, Section of Hematology and Stem Cell Transplantation
Rush University Medical Center
Chicago, Illinois
(312)942-5982

Submitter : Dr. robert capizzi **Date & Time:** 09/22/2004 06:09:15

Organization : Dr. robert capizzi

Category : Physician

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-imbursement will be subject to a significant reduction compared to 2004 levels. This re-imbursement 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-imbursement 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-imbursement 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

Submitter : Mr. Dean Bowers **Date & Time:** 09/23/2004 06:09:21

Organization : Mon Health Systems

Category : Hospital

Issue Areas/Comments

Issues 1-10

Physical Examinations

I feel tests should be covered with the initial evaluation. Many diseases that are missed by physical exam can be detected by laboratory tests.

Submitter : Dr. Joseph O'Connell **Date & Time:** 09/23/2004 06:09:03

Organization : Oncology Hematology Care Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The Proposed rule will devastate our two physician practice. We participate in a large group purchasing process already, have limited our overhed by curtailing staff hours, are laing off our Social Worker because of inadequate eimbursement. The private payers are reimbursing LESS THAN MEDICARE NOW, and will we will not be able to remain in business as the only pracetice in our comunity of 60,000 due to the 17% cut in reimbusement going into effect next year.

Submitter : Mrs. Brenda Newbrough **Date & Time:** 09/23/2004 07:09:26

Organization : Monongalia Health Systems

Category : Hospital

Issue Areas/Comments

Issues 1-10

Inpatient List

It is my recommendation that we need to continue now and in the future the "Inpt only List". It is a valuable resource to our facility,it helps us to assist our staff,physicians and their staff as to what the appropriate status of the patient should be.If the Inpt only list would be eliminated,I foresee that hospitals could have an increase in inappropriate observation stays when in reality the patient should have been an appropriate inpt stay. I feel the guidelines that are now in place for inpt only procedures should remain.This will continue to ensure the safety of patients.

Submitter : Mr. Dean Bowers **Date & Time:** 09/23/2004 06:09:21

Organization : Mon Health Systems

Category : Hospital

Issue Areas/Comments

Issues 1-10

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Submitter : Dr. Joseph O'Connell **Date & Time:** 09/23/2004 06:09:03

Organization : Oncology Hematology Care Associates

Category : Physician

Issue Areas/Comments

GENERAL

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Submitter : Mrs. Brenda Newbrough **Date & Time:** 09/23/2004 07:09:26

Organization : Monongalia Health Systems

Category : Hospital

Issue Areas/Comments

Issues 1-10

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Submitter : Dr. Robert Meredith **Date & Time:** 09/24/2004 01:09:18

Organization : Dr. Robert Meredith

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule for hospital outpatient reimbursement with regard to I-131 tositumomab (Bexxar)sets a level of reimbursement that will likely be below the level at which hospitals can acquire this particular drug.
This decreased reimbursment will likely severely limit the ability of clinicians like myself to make treatment decisions based upon medical considerations rather than financial considerations. Radioimmunotherapy represents a novel and revolutionary approach to treating lymphoma and in many cases represents the last and best hope that these patients have for a cure or prolonged remission.
This is a complex therapy with many medical and clinical barriers, it requires individualization of the dosage and complex compounding of the drug as well as specialized equipment and specially trained personnel.
To add another barrier will likely deny this therapy to individuals who would benefit from it. Currently in Wisconsin, this is already an infrequent and under-utilized therapy. Further reduction in reimbursment will only add to this problem.
I strongly urge you to reconsider your reimbursement amounts for I-131 tositumomab to a level that will at least not financially penalize hospitals for acquiring this drug.

Submitter : Dr. Oliver Press **Date & Time:** 09/24/2004 03:09:06

Organization : Fred Hutchinson Cancer Research Center

Category : Physician

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

September 22, 2004

Re: Reimbursement for Tositumomab (Bexxar)

As a Professor of Medicine at the University of Washington and as a member of the Fred Hutchinson Cancer Research Center, I am writing to protest the proposed rules for 2005 Hospital Outpatient Prospective Payment for radioimmunotherapy, particularly Bexxar. As a specialist in the treatment of patients with malignant lymphoma, I believe that the availability of radiolabeled monoclonal antibodies such as Bexxar and Zevalin, provides an important new treatment and hope for patients with this type of cancer who have failed conventional chemotherapy and antibody regimens. Clinical studies have shown that 50-80 % of patients who have failed other types of treatment will respond to this treatment, and that 15-20% of patients will not experience recurrence of their disease for many years after treatment. Although this sophisticated treatment is very safe and effective, it is expensive to produce and administer. The proposed reduction in reimbursement for Bexxar from $24,777 in 2004 to $21,663 in 2005 will make it virtually impossible to administer this novel new treatment because hospitals and physicians will lose money with every dose they administer. Indeed, the proposed reimbursement amount for the product is below the acquisition price of the product without even accounting for the necessary expenses for compounding each patient?s dose, administering the doses, and providing professional fees to supervise the treatment in a safe environment. We believe that this 13% reimbursement rate reduction is excessive and unwarranted and will prevent the delivery of this important new treatment to the patients who could benefit from it.

Thank you for considering this request.

Sincerely,

Oliver W. Press, MD, PhD
Member, The Fred Hutchinson Cancer Research Center
Recipient, Dr. Penny E. Petersen Memorial Chair for Lymphoma Research
Professor of Medicine and Biological Structure
Associate Director, Medical Scientist Training Program
University of Washington Medical Center

CMS-1427-P-47

Submitter : **Dr. Peter Allinson** **Date & Time:** **09/24/2004 09:09:04**

Organization : **GBMC Healthcare**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS?1427?P; APC 0659 Hyperbaric Oxygen Therapy

CMS-1427-P-47-Attach-1.txt

CMS-1427-P-Attach-047

Peter G Allinson, M.D.
6701 North Charles Street
Baltimore, MD 21204
GBMC Healthcare
Division of Hyperbaric Medicine
September 24, 2004

Secretary Tommy G. Thompson Center for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, MD 21244-8018
Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Tommy G. Thompson:

I am a physician practicing Hyperbaric medicine in the Baltimore area, I have been practicing Hyperbaric medicine since 1978 and am American Board certified in Anesthesiology, Critical Care Medicine and Hyperbaric Medicine. While I have not changed the fees that I charge for my services for the past 14 years, I have experienced Medicare and private insurers lowering the “allowed” charges both for the physician and the facility despite increasing costs of practice. It is interesting that the insurers have continued to raise the fees they charge while lowering the monies they pay out for a particular procedure all the while claiming that health care costs are going up. Both the hospitals and physicians are now expected to provide care with less and lees money received to cover expenses, this will only result in the closure of facilities and the prevention of access of patients to medical care. The hospital that I work at is a community 400 bed size. We have 3 sechrist monoplace chambers running 12+ hours per day at full capacity with a wait list that sometimes is 4-6 weeks long. The hospital can’t afford to expand us despite the need and recently cut back our nursing staff to the point that if someone is out sick or on vacation , one of the chambers is closed. The Maryland HSCRC sets the rate of reimbursement in our state and it is below the published Medicare rate. I believe that a facility rate of greater than $120 per 30 minutes of treatment with adjustment for increased costs (malpractice, fuel,, etc) is fair. The physician charges should also be time based as well. My current charge is $ 250 per treatment, Medicare “allows” $134 per treatment and is proposing reducing this further, this does not make any sense. Malpractice is going up in our state by at least 60% this year, gas prices, telephone, electric and support salaries have also risen further lowering net reimbursement.

Sincerely,

Peter G. Allinson, M.D.
Co-director

Submitter : Karl P. Carlson Jr. **Date & Time:** 09/24/2004 08:09:16

Organization : Cape Fear Orthotics and Prosthetics Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Date: September 23, 2004

To: CMS

From: Karl P. Carlson Jr. CP

Re: Section 302 Comments for CMS MMA Proposal

1. We appreciate the goal of CMS to mitigate the over-usage of DMEPOS items. But it is important also to recognize the impact to the end user, the patient. Requiring patients to pay out of pocket for a face to face physician exam in order to obtain a prescription for vital repairs or simple replacement of worn DMEPOS items is of great concern. Patients who cannot afford an office visit charge could potentially cause themselves further physical harm by disregarding their medical need, due to financial constraints. As a result CMS could incur more costs while simultaneously decreasing the potential to achieve quality patient care. The impact of further physical harm will create further economic hardships to the patient and their families.
2. Commonly replaced items such as suspension sleeves, limb shrinker socks, prosthetic socks etc. should be exempt from a face-to-face visit. Physicians should be reimbursed by CMS for their services regardless of whether the visit is related to DMEPOS services or not.
3. Due to the complex nature of orthotic/prosthetic management, a time frame of 30 days to fulfill prescription order is not always feasible. Transportation issues alone for the patient to see the physician as well as orthotic/prosthetic provider often engulf 30 days for the initial evaluation.

Submitter : Ms. Lillian Schmidt **Date & Time:** 09/24/2004 08:09:45

Organization : Ms. Lillian Schmidt

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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-1427-P-50

Submitter : **Date & Time:** 09/24/2004 09:09:16

Organization :

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

Re: Therapy "Incident to"
Dear Dr. McClellan:

I am writing as a concerned, licensed physical therapist with 28 years of practice experience, primarily in the state of Pennsylvania and also on behalf of my parents, ages 76 and 80 who have received care in the Medicare system in the past few years for total knee replacement and rehabilitation following kidney cancer. Both of them had co-morbidities that absolutely would have made treatment in an ?incident to? environment with unlicensed, technically trained personnel dangerous and likely would have resulted in a protracted period of recovery.

I strongly support CMS? proposal that qualifications of individuals providing physical therapy services "incident to" a physician should meet personnel qualifications for physical therapy in 42 CFR ?484.4, with the exception of licensure. This would assure that individuals providing physical therapy must be graduates of an accredited professional physical therapist program or must meet certain grandfathering clauses or educational requirements for foreign trained physical therapists. Physical therapists receive significant training in anatomy and physiology, have a broad understanding of the body and its functions, and have completed comprehensive patient care experience. This background and training enables physical therapists to obtain positive outcomes for individuals with disabilities and other conditions needing rehabilitation.

Medicare dollars are too precious to allow them to be spent on provision of care by anyone other than a professional with expertise to evaluate and treat with the utmost efficacy. It is not in the best interest of the consumer for a doctor to tell his /her patient that they need physical therapy and to encourage them to receive it in their office, from their ?therapists? when the ?therapist? has minimal training to provide the care. Section 1862(a)(20) of the Social Security Act clearly requires that in order for a physician to bill "incident to" for physical therapy services, those services must meet the same requirements for outpatient therapy services in all settings. Thus, it would seem that the services must be performed by individuals, who are graduates of accredited professional physical therapist education programs.

In January, 2006, a moratorium on the financial limitation on physical therapy services is due to expire. If untrained personnel are allowed to deliver physical therapy services, it is conceivable that a Medicare beneficiary could exhaust their benefit without ever having been evaluated or treated by a licensed physical therapist.

Thank you for consideration of my comments on this very important issue.

Sincerely,

Carole S. Galletta PT, MPH
Philadelphia, PA 19106

Submitter : Dr. Thomas Bozzuto **Date & Time:** 09/25/2004 01:09:35

Organization : Baptist Health Sysgem

Category : Physician

Issue Areas/Comments

Issues 21-30

Cost-to-Charge Ratios

VIA ELECTRONIC MAIL
www.cms.hhs.gov/regulations/ecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS?1427?P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson

? This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).

? Baptist Health System is a collection of three hospitals in the northeast Florida area (Jacksonville). We are the only hyperbaric facility in a 90 mile radius that serves over 1.5 million people. We are currently the 6th busiest hyperbaric facility in the United States and provide over 3,000 patient treatments per year.

? If the new rates are implemented, our ability to provide services to our patient population would be severely hampered because the reimbursement will not compensate for the costs of running such a large department. Nearly 500 patients per year would lose the ability to have hyperbaric oxygen therapy which would severely impact loss of limb and loss of life.

? Our department firmly supports the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group?s findings. We support consideration of the following four alternatives which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

I appreciate your consideration for this very important matter.

Very sincerely.

Thomas M. Bozzuto, D.O, FAAEM, FACHM, CWS
Medical Director, Hyperbaric Medicine and Wound Care Institute
Baptist Health System, Jacksonville, FL

Immediate Past-President

American College of Hyperbaric Medicine

Submitter : Dr. Jonathan Titus **Date & Time:** 09/26/2004 03:09:14

Organization : Inova Mt. Vernon Hospital, Alexandria VA

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

APC 0659 Hyperbaric Oxygen Therapy
For several years the payment for 99183 had been low due to a technical error at CMS. This was repaired and the fee raised. We revised budgets. We hired people. And now suddenly the rate is to be dropped again.
Please use the methodologies worked out with Lewan assoc or somesuch and try to maintain some dependability. We are a not-for-profit hospital, adhere to rigorous quality standards, utilization guidelines etc and cannot withstand these wild swings in payment rates
Jonathan Titus, MD, Medical Director, Hyperbaric Medicine Unit, Inova Mt Vernon Hospital

Submitter : Dr. Gary Mailman **Date & Time:** 09/27/2004 01:09:43

Organization : Hyperbaric Med Consultants, PA

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Relative Weights

9/27/2004

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

This comment concerns the Dept. Of Health and Human Services Centers for Medicare & Medicaid Services. 2005 Hospital Outpt. Prospective Payment System proposed rule ('Proposed Rule') that sets forth new reimbursement rates for hyperbaric oxygen therapy treatments ('HBOT'). 69 Fed. Reg. 50448 (AUG.16, 2004).

I am a full time hyperbaric physician practicing at a medium sized urban hospital here in Austin, TX. St. David's Medical center is currently the only hospital in a multi-county area providing emergency hyperbaric oxygen treatments. Your proposed rates will threaten the ability for us to stay open. This will threaten access to patient care.

I support the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group's findings. I would support consideration of the following four alternatives listed below:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an Opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported Hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 min. increment.

We appreciate your consideration for this very important matter.

Sincerely yours,
Gary M. Mailman, MD

Submitter : Dr. Michael Torma **Date & Time:** 09/27/2004 02:09:34

Organization : Torma Executive Consult

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Groups

APC 0659 Hyperbaric Oxygen Therapy

CMS-1427-P-54-Attach-1.doc

To:
Secretary Tommy Thompson
Center for Medicare & Medicaid Services
CMS-1427-P
Concerning:
CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

I am writing to express grave concern for the proposed rule setting forth new 2005 reimbursement rates for hyperbaric oxygen therapy (HBOT), as published in the August 16th Federal Register, 50448.

As a physician involved in the care of patients at the Christus Schumpert Wound and Hyperbaric Medicine Center in Shreveport, Louisiana, it is apparent to me that the impact of your proposed rates would be to cripple and/or cause the closure of the operation just begun this year. It would thus disenfranchise hundreds of patients, urban and rural, who have begun to look to this center for the only really comprehensive care in the region (this is not to say the only HBOT care available).

I am aware of the CMS study that led to the proposed rate changes. I am also aware of the Lewin Group paper and its findings. From my personal perspective, as I see the resources needed by Christus Schumpert to field its impressively effective wound healing program, I am totally convinced that adopting the Lewin Group $118.21/30 minute increment (facility charge) is the appropriate immediate action that CMS should take. It would be my second choice that you use the cost to charge ratio of 0.47.

Respectfully submitted:

Michael J Torma, MD, FACS, FACPE
7013 Sand Beach Blvd
Shreveport Louisiana, 71105
318 681 5050

CMS-1427-P-55

Submitter : Mr. Jack Tench **Date & Time:** 09/27/2004 03:09:45

Organization : Carolinas Medical center

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Department of Hyperbaric Medicine
Carolinas Medical Center
PO Box 32861
Charlotte, North Carolina 28232

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, Maryland 21244-8018

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Mr. Thompson,
This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).
I am currently employed by Carolinas HealthCare System, Department of Hyperbaric Medicine. CHS is a 700+ major trauma center located in Charlotte, NC. Patients throughout the state are referred to our center for HBO services as well as many other medical procedures offered by our system. All patients referred to HBO are seen and evaluated by a Hyperbaric Physician to determine medical necessity guidelines and benefits of therapy per their respective diagnosis. Communication is maintained to the patient, referring physician to document status and progress of the treatments, etc.
The proposed rates for HBO for 2005 pose potential threats to hospital Hyperbaric Departments by compromising their ability to remain open and threatens the access to a viable center by patients needing the services by having them close.
I support the Hyperbaric Oxygen Therapy Association (HOTA) and the Lewin?s Group?s findings. I support consideration of the following four alternatives which are:
1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47.
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.
I appreciate your consideration for this very important matter at this time.
Professionally submitted,

Jack Tench CHT, RCP, MBA

CMS-1427-P-56

Submitter : Dr. Roberto Penne-Casanova **Date & Time:** 09/27/2004 04:09:22

Organization : Norton Suburban Wound Treatment and Hyperbaric Cen

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

VIA ELECTRONIC MAIL
www.cms.hhs.gov/regulations/ecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS?1427?P; APC 0659 Hyperbaric Oxygen Therapy

1. This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).

2. I am a physician and medical director of a wound care and hyperbaric medicine clinic. We are a hospital based outpatient clinic in Louisville, KY. Our program is the only program in Louisville offering clinical hyperbaric medicine services to our community. Our Hospital, Norton Suburban Hospital, has 500 beds and we do about 1500 hyperbaric treatments per year. Our patients come not only from the metropolitan area of Louisville but also from the surrounding rural communities. We only treat approved indications as stated by CMS and the Undersea and Hyperbaric Medical Society. This is my sole full time medical practice after being trained and work for the United States Air Force as a hyperbaric medicine specialist for 20 years and retired.

3. The above mentioned proposed changes in rates will threaten our ability to stay open. With the current rates we can barely stay open due to the high cost of providing these services. If the proposed rates become effective for 2005, it is most likely that we will be forced to close our services. Our patient population will not be able to receive these treatments increasing their morbidity and in some cases their mortality. If hyperbaric medicine is not available, the cost of managing diabetic ulcers, osteomyelitis, and other serious conditions will be much prolonged and the cost for their care will dramatically increase.

4. I strongly support the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group?s findings that CMS cost and cost-to-charge ratios calculations are not accurate. I strongly urge CMS to consider the following four alternatives which are:

a. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
b. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

c. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

d. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Very sincerely

ROBERTO A. PENNE-CASANOVA, MD

CMS-1427-P-56-Attach-1.doc

VIA ELECTRONIC MAIL

www.cms.hhs.gov/regulations/ecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

1. This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"). 69 Fed. Reg. 50448 (Aug. 16, 2004).

2. I am a physician and medical director of a wound care and hyperbaric medicine clinic. We are a hospital based outpatient clinic in Louisville, KY. Our program is the only program in Louisville offering clinical hyperbaric medicine services to our community. Our Hospital, Norton Suburban Hospital, has 500 beds and we do about 1500 hyperbaric treatments per year. Our patients come not only from the metropolitan area of Louisville but also from the surrounding rural communities. We only treat approved indications as stated by CMS and the Undersea and Hyperbaric Medical Society. This is my sole full time medical practice after being trained and work for the United States Air Force as a hyperbaric medicine specialist for 20 years and retired.

3. The above mentioned proposed changes in rates will threaten our ability to stay open. With the current rates we can barely stay open due to the high cost of providing these services. If the proposed rates become effective for 2005, it is most likely that we will be forced to close our services. Our patient population will not be able to receive these treatments increasing their morbidity and in some cases their mortality. If hyperbaric medicine is not available, the cost of managing diabetic ulcers, osteomyelitis, and other serious conditions will be much prolonged and the cost for their care will dramatically increase.

4. I strongly support the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group's findings that CMS cost and cost-to-charge ratios calculations are not accurate. I strongly urge CMS to consider the following four alternatives which are:

a. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.

b. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

c. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year **2003.**

d. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Very sincerely

ROBERTO A. PENNE-CASANOVA, MD

CMS-1427-P-57

Submitter : Mr. William Ryan **Date & Time:** 09/27/2004 05:09:30

Organization : Bay Medical Center

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Groups

Reguarding APC 0659
To whom it may concern:
This letter is to express my grave concerns on the proposed changes in reimbursement for Hyperbaric Services covered under the "Proposed Rule" that sets forth new reimbursement rules for hyperbaric oxygen treatment. 69Fed. Reg. 50448 (Aug. 16, 2004)
I am the Hyperbaric coordinator at Bay Medical Center in Panama City, FL. We are a 400 bed not for profit county hospital located in the panhandle of Florida. We are the sole provider of Hyperbaric therapy both emergent and non-emergent for an area that extends 100 miles to our North, East, and West. A very large percentage of our patients are Medicare recipients who would be forced to go without this life and limb saving service and technology. At this time I don't see how we could maintain our current level of care after these cuts take place and still remain financially responsible to the community. We completely support the Hyperbaric Oxygen Therapy Association (HOTA)position on the finding of the Lewin Groups survey of which we were a participant. Hopefully, you will consider the following four alternatives when you are considering the future of our Hyperbaric Medicine department.
1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47.
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.
We appreicate your consideration for this very important matter.

Very Sincerely,
William Ryan EMT/P, CHT
Hyperbaric Medicine Coordinator
Bay Medical Center, Panama City, FL

Submitter : Mr. WILLIAM RYAN **Date & Time:** 09/27/2004 05:09:18

Organization : BAY MEDICAL CENTER

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

REGUARDING APC 0659. TO WHOM IT MAY CONCERN: THIS LETTER IS TO EXPRESS MY GRAVE CONCERNS ON THE PROPOSED CHANGES IN REIMBURSEMENT FOR HYPERBARIC SERVICES COVERED UNDER THE "PROPOSED RULE" THAT SETS FORTH NEW REIMBURSEMENT RULES FOR HYPERBARIC OXYGEN TREATMENT 69FED. REG 50448 (AUG. 16, 2004) I AM THE HYPERBARIC COORDIANTOR AT BAY MEDICAL CENTER IN PANAMA CITY, FL. WE ARE A 400 BED NOT FOR PROFIT COUNTY HOSPTAL LOCATED IN THE PANHANDLE OF FLORIDA. WE ARE THE SOLE PROVIDER OF HYPERBARIC THERAPY BOTH EMERGENT AND NOT-EMERGENT FOR AN AREA THAT EXTENDS 100 MILES TO OUR NORTH, EAST, AND WEST. A VERY LARGE PERCENTAGE OF OUR PATIENTS ARE MEDICARE RECIPIENTS WHO WOULD BE FORCED TO GO WITHOUT THIS LIFE AND LIMB SAVING SERVICE AND TECHNOLOGY. AT THIS TIME I DON'T SEE HOW WE COULD MAINTAIN OUR CURRENT LEVEL OF CARE AFTER THESE CUTS TAKE PLACE AND STILL REMAIN FINACIALLY RESPOSIBLE TO THE COMMUNITY. WE COMPLETELY SUPPORT THE HYPERBARIC OXYGEN THERAPY ASSOCIATION (HOTA) POSITION ON THE FINDING OF THE LEWIN GROUPS SRUVEY OF WHICH WE WERE A PARTICIPANT. HOPEFULLY, YOU WILL CONSIDER THE FOLLOWING FOUR ALTERNATIVES WHEN YOU ARE CONSIDERING THE FUTURE OF OUR HYPERBAIC MEDICINE DEPARTMENT. 1. LEAVE THE HBOT REIMBURSEMENT RATE AT CY2004 LEVELS UNTILL CMS HAS AN OPPORTUNITY TO DEVELOP AND PERFORM A CLACULATION THAT WILL ACCURATELY DETAIL HBOT COSTS AND COST-TO-RATIOS. 2. DUE TO THE DIFFERENCES IN WHICH THE HOSPITALS HAVE REPORTED COSTS. ADOPT THE OVERALL COST TO CHARG RATIO (CCR) OF .47. 5. APPLY THE LEWIN GROUP METHODOLOGY TO THE 389 HOSPITALS THAT REPORTED HYPERBAIC CLAIMS FOR THE YEAR 2003. 4. ADOPT THE LEWIN GROUP APPROACH OF $118.21 PER 30 MINUTE INCREMENT. WE APPREICATE YOU CONSIDERATION ON THIS VERY IMPORTANT MATTER. VERY SINCERELY, WILLIAM RYAN EMT/P, CHT HYPERBARIC MEDICINE COORDINATOR, BAY MEDICAL CENTER, PANAMA CITY, FL

CMS-1427-P-59

Submitter : Ms. Mary Jim Montgomery **Date & Time:** 09/27/2004 07:09:41

Organization : Bay Medical Center, Panama City, Fl

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

As the Chief Operating Officer of Bay Medical Center in Panama City, I wanted to make my opinion known as it relates to the HBOT (69 Fed. Reg. 50448 dated August 16,2004). As the provider of choice hospital in our community, we provide the majority of care to the community?s wound therapy patients. We have the only HBO unit and serve the catchment area of over 150,000 patients. We strongly support the efforts and recommendations that the LEWIN group proposed. It is critical to our continued survival in our Wound Care program that the reimbursement covers our cost of doing business. The proposed cut would jeopardize our program. Please adopt the approach of paying the $118.21 per 30 minute treatments so that we can continue to provide this valuable service.

Thank you for your willingness to review the calculations that will closely correlate the costs and the cost-to-charges ratio (CCR) of .47.

CMS-1427-P-60

Submitter : Dr. Eugene Worth **Date & Time:** 09/27/2004 07:09:21

Organization : University of Missouri-Columbia Hyperbaric Medicin

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please see attached document about reimbursement for hyperbaric oxygen therapy.

CMS-1427-P-60-Attach-1.doc

September 27, 2004

Secretary Tommy G. Thompson
Center for Medicare and Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

This comment concerns the Department of Health and Human Services Centers for Medicare and Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule that sets forth new reimbursement rates for hyperbaric oxygen therapy (HBOT) 69 Fed Reg 50448 (8/16/2004).

I am the medical director of the Hyperbaric Medicine Center at the University of Missouri-Columbia. The University of Missouri Hospital is a vital provider of tertiary medical services for patients in all of central Missouri, and further, the Hyperbaric Medicine Center is the only full-service hyperbaric center between Kansas City and St. Louis, north to the Iowa state line, or south to Springfield, Missouri.

If the proposed reduction in rates for hyperbaric medicine services goes into effect, this will have profoundly negative impact on the hospital's ability to provide critical and life-saving hyperbaric medicine services to the patient population that we serve. As an example, I am currently treating 2 potentially life-threatening infections now, one a necrotizing fasciitis of the leg and the second a mucormycosis of the sinus and orbit of the eye. Reduction in services means a failure to treat these patients appropriately and may cost them life or limb.

I fully support the the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group's findings. Mr. Secretary, I ask you to consider the following alternatives:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS is able to develop and perform an accurate calculation that details HBOT costs and cost-to-charge ratios.
2. Due to the differences in which hospitals have reported costs, adopt an overall cost-to-charge ratio (CCR) of 0.47.
3. Apply the Lewin Group's methodology to the 389 hospitals that have reported hyperbaric claims for fiscal 2003.
4. Adopt the Lewin Group's approach at $118.21 per 30-minute increment.

Thank you for your consideration for this very important matter.

Sincerely,

Eugene R. Worth, M.D., M, Ed.
Medical Director, Hyperbaric Medicine Center
Associate Professor of Clinical Anesthesiology
University of Missouri Hospital and Clinics

CMS-1427-P-61

Submitter : Steve Anderson **Date & Time:** 09/27/2004 08:09:04

Organization : Lakeview Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

I am the Chief Executive Officer of Lakeview Hospital, a 128 bed primary care hospital located in Bountiful, Utah. In addition to the many needed services we provide to the Bountiful community, Lakeview also provides a valuable service to the state of Utah and the surrounding intermountain region - Hyperbaric Oxygen Therapy Treatement (HBOT). Lakeview has the only multi-place hyperbaric oxygen chamber in the state of Utah. The chamber seats 12 people which has allowed Lakeview to treat entire families traumatized by carbon monoxide poisoning (one of the many approved indications for HBOT). Operating in connection with our hyperbaric oxygen chamber is the only comprehensive wound clinic in our community and surrounding area. The combination of our hyperbaric oxygen chamber and comprehensive wound clinic has literally saved lives and prevented countless amputations. Under the proposed 2005 reimbursement rates for 2005 Lakeview will not be able to continue offering either HBOT or wound care. Why? The costs of providing HBOT is much higher than the proposed reimbursement and we have no way of subsidizing the cost of continuing the HBOT services.

In light of these grim prospects, I want to communicate to you my endorsement of the Hyperbaric Oxygen Therapy Association's position and the findings of the Lewin Group. Please consider the following alternatives:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

Thank you for your time and consideration.

Submitter : Dr. Marilyn Althoff **Date & Time:** 09/27/2004 09:09:34

Organization : Morristown memorial Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

This comment concerns the DHHS/CMS proposed new reimbursement rates for HBOT. THis proposed rate change will threaten the ability of this hospital to continue offering the HBOT service to the community

CMS-1427-P-62-Attach-1.doc

CMS-1427-P-62-Attach-2.doc

Atlantic Hyperbaric Associates, LLC

Marilyn Althoff, MD, Medical Director
Carol Irving, MD, Assistant Director
Dennis Cochrane, MD
Frederick Fiesseler, DO
Oliver Hung, MD
Michael Silverman, MD
Paul Szucs, MD

Phone: (973) 971-6015
Fax: (973) 401-2420

Secretary Tommy G. Thompson

Attention: CMS-1427-P

P.O. Box 8010

Baltimore, MD 21244-8018

September 27, 2004

Dear Mr. Thompson,

This letter is in response to the Department of Health and Human Services Centers for Medicare and Medicaid Services 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy. 69 Fed. Reg. 50448 (Aug. 16, 2004).

I am the medical director of the hyperbaric unit in Morristown Memorial Hospital. This is a 560-bed tertiary care hospital that serves a four county catchment area in northern New Jersey. We are the sole provider in a five county area. We have a physician – registered nurse professional model. We have been providing service to all comers, including the poor and uninsured for almost five years.

We are located in Morris County, the second most expensive county to live in and provide services in the United States. Unfortunately, we are also in a state where the hospitals and physicians have been hit hard by the malpractice crisis. We have had huge increases in the costs associated with providing care to our community.

We are concerned that if CMS proposed rates are finalized for 2005, this will threaten the ability of our unit to stay open. The hospital is not in a position to subsidize services that are not self-supporting.

Our hospital supports the Hyperbaric Oxygen Association (HOTA) position and the Lewin's Group findings. We support consideration of the following four alternatives which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios

2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30-minute increment.

Thank you for your consideration in this very important matter.

Yours truly,

Marilyn Althoff, M.D.
Medical Director
Hyperbaric Unit
Morristown Memorial Hospital
Morristown, NJ 07960
973-971-6015

Atlantic Hyperbaric Associates, LLC

Marilyn Althoff, MD, Medical Director
Carol Irving, MD, Assistant Director
Dennis Cochrane, MD
Frederick Fiesseler, DO
Oliver Hung, MD
Michael Silverman, MD
Paul Szucs, MD

Phone: (973) 971-6015
Fax: (973) 401-2420

Secretary Tommy G. Thompson

Attention: CMS-1427-P

P.O. Box 8010

Baltimore, MD 21244-8018

September 27, 2004

Dear Mr. Thompson,

This letter is in response to the Department of Health and Human Services Centers for Medicare and Medicaid Services 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy. 69 Fed. Reg. 50448 (Aug. 16, 2004).

I am the medical director of the hyperbaric unit in Morristown Memorial Hospital. This is a 560-bed tertiary care hospital that serves a four county catchment area in northern New Jersey. We are the sole provider in a five county area. We have a physician – registered nurse professional model. We have been providing service to all comers, including the poor and uninsured for almost five years.

We are located in Morris County, the second most expensive county to live in and provide services in the United States. Unfortunately, we are also in a state where the hospitals and physicians have been hit hard by the malpractice crisis. We have had huge increases in the costs associated with providing care to our community.

We are concerned that if CMS proposed rates are finalized for 2005, this will threaten the ability of our unit to stay open. The hospital is not in a position to subsidize services that are not self-supporting.

Our hospital supports the Hyperbaric Oxygen Association (HOTA) position and the Lewin's Group findings. We support consideration of the following four alternatives which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios

2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30-minute increment.

Thank you for your consideration in this very important matter.

Yours truly,

Marilyn Althoff, M.D.
Medical Director
Hyperbaric Unit
Morristown Memorial Hospital
Morristown, NJ 07960
973-971-6015

Submitter : Mrs. Rebecca Herman **Date & Time:** 09/27/2004 09:09:47

Organization : Longmont United Hospital

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please take the time to review my response to the Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates.
September 27, 2004
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201
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 Director of Clinical Support Services at Longmont United Hospital, 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. Longmont United Hospital has been providing Positron Emission Tomography (PET) services since June 2004.
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.)
We feel FDG PET is a very valuable diagnostic tool and have worked hard to find a cost-effective way to bring these services to our community members. Our decision to bring FDG PET services to our hospital was based on receiving reasonable reimbursement that covers all of our costs. 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 our ability to continue to provide 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.

Longmont United Hospital provides PET services on a mobile basis, under contract with an outside supplier. While the supplier provides the equipment and certain technical personnel, the hospital must incur significant indirect costs to provide this service to our patients, including administrative services such as scheduling, preauthorization and management of medical records; nursing services to prepare and monitor patients during exams; information technology services to support digital management of images and other organizational support as needed.
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

CMS-1427-P-64

Submitter : Dr. Tiffany Chow **Date & Time:** 09/27/2004 11:09:08

Organization : University of Toronto

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

As a neurologist and consultant on SCUBA diving accidents, it is my understanding that quality care relies upon hyperbaric oxygen chambers being located near scenes of accidents. Patients' conditions are often worsened by prolonged transit or flights from the accident site to the treatment facility. As such, it is important to maintain the current number of HBO facilities in operation. If the reimbursement rate were to fall, critical access for patients with emergencies or whose care is greatly bolstered by HBO (complicated wound healing in diabetics) will suffer.

I support the Undersea and Hyperbaric Medical Society's recommendations as being reasonable and fair. They are based on reported data, as opposed to kneejerk reactions. They are as follows:
1. Leave the HBO Treatment reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

Thank you for your attention to this matter.

CMS-1427-P-65

Submitter : **Date & Time:** 09/28/2004 01:09:07

Organization :

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

the new rates will cause hyperbaric medicine to go out of business. Please consider other options.

thank you,
Peter A. Salzer, M.D., Medical director Wound Care and Hyperbaric Medicine Center at New Island hospital, Bethpage N.Y. 11714

Submitter : Dr. Richard Hodgson **Date & Time:** 09/28/2004 02:09:14

Organization : Spectrum Health

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

PLEASE REVIEW ATTATCHED LETTER

CMS-1427-P-66-Attach-1.doc

September 25, 2004

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson,

I represent the only Undersea and Hyperbaric Medicine Society fully-accredited hyperbaric medicine facility in the state of Michigan. I write now to voice my concerns regarding the Department of Health and Human Services Center for Medicare and Medicaid Services 2005 Hospital Outpatient Prospective Payment Program proposed rule for Hyperbaric Oxygen Therapy (HBOT) 69 Fed Reg. 50448 (Aug 16, 2004).

Spectrum Health (formerly Butterworth Hospital) has provided hyperbaric medicine services to Western Michigan for over 20 years. Butterworth Hospital and Spectrum Health have been providing this vital service to inhabitants from a 30 county area that encompases most of the western and northern portions of Michigan, most of which is rural. Vital services are provided to the state through our very active hyperbaric medicine department. Hyperbaric Oxygen therapy has allowed preservation of life and limb literally to thousands of patients over the past 20 years. Emergency services are provided 24/7 for diving and decompression emergencies, carbon Monoxide poisonings, gas gangrene, necrotizing fasciitis, therapy for ischemic and diabetic limbs that have no other recourse other than amputation. The majority of our patients are Medicare recipients.

Major decrease of the reimbursement for HBOT therapy will definitely affect availability of these valuable services to Western Michigan. It is highly likely that financial viability of hyperbaric programs, such as ours, will be threatened resulting in threatened patient care access.

We are strongly supportive of the Hyperbaric Oxygen Therapy Association (HOTA) and the Lewin Group's findings that recent calculations being applied to reimbursement rules for HBOT were incorrectly applied to general hospital respiratory therapy care rates.

We propose and strongly encourage that CMMS leave the HBOT reimbursement rate at CY 2004 levels pending CMMS opportunity to develop a calculation accurately detailing HBO costs and cost-to-charge ratios. Hospitals have reported costs in different manners resulting in "apple to orange" comparisons. We advocate adoption of the overall cost-to-charge ratio (CCR) of 0.47. Apply the Lewin Group Methodology to the 389 hospitals that reported FY 2003 claims and finally, adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your vital consideration of this critically important matter.

Sincerely,

Richard J. Hodgson, MD., MBA.

Chief of Hyperbaric Medicine

Clinical Professor of Medicine

Michigan State University College of Human Medicine

Grand Rapids Campus
Spectrum Health Wound Healing Program
221 Michigan St. NE.
Suite 200
Grand Rapids, MI 49503
616 391 8635
grscubadoc@sbcglobal.net

Submitter : Mrs. Dawn Truex **Date & Time:** 09/28/2004 11:09:54

Organization : Mrs. Dawn Truex

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Covered outpatient services should include Massage Therapy performed by licensed massage therapists. No other medical professional receives as much training in the administration and application of massage as licensed massage therapy. Would you want an occupational therapist treating you for chronic arm pain? Physical therapists are trained to return function not comfort. Physical therapy is necessary for adjustments to major trauma. Massage therapy is appropriate for preventative care, chronic issues, the effects of aging, and psycologically manifested physical symptoms. The focus and purpose are entirely different. All should be covered by reimbersement.

Submitter : Dr. Gary Mailman **Date & Time:** 09/28/2004 12:09:40

Organization : Hyperbaric Med Consultants, PA

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

9/27/2004

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

This comment concerns the Dept. Of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpt. Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatments (?HBOT?). 69 Fed. Reg. 50448 (AUG.16, 2004).

I am a full time hyperbaric physician practicing at a medium sized urban hospital here in Austin, TX. St. David?s Medical center is currently the only hospital in a multi-county area providing emergency hyperbaric oxygen treatments. Your proposed rates will threaten the ability for us to stay open. This will threaten access to patient care.

I support the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group?s findings. I would support consideration of the following four alternatives listed below:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an Opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported Hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 min. increment.

We appreciate your consideration for this very important matter.

Sincerely yours,
Gary M. Mailman, MD

CMS-1427-P-69

Submitter : Mrs. Anna Mary Peterson **Date & Time:** 09/28/2004 12:09:02

Organization : Mrs. Anna Mary Peterson

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

APC Relative Weights

I was delighted to see that Medicare has proposed an increase in payment for cochlear implantation (APC 259, 69930). I very much support this proposal. However, the proposed payment for 2005 is still less than it costs hospitals to implant the device for patients. This may be due to the 2003 data that was used to analyze the actual costs involved in cochlear implantation. Please continue to evaluate this issue and work toward improving coverage so that hospitals can at least break even. Cochlear implants are likely the most important advancement in improving hearing that has come along in many years. It would be very unfortunate if hospitals are unable to provide this important health care service because of funding.

CMS-1427-P-70

Submitter : Mrs. Theresa Bostock **Date & Time:** 09/28/2004 02:09:58

Organization : St. Francis Hospital

Category : Hospital

Issue Areas/Comments

Issues 11-20

Blood and Blood Products

I am writing concerning the proposed OPPS rule for reimbursement rates for blood and blood products. I am the Blood Bank Supervisor at St. Francis Hospital in Poughkeepsie, NY. We are a level II trauma center and also have a center of excellence in orthopedic surgery, so we transfuse a fair amount of blood. I am writing to emphasize the need for continued increased reimbursement for blood products. Although the reimbursement for red cells will increase in 2005, it is still nowhere near the amount that we actually pay, not including our costs for testing and storing the products. Hospitals in the Hudson Valley area are struggling financially. Due to the extreme shortage of medical technologists and nurses and lack of financial resources, hospitals are floundering. Our hospital has started a Blood Conservation/Bloodless Medicine and Surgery program to address the critical blood shortage and ever-rising prices for blood. Although our usage has decreased, safe blood is still needed every day to support our trauma patients and cancer patients. We encourage our physicians to use non-blood alternatives, but after alternatives fail, blood is still needed. There is still no substitute for blood, and hospitals must be able to support the transfusion needs of its patients. Greater medical technology has actually increased blood use; more and more patients are surviving cancer, organ transplants, and massive traumas due to innovative medical techniques. A safe and adequate blood supply is necessary to support these advancements in medical care.

More accurate data from hospitals is also necessary to reflect actual costs that hospitals incur as a result of transfusions. I urge CMS to institute extensive surveys to all hospitals in all areas of the country to investigate direct as well as indirect costs for blood. Blood Banks would be more than willing to participate to correct this gross inadequacy in reimbursement rates.

Thank you for your consideration in this urgent matter.

Sincerely,
Theresa Bostock, MT(ASCP)
Blood Bank Supervisor
St. Francis Hospital
241 North Road
Poughkeepsie, NY 12601
(845)431-8189
tbostock@sfhhc.org

Submitter : Ms. Edith Keating **Date & Time:** 09/28/2004 02:09:41

Organization : Diversified Therapy/ Edward White Hospital

Category : Other Health Care Provider

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Edward White Hospital (EWH) is a 120 bed facility. Our Hyperbaric Oxygen Therapy (HBOT) Center is an out-patient facility located on the 3rd floor of EWH and is an essential therapy used in a variety of types of wound therapy/healing and has proven istself to be a vital role in saving both life and limb. To decrease the reimbursement would decrease the financial viability of the of the HBOT program remaining open and thus depriving the community of this medicinal service. We, EWH, support HOTA's position and the Lewin's Group findings: leaving the reimbursement at the, current year, 2004 levels until CMS has the opportunity to develop and perform an accurate calculation HBOT costs and cost-to-charges ratio; adopting a cost-to-charges ratio of 0.47; apply the Lewin Group methodology to the 389 hospitals that reported HBOT claims for the year 2003; and the Lewin Groups proposed reimbursement of $118.21 per 30 minute increment.

Submitter : Dr. Julie Rhoades **Date & Time:** 09/28/2004 04:09:20

Organization : Penn State Milton S Hershey Medical Center

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Relative Weights

September 28, 2004

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Medicare Progra: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; CMS-1427-P; Proposed Recalibration of APC Weights for CY 2005

Dear Dr. McClellan:

On behalf of Penn State Milton S Hershey Medical Center we are pleased to submit the following comments on the proposed rule CMS-1427-P published in the Federal Register on August 16, 2004. We are pleased to see the proposed increase in payment for cochlear implantation (APC 259, 69930) and recognize the progress this represents. However, the 2005 proposed payment under the outpatient prospective payment system (OPPS) is less than our hospital?s cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the 2003 data analyzed by CMS is not representative of the costs of the device and procedure.

Because the cost of surgery continues to exceed reimbursement for cochlear implantation, our hospital has limited the number of surgeries we have been able to perform. Although our program has been in existence since the mid 1990s we have actually had to reduce the number of new implants we are performing over the years due to insurance reimbursement issues. This reduction is despite the absence of a decline in the population in our area in need of cochlear implantation services.

We are also concerned about the billing and coding errors made by hospitals. While there has been some improvement, we urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for cochlear implant devices and other technology. In addition to using L8614, hospitals need to be educated on how to report charges for cochlear implants utilized in the outpatient department.

In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. It is well documented that cochlear implantation has been significantly underpaid relative to the actual costs for the device and procedure. Therefore, we disagree with the Advisory Panel?s recommendation because it is arbitrary and a hindrance to CMS? goal to ultimately rely on accurate claims data to establish rates for device-dependent APCs.

In conclusion, the proposed increase in payment for APC 0259 is based upon available data. Based upon the proposed rate, it is anticipated that our hospital will lose money on every Medicare cochlear implant surgery in 2005. Combined with the anticipated loses for Medicaid patients, this may force our program to close its doors. We ask CMS to improve educational outreach programs to hospitals. Similarly, we oppose arbitrary measures such as the APC Panel?s 5% recommendation to cap increases at 5%.

Penn State Milton S Hershey Medical Center appreciates the agency?s recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendations we have submitted. If you require further information, please do not hesitate to contact the Audiology and/or Otolaryngology Departments at 717/531-7171.

Sincerely,

Erica D Colt, AuD
Michele L Gerrish, AuD
Roxanne R Hagenbuch, MS
Jon E Isaacson, MD
Julie A Rhoades, AuD

Submitter : Dr. Bret Boyle **Date & Time:** 09/28/2004 04:09:27

Organization : Eisenhower Army Medical Center

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I am a Military physician who specializes in Hyperbaric Medicine and Wound Care for our service members and retirees. My current income is a fraction of what would be possible in the civilian world of Hyperbaric Medicine and Wound Care. I have made a deliberate choice to remain in the military and complete a full career of service to my country, however I plan to continue with this medical specialty when my 20 years of service are over. It is disappointing and disturbing to find that the reimbursement rates are attempting to drop to the low level where I am currently being paid as an active duty service member, which makes it rather difficult to "catch up" monetarily once we are civilians.

CMS-1427-P-74

Submitter : Mr. Mike Fitzgerald **Date & Time:** 09/28/2004 05:09:36

Organization : St. Joseph Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

St. Joseph Medical Center is one of only three facilities in the state of WA that provide hyperbaric oxygen therapy. If the proposed rates for reimbursement are finalized for 2005, our ability to provide this service will be threatened.
We support the findings of the Hyperbaric Oxygen Therapy Association (HOTA) and the Lewin Group in regard to reimbursement. We would encourage you to consider the following alterantives to the proposed rate change:
- Do not change reimbursement from the CY 2004 rate until CMS has had an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
- Adopt the overall cost to charge ratio of .47, due to the differences in which the hospitals have reported costs.
- Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003
- Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

CMS-1427-P-74-Attach-1.doc

CATHOLIC HEALTH INITIATIVES

Franciscan Health System

1149 Market Street, Tacoma, WA 98402 - 253-426-4100

September 27, 2004

Secretary Tommy G. Thompson
Center for Medicare and Medicaid Services
Attention: CMS – 1427-P
P.O. Box 8010
Baltimore MD 21244-8018

Re: CMS – 1427 – P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

This comment concerns the Department of Health and Human Services Centers for Medicare and Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment. 69 Fed. Reg. 50448 (Aug. 16, 2004).

St. Joseph Medical Center is a 320 bed tertiary hospital in Tacoma, Washington. The hospital is one of only three facilities in the state of Washington that provide hyperbaric oxygen therapy. We are the sole provider between Seattle and Portland, Oregon. Our patient population comes from all over southwest and western Washington.

If the proposed rates for reimbursement are finalized for 2005, our ability to provide this service will be threatened. Patients in our service area will not have access to the care approved for such conditions as radiation necrosis, diabetic ulcers, carbon monoxide poisoning and decompression illness.

We support the findings of the Hyperbaric Oxygen Therapy Association (HOTA) and the Lewin Group in regard to reimbursement. We would encourage you to consider the following alternatives to the proposed rate change:

- Do not change reimbursement from the CY 2004 rate until CMS has had an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
- Adopt the overall cost to charge ratio or .47, due to the differences in which the hospitals have reported costs.
- Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
- Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Sincerely,

Mike Fitzgerald

Mike Fitzgerald
Chief Financial Officer

CMS-1427-P-75

Submitter : Christine Epstein **Date & Time:** 09/28/2004 05:09:18

Organization : Presbyterian Ear Institute

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

APC Relative Weights

9-28-04
Dear Dr. McClellan:
On behalf of Presbyterian Ear Institute, we are pleased to submit the following comments on the proposed rule CMS-1427-P. We are pleased to see the proposed increase in payment for cochlear implantation (APC 259, 69930) and recognize the progress this represents. However, the 2005 proposed hospital's cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the 2003 data analyzed by CMS is not representative of the costs of the device and procedure.
Presbyterian Ear Institute has been doing cochlear implant surgeries since 1987. We have performed approximately 120 cochlear implant surgeries since that time and did 27 surgeries in 2003. Over half of our patients have Medicare or Medicaid.
We are concerned about the billing and coding errors made by hospitals. While there has been some improvement, we urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for cochlear implant devices and other technology. In addition to using L8614, hospitals need to be educated on how to report charges for cochlear implants utilized in the outpatient department.
In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. It is well established that cochlear implantation has been significantly underpaid relative to the actual costs for the device and procedure. Therefore, we disagree with the Advisory Panel's recommendation because it is arbitrary and hindrance to CMS' goal to ultimately rely on accurate claims data to establish rates for device-dependent APCs.
In conclusion, the proposed increase in payment for APC 0259 is based upon available data. We ask CMS to improve educational outreach programs to hospitals. Similarly, we oppose arbitrary measures such as the APC Panel's 5% recommendation to cap increases at 5%
Presbyterian Ear Institute appreciates the agency's recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendations that we have submitted. If you require further information, plese do not hesitate to contact Christine Epstein, at 505/224-7020.
Thanks you,
Christine Epstein, MA, CCC-A

Submitter : Ms. Carla and Sue **Date & Time:** 09/28/2004 05:09:57

Organization : Monongalia General Hospital

Category : Nurse

Issue Areas/Comments

Issues 21-30

Observation Services

"Observation Services"
Upon review of the proposed observation services changes. We were happy to see that the requiements for specific test for asthma, congestive heart failure and chest pain will no longer be required to recieve payment.
The current practice of using the time the patient arrives to the observation bed and the time the discharge order is written works well for us because we have a computer system that helps capture these times. The proposal to change the discharge time to reflect the time the patient is actually discharged from the hospital will be a problem if they are just waiting for transportation. In these cases would we still use the time the order was written?

Submitter : Dr. Terry Douglass **Date & Time:** 09/28/2004 07:09:33

Organization : CTI Molecular Imaging, Inc.

Category : Device Industry

Issue Areas/Comments

Issues 1-10

New Technology APCs

CMS-1247-P
New Technology APCs

CMS is considering three options as the proposed payment for FDG PET procedures in CY 2005. CMS-1427-P 63

My recommendation to CMS is that CMS choose Option 1 which is: Continue in CY 2005 the current assignment of the scans to New Technology APC 1516 prior to assigning to a clinical APC. $1450.00

Simply stated, the current utilization of FDG PET is not sufficient to support the costs of this important procedure at the rates proposed in Options 2 and 3. Therefore, it is reommended that the rates for FDG PET remain essentially as they were in 2004 or increased sufficiently to cover the costs of this procedure.

If CMS were to choose to lower the rates, access to this technology would continue to fall well short of the access needed by Medicare patients and other recipients since providers would not choose to provide PET at a loss.

Data supporting the fact that the current utilization of FDG PET are not sufficient to support the costs of this important procedure at the rates proposed in Options 2 and 3 is available to CMS as required.

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status That Are Not Packaged:

A reduction in the reimbursement for FDG from $324.48 to $220.50 will limit utilization and access to FDG PET because a $220.50 FDG dose rate will result in losses for providers of the FDG. Therefore, it is recommended that the $324.48 FDG dose price be retained. If CMS were to choose to lower the rates, access to this technology would continue to fall well short of the access needed by Medicare patients and other recipients since providers would not choose to provide PET at a loss. Data supporting the fact that the current utilization of FDG PET are not sufficient to support the costs of this important procedure are available if required by CMS.

Submitter : Dr. Richard Fisher **Date & Time:** 09/28/2004 07:09:03

Organization : James P. Wilmot Cancer Center

Category : Physician

Issue Areas/Comments

Issues 11-20

Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs

CMS 1427-P Docket: Subject: Reimbursement for Iodine I 1314 Tositumomab (Bexxar)

-To Whom It May Concern:

I have recently been informed that the proposed reimbursement rate for the drug Bexxar is significantly below the hospital's cost to purchase and administer it. The development of this new drug has extensively increased the response and remission duration for patients with follicular non-Hodgkin's lymphoma and access to this medication should not be dictated by reimbursement issues when there are no other therapeutic options.

The use of this medication is complicated requiring multiple calculations and specific measurements so each dose can be adapted to the specific needs of each patient. Due to the complexity, only select hospitals have the ability to provide treatment and healthcare professionals must be thoroughly trained to prescribe and administer. If the cost to administer this medication falls upon the hospitals, the shortfall may mean that patients with non-Hodgkin's lymphoma will not have access to this life-saving and less toxic therapy.

Statistics indicate that non-Hodgkin's lymphoma in the elderly is on the rise and this proposed decision could literally mean the difference between life and death for many of these patients. I ask that you reconsider the proposed changes and decide to provide adequate reimbursement to cover actual costs and necessary compounding procedures.

Sincerely,

Richard I. Fisher, M.D.
Director, James P. Wilmot Cancer Center
Chief, Hematology-Oncology Department
University of Rochester Medical Center

Submitter : Mr. Davison **Date & Time:** 09/28/2004 08:09:59

Organization : Mr. Davison

Category : Other Health Care Professional

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I manage a hospital based hyperbaric program in Denver, CO. We are the sole provider of Hyperbaric Oxygen Therapy in Denver. I support the Hyperbaric Oxygen Therapy Association's position and the Lewin Group's findings. Please consider leaving the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios. Thank you for your time.

Submitter : Dr. Martin Jacobs **Date & Time:** 09/29/2004 01:09:25

Organization : Kettering Medical Center

Category : Physician

Issue Areas/Comments

Issues 11-20

Orphan Drugs

This comment concerns CMS-1427-P, orphan drugs.

I am a practicing hospital based Nuclear Medicine physician in Dayton, Ohio. My practice includes the management of patients with thyroid cancer of whom we see at least ten per month. Most of these patients are seen in follow up of their treated thyroid cancers and undergo Thyrogen stimulated I-131 whole body scans and thyroglobulin assays. Our staff prepares the patients for the study and administers the Thyrogen injections. We have found that the process runs much smoother when we give the shots here at the hospital rather than having each of the referring doctors offices do it. We do have one physician who administers his own Thyrogen however other offices have not developed the protocol. Even in the one office that has worked out the details, the process still does not run as smoothly.

With the financial disincentive for the hospital to give the Thyrogen shots, I feel that patient care would be compromised and an already difficult process for the patient becomes even more arduous.

I do not understand why the hospitals should be penalized for providing the best possible patient care. In this situation, care is certainly not more cost effective by steering the patient away from the hospital and to the outpatient office.

CMS-1427-P-81

Submitter : Dr. Jay Buckey **Date & Time:** 09/29/2004 02:09:11

Organization : Dartmouth Medical School

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).

I run the hyperbaric medicine program at Dartmouth-Hitchcock Medical Center in Lebanon, NH. We are the only provider of hyperbaric services in our area. Most of our patients are patients who have had radiation therapy for cancer. They have been cured, but have non-healing wounds or other complications as a consequence of the successful radiation therapy.

The proposed rates for hyperbaric oxygen therapy, would threaten our clinical service. We treat patients without regard to their ability to pay, but if we cannot cover our costs, this will threaten the future of the program. We support of the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group?s findings. We support consideration of the following four alternatives, which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

4. Adopt the Lewin Group approach at $118.21 per 30-minute increment.

CMS-1427-P-82

Submitter : **Date & Time:** 09/29/2004 03:09:42

Organization :

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

please consider other options for the hyperbaric reimbursement rates that have been proposed. I feel they will have a very negative effect on the viability of the hyperbaric medicine program at New Island Hospital, Bethpage, New york 11714.

sincerely yours,
Peter A. Salzer M.D., F.A.C.S., A.B.P.M.
Medical Director

CMS-1427-P-82-Attach-2.doc

CMS-1427-P-82-Attach-1.doc

Long Island Hyperbaric and Wound Care
Medical Associates
4295 Hempstead Turnpike
Bethpage, New York 11714
516-796-1313
516-719-3933 fax

www.cms.hhs.gov/regulationsecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Sept. 27, 2004

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

We are a group of ten physicians who started a wound care and hyperbaric medicine center at New Island Hospital in Bethpage New York, 11714, about 5 years ago. New Island Hospital is a 220-bed hospital located in Nassau County with a surrounding population of 2 million. Almost half of the patients seen here at the wound care and hyperbaric medicine center have Medicare as their medical insurance. Over the last 5 years we have treated more than 800 patients with hyperbaric Oxygen therapy with an overall success rate (limb salvage) of 85%. Our facility has 4 monoplace chambers and is the only one of its kind in Nassau County.

We are certain that the Proposed Rule that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment as outlined in the 69 Fed. Reg. 50448 (Aug. 16, 2004) will threaten the ability of New Island Hospital to continue its wound care and hyperbaric medicine program. This will have a very negative impact on the patients of our community who have come to depend on the advanced quality of care available here. Stan Weber, the vice president of finances for New Island

hospital has told me that the proposed new reimbursement will not be sufficient to keep the service alive.

We are in support of the HOTA position, the Lewin Group's findings and the UHMS position on this controversy. I support one of the following 4 alternatives:

1- Leave the HBOT reimbursement at CY 2004 level.
2- Use the overall (CCR) of .47
3- Use the Lewin Group method for year 2003
4- Adopt Lewin Group rate of $118.21/30 minutes

Sincerely yours,

Peter A. Salzer, M.D., F.A.C.S., Medical Director

Long Island Hyperbaric and Wound Care
Medical Associates
4295 Hempstead Turnpike
Bethpage, New York 11714
516-796-1313
516-719-3933 fax

www.cms.hhs.gov/regulationsecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Sept. 27, 2004

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

We are a group of ten physicians who started a wound care and hyperbaric medicine center at New Island Hospital in Bethpage New York, 11714, about 5 years ago. New Island Hospital is a 220-bed hospital located in Nassau County with a surrounding population of 2 million. Almost half of the patients seen here at the wound care and hyperbaric medicine center have Medicare as their medical insurance. Over the last 5 years we have treated more than 800 patients with hyperbaric Oxygen therapy with an overall success rate (limb salvage) of 85%. Our facility has 4 monoplace chambers and is the only one of its kind in Nassau County.

We are certain that the Proposed Rule that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment as outlined in the 69 Fed. Reg. 50448 (Aug. 16, 2004) will threaten the ability of New Island Hospital to continue its wound care and hyperbaric medicine program. This will have a very negative impact on the patients of our community who have come to depend on the advanced quality of care available here. Stan Weber, the vice president of finances for New Island

hospital has told me that the proposed new reimbursement will not be sufficient to keep the service alive.

We are in support of the HOTA position, the Lewin Group's findings and the UHMS position on this controversy. I support one of the following 4 alternatives:

1- Leave the HBOT reimbursement at CY 2004 level.
2- Use the overall (CCR) of .47
3- Use the Lewin Group method for year 2003
4- Adopt Lewin Group rate of $118.21/30 minutes

Sincerely yours,

Peter A. Salzer, M.D., F.A.C.S., Medical Director

CMS-1427-P-83

Submitter : Mr. Barney Osborne **Date & Time:** 09/29/2004 03:09:55

Organization : Bamberg County Hospital and Nursing Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Attached Please find a Microsoft Word doccument entitled "BCHNC comment on CMS 05 OPPS changes" CMS reference CMS-1427-P. Thank your for the opportunity to comment. Please feel free to contact me for any additional information. Thank you.

CMS-1427-P-83-Attach-1.doc

Bamberg County Hospital
And Nursing Center

September 29, 2004

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

Re: CMS-1427-P
Comment on Proposed Changes to the Hospital OPPS and calendar year 2005 Rates

Bamberg County Hospital is a 59-bed acute care facility in the low country of South Carolina serving a primarily low-income population. We anticipate a $40,000,000 annual income for fiscal year 2004 (09/30/2004) and contractual adjustments near 60% with admissions at or near 1,800 and total days of care of 6,700. BCH maintains, on the average, 8 days operating cash on hand and 30 days total cash days on hand which includes all reserves. Because of our high Medicare utilization, Medicare reimbursement has a profound impact on the financial viability of our organization. For FYTD 2004 Medicare charges constitute 51.28% of our total outpatient charges, 67.19% of our total inpatient charges and 57.47% of our combined total charges.

Bamberg County Hospital is located in an area noted as one of the highest in the country for End Stage Renal Disease (ESRD). In an effort to better serve these patients our local surgeon and our facility have become very specialized in vascular access procedures over the past five years. Bamberg County Hospital has become noted across the nation as a leader in innovation for these procedures due to our surgical expertise in this area. Our program focuses on scheduling that allows surgical attention at the time a problem is recognized by a nephrologists or dialysis clinic and provides quick response to arterial and vascular blockages which hinder the patient's access to regularly scheduled dialysis. Immediate surgical attention is key in this process as interruption of the patients normal dialysis schedule complicates the patient's condition, causing unnecessary pain and suffering to the patient and most often resulting in more expensive inpatient care.

Our facility has developed transportation that provides immediate transport to our facility from outlying areas for treatment of often-immobile patients. Usually, patients receive surgical correction to access complications soon enough to avoid interruption of their normal dialysis regime. We have been recognized as a leader in this field as well by the National Kidney Foundation and have received a transportation grant from this important proponent of ESRD patients for the purchase of a transport bus.

509 North Street
PO Drawer 507
Bamberg, SC 29003
(803) 245-4321

Our surgery department receives referrals from across the state and indeed throughout the southeast. Our facility has also become a host site for review of this process to surgeons across the country and our surgeon is a well-known expert regarding these processes and procedures. We feel that our diligence, expertise and innovation in these matters has not only provided a new quality of life for our patients, but has avoided a much higher level of care to patients, subsequently reducing the overall cost of care to ESRD patients who are most often Medicare recipients. We have been diligent in sharing our processes with many other facilities, quite often much larger than our own. The extended affect of our practices could have a tremendous potential impact on the cost of care to the Medicare program for these patients.

Unfortunately, upon review of the 2005 proposed changes to OPPS reimbursement, we anticipate a minimum reduction in net reimbursement to our facility of nearly $450,000 specifically related to vascular access procedures. This decrease when compounded with this year's (2004) decrease of $150,000 for the same procedures, total a net decrease of 24.2% of net reimbursement over a two-year period. While we were diligent in billing C-codes during the OPPS conversion, we have also suffered a tremendous loss since FFY 2002 due to these expenses being "folded in" to the APC codes. Most facilities did not bill C-codes so the amount folded-in did not constitute the 75% of our actual cost as predicted. We are estimating a decrease of $1,500,000 in net reimbursement since CMS began to fold in C-codes in 2002, which could place this program and potentially our entire existence at risk

We request that you consider the consequential impact that the loss or even reduction of these interventional services throughout the country could have on the inpatient component of Medicare cost for ESRD care. We are convinced that these OPPS preventative practices, if applied nationally, could save the Medicare program a substantial amount annually while providing a higher quality of life to many ESRD patients. Therefore we request that these reductions be given reconsideration for their impact on IPPS cost and total cost of care and not simply as outpatient procedures.

We have prepared a detailed analysis of the impact of the 2005 changes on our specific patient mix and historical surgical procedures and will be happy to share these results with your office.

Thank you for the opportunity to comment on these proposed changes. Please feel free to contact me directly at (803) 245-6797 (office) or (803) 707-8431 (cell). We will be happy to provide any information available from our facility.

Respectfully,
Barney Osborne
Chief Financial Officer

Submitter : Dr. Lorre Henderson **Date & Time:** 09/29/2004 06:09:47

Organization : Lorre T. Henderson, MD

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

29 September, 2004

Secretary Tommy G. Thompson
Center for Mediare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 2244-8018

RE: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

I am extremely concerned about the ?Proposed Rule? by the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System which would change reimbursement rates for hyperbaric oxygen therapy treatment. This was found in ? 69 Fed. Reg. 50448 (August 16, 2004).

Adoption of the proposed rates for 2005 directly threatens the ability of the three different hyperbaric units I work to remain open. All three units I work at are the sole providers for there respective areas and are strategically located to maximize service to the extremely large population of the San Francisco Bay Area.

Please review the Hyperbaric Oxygen Therapy Association (HOTA) position and the findings of the Lewin Group so you have an understanding of our services. I would ask you to consider supporting the following alternatives:

1. Leave the HBOT reimbursement rates at CY 2004 levels, which will allow CMS an opportunity to develop and perform calculations that will accurately detail HBOT costs and those cost-to-charge rations.
2. Apply the Lewin Group methodology to the 389 hospitals who reported hyperbaric claims for the year 2003.
3. Adopt the overall cost to charge ration (CCR) of .47, which takes into account the differences in which hospitals have reported costs.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

I truly appreciate your consideration regarding this very important matter.

Sincerely,

Lorre T. Henderson, OD, MD, FACS

Submitter : Cat Taylor **Date & Time:** 09/29/2004 08:09:58

Organization : South Nassau Communities Hospital

Category : Hospital

Issue Areas/Comments

Issues 1-10

Stereotactic Radiosurgery

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

RE: Stereotactic Radiosurgery CMS 1427-P
Issues with Medicare Coding for Cobalt Gamma Stereotactic Radiosurgery:

I am the administrator for the Long Island Gamma Knife located on the campus of South Nassau Communities Hospital in Oceanside, New York. It is my responsibility to oversee the entire Gamma Knife program, including billing and coding for the radiosurgery procedures that we conduct. Our facility is the fastest growing Gamma Knife program nationally to date performing over 150 procedures in our first year of operation. A neurosurgeon and radiation oncologist work together to develop and approve all treatments and both are present throughout the entire procedure. Our facility is set up and staffed within the division of radiation oncology utilizing specially trained registered nurses.

As a Board member of The International RadioSurgery Association (IRSA), I was asked to correspond with CMS on coding issues related to Gamma Knife. To that end, I am pleased to acknowledge that we do not have any issues with the current coding structure. Our hospital has carefully and diligently researched the required coding procedures, using the current G-codes available. We obtain preauthorization?s on each patient and can report that there are no current issues regarding reimbursement.

Having said that, we do have concerns that CMS is being asked to move all Gamma Knife codes into a surgical (OPPS) category. At this time, we do not see any justification for such a move and believe that such a move will create confusion relative to coding.

First, Gamma Knife treatment is radiation therapy, albeit, with the assistance of a neurosurgeon. The indirect costs of running a radiation therapy department are considerably higher than that of a surgery department, when factoring the cost of a radiation physicist and therapist to the standard nursing care that occurs. The cost center cost-to-charge ratio for radiation therapy better reflects these costs relative to a surgical designation. I have concerns that moving Gamma Knife codes to a surgical designation will create imbalances relative to appropriate staff time accounting.

Second, there are other forms of stereotactic radiation therapy, such as linac based or robotic based treatments (based on current G-code designations). Moving one component of stereotactic radiation therapy from radiation oncology to surgery will cause considerable confusion as to the appropriate cost center designation of linac and/or robotic based stereotactic radiation relative to Gamma Knife.

While I cannot speak for other IRSA Board members and the problems they may or may not be having, I think it important that you know that our neurosurgeons and radiation oncologists work as a true team, with patient care as the primary endpoint. In fact, the success of our program is based on the relationship of the radiation oncologists and neurosurgeons, along with our staff. To suggest that Gamma Knife treatment is not radiation therapy is without basis relative to how we are treating our patients. We have converted open craniotomies to closed Gamma Knife treatments, with successful outcomes, but by doing so, we can not now define a radiation delivery procedure as surgery.

I appreciate the opportunity to comment to CMS on this issue. Understanding that the G code designations need to be converted some time to HCPCS codes, I would be most interested in assisting CMS with comments on how our department is structured and run.

Sincerely,

Cat Taylor, MBA
Administrative Director ? Oncology Services
South Nassau's Cancer Center
1 Healthy Way
Oceanside, NY 11572
516-632-3311

Submitter : Mr. Jeff Egbert **Date & Time:** 09/29/2004 08:09:58

Organization : Tempe St. Luke's Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Mr. Thompson:

I would like to formally submit my comments/concerns regarding the 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).

I am the CEO of Tempe St Luke?s Hospital, we are a 109 bed acute care hospital. We opened a comprehensive wound care program in January of 2003. Our wound care program is very busy, mainly due to the high incidence rate of diabetes in Arizona, which is twice the national average. As you may already know one of the major problems that diabetics face is the ability to heal even the smallest of wounds.

We started our program under the promise of the 2003 APC rates which were $174.00 per 30 minute session. Under the proposed 2005 rates which are $82.62 per 30 minute session, which reduces the rate by more than 53%, it would be very difficult continue to operate the wound center. As you may already know, our insurance, supply costs, labor cost all have increased each year and to take such a drastic reduction in the payment rate would be devastating to our program not to mention the rest of the wound care programs across the country.

We are currently affiliated with the Hyperbaric Oxygen Therapy Association (HOTA) and support their position and the Lewin Group?s findings. We would like you to consider the four options presented to your committee on September 9, 2004, which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

4. Adopt the Lewin Group approach at $118.21 per 30-minute increment.

We appreciate your consideration for this very important matter.

Very sincerely

Jeff Egbert
CEO,Tempe St Luke?s Hospital

Submitter : Mr. Brian Dunn **Date & Time:** 09/29/2004 11:09:43

Organization : Salt Lake Regional Medical Center

Category : Hospice

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

September 27, 2004

VIA ELECTRONIC MAIL www.cms.hhs.gov/regulations/ecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS?1427?P; APC 0659 Hyperbaric Oxygen Therapy

Dear Mr. Thompson:

Salt Lake Regional Medical Center is located on the outskirts of Downtown Salt Lake City, Utah. We are currently in the process of opening a wound care and hyperbaric oxygen therapy center in early 2005. Other than our program opening in 2005, there are only two other such programs in the whole state of Utah. The state is in desperate needs for these services due to high incidence of diabetes among their population. A reduction in rates would dramatically impact our ability to grow this program to adequately meet the needs of this community.

I would like to formally submit my comments/concerns regarding the 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?). 69 Fed. Reg. 50448 (Aug. 16, 2004).

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3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Very sincerely

Brian Dunn
President & CEO

CMS-1427-P-88

Submitter : Scott Winslow **Date & Time:** 09/30/2004 12:09:20

Organization : St. Luke's Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please review attachment

CMS-1427-P-88-Attach-1.doc

CMS-1427-P-88-Attach-2.txt

September 29, 2004

VIA ELECTRONIC MAIL www.cms.hhs.gov/regulations/ecomments

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Mr. Thompson:

I am the President & CEO of St Luke's Medical Center, we are a 269 bed acute care hospital. We opened a comprehensive wound care program in January of 2003. Our wound care program has been extremely busy, mainly due to the high incidence rate of diabetes in Arizona, which is twice the national average. As you may already know, one of the major problems that diabetics face the ability to heal even the smallest of wounds.

I would like to formally submit my comments/concerns regarding the 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"). 69 Fed. Reg. 50448 (Aug. 16, 2004).

We started our program under the promise of the 2003 APC rates which were $174.00 per 30 minute session. Under the proposed 2005 rates which are $82.62 per 30 minute session, which reduces the rate by more than 53%, it would be very difficult continue to operate the wound center. As you may already know, our insurance, supply costs, labor cost all have increased each year and to take such a drastic reduction in the payment rate would be devastating to our program not to mention the rest of the wound care programs across the country.

We are currently affiliated with the Hyperbaric Oxygen Therapy Association (HOTA) and support their position and the Lewin Group's findings. We would like you to consider the four options presented to your committee on September 9, 2004, which are:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.

2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year **2003.**

4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Very sincerely

Scott Winslow
Interim President & CEO
St Luke's Medical Center

Attention: CMS-1427-P

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Mr. Thompson:

I am the President & CEO of St Luke's Medical Center, we are a 269 bed acute care hospital. We opened a comprehensive wound care program in January of 2003. Our wound care program has been extremely busy, mainly due to the high incidence rate of diabetes in Arizona, which is twice the national average. As you may already know, one of the major problems that diabetics face the ability to heal even the smallest of wounds. I would like to formally submit my comments/concerns regarding the 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"). 69 Fed. Reg. 50448 (Aug. 16, 2004). We started our program under the promise of the 2003 APC rates which were $174.00 per 30 minute session. Under the proposed 2005 rates which are $82.62 per 30 minute session, which reduces the rate by more than 53%, it would be very difficult continue to operate the wound center. As you may already know, our insurance, supply costs, labor cost all have increased each year and to take such a drastic reduction in the payment rate would be devastating to our program not to mention the rest of the wound care programs across the country.

We are currently affiliated with the Hyperbaric Oxygen Therapy Association (HOTA) and support their position and the Lewin Group's findings. We would like you to consider the four options presented to your committee on September 9, 2004, which are: Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003. Adopt the Lewin Group approach at $118.21 per 30 minute increment. We appreciate your consideration for this very important matter.

Very sincerely

Scott Winslow
Interim President & CEO
St Luke's Medical Center

Submitter : Dr. Mahmoud Aqel **Date & Time:** 09/30/2004 02:09:02

Organization : Barnet Hospital

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

This comment concerns the Department of health and Human Services centers for Medicare & Medicaid Services'2005 Hospital Outpatient prospective payment System proposed rule that sets forth new reimbursement rates for hyberbaric oxygen therapy treatment (HBOT).69 FEd.Reg.50448(Aug.16,2004).
We are at Barnert Hospital in Paterson, the largest city of Passaic County, in New Jersey,have a Wound care & Hyberbaric Center which serves the whole Passaic county in New Jersy.The proposed reimbursement rates for HBOT in 2005 will threaten our ablity to keep this center open and this will deny the patients access to HBOT in Passaic county.
We appreciate if you consider the following four alternatives:
1-leave the HBOT reimbursement rate at CY 2004 levels untill CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2-Due to the differences in which the hospitals have reported costs,adopt the overall cost to charge ratio (CCR) of .47
3-Apply the Lewin Group methodology to the 389 hospitals that reported hyberbaric claims for the year 2003.
4- Adopt the Lewin Group approach at $ 118.21 per 30 minute increment.

We appreciate your consideration for this important matter.

CMS-1427-P-90

Submitter : Karen Stansbury **Date & Time:** 09/30/2004 04:09:46

Organization : Morehouse General Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please review the attached letter referencing comments on the proposed change in payment rate for hyperbaric oxygen therapy.

CMS-1427-P-90-Attach-1.txt

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P. O. Box 8010
Baltimore, MD. 21244-8018

Dear Mr. Thompson,

The intent of this comment letter is to address the proposed new rate for systemic hyperbaric oxygen therapy (HBOT) as described in the 2005 Hospital Outpatient Prospective Payment System "Proposed Rule", published in the 69 Federal Register 50448, August 16, 2004.

Our facility has 100 beds and serves a rural area of 40,000 with a geographical population pool from outlying areas of approximately 140,000. Our program has been in place for 8 years and has a very low amputation rate of lower extremities. We have become recognized as leaders in comprehensive wound care due to successful outcomes. This successful salvage of limbs has been highly attributed to the addition of systemic hyperbaric oxygen therapy to the treatment regimen of these hard to heal wounds. We have been the sole provider for hyperbaric oxygen therapy in the Northeast Region of our state for many years.

The new proposed rate, per 30 minute session, was decreased by half of the current rate. The methodology used to calculate this proposed rate is under question both in format and with the hyperbaric claims population utilized in the calculation methodology. The Hyperbaric Oxygen Therapy Association enlisted the assistance of the Lewin Group to work with CMS on this issue. The Lewin Group presented findings from their research, data collection and calculation methodology to CMS September 9, 2004. This presentation detailed the reasons contributing to the variation in calculation results as well as data supporting the validity of the Lewin Group's findings. We hope this information will show, more accurately, facility cost for providing this therapy. Should this proposed 2005 rate, published by CMS, be implemented our facility will be forced to evaluate the viability of this service, even with a restructuring of facility cost.

Our facility strongly urges you to review and support the findings and recommendations provided by the Lewin Group and HOTA. The recommendations are:

1. Leave the current rates for 2004 as they are until CMS will accurately look at numbers for cost to charge ratio.
2. Adopt the cost to charge ratio of .47 due to the differences in which hospitals have reported costs.
3. For the year 2003 information submitted by 389 hospitals, apply the Lewin Group methodology.
4. If the Lewin Group methodology is utilized for calculating the rate for 2005, then $118.21 would be the rate per 30 minute increment.

We appreciate your consideration in this very important matter.

Very Sincerely, Karen Stansbury, RN, APRN-BC, CWOCN, CHRN on behalf of Morehouse General Hospital 323 Walnut Street, Bastrop, La. 71220

Submitter : Dr. John Weinberg **Date & Time:** 09/30/2004 05:09:07

Organization : Enzon Pharmacuticals, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached word file

CMS-1427-P-91-Attach-1.doc

Enzon, Inc.
685 Route 202/206
Bridgewater, NJ 08807

Phone: 908 541 8600
Fax: 908 575 9457
www.enzon.com

September 29, 2004

Submitted electronically

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–1427-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS–1427–P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; Proposed Rule

Dear Administrator McClellan:

On behalf of Enzon, Inc., I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule entitled "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates." See 69 Fed. Reg. 157 50,448 (Aug. 16, 2004) (the "Proposed Rule"). Enzon appreciates this opportunity to comment on an important aspect of the Proposed Rule, and looks forward to working with CMS to make appropriate adjustments in the final rule to reflect its concerns.

I. BACKGROUND

As a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics to treat life-threatening diseases, Enzon is committed to ensuring equitable and fair access to all necessary medicines for all patients. Enzon manufactures Pegaspargase (brand name Oncaspar), an oncolytic agent used in combination chemotherapy for the treatment of patients with acute lymphoblastic leukemia who are hypersensitive to native forms of L-asparaginase. Oncaspar is supplied in 5 mL single-dose vials as an isotonic sterile solution for intramuscular or intravenous administration only. The product is used by patients who suffer from the life-threatening effects of acute lymphoblastic leukemia, enabling these individuals to receive combination chemotherapy treatments with a more convenient dosing schedule, a lower incidence of toxicity, and less tendency for resistance development.[1]

[1] Enzon also manufactures two other treatments, Adagen®, for ADA-deficient Severe Combined Immunodeficiency Disease, and Abelcet®, for invasive fungal infections related to cancer, organ transplantation and other conditions in patients refractory or intolerant of conventional amphotericin B therapy.

II. THE PROPOSED RULE

Enzon is deeply concerned that the proposed 2004 outpatient prospective payment system (OPPS) payment rate for Pegaspargase (J9266 / APC 0843 / single dose vial), a sole source drug, is computed as packaged instead of separately paid. We believe the data used to compute the rate is flawed and we present our case within these comments. We request the rate for the sole source drug Pegaspargase (Oncaspar) (J9266 / APC 0843 / single dose vial) be corrected from a packaged drug to a separately paid drug. Supporting data is provided as follows.

In the J9266 per the OPPS 2005 Proposed Rule (Addendum B) J9266 is listed as:

Table 1. Current OPPS Proposed Payment Status for 2005 (SI "N")

CPT / HCPCS	Description	Status Indicator	Payment Rate
J9266	**Pegaspargase / single dose vial**	**N**	**-0- [packaged]**

Source: 69 Fed. Reg. 50794 (August 16, 2004)

The OPPS payment status sequence of Pegaspargase (Oncaspar) is as follows.

Table 2. Five-Year OPPS Payment Status History

Calendar Year	CPT / HCPCS	Description	APC	Status Indicator	Payment Rate
2001	**J9266**	**Pegaspargase / single dose vial**	**0843**	**G**	**$1,321.65**
2002	**J9266**	**Pegaspargase / single dose vial**	**0843**	**G**	**$1,225.57**
2003	**J9266**	**Pegaspargase / single dose vial**	**0843**	**K**	**$459.34**
2004	**J9266**	**Pegaspargase / single dose vial**	**---**	**N**	**-0-**
Proposed 2005	**J9266**	**Pegaspargase / single dose vial**	**---**	**N**	**-0-**

Sources: 65 Fed. Reg. 67982 (November 13, 2000); 67 Fed. Reg. 9574 (March 1, 2002) (subject to sole source pro-rata reduction); 67 Fed. Reg. 66988 (November 1, 2002); 68 Fed. Reg. 63634 (November 7, 2003); 69 Fed. Reg. 50794 (August 16, 2004).

As reflected on Table 2, in calendar year (CY) 2001, J9266 Pegaspargase/single dose vial had a status indicator of "G" and was paid as a pass-through drug (APC 0843) at a rate of $1,321.65. In calendar year (CY) 2002, J9266 Pegaspargase/single dose vial had a status indicator of "G" and was paid as a pass-through drug (APC 0843) and was assigned a rate of $1,225.57, subject to pro-rata reduction. In CY 2003 J9266 Pegaspargase was removed from pass-through status and was assigned a status indicator of K with a computed payment rate of $459.34. In CY 2004, and as proposed for CY 2005, J9266 Pegaspargase has been assigned the packaged status indicator of "N".

We believe the data used to compute the payment rate is flawed. Our consultants, The Resource Group, commissioned a data run from The Moran Company. Moran's comparative data analysis, attached as Appendix A, reflects J9266 information from the OPPS claims database for calendar years 2003, 2004 and 2005.

The computed 2005 median cost amounts to $1,313.01. According to The Moran Company, the 2005 median cost per unit for J9266 using CMS methodology is $1,313.01 and the mean cost per unit is $1,116.51. This analysis of the 2005 data that replicates CMS methodology indicates a cost well over the threshold for a separately paid drug. (See details in Appendix A.)

Miscoded claims for certain hospitals appear in the J9266 claims database. The three-year data analysis contains multiple providers with a nominal charge per unit (such as $17.00, $17.60, etc.). In 2004, for example, five Methodist hospitals (provider numbers 440061, 440189, 440168, 440182 and 440072) accounted for seventy percent of all claims appearing in the claims database analysis during that time period. The average charge on these claims was $59.68 and the average unit cost was $6.20 for a drug that costs in excess of $1,200 per unit. A review of the distributors' records revealed that no Pegaspargase has ever been sold to any of the above listed hospitals. We believe the miscoded claims from these hospitals resulted in J9266 being reported at an erroneously low unit cost. The errors in turn caused J9266 to fall below the threshold and be reclassified as a packaged drug.

In the physician's office Pegaspargase is currently being paid at 85% of AWP. Table 3 below reflects the 2004 payment rate for J9266 Pegaspargase in the physician's office. This current payment rate of $1,277.13 in the physician's office is inconsistent with the packaged rate for the hospital outpatient department. Within the current OPPS proposed rule CMS affirms that " . . .we generally intend to establish, wherever possible, consistent payment policies for drugs whether they are furnished in a hospital outpatient setting or in a physician's office or clinic".[2]

Table 3. 2004 Physician In-Office Payment at 85% of AWP

CPT / HCPCS	Payment Status	Description	Physician In-Office Payment Rate
J9266	**85% AWP**	**Pegaspargase / single dose vial**	**$1,277.13**

Source: www.cms.hhs.gov/providers/drugs/default.asp. "HCPCS Drug Pricing File: Microsoft Excel file updated 6-17-04"; file name R75_CP2_rev061704.zip.

III. RECOMMENDATIONS

As described above, the Proposed Rule reflects an incorrectly packaged rate for this treatment furnished by hospital outpatient departments to Medicare beneficiaries, thereby jeopardizing patient access to this important therapy. To address the issue, Enzon strongly encourages CMS to correct the OPPS payment status for J9266 Pegaspargase and to properly reflect the rate as a separately paid drug with a status indicator of K.

Requested Correction to OPPS Proposed Payment Status for 2005 (SI "K")

CPT / HCPCS	APC	Description	Status Indicator	Payment Rate
J9266	**0843**	**Pegaspargase / single dose vial**	**K**	**[separately paid]**

[2] 69 Fed. Reg. 50516 (August 16, 2004)

IV. CONCLUSION

I appreciate the opportunity to comment on this important issue contained within CMS's Proposed Rule, and look forward to working with the agency to ensure that the final rule is implemented in an equitable manner that preserves beneficiaries' access to quality health care under the Medicare Program. If additional information is required, do not hesitate to contact me.

Sincerely,

John Weinberg, MD
Senior Director, Oncology
Enzon Pharmaceuticals, Inc.

Appendix A		Medicare Claims Summary 2003, 2004, 2005											
Medicare Provider Number	State	2003				2004				2005			
		% of total Units	Units/ Line	Charge/ Unit	Cost/ Unit	% of total Units	Units/ Line	Charge/ Unit	Cost/ Unit	% of total Units	Units/ Line	Charge/ Unit	Cost/ Unit
500027	WA	0%	0.00	$0.00	$0.00	3%	3.00	$474.67	$102.12	0%	0.00	$0.00	$0.00
450076	TX	2%	1.00	$2,824.17	$1,411.80	2%	2.00	$1,889.00	$791.60	0%	0.00	$0.00	$0.00
450462	TX	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
440049	TN	2%	1.00	$67.47	$17.96	2%	1.00	$1,895.50	$579.66	4%	1.00	$17.60	$5.31
440061	TN	6%	1.00	$1,653.01	$390.61	12%	1.22	$71.82	$0.11	0%	0.00	$0.00	$0.00
440072	TN	17%	2.10	$415.28	$133.06	24%	1.28	$68.96	$15.59	2%	1.00	$84.40	$15.60
440168	TN	0%	0.00	$0.00	$0.00	1%	1.00	$17.00	$2.97	0%	0.00	$0.00	$0.00
440174	TN	1%	1.00	$62.70	$15.05	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
440182	TN	0%	0.00	$0.00	$0.00	2%	1.00	$69.50	$11.92	0%	0.00	$0.00	$0.00
440189	TN	14%	1.42	$502.91	$87.50	12%	1.10	$71.09	$0.40	0%	0.00	$0.00	$0.00
420071	SC	0%	0.00	$0.00	$0.00	1%	1.00	$5,838.00	$1,638.73	31%	1.07	$5,838.04	$1,629.39
390006	PA	2%	2.00	$3,559.88	$1,640.39	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
390196	PA	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	10%	5.00	$934.52	$381.47
360141	OH	35%	11.00	$394.50	$129.36	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
330011	NY	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	2%	1.00	$954.27	$326.16
330136	NY	5%	3.00	$1,808.60	$1,133.45	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
340030	NC	0%	0.00	$0.00	$0.00	1%	1.00	$2,116.00	$1,172.96	0%	0.00	$0.00	$0.00
240061	MN	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	8%	4.00	$714.72	$371.73
230046	MI	0%	0.00	$0.00	$0.00	37%	7.00	$522.29	$314.56	25%	2.00	$1,432.69	$822.50
220033	MA	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
220050	MA	2%	3.00	$1,883.00	$1,070.67	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
220095	MA	10%	2.00	$1,170.20	$970.68	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
220162	MA	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	2%	1.00	$5,850.00	$2,482.74
180067	KY	3%	2.00	$1,977.70	$867.02	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
140088	IL	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	4%	1.00	$8,425.90	$2,009.57
140280	IL	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	6%	1.00	$3,684.20	$1,508.67
130006	ID	0%	0.00	$0.00	$0.00	2%	2.00	$2,404.00	$1,418.36	0%	0.00	$0.00	$0.00
100038	FL	2%	2.00	$5,112.00	$651.26	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00
50193	CA	0%	0.00	$0.00	$0.00	1%	1.00	$8,470.00	$1,038.42	0%	0.00	$0.00	$0.00
50660	CA	0%	0.00	$0.00	$0.00	0%	0.00	$0.00	$0.00	4%	1.00	$10,317.95	$2,253.44
Total		100%	2.38	$870.25	$365.42	100%	1.79	$545.46	$222.48	100%	1.41	$3,494.97	$1,116.51
Source: Prepared by The Moran Company from OPPS claims data replicating CMS methodology													

Submitter : Dr. Lindell Weaver **Date & Time:** 09/30/2004 06:09:17

Organization : LDS Hospital

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Dr. Thompson:

I am the Medical Director of Hyperbaric Medicine at LDS Hospital and a Professor of Medicine at the University of Utah School of Medicine. I would like to express my concerns for the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?), 69 Fed. Reg. 50448 (Aug. 16, 2004).

I have practiced Hyperbaric Medicine for over 15 years, and am one of only a few full-time academic hyperbaric medicine directors in the United States. By way of background, I authored the lead article in the October 4, 2002 issue of the New England Journal of Medicine regarding efficacy of hyperbaric oxygen for acute carbon monoxide poisoning. Our hospital is a Level I tertiary care facility, and our hyperbaric medicine service provides care to patients from throughout the Intermountain West, comprising several states.

If the proposed reductions for hyperbaric oxygen therapy take effect, our ability to deliver quality care, 24 hours per day will be compromised. We supplied cost-reporting information to the Hyperbaric Oxygen Therapy Association and support the Lewin Group?s findings. It seems reasonable for you to consider two different proposals which include: (1) continuing the CMS 2004 reimbursement schedule pending a detailed analysis of hyperbaric oxygen costs and cost-to-charge ratios; or (2) Adopt the Lewin Group?s recommendation to reimburse hospitals at $118.21 per 30-minute increment of hyperbaric oxygen treatment.

I appreciate your consideration for this important request.

Sincerely,

Lindell K. Weaver, MD, FACP, FCCP, FCCM

CMS-1427-P-92-Attach-1.pdf

LDS HOSPITAL
IHC A Service of Intermountain Health Care

Intermountain Hyperbaric Medicine Department

LDS Hospital
Eighth Avenue and C Street
Salt Lake City, Utah 84143
801-408-3623
Fax 801-408-8578

Lindell Weaver, M.D.
Susan Churchill, N.P.

September 24, 2004

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018
www.cms.hhs.gov/regulations/ecomments

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Dr. Thompson:

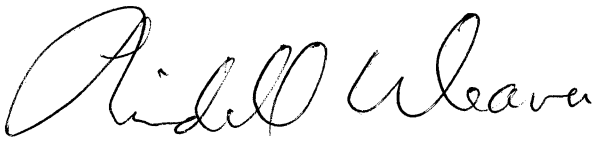
I am the Medical Director of Hyperbaric Medicine at LDS Hospital and a Professor of Medicine at the University of Utah School of Medicine. I would like to express my concerns for the Department of Health and Human Services Centers for Medicare & Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"), 69 Fed. Reg. 50448 (Aug. 16, 2004).

I have practiced Hyperbaric Medicine for over 15 years, and am one of only a few full-time academic hyperbaric medicine directors in the United States. By way of background, I authored the lead article in the October 4, 2002 issue of the New England Journal of Medicine regarding efficacy of hyperbaric oxygen for acute carbon monoxide poisoning. Our hospital is a Level I tertiary care facility, and our hyperbaric medicine service provides care to patients from throughout the Intermountain West, comprising several states.

If the proposed reductions for hyperbaric oxygen therapy take effect, our ability to deliver quality care, 24 hours per day will be compromised. We supplied cost-reporting information to the Hyperbaric Oxygen Therapy Association and support the Lewin Group's findings. It seems reasonable for you to consider two different proposals which include: (1) continuing the CMS 2004 reimbursement schedule pending a detailed analysis of hyperbaric oxygen costs and cost-to-charge ratios; or (2) Adopt the Lewin Group's recommendation to reimburse hospitals at $118.21 per 30-minute increment of hyperbaric oxygen treatment.

I appreciate your consideration for this important request.

Sincerely,



Lindell K. Weaver, MD, FACP, FCCP, FCCM
Medical Director Hyperbaric Medicine
LDS Hospital
8th Avenue and C Street
Salt Lake City, UT 84143

CC: Senator Robert Bennett
431 Dirksen Senate Office Building
Washington, D.C. 20510-4403

Representative Robert Bishop
124 Cannon House Office Building
Washington, D.C. 20515-4401

Representative Chris Cannon
118 Cannon House Office Building
Washington, D.C. 20515-4403

Senator Orrin Hatch
104 Hart Senate Office Building
Washington, D.C. 20510-4402

Representative Jim Matheson
410 Cannon House Office Building
Washington, D.C. 20515-4402

Submitter : Dr. Lindell Weaver **Date & Time:** 09/30/2004 06:09:08

Organization : UHMS

Category : Other Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I am the President of the Undersea and Hyperbaric Medical Society, the scientific professional organization regarding the practice of hyperbaric medicine. I would like to express my concerns to the Department of Health and Human Services Centers for Medicare & Medicaid Services? 2005 Hospital Outpatient Prospective Payment System proposed rule (?Proposed Rule?) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (?HBOT?), 69 Fed. Reg. 50448 (Aug. 16, 2004). The UHMS has had a cordial relationship with Medicare dating back to the 1970?s when we were approached by Medicare to help establish criteria for hyperbaric oxygen therapy, which resulted in the Health Care Carriers Manual, section 35-10.

I am deeply concerned that access to hyperbaric oxygen therapy will be compromised if the new proposed reimbursement rates take effect. Only recently have sufficient hyperbaric medicine centers opened to permit easier access of this important treatment modality, and now this access may indeed be compromised. Regarding efficacy, hyperbaric medicine is on a solid foundation and it would be unfortunate if Medicare-recipients could not be adequately treated because existing hyperbaric medicine centers closed, or new centers could not open.

As president of the UHMS, I support the Hyperbaric Oxygen Therapy Association and the Lewin Group?s findings, recently presented to CMS on September 9, 2004. Given the data presented at this meeting, it seems reasonable for you to consider different proposals for future hyperbaric oxygen therapy reimbursement, including: (1) continuing the CMS 2004 reimbursement schedule pending a detailed analysis of hyperbaric oxygen costs and cost-to-charge ratios; (2) Apply the Lewin Group methodology for hyperbaric oxygen therapy claims for 2003 to the 389 hospitals that submitted bills to CMS; (3) Adopt the overall cost to charge ratio (CCR) of 0.47; or (4) Adopt the Lewin Group?s recommendation to reimburse hospitals at $118.21 per 30-minute increment of hyperbaric oxygen treatment.

I appreciate your consideration of this important request.

Sincerely,
Lindell K. Weaver, MD, FACP, FCCP, FCCM,
President, Undersea and Hyperbaric Medical Society

CMS-1427-P-93-Attach-1.pdf

September 24, 2004

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018
www.cms.hhs.gov/regulations/ecomments

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Dr. Thompson:

I am the President of the Undersea and Hyperbaric Medical Society, the scientific professional organization regarding the practice of hyperbaric medicine. I would like to express my concerns to the Department of Health and Human Services Centers for Medicare & Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"), 69 Fed. Reg. 50448 (Aug. 16, 2004). The UHMS has had a cordial relationship with Medicare dating back to the 1970's when we were approached by Medicare to help establish criteria for hyperbaric oxygen therapy, which resulted in the Health Care Carriers Manual, section 35-10.

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UNDERSEA & HYPERBARIC MEDICAL SOCIETY
10531 METROPOLITAN AVENUE • KENSINGTON, MARYLAND 20895-2627 • PHONE (301) 942-2980 • FAX (301) 942-7804
WWW.UHMS.ORG

As president of the UHMS, I support the Hyperbaric Oxygen Therapy Association and the Lewin Group's findings, recently presented to CMS on September 9, 2004. Given the data presented at this meeting, it seems reasonable for you to consider different proposals for future hyperbaric oxygen therapy reimbursement, including: (1) continuing the CMS 2004 reimbursement schedule pending a detailed analysis of hyperbaric oxygen costs and cost-to-charge ratios; (2) Apply the Lewin Group methodology for hyperbaric oxygen therapy claims for 2003 to the 389 hospitals that submitted bills to CMS; (3) Adopt the overall cost to charge ratio (CCR) of 0.47; or (4) Adopt the Lewin Group's recommendation to reimburse hospitals at $118.21 per 30-minute increment of hyperbaric oxygen treatment.

I appreciate your consideration of this important request.

Sincerely,

Lindell K. Weaver, MD, FACP, FCCP, FCCM
President, Undersea and Hyperbaric Medical Society

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WWW.UHMS.ORG

Submitter : Ms. Sheryl Dominico **Date & Time:** 09/30/2004 10:09:00

Organization : MartinMemorial Health Systems, Inc

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

HBO Therapy

CMS-1427-P-94-Attach-1.doc

Secretary Tommy G. Thompson
Center for Medicare and Medicaid Services
Attention: CMS-1427-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Sir:

The Department of Health and Human Services Center for Medicare and Medicaid Services' 2005 Hospital Outpatient Prospective Payment System proposed rule indicates decreased reimbursement rates for HBOT (hyperbaric oxygen therapy). 69 Fed. Reg. 50448 (Aug. 16, 2004).

As a top 100 integrated health system, and a top 20 large community hospital, this proposed decrease in reimbursement would have a negative impact on our operations in the future. Martin Memorial Health Systems in Stuart, Florida is a two-hospital system, and the only hospital in Martin County. MMHS is a not-for-profit community based health care organization providing services to Stuart, Hobe Sound, Jensen Beach, Palm City, and Port St. Lucie. Total capacity of in-patient beds is 336. Our Wound Medicine Center was opened less than 2 years ago and has 3 HBO chambers. We are the only provider of hyperbaric oxygen therapy in Martin or St. Lucie Counties.

As Martin County is primarily a retirement community, over 60 % of our patients are Medicare. We treat a large number of diabetic patients with foot ulcers and flap or graft failures that require HBOT. There are also many older patients in the area suffering from delayed effects of radiation therapy and other disease processes that respond well to HBOT. We are straining our resources to provide the best possible medical care to these, and to all our patients. It is a constant challenge to meet the needs of a rapidly growing older population. Any decrease in reimbursement at this time could be devastating to the viability and growth of our much-needed Wound Medicine/HBO program at Martin Memorial Health Systems.

We respectfully request that you support the HOTA (Hyperbaric Oxygen Therapy Association) position and the Lewin Group findings as outlined below:

1) Leave the HBOT reimbursement rate at the current 2004 levels until CMS is able to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2) Adopt the overall cost-to-charge ratio of. CCR.47, due to the inconsistent methods of hospital cost reporting.
3) Utilize the Lewen Group methodology for the 389 hospitals that have reported HBO claims during 2003.
4) Adopt the Lewen Group approach of $118.21 for 30 minutes increments of HBO treatment.

Your consideration in this matter is greatly appreciated.

Sincerely,
Sheryl Dominico
Director Reimbursement Services
Martin Memorial Health Systems, Inc.
Stuart, FL 34996
sdominico@mmhs-fla.org
772.781.2754

Submitter : Ms. Lisa Hill **Date & Time:** 10/01/2004 01:10:13

Organization : Abington Memorial Hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I hope further consideration can be given to the proposed HBOT rate changes so that we may continue to provide timely, effective and cost-managed HBOT for those patients in need. Please see attached note. Thank you.

CMS-1427-P-95-Attach-1.doc

CMS-1427-P-95-Attach-2.doc

September 30, 2004

Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Proposed Changes to Hyperbaric Oxygen Therapy Reimbursement under the Medicare Hospital Outpatient Prospective Payment System (OPPS)

Dear Secretary Thompson:

I am writing in concern to the proposed rule (69 Federal Regulation 50448, 8/16/04) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (HBOT). I am a wound expert in the Comprehensive Wound Healing Center affiliated with Abington Memorial Hospital, a suburban level one trauma center. Our center is the only center within a 15-mile radius to provide comprehensive wound consultation and care in addition to HBOT.

The use of HBOT as an adjunctive treatment is often the critical step in resolving long-standing complicated wounds. The presence of higher levels of oxygen in the bloodstream increases the ability of white blood cells to heal wounds. Healing wounds translates into fewer amputations and greater health care savings. If the proposed rates are finalized for 2005, it will limit our availability to provide HBOT to patients within our community that may otherwise require an amputation or chronic wound management.

HOTA, which represents the majority of hospitals in the country currently providing HBOT, commissioned the Lewin Group to study the methods used by CMS to develop the proposed payment rate and to assess its accuracy. The Lewin Group prepared a report that concluded that the CMS calculation was flawed and made several recommendations to ensure the necessary patient access to HBOT and control expenses.

Given the concerns raised by the CMS calculation and the impact of the reimbursement decrease on Medicare patients, I support consideration of the Lewin Group's suggestions:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has performed a calculation that will accurately assess HBOT costs and cost to charge ratio.

2. Adopt the overall cost to charge ratio of 0.47.

3. Apply the Lewin Group methodology to the 389 hospital that reported hyperbaric claims for the year 2003.

4. Adjust the HBOT rate to $118.21 per 30 minute increment.

I appreciate your consideration of the matter.

Sincerely,

Lisa Hill, MSN, RN, CWOCN

Wound Program Coordinator

Abington Memorial Hospital

September 30, 2004

Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Proposed Changes to Hyperbaric Oxygen Therapy Reimbursement under the Medicare Hospital Outpatient Prospective Payment System (OPPS)

Dear Secretary Thompson:

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1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has performed a calculation that will accurately assess HBOT costs and cost to charge ratio.

2. Adopt the overall cost to charge ratio of 0.47.

3. Apply the Lewin Group methodology to the 389 hospital that reported hyperbaric claims for the year 2003.

4. Adjust the HBOT rate to $118.21 per 30 minute increment.

I appreciate your consideration of the matter.

Sincerely,

Lisa Hill, MSN, RN, CWOCN

Wound Program Coordinator

Abington Memorial Hospital

CMS-1427-P-96

Submitter : Ms. Marilyn Litka-Klein **Date & Time:** 10/01/2004 03:10:38

Organization : Michigan Health & Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the MHA's attached comment letter regarding the 2005 OPPS Proposed Rule.

Thank you!

CMS-1427-P-96-Attach-1.doc

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Linking patients, communities, and providers together for better health.

Sept. 29, 2004

Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department for Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1427-P — Medicare Program; Changes to the Outpatient Prospective Payment System and 2005 Rates; Proposed Rule, Aug. 16, 2004 *Federal Register*

Dear Dr. McClellan:

On behalf of its 143 member hospitals, the Michigan Health and Hospital Association welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services regarding the proposed rule for the calendar year 2005 Outpatient Prospective Payment System, released on the CMS web site on Aug. 9, 2004, and published in the Aug. 16, 2004 *Federal Register*. Although this rule provides a 4.6 percent increase in the outpatient conversion factor, we are very concerned about other policy changes which will result in significant payment decreases for some hospitals.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of Michigan's nonprofit hospitals. Based on the latest data available, **44 percent** of Michigan hospitals experienced a negative margin on Medicare inpatient services while **74 percent** experienced a negative margin on Medicare outpatient services. As such, we are gravely concerned about the consequences of the additional negative financial impact of the proposed changes. These changes will further threaten the future viability of hospitals and access to healthcare services for Medicare beneficiaries and other residents of the state of Michigan.

WAGE INDEX ADJUSTMENT (*Federal Register* Page 50541)

The CMS proposes to use the final FY 2005 hospital inpatient wage index to calculate the payment rates and coinsurance amounts that they will publish in the final OPPS rule. The wage index in this proposed rule is based on the FY 2005 hospital inpatient PPS proposed rule wage index. These indices reflect proposed major changes for 2005 relating to hospital labor market areas as a result of Office of Management and Budget revised definitions of geographical statistical areas; implementation of an occupational mix adjustment as part of the wage index; hospital reclassifications and redesignations – including the one-time reclassifications under section 508 of the MMA; and the wage index adjustment based on commuting patterns of hospital employees under section 505 of MMA. Consistent with current policy, for 2005, the CMS proposes to adjust 60 percent of the APC payment by the wage index.

Subsequent to the publication of this proposed OPPS rule, the CMS released information regarding transitional relief for hospitals that would see their wage index decline due to the revised labor market areas. For example, the CMS will provide temporary one year relief for hospitals with wage areas that changed due to the revised geographic definitions under which hospitals would receive a 50/50 blend calculated from the old and new definitions. In addition, CMS will allow hospitals re-designated from urban to rural areas to maintain their urban designation for a three year period, FY 2005-07. **In our review of the OPPS proposed rule, it is unclear whether these modifications will be incorporated in the OPPS 2005 final regulation. The MHA requests that the CMS provide these same benefits under the OPPS to prevent further negative impact to these hospitals.**

In addition, the Medicare Modernization Act of 2003 reduced the labor portion of the inpatient operating rate from the current 71.1 percent to 62 percent for hospitals located in areas with a wage index of 1.0 or lower, in order to minimize the negative impact to hospitals with lower wage indices**. The MHA requests that the CMS reduce the labor portion from the current 60 percent to 52 percent for outpatient payment purposes for hospitals in areas with a Medicare wage index of 1.0 or lower to maintain consistency with inpatient payments and mitigate the negative impact for many hospitals whose main source of business is outpatient services.**

APC RELATIVE WEIGHTS (*Federal Register Page 50473*)

Current law requires the CMS review and revise the relative payment weights for APCs at least annually. The MHA supports the agency's use of the most recent hospital claims and cost report data for establishing the payment rates, since this data most accurately reflects the hospital charges for providing outpatient services. However, since the implementation of the OPPS in August 2000, payment rates for specific APCs have fluctuated dramatically. For 2005, this continues to be the case with many APCs experiencing significant weight changes. We are concerned that, although the proposed rule provides a detailed description of the methodology employed in calculating the APC weights, it fails to provide adequate information for hospitals to utilize in evaluating the impact of each of the proposed policy changes. **As a result, the MHA requests that the CMS provide additional data upon which hospitals can assess the impact of these important changes in methodology on the APC weights. We recommend that the CMS provide a public use file to indicate the impact of each individual proposed methodology change so that hospital staff can review these impacts to determine how it would affect their operations** and provide a basis for submitting specific comments to the agency. If this cannot be accomplished for the 2005 changes, we recommend that the CMS incorporate this type of analysis into all future proposed regulations.

OUTLIER PAYMENTS (*Federal Register* page 50542)

Outlier payments are a critical and necessary component of any prospective payment system based on averages. By statute, Medicare provides these payments for unusually high cost cases in order to limit the financial risk of hospitals while ensuring that elderly patients with especially serious illnesses receive appropriate care. The CMS is proposing a major change in the outlier methodology to target payments to complex, expensive procedures. Under current policy, outlier

payments are made for outpatient services when the cost of care exceeds 2.6 times the APC payment rate. Based on the proposed OPPS rule, outlier payments would be made when the cost of care **exceeds both 1.5 times the APC payment plus a $625 fixed dollar amount.**

The CMS states that the new methodology will continue to pay 2 percent of total OPPS payments as outliers. However, the CMS does not provide details of this estimate. In the FY 2005 inpatient proposed rule, the CMS suggested a substantial increase in the outlier threshold based on inflated charge estimates, but failed to consider the charge decreases that many hospitals implemented in 2003 and 2004. In 2003, the CMS issued a rule requiring the use of more up-to-date data when determining a hospital's cost-to- charge ratio, specifically, a hospital's most recent final or tentatively settled cost report. The CMS also instructed fiscal intermediaries, in certain situations, to retrospectively reconcile outlier payments when a hospital's cost report is settled. As a result of these changes, many hospitals decreased their charges and the overall rate of increase declined. Based on comments from the American Hospital Association, the MHA and other state associations, in the final FY 2005 inpatient rule, the CMS reduced the outlier threshold from its proposed $35,085 to $25,800, which represents a 17 percent reduction from the FY 2004 threshold.

The MHA urges the CMS to release the data that supports the revised outlier methodology will result in payment of 2 percent of total OPPS payments. Absent data verification, the MHA is concerned that the proposed OPPS includes similar inflation utilized in the inpatient proposed rule. If the $625 was established using similar methodology and is overstated, the MHA recommends the CMS reduce the threshold to $460 based on the 26 percent overstatement of the inpatient proposed outlier threshold.

Default Cost-to-Charge Ratios (*Federal Register* page 50527)

The CMS uses CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS, with default CCRs utilized for hospitals that are determined to have invalid CCRs. These include new hospitals, hospitals that have a CCR that falls outside predetermined floor and ceiling thresholds, or hospitals that have recently given up their all-inclusive rate status. Currently, the CMS uses 1996 and 1997 cost reports for calculating the statewide urban and rural CCRs to use as a default.

For 2005, the CMS proposes to update the default CCRs based on the most recent available cost reports, which is 2002 cost reports for most hospitals. Under the proposal, most areas would experience a decrease in the default CCR, resulting in a significant payment decrease for hospitals that use the default CCR.

The decrease in ratios is caused by the fact that charges were increasing faster than costs during the period between 1996 and 2002. As noted above, charges increased at a much lower rate after 2003. **The MHA believes the CMS should take this into account in developing the default CCRs. As a result, we request that the CMS instruct intermediaries to work with these hospitals in determining CCRs that will provide an accurate cost estimate.**

Payment for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals (*Federal Register* Page 50503)

In 2004 and prior years, drugs and biologicals that were granted pass-through status were paid at 95 percent of the Average Wholesale Price. The MMA provided that pass-through drugs would be paid at 85 percent of AWP in 2004 and Average Sales Price plus six percent in 2005 and subsequent years. The ASP drug payment system is based on data submitted by manufacturers and applies to most Medicare Part B drugs not paid on a cost or prospective payment basis, including payments under the physician fee schedule and some payments under the OPPS. There are 13 drugs that have pass-through status in 2004 that will maintain their pass-through status in 2005. However, due to the change in payment methodology, rates for eight of current pass-through drugs will decrease in 2005. Another five drugs are granted pass-through status for the first time in 2005. **Due to increasing drug costs, the MHA is very concerned that payment rates for eight drugs scheduled to decrease in 2005 would not cover the current acquisition costs for these drugs. Therefore, the MHA urges the CMS to maintain payment rates at the current 2004 level, for drugs that would experience a payment decrease in 2005.**

Expiration of Pass-through Payments (*Federal Register* Page 50500)

Present Medicare law limits payment for pass-through items to between two and three years. The CMS' current policy to remove drugs and devices from pass-through status as quickly as possible, with most pass-through items incorporated into the APC rates after two years. The CMS proposes to eliminate six devices from pass-through status after Dec. 31, 2004, with these items treated as packaged items with no separate payment provided. Instead, the cost of these devices will be incorporated into the rates of associated procedure APCs. The CMS has not provided data to quantify spending for pass-through payments. **As a result, the MHA urges the CMS to provide the data so that hospitals can verify that the proposed APC rates will adequately compensate hospitals for the costs to provide these services to Medicare beneficiaries.**

Payment for "Specified Covered Outpatient Drugs" (*Federal Register* page 50506)

The MMA established a class of drugs known as "specified covered outpatient drugs", defined as any existing APC that is a drug, biological, or radio pharmaceutical agent for which payment was made on a pass-through basis on or before Dec. 31, 2002. Pass-through status for these drugs has expired and they are currently paid through the APC rates. The MMA requires that payment for these drugs be based on the AWP, with payments determined based on three categories: sole source, innovator multiple source, and non-innovator multiple source. Effective Jan. 1, 2004, payments for these categories became subject to various floors and ceilings.

Sole source drugs currently require no Food and Drug Administration approval since they are considered brand-name drugs. In 2004, sole source drugs could be paid no less than 88 percent and no more than 95 percent of the AWP. For 2005, the CMS proposes that the floor for these drugs will decrease from 88 percent to 83 percent of the AWP, while the ceiling will remain at 95 percent of the AWP. As a result, 85 percent, or 118 out of 138, of these drugs will

experience a payment decrease in 2005. **The MHA strongly opposes this decrease and believes it to be inappropriate and that it lacks sound policy justification, for allowing the CMS an additional 5 percent discount opportunity on these drugs. As a result, the MHA recommends that the floor be maintained at the current 88 percent.**

Payment for New Drugs and Biologicals Prior to Assignment of HCPCS Codes (*Federal Register* Page 50516)

Upon a drug's approval by the FDA, a period of time passes before it is assigned a HCPCS code and it becomes eligible for pas-through payment. Currently, hospitals are instructed to bill for drugs without HCPCS codes using a general code for unlisted or unclassified drugs. There is no payment for these drugs, and the reported charges for which a HCPCS code has not been assigned is paid at 95 percent of the AWP. Although this provision became effective Jan. 1, 2004, it has not been implemented because the CMS has not yet determined a methodology for billing these drugs.

The CMS adopted an interim approach and issued a program transmittal on May 28, 2004, regarding billing these drugs. This transmittal instructed hospitals to bill for a drug or biological that is newly approved by the FDA by reporting the National Drug Code for the product along with the HCPCS code C9399, unclassified drug or biological. When code C9399 appears on a claim, it is suspended for manual pricing by the fiscal intermediary. The fiscal intermediary prices the claim at 95 percent of its AWP. The CMS proposes to make this payment methodology permanent and to expand it to include payment for new radiopharmaceuticals to which a HCPCS code is not assigned. While the MHA is pleased that this MMA provision now allows these new drugs to receive separate payment, we remain concerned about the ability of hospitals to correctly code these items using the NDC codes, as required in the current approach. Most hospital billing systems are not able to handle the reporting of NDC codes. Typically, it is only pharmacy systems within hospitals, which handle the purchasing of drugs, that can properly handle the assignment of a drug's NDC. This results in a difficult and burdensome process for hospitals to correctly link the drug administered a particular patient to the exact NDC code that the pharmacy obtained when the drug was purchased.

In addition, for electronic reporting, hospitals report the NDC code using the HIPAA 837i standard that requires use of the appropriate data segment. We request that the CMS consider a different approach for the paper UB-92. Currently, the UB-92 paper instructions from the CMS require that providers use the Remarks field to report the NDC. The use of this field creates payment delays since it requires manual review. **The MHA recommends that the CMS adopt a new revenue code subcategory for the reporting of these newly FDA-approved drugs and biologicals. We believe this would greatly improve the current process for both hospitals and fiscal intermediaries.**

Payment for Blood and Blood Products (*Federal Register* page 50521)

Payment for blood and blood products under the OPPS have been made through separate payments in APCs rather than packaging them into payment for the procedures with which they were administered. Since implementation of the OPPS, due to limited Medicare claims data,

payments for blood were established based on external data. In addition, rate decreases for blood products were subject to limits in 2003 and payments were frozen at the 2003 level in 2004. In general, the CMS prefers to utilize Medicare claims data when setting payments rates but has had difficulty establishing blood product rates.

For 2005, the CMS proposes several modifications to its payment methodology for blood and blood products. First, the CMS proposes to establish new APCs that would allow each blood product to be in its own separate APC while also reassigning some of the HCPCS codes already contained in certain APCs to new APCs. Secondly, the CMS proposes to set payment rates for all blood and blood products based on their 2003 claims data, utilizing an actual or simulated hospital blood-specific CCR to convert charges to costs for blood and blood products. For certain low-volume products, the CMS would combine claims data for 2002 and 2003. While this approach results in modest payment increases for many blood and blood product related APCs, payment rates for certain low-volume APCs will decline significantly under this methodology.

To ensure continued beneficiary access to low-volume blood products, **the MHA urges the CMS to maintain 2005 payment rates at the 2004 levels for those blood products whose rates would decrease under the CMS' proposed methodology.** This is critical since many hospitals indicate that blood costs have increased 15 percent annually for the past several years. In addition, we are aware that the APC Advisory Panel and other groups representing the blood and blood product industry have recommended that the CMS utilize external data for settling payment weights and rates. **The MHA continues to prefer that hospital OPPS payments be based on hospital data and urges the CMS to proceed very cautiously in considering whether to utilize blood industry data for blood. If the CMS does opt to use external data in an interim fashion, then it is crucial that the external data needs to be valid, reliable, publicly available, reflective of geographic variations in costs, and subject to audit.**

APC GROUP CHANGES

Reassignment of New Technology Codes to Clinically Appropriate APCs (Federal Register page 50465)

In 2002, the CMS added "new device technology" APCs to cover devices that were not represented in the 1996 base year data, and which did not meet the transitional payment pass-through criteria. Procedures are assigned to new technology APCs until enough data are collected to allow assignment to clinically appropriate APCs. For 2005, the CMS has identified 24 procedures that were assigned to new technology APCs that now have adequate data to support assignment into specific clinical APCs. This reassignment will cause a decrease in APC payments for 17 of the 24 procedures. The MHA is very concerned about the impact of these payment decreases on hospitals.

In addition, the CMS indicates that a number of positron emission tomography scans currently classified into New Technology APC 1516 now have sufficient data for assignment to clinical APCs. However, this will reduce payments for PET scans and the CMS is concerned that this might hinder beneficiary access to this technology. As a result, the CMS indicated that the agency was considering three options as the proposed payment for PET scans in 2005: **Upon review of these options, the MHA strongly believes that the CMS should implement Option 1, which would continue**

the current assignment of the PET scans to New Technology APC 1516, which has a payment rate of $1,450, prior to assigning it to a clinical APC. This is vital for ensuring continued beneficiary access to expensive, high-tech procedures.

PAYMENT FOR DRUG ADMINISTRATION AND CHEMOTHERAPY (*Federal Register* page 50519)

Currently, the CMS pays separately for the administration of drugs through hospital use of one of the following four "Q" codes:

- Q0081 Infusion therapy other than chemotherapy
- Q0083 Chemotherapy by other than infusion
- Q0084 Chemotherapy by infusion
- Q0085 Chemotherapy by both infusion and other

Each code is reported once per visit no matter how many drugs are administered. Data has shown that costs appear to vary widely based upon whether the drug is packaged or is a separately payable APC. This is due to the fact that payment for administration is included in the payment for packaged drugs, yet a separate, additional payment is made for the administration of separately payable drugs. In the 2004 proposed rule, the CMS expressed concern that inappropriate payment was being made for drugs and drug administration.

For 2005, the CMS proposes to use the CPT codes for drug administration but to crosswalk the CPT codes into APCs that reflect how the services would have been paid under the "Q" codes. Since hospitals currently use CPT codes to report drug administration to all non-Medicare payers, eliminating the "Q" codes for drug administration will standardize the way hospitals report this service across all payers. In addition, the CPT codes distinguish between the clinical and cost differences of the different types of chemotherapy administration—something that the current "Q" codes fail to do. The "Q" codes take into account only the route of administration and not the site or the complexities involved with different types of chemotherapy administration. Hospital coders will need to be educated regarding Medicare's requirements for the use of CPT codes for drug administration. In particular, clarification is needed regarding the following codes:

- 90780 (intravenous infusion for therapy/diagnosis, administered by physician or under direct supervision of physician; up to one hour), and
- 90781 (each additional hour; up to eight hours)

While the MHA welcomes the opportunity to work with the CMS on coding education, as well as in the development of appropriate future rate setting for drug administration, **we strongly believe that clarification is needed regarding whether for hospital providers, a physician is required to administer the infusion or be physically present at the time of the administration.** If the CMS' interpretation is that the physicians' presence is required, then it would not be an appropriate crosswalk code for Q0081**. None of the current "Q" codes require the physician to provide the service, nor do they require the physician to provide direct supervision.**

DEVICE-DEPENDENT APCS (*Federal Register* page 50490)

The CMS is proposing to limit payment decreases for 43 "device-dependent" APCs. These are APCs for services that the CMS has determined cannot be provided without an associated

medical device. These include procedures such as insertion of a pacemaker, diagnostic cardiac catherization, and brachytherapy. Many of these devices were previously paid as pass-through items but are now packaged into the procedure APC.

In 2003, the pass-through status of many new technology devices expired. These devices were packaged into the payment for the primary procedure or service with which they are associated and the CMS eliminated device coding requirements. These items had previously been identified with "C" codes. As a result of being packaged, hospitals no longer received pas-through payments for these items and were no longer required to report codes for the devices. The CMS continued this policy in subsequent years by packaging devices as their pass-through status expired. For 2004 rates, the CMS used only claims on which hospitals had reported devices using the "C" codes to establish the median cost for certain APCs and the CMS reinstated, on a voluntary basis, the reporting of "C" codes for devices.

The CMS has consistently experienced problems in determining payment rates for the procedures that include packaged devices. When APC rates were calculated for these procedures using claims data, the resulting rates were often substantially less than the cost of the device. In 2003 and 2004, the CMS determined that many hospitals were not consistently reporting charges for the devices. Therefore, the CMS limited the calculation to claims that reported a separate charge for the device and placed limits on rate decreases for these APCs. The calculation of rates for device-dependent APCs is more problematic for 2005. The 2005 APC rates are calculated using 2003 claims data, which does not contain any "C" code data on device use since the CMS eliminated it, making it impossible to follow the past practice of limiting the calculation to claims with device charges.

For 2005, the CMS proposes to determine rates for device-dependent APCs based on the greater of:

- median costs calculated using 2003 claims data, or
- 90 percent of the APC payment median for 2004 for such services.

As a result, proposed rates for the device-dependent APCs were limited to a 6.5 percent decrease. Out of the 43 device-dependent APCs: rates for 13 APCs decreased by 6.5 percent and rates for 12 APCs decreased by a lesser amount. APC 0048 experienced a decrease greater than 6.5 percent, however this was due to a change in the definition for the APC.

The MHA is concerned that the CMS' proposal of using median cost data for 2003 and 90 percent of median cost for 2004 does not closely represent hospital costs for these items. Rather than using 2003 data, the MHA recommends that the median cost for the device-dependent APCs listed in Table 19 of the rule be based upon the greater of 2003 median costs or 100 percent of the APC payment median in 2004.

Transitional Corridor Payments

Consistent with the requirements of the MMA, transitional corridor "hold harmless" payments are extended through Dec. 31, 2005, for rural hospitals with 100 or fewer beds and to sole community hospitals located in rural areas. Cancer hospitals and children's hospitals are

held harmless permanently under the transitional corridor provisions of the statute. This resulted in "hold harmless" payments being available only to children's hospitals, cancer hospitals, rural hospitals having 100 or fewer beds, and sole community hospitals located in rural areas. The MHA remains concerned about the negative impact that will result from the Dec. 31, 2005 sunsetting of the transitional corridor "hold harmless" payments for small rural hospitals and sole community hospitals located in rural areas. We believe that these protections are important for the continued viability of these vulnerable facilities. **As a result, the MHA requests that the CMS extend these provisions permanently for all hospitals that currently receive these payments.**

OBSERVATION SERVICES (*Federal Register* page 50532)

Beginning in 2002, the CMS established separate payment for observation services under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma, with a number of accompanying requirements established, including provision of specific diagnostic tests to beneficiaries based on their diagnoses. The CMS has responded to comments from the hospital industry and the APC Panel asserting that the requirements for specific diagnostic tests are overly prescriptive and administratively burdensome by proposing that, beginning in 2005, **the following tests would no longer be required** to receive payment for APC 0339 (Observation):

- for congestive heart failure, a chest x-ray and electrocardiogram and pulse oximetry;
- for asthma, a breathing capacity test or pulse oximetry;
- for chest pain, two sets of cardiac enzyme tests; either two CPK or two troponins and two sequential electrocardiograms.

In addition, the CMS is proposing to change the requirements for counting patient time in observation care. Currently, hospitals report the time in observation beginning with the admission of the beneficiary to observation and ending with the physician's order to discharge the patient from observation. Hospitals have indicated that a manual record review is required in order to capture the time of the physician's orders for discharge. In addition, hospitals continue providing specific discharge-related observation care for a short time after the discharge orders are written. In response, the CMS is proposing to modify the rules so that time in observation care would end when the outpatient is actually discharged from the hospital or admitted as an inpatient.

The CMS provides the following requirements to receive separate payment for "G0244: medically necessary observation services" in 2005:

- The beneficiary must have one of three medical conditions: congestive heart failure, chest pain, or asthma. The hospital bill must report an appropriate admitting or principal diagnosis to reflect the condition.
- The hospital must provide and report on the bill an emergency department visit, clinic visit, or critical care on the same day or the day before the separately payable observation care is provided. For direct admissions to observation, in lieu of an emergency

department visit, clinic visit, or critical care, code "G0263: admission with CHF, CP, asthma" must be billed on the same day as the observation care.
- "G0244: medically necessary observation services" must be billed for a minimum of 8 hours.
- No procedures with a 'T' status indicator, except the code for infusion therapy of other than a chemotherapy drug can be reported on the same day or day before observation care is provided.
- Observation time must be documented in the medical record and begins with the beneficiary's admission to an observation bed and ends when he or she is discharged from the hospital.
- The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.
- The medical record must include documentation that the physician **explicitly** assessed patient risk to determine that the beneficiary would **benefit from observation care.**

While the MHA supports the CMS' proposed changes that simplify the process for receiving payment for outpatient observation services, we are very concerned that uniform standards will not be consistently applied by fiscal intermediaries in determining proper documentation. We are also concerned that the physician documentation requirements are more stringent than that required in other cases. Further, the MHA opposes the CMS' decision to exclude claims reporting more than 48 hours of observation care in calculating the final payment rate for APC 0339. We strongly believe the costs for these covered services should be included in calculating the payment rate because these observation services claims have been paid by Medicare and therefore, reflect services that have been reviewed and have been determined to be medically necessary.

PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT (*Federal Register* page 50536)

The CMS identifies certain procedures that are typically provided only in an inpatient setting. These procedures are assigned a status of "C: inpatient procedure, not payable under the OPPS". Hospitals were advised to admit these patients in order to receive payment. The CMS rejected an APC Panel recommendation to eliminate the list of inpatient only procedures. However, the CMS did review the current list and removed 22 procedures from it. **The MHA continues to believe this list should be eliminated, as physicians, not hospitals, determine where procedures should be performed, as well as whether a specific patient's condition warrants an inpatient admission. As a result, we urge the CMS to eliminate this list.** The current rules inappropriately penalize hospitals if a procedure is on the "inpatient only" list and is performed in the outpatient setting, although the physician believes that setting is the most appropriate for the procedure based on the patient's medical condition. At a minimum, if the CMS opts to maintain this list for 2005, we strongly encourage the CMS to share the list with physician specialty societies so that they can recommend additional procedures that can be safely performed in an outpatient setting and therefore removed from the list.

PAYMENT FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (*Federal Register* page 50540)

In 2003, the CMS implemented a new modifier: "CA: procedure payable only in the inpatient setting when performed emergently on an outpatient who dies before admission". Use of this modifier allows payment for outpatient services on a claim that has the same date of service as a procedure that is on the "inpatient only" list. In 2004, the CMS created APC 0375 to pay for these services, with the payment rate for APC 0375 set at $1,150, which was the payment amount for APC 1513: New Technology – Level XIII. The CMS now has actual claims data for this APC and proposes to use the standard APC methodology for determining the payment rate for APC 0375. Using this methodology, the CMS has proposed a 2005 payment rate of $2,757.68 for APC 0375. **The MHA is concerned as to whether this payment rate appropriately reflects hospital costs and believes that the CMS should review 2004 claims and adjust the rate accordingly in 2006.**

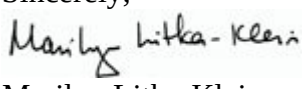
GUIDELINES FOR EVALUATION AND MANAGEMENT CODES (*Federal Register* page 50538)

Since the implementation of the OPPS, hospitals have coded clinic and emergency department visits using the same procedural terminology code utilized by physicians. The CMS has recognized that existing E/M codes may correspond to different levels of physician effort, but fail to adequately reflect differences in the resources used in the hospital setting such as nursing time, patient education, and preparation for diagnostic testing.

Although in the 2004 OPPS rule, the CMS stated that is was evaluating proposed national coding guidelines recommend by a panel comprised of the American Hospital Association and the American Health Information Management Association, the agency has yet to issue proposed guidelines**. The MHA is disappointed that the 2005 rule again fails to address national guidelines for facility E/M reporting.** While we are supportive of the CMS' continued efforts in developing the new codes, hospitals continue to lack a uniform methodology for reporting clinic and ED services. This lack of uniformity not only puts hospitals at risk for upcoding, but also adversely impacts the ability of the CMS to gather consistent, meaningful data on services provided in the emergency department and hospital clinics. **The MHA believes it is vital that the CMS finalize its efforts for E/M reporting and ensure that hospitals have a minimum of 12 months to allow for necessary provider education and system modifications. In addition, we also believe that there should be coordination between the CMS and the Office of HIPAA Standards to ensure that all payers are aware that it is appropriate for hospitals to use CPT E/M codes with their uniquely developed interpretation of the different levels of service. This coordination will be even more important once the CMS decides on uniform guidelines for hospital E/M coding.**

Thank you for your review and consideration of these comments. If you have any questions, please contact me at (517)703-8608 or via email at mklein@mha.org.

Sincerely,



Marilyn Litka-Klein
Senior Director, Health Policy

Submitter : Gloria Ransom **Date & Time:** 10/01/2004 04:10:06

Organization : Munson Medical Center

Category : Hospital

Issue Areas/Comments

Issues 11-20

Drug Administration

We support the proposed change that will allow providers to use CPT codes, rather than Q codes, for reporting drug administration. This change will allow the reporting of drug administration charges to all payers using a uniform set of codes.

Issues 21-30

Observation Services

We support the proposed changes for billing observation services that are provided to patients with asthma, congestive heart failure or chest pain. This change will reduce the provider's administrative burden for billing, and it will allow reimbursement to providers, who have provided high quality, medically necessary observation care to its patients.

CMS-1427-P-98

Submitter : Ms. Sandy Rosenberger **Date & Time:** 09/28/2004 12:09:00

Organization :

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

"Physical Examinations"

As a health care provider, I believe these changes are a positive move for Medicare patients. This allows them to get the screening that is provided by most other health insurers and it seems that it would likely save money to Medicare in the long run to be able to catch costly diseases earlier. Also by allowing earlier treatment in the course of the disease, this could possibly be less treament required for the patient which could transfer not only into less cost in treatment, but also potentially provide for a more overall positive outcome for the patients recovery.

CMS-1427-P-99

Submitter : Ms. Stephanie Spiegel **Date & Time:** 10/01/2004 05:10:40

Organization : The Neurologic

Category : Hospital

Issue Areas/Comments

Issues 1-10

Stereotactic Radiosurgery

I am commenting on SRS. A letter is attached.

CMS-1427-P-99-Attach-1.txt

THE
NEUROLOGIC & ORTHOPEDIC INSTITUTE
OF CHICAGO

October 1, 2004

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

RE: CMS-1727-P, Stereotactic Radiosurgery

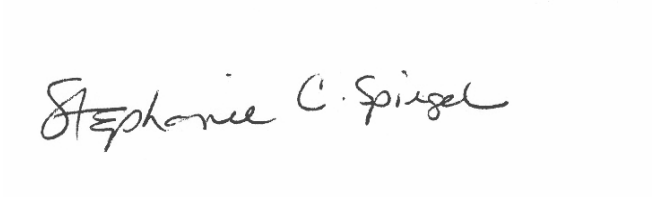
Dear Sirs:

As the president and chief operating officer of the Neurologic & Orthopedic Institute of Chicago, I represent one of Midwest's busiest Gamma Knife centers. Our neurosurgeons have pioneered Gamma Knife stereotactic radiosurgery (SRS), and as a group they have performed more than 1,800 procedures. It is with great concern that I write CMS and urge your organization to correct mistakes it is making in SRS and Gamma Knife coding.

We urge Medicare to combine the two existing codes of G0242 and G0243 into a single code that will pay the combined Gamma Knife SRS medians, as collected in the CMS data. Clearly, with healthcare high atop our nation's priority list, with neurosurgeons in critically short supply, and with most hospitals hemorrhaging financially, it is time to correct the problem.

Thank you so much for your consideration to this matter.

Sincerely,



Stephanie C. Spiegel
President and Chief Operating Officer
The Neurologic & Orthopedic Institute of Chicago

4501 North Winchester Avenue Chicago, IL 60640 P 773-250-0000 F 773-250-0497

Submitter : Ms. Sarah Wells **Date & Time:** 10/01/2004 05:10:53

Organization : Boston Scientific Corporation

Category : Device Industry

Issue Areas/Comments

Issues 1-10

APC Groups

See attached PDF file

Devices

See attached PDF

New Technology APCs

See attached PDF

Physical Examinations

See attached PDF

Unlisted HCPCS Codes

See attached PDF

Issues 21-30

Payment Rate for APCs

See attached PDF

Status Indicators and Comment Indicators

See attached PDF File

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

The attachment to this document is not provided because:

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

Submitter : Mr. Walter K. Moore **Date & Time:** 10/01/2004 06:10:31

Organization : Genentech, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Genentech, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services? (CMS) proposed rule regarding 2005 Medicare Hospital Outpatient Prospective Payment System (OPPS) reimbursement. As you are aware, Genentech is a leading biotechnology company headquartered in South San Francisco, California. Our primary mission is to develop, manufacture, and market breakthrough biologics that address significant unmet medical needs, including cancer, heart disease, and immunological diseases. Several of our therapies are currently provided to Medicare beneficiaries in the hospital outpatient setting.

Since most of our products are injectable therapies for conditions that heavily impact the elderly, Medicare is a significant purchaser of our products, and thousands of Medicare beneficiaries benefit daily from use of Genentech therapies. As such, Medicare reimbursement policies can and often do have a dramatic impact on beneficiary access to these and other breakthrough biologics. Specifically, we oppose payment policies that fail to adequately reimburse hospitals for the costs associated with purchasing and delivering the breakthrough therapies available to the over-65 population. Without sufficient reimbursement for these products and the services required to administer these products, hospitals may simply be unable to provide the best available therapies to Medicare patients.

Issues 11-20

Drug Administration

While Genentech applauds CMS? proposal to crosswalk drug administration Q codes utilized by hospitals to more appropriate CPT codes utilized by physician offices, we are concerned that the crosswalk with current CPT codes will inadequately capture the time and resources required for complex infusions including innovative biologics. The AMA CPT Editorial Panel has provided CMS and Medicare with a valuable opportunity to more accurately and appropriately value the time and resources associated with drug administration. The AMA has approved 12 new and 14 revised codes that better reflect utilization of resources and complexity of drug administration. The new and revised CPT codes will provide new levels of details necessary to properly capture costs associated with types of different infusions ranging from simple saline hydration to complex infusions of innovative biologics such as monoclonal antibodies. The adoption of these more detailed and descriptive CPT drug administration codes will also help to alleviate concerns related to the overpayment for non-bundled drugs and biologics associated with the current single visit rate.

We strongly urge CMS to immediately adopt the recommended AMA CPT codes for the 2005 OPPS. Proper hospital billing of the most appropriate codes will help to ensure the long term access of Medicare beneficiaries to innovative and increasingly complex therapies. In addition, we also urge CMS to provide necessary education to hospitals related to the change in billing codes for drug administration codes in order to ensure that hospital costs are accurately reflected in CY 2005 OPPS claims data.

Issues 21-30

Payment Rate for APCs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the reduction of the threshold for the establishment of separate APC groups with respect to drugs and biologics with median costs greater than $50 furnished in 2005 and 2006. Although we were pleased that Congress reduced the payment threshold in the MMA, we are concerned by CMS? continued application of the payment methodology for drugs and biologics not eligible for the statutory payment floors.

In addition to establishing payment floors, the MMA also includes a provision directing the GAO to conduct a product-specific hospital acquisition survey, upon which payment rates would be based beginning in 2006. Although Congress had the difficult task for defining which

drugs would be eligible for which payment floors, it clearly intended for CMS to move toward acquisition-based reimbursement for all separately payable drugs delivered in the hospital outpatient setting. Furthermore, in enacting statutory reimbursement floors for covered drugs, Congress recognized the inadequacy of the cost-to-charge methodology. As such, it is difficult to understand why CMS would continue to use this flawed tool for determining payment rates for any separately payable products administered in the hospital outpatient setting.

For example, the CMS Proposed Rule would establish a payment rate equivalent to 56% of AWP for Activase, a Genentech cardiovascular product. Approved by the FDA in 1987, Activase is a life-saving therapy for heart attack and stroke that was never eligible for transitional pass-through status and therefore does not meet the definition of ?specified covered outpatient drug?. Although ineligible for the statutory payment floor of 83% of AWP, this rate is grossly inadequate and bears no relation to hospitals? acquisition costs for the product. The rate was derived based on faulty and limited data, as well as the use of CMS? hospital cost-to-charge ratio, which consistently bias? against higher cost biologics.

Specifically, the use of an average hospital cost-to-charge ratio consistently penalizes higher-cost products, such as biologics. This occurs largely because hospitals generally do not mark up higher-cost products by the same percentage they mark-up lower cost items. Thus, when the ratio is applied uniformly across all products, the result is a significant dampening on costs for high-cost products and an inflation of costs of lower-cost products. When translated into reimbursement rates, the impact is severely skewed and results in significant under-reimbursement for higher-cost products, yet adequate and, at times, over-reimbursement for lower-cost products.

Providing reimbursement to hospitals that is significantly lower than product acquisition costs forces hospitals to choose either to lose money each time the therapy is provided, or to provide beneficiaries with less expensive, less effective therapies. In either situation, the best interests of the beneficiary are not met, and Congress? original intent of ensuring seniors? access to the best available therapies is defeated.

Going forward, Genentech feels strongly that a rate-setting methodology based on actual hospital acquisition costs for drugs and biologics is far more appropriate than a rate-setting methodology based on determining costs from hospital charges. We believe the mandated GAO studies and subsequent CMS studies should include all separately payable drugs, and that a new methodology based on hospital acquisition should be developed for implementation beginning in 2006.

CMS-1427-P-101-Attach-1.pdf

CMS-1427-P-101-Attach-1.pdf

CMS-1427-P-101-Attach-1.pdf

Genentech
IN BUSINESS FOR LIFE

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October 1, 2004

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. – Room 445-G
Washington, D.C. 20201

Re: Comments on CMS-1427-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates)

Dear Administrator McClellan:

Genentech, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding 2005 Medicare Hospital Outpatient Prospective Payment System (OPPS) reimbursement. As you are aware, Genentech is a leading biotechnology company headquartered in South San Francisco, California. Our primary mission is to develop, manufacture, and market breakthrough biologics that address significant unmet medical needs, including cancer, heart disease, and immunological diseases. Several of our therapies are currently provided to Medicare beneficiaries in the hospital outpatient setting.

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Specifically, Genentech is concerned with CMS' continued reliance on its flawed hospital cost-to-charge methodology, which it uses to calculate payments for separately payable drugs and biologics that are not eligible for statutory payment floors. This methodology has proven inaccurate and an inappropriate basis upon which to calculate reimbursement. As such, we urge CMS to adopt a reimbursement methodology that relies on hospital acquisition data, rather than on flawed claims data.

In addition, we urge CMS to adopt the new and revised American Medical Association (AMA) Current Procedural Terminology (CPT) codes and payment rates in order to more appropriately capture the costs and complexity of drug administrations.

Ensuring Adequate Payment for Separately Payable Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the reduction of the threshold for the establishment of separate APC groups with respect to drugs and biologics with median costs greater than $50 furnished in 2005 and 2006. Although we were pleased that Congress reduced the payment threshold in the MMA, we are concerned by CMS' continued application of the payment methodology for drugs and biologics not eligible for the statutory payment floors.

In addition to establishing payment floors, the MMA also includes a provision directing the GAO to conduct a product-specific hospital acquisition survey, upon which payment rates would be based beginning in 2006. Although Congress had the difficult task for defining which drugs would be eligible for which payment floors, it clearly intended for CMS to move toward acquisition-based reimbursement for all separately payable drugs delivered in the hospital outpatient setting. Furthermore, in enacting statutory reimbursement floors for covered drugs, Congress recognized the inadequacy of the cost-to-charge methodology. As such, it is difficult to understand why CMS would continue to use this flawed tool for determining payment rates for any separately payable products administered in the hospital outpatient setting.

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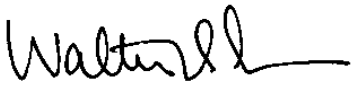
While Genentech applauds CMS' proposal to crosswalk drug administration Q codes utilized by hospitals to more appropriate CPT codes utilized by physician offices, we are concerned that the crosswalk with current CPT codes will inadequately capture the time and resources required for complex infusions including innovative biologics. The AMA CPT Editorial Panel has provided CMS and Medicare with a valuable opportunity to more accurately and appropriately value the time and resources associated with drug administration. The AMA has approved 12 new and 14 revised codes that better reflect utilization of resources and complexity of drug administration. The new and revised CPT codes will provide new levels of details necessary to properly capture costs associated with types of different infusions ranging from simple saline hydration to complex infusions of innovative biologics such as monoclonal antibodies. The adoption of these more detailed and descriptive CPT drug administration codes will also help to alleviate concerns related to the overpayment for non-bundled drugs and biologics associated with the current single visit rate.

We strongly urge CMS to immediately adopt the recommended AMA CPT codes for the 2005 OPPS. Proper hospital billing of the most appropriate codes will help to ensure the long term access of Medicare beneficiaries to innovative and increasingly complex therapies. In addition, we also urge CMS to provide necessary education to hospitals related to the change in billing codes for drug administration codes in order to ensure that hospital costs are accurately reflected in CY 2005 OPPS claims data.

Conclusion

Again, Genentech, Inc. appreciates this opportunity to comment. We look forward to working with you and the CMS staff toward developing a more effective system for the benefit of Medicare beneficiaries.

Sincerely,



Walter K. Moore, Vice President
Government Affairs

CMS-1427-P-102

Submitter : Dr. Joseph Roberson **Date & Time:** 10/01/2004 06:10:39

Organization : California Ear Institute

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Relative Weights

Please see attachment regarding File Code: CMS-1427-P
Proposed Recalibration of APC Weights for CY 2005

CMS-1427-P-102-Attach-1.pdf

October 1, 2004

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. box 8010
Baltimore, MD 21244-8018

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates; CMS-1427-P; Proposed Recalibration of AOC Weights for CY 2005

Dear Dr. McClellan:

On behalf of California Ear Institute, we are pleased to submit the following comments on the proposed rule CMS-1427-P published in the Federal Register on August 16, 2004. We are pleased to see the proposed increase in payment for cochlear implantation (APC 259, 69930) and recognize the progress this represents. However, the 2005 proposed payment under the outpatient prospective payment system (OPPS) is less than our hospital's cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the 2003 data analyzed by CMS is not representative of the costs of the device and procedure.

California Ear Institute has been providing cochlear implants to patients since 1992. Since 1997 our clinic has implanted over 240 patients with 41 of those patients implanted in 2003. Our center has already reached 41 implants in 2004. As cochlear implant technology expands to a larger patient population, the demand for surgeries will increase.

We are also concerned about the billing and coding errors made by hospitals. While there has been some improvement, we urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for cochlear implant devices and other technology.

In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. It is well established that cochlear implantation has been significantly underpaid relative to the actual costs for the device and procedure. Therefore, we disagree with the Advisory Panel's recommendation because it is arbitrary and a hindrance to CMS's goal to ultimately rely on accurate claims data to establish rates for device-dependent APCs.

In conclusion, the proposed increase in payment for APC 0259 is based upon available date. Based upon the proposed rate, it is anticipated our hospital will lose about $60,000 per Medicare cochlear implant surgery in 2005. We ask CMS to improve educational outreach programs to hospitals. Similarly, we oppose arbitrary measures such as the APC Panel's 5% recommendation to cap increases at 5%.

California Ear Institute appreciates the agency's recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendation that we have submitted. If you require additional information, please do no hesitate to contact Monica Hellner at 650-494-1000.

Sincerely,

Joseph B. Roberson, Jr., M.D.
CEO

CMS-1427-P-103

Submitter : Mr. Gerald Dubinski **Date & Time:** 10/01/2004 06:10:28

Organization : Cancer Therapy

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

Stereotactic Radiosurgery

See attached document.

Issues 21-30

Brachytherapy

See attached document.

CMS-1427-P-103-Attach-1.doc

CMS-1427-P-103-Attach-1.doc

Your Life.
Our Commitment.

CTRC
Cancer Therapy & Research Center

www.ctrc.cc

Gerald Z. Dubinski
Executive Vice President
Urschel Tower
Suite 600
t. 210.616.5810
f. 210.692.9823

October 1, 2004

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-1427-P,
P.O. Box 8010,
Baltimore, MD 21244-8018

Dear Dr. McClellan:

Cancer Therapy and Research Center (CTRC) wishes to express our deep concern regarding the Notice of Proposed Rulemaking issued by the Centers for Medicare and Medicaid Services (CMS) in August 2004, regarding reductions in reimbursement. This rule will have an adverse effect on our patients, our practices and our community.

CTRC operates 3 facilities in San Antonio and has grown from 2 linear accelerators in 1976 to full time operation of 9 accelerators today. We treat 200 patients each day on these machines.

Radiation oncology is an essential tool in the war on cancer. Over 50 percent of cancer patients are treated with radiation, either alone or in conjunction with surgery or chemotherapy. Yet, in spite of its importance in treating cancer, radiotherapy is among the most negatively impacted under this proposed CMS rule, with a disproportionate impact on those most in need. We request the following:

A). Re-evaluation of code 77370.

The reduction in payment for CPT 77370 (special physics consult) is unmistakably an error. This code was reduced by 50% and was previously undervalued. At a minimum, the code should be returned to its previous value.

B). Increased payment rate on brachytherapy codes 77761-77777

The payment rate for brachytherapy codes 77761-77777 is:

- CPT 77761 - $185.45
- CPT 77762 - $126.37
- CPT 77763 - $156.85
- CPT 77766 - $76.71
- CPT 77777 - $148.24

This payment rate is grossly undervalued and will lead to abandonment of the procedure in the hospital outpatient setting.

C). Stereotactic Radio-Surgery and Stereotactic Radiation

Treatment revisions.

In the current APC groupings, the Physics planning codes G0242 (cobalt multi-source physics planning) and G0338 (linear accelerator based physics planning) combined into a single APC grouping. This new APC should have the CCI edits removed for codes, 77290, 77280, 77300, 77321, 77336, and 77370. The CCI edit for code 77295 (3-D planning) and 77301 (IMRT planning) should remain. The APC code for stereotactic radiosurgery treatment delivery G0173-linac single session treatment should be billed for fraction one and G0251-SRT multi-fraction for subsequent fractions 2-5.

D). Elimination of the 90-day global period for CPT 77427.

The 2005 proposed rules established a 90-day global period for billing physicians' weekly management CPT 77427. Radiation treatment management is a professional code representing the physician work to manage a patient's care while undergoing radiation therapy. The code is billed every fifth treatment, with exceptions for a course of treatment of 3-4 fractions or when the final week of a long course of treatment is only 3-4 fractions. A course of radiation therapy ranges for a single fraction to eight weeks of therapy. In an example of where 7 weeks of therapy are medically necessary, CPT 77427 is warranted and billed with 7 dates of service. The implication created (I believe unintentionally) is that the subsequent 6 units would fall in the 90 day global period. As another example, a patient completes a course of radiation therapy and returns 1 week later with new symptoms of metastatic cancer to another area, necessitating treatment. The new course of therapy for an unrelated area could fall in the 90-day global period.

Very truly yours,

Cancer Therapy & Research Center

Gerald Z. Dubinski
Executive Vice President

Submitter : Mr. Jeffrey Becker **Date & Time:** 10/01/2004 07:10:42

Organization : Tufts-New England Medical Center

Category : Other Health Care Professional

Issue Areas/Comments

Issues 11-20

Radiopharmaceuticals

Our institution endeavors to provide our patients with the most effective and appropriate diagnostic and therapeutic radiopharmaceuticals. This works only if we are reimbursed fairly for these products and the labor associated with their preparation and administration.

One of the more promising new fields is radioimmunotherapy (RIT). RIT is currently limited to two new drugs for the treatment of non-Hodgkins lymphoma. Bexxar e.g. is a complex new therapy that involves multiple administrations of both labelled and unlabelled monoclonal antibodies over a 7-14 day period. This is very labor intensive in addition to the high cost of the drug components themselves.

If the reimbursement under this proposed rule is reduced to a number below the actual cost of procuring, preparing and administering this product we may have to limit or discontinue it's use. This would be discomforting as the more we use this product the more we are excited about it's potential for broader impact in the treatment of NHL. This could end up to be a money saver as well if it replaces multiple courses of other therapies. Also-we gain valuable experience in this new and emerging area.

Please revist the reimbursement for RIT in general and Bexxar in particular.

Submitter : Mrs. Susan McKay **Date & Time:** 10/01/2004 11:10:16

Organization : Office of Susan B. McKay

Category : Social Worker

Issue Areas/Comments

Issues 1-10

Physical Examinations

In the Welcome to Medicare Program - screenings for mental health should also be included with physical exams and sreenings for heart disaease and other conditions. This would be cost effective for an internist to refer a client for an evaluation with a therapist.

CMS-1427-P-106

Submitter : Mr. Renato V. Baciarelli **Date & Time:** 10/01/2004 09:10:52

Organization : St. Rose Dominican Hospitals

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:
St. Rose Dominican Hospitals Rose deLima Campus is a 138 bed hospital located in Henderson, NV. We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which have the median cost for APC 0659, hyperbaric oxygen therapy treatment declining to $82.91 from the 2004 payment of $164.93.

The hospital recently made a significant commitment to provide hyperbaric oxygen therapy (HBOT) to our community and will be the sole provider of this service in Henderson. Hyperbaric oxygen therapy is an integral component of our newly established comprehensive program for the management of chronic wounds. The proposed lower payment will have a dramatic impact on our ability to provide this care and may threaten our patient?s access to this effective and efficient treatment.

The Lewin Group?s report indicates that Respiratory Therapy?s cost-to-charge ratio was applied in determining the proposed reimbursement. Clearly, this will not be the same situation with hyperbaric therapy provided with our wound program.
I am hopeful that CMS will reconsider their proposed rate structure revisions.
I appreciate your time in reviewing my concern.

Very Truly Yours,

Renato V. Baciarelli
President

CMS-1427-P-107

Submitter : Ms. Marga Ortigas-Wedekind **Date & Time:** 10/01/2004 09:10:25

Organization : Xoft microTube, Inc.

Category : Device Industry

Issue Areas/Comments

Issues 21-30

Brachytherapy

Comment on need for the creation of a miscellaneous brachytherapy source code.

CMS-1427-P-107-Attach-1.pdf

CMS-1427-P-107-Attach-2.doc

October 1, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Comments on August 16, 2004 Hospital Outpatient Prospective Payment System Proposed Rule; CMS-1427-P

Dear Dr. McClellan:

On behalf of Xoft microTube, Inc., I am submitting the following comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 16, 2004 Federal Register Proposed Rule for the Hospital Outpatient Prospective Payment System (HOPPS).

EXECUTIVE SUMMARY

We would like to thank and commend CMS for its continuing efforts in developing the appropriate mechanisms for hospital providers to bill and be reimbursed for brachytherapy sources as defined by legislation put forth under the Medicare Modernization Act of 2003 (MMA – please see Section 621(b) of Pub. L 108-173).

Xoft microTube, Inc., developer of a brachytherapy radiation system for early-stage breast cancer patients, respectfully submits the following comments for CMS consideration under the HOPPS for calendar year 2005:

- In keeping with previous, comprehensive policy making regarding coding of drugs, devices, and procedures/services, Xoft microTube requests that CMS create an Ambulatory Payment Classification (APC) for miscellaneous brachytherapy sources for Medicare to pay hospital providers, as mandated under MMA. This would allow hospitals to be paid for any brachytherapy source in the interim between FDA approval of a new brachytherapy source and the development of more specific coding per source.

- To facilitate claims processing, Xoft microTube recommends that CMS create a temporary C code for miscellaneous brachytherapy sources for hospital providers in order to bill for these sources in the hospital outpatient department until more specific coding per source is available.

BACKGROUND

Historically, the development of miscellaneous codes has been a necessary component of billing to ensure that providers are capable of recouping costs of innovative drugs/biologicals, medical devices, diagnostic tests, and other items and services. For example, to address this specific gap for drugs and biologicals, CMS has implemented a miscellaneous drug code, C9399, for payment under the APC payment system. The C9399 code facilitates claims processing for innovative drugs in the time between FDA approval and the development of more specific coding. We believe this precedent paves the way for the creation of a miscellaneous code for brachytherapy sources.

In materials submitted by the Coalition for the Advancement of Brachytherapy (CAB) to the Government Accountability Office (GAO) on brachytherapy, brachytherapy is defined as "a technique that places radiation sources as close as possible to the tumor site or directly into the tumor. The radioactive sources or isotopes are in the form of seeds, wires, rods, liquid, microspheres or electronic sources in the form of x-ray tubes or probes."

MMA mandated that brachytherapy sources be paid at hospital charges adjusted to cost as an interim measure to ensure that hospitals receive separate reimbursement for these items. CMS has been diligent in creating C codes for specific sources. Most recently, in the August 16, 2004 proposed rule, CMS accepted and proposed to implement APC Advisory Panel recommendations regarding the accommodation of brachytherapy sources into the HOPPS not already defined by coding. These brachytherapy sources are high activity Iodine-125 and high activity Palladium-103. This development is in keeping with CMS's legislated mandate described above.

However, while CMS has created C codes for specific brachytherapy sources and structured APCs to allow for this mandated interim payment methodology, a gap still exists in accomplishing its mandate – that is, innovative brachytherapy sources used by hospitals but not yet defined by coding, would not be payable under the HOPPS. In this respect, the Agency would fail to meet its legislative mandate.

RECOMMENDATIONS AND RATIONALE

The APC payment system is not equipped to accommodate the newest innovative sources in a matter timely with hospital uptake and use of these innovative sources. As a result, hospitals using these sources have no established pathway for recouping costs in the period between FDA approval of a new source and the creation of source-specific codes. The development of an APC for "Brachytherapy source, miscellaneous" is warranted to allow CMS to fully comply with its legislated mandate and ensure payment for all brachytherapy sources they would use.

To facilitate claims processing and reimbursement to hospital providers, the development of a C code for "Brachytherapy source, miscellaneous" is warranted to enable hospital providers to bill for sources that have just entered the market prior to the availability of specific coding for each new source.

APC	APC Title	HCPCS	Descriptor	Status Indicator
xxxx	Brachytherapy source, miscellaneous	Cxxxx	Brachytherapy source, miscellaneous	H

This subject was presented to and discussed with the APC Advisory Panel this year at their September meeting. At the time, APC Panel members noted the need to study the MMA legislation on this issue further, but also noted that as newer brachytherapy sources come to market, government decision-makers would have to find a way to accommodate these new sources.

The creation of a miscellaneous code for these sources is a sound option to meet this accommodation, and it would not disrupt the current process of creating source-specific codes. Because the legislative mandate designates the agency to pay hospitals for brachytherapy sources at cost, payment methodology is already established and would be handled on a source-by-source basis, so in this respect, a miscellaneous code would not "dilute" payment for specific sources. In addition, for the sake of data quality and source identification, a specific code is always preferable, so it is still in the best interest of providers and manufacturers to seek specific C codes when new brachytherapy sources become available.

* * * * *

We believe that the implementation of a miscellaneous brachytherapy APC and corresponding miscellaneous brachytherapy C code is good policy with strong precedent to fill a gap in provider reimbursement, and a most responsible method for CMS to meet fully its legislated mandate.

Xoft microTube, Inc. is an active member of the Coalition for the Advancement of Brachytherapy, and we are currently working with representatives from interested professional medical societies to eliminate barriers in hospital use of innovative sources. We welcome the opportunity to discuss these comments in more detail. If you have any questions, please reach me via the contact information listed below. Thank you for your consideration.

Sincerely,

Marga Ortigas-Wedekind
Vice President, Marketing and Sales
Xoft microTube, Inc.

October 1, 2004

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Comments on August 16, 2004 Hospital Outpatient Prospective Payment System Proposed Rule; CMS-1427-P

Dear Dr. McClellan:

On behalf of Xoft microTube, Inc., I am submitting the following comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 16, 2004 Federal Register Proposed Rule for the Hospital Outpatient Prospective Payment System (HOPPS).

EXECUTIVE SUMMARY

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- In keeping with previous, comprehensive policy making regarding coding of drugs, devices, and procedures/services, Xoft microTube requests that CMS create an Ambulatory Payment Classification (APC) for miscellaneous brachytherapy sources for Medicare to pay hospital providers, as mandated under MMA. This would allow hospitals to be paid for any brachytherapy source in the interim between FDA approval of a new brachytherapy source and the development of more specific coding per source.

- To facilitate claims processing, Xoft microTube recommends that CMS create a temporary C code for miscellaneous brachytherapy sources for hospital providers in order to bill for these sources in the hospital outpatient department until more specific coding per source is available.

BACKGROUND

Historically, the development of miscellaneous codes has been a necessary component of billing to ensure that providers are capable of recouping costs of innovative drugs/biologicals, medical devices, diagnostic tests, and other items and services. For example, to address this specific gap for drugs and biologicals, CMS has implemented a miscellaneous drug code, C9399, for payment under the APC payment system. The C9399 code facilitates claims processing for innovative drugs in the time between FDA approval and the development of more specific coding. We believe this precedent paves the way for the creation of a miscellaneous code for brachytherapy sources.

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MMA mandated that brachytherapy sources be paid at hospital charges adjusted to cost as an interim measure to ensure that hospitals receive separate reimbursement for these items. CMS has been diligent in creating C codes for specific sources. Most recently, in the August 16, 2004 proposed rule, CMS accepted and proposed to implement APC Advisory Panel recommendations regarding the accommodation of brachytherapy sources into the HOPPS not already defined by coding. These brachytherapy sources are high activity Iodine-125 and high activity Palladium-103. This development is in keeping with CMS's legislated mandate described above.

However, while CMS has created C codes for specific brachytherapy sources and structured APCs to allow for this mandated interim payment methodology, a gap still exists in accomplishing its mandate – that is, innovative brachytherapy sources used by hospitals but not yet defined by coding, would not be payable under the HOPPS. In this respect, the Agency would fail to meet its legislative mandate.

RECOMMENDATIONS AND RATIONALE

The APC payment system is not equipped to accommodate the newest innovative sources in a matter timely with hospital uptake and use of these innovative sources. As a result, hospitals using these sources have no established pathway for recouping costs in the period between FDA approval of a new source and the creation of source-specific codes. The development of an APC for "Brachytherapy source, miscellaneous" is warranted to allow CMS to fully comply with its legislated mandate and ensure payment for all brachytherapy sources they would use.

To facilitate claims processing and reimbursement to hospital providers, the development of a C code for "Brachytherapy source, miscellaneous" is warranted to enable hospital providers to bill for sources that have just entered the market prior to the availability of specific coding for each new source.

APC	APC Title	HCPCS	Descriptor	Status Indicator
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This subject was presented to and discussed with the APC Advisory Panel this year at their September meeting. At the time, APC Panel members noted the need to study the MMA legislation on this issue further, but also noted that as newer brachytherapy sources come to market, government decision-makers would have to find a way to accommodate these new sources.

The creation of a miscellaneous code for these sources is a sound option to meet this accommodation, and it would not disrupt the current process of creating source-specific codes. Because the legislative mandate designates the agency to pay hospitals for brachytherapy sources at cost, payment methodology is already established and would be handled on a source-by-source basis, so in this respect, a miscellaneous code would not "dilute" payment for specific sources. In addition, for the sake of data quality and source identification, a specific code is always preferable, so it is still in the best interest of providers and manufacturers to seek specific C codes when new brachytherapy sources become available.

* * * * *

We believe that the implementation of a miscellaneous brachytherapy APC and corresponding miscellaneous brachytherapy C code is good policy with strong precedent to fill a gap in provider reimbursement, and a most responsible method for CMS to meet fully its legislated mandate.

Xoft microTube, Inc. is an active member of the Coalition for the Advancement of Brachytherapy, and we are currently working with representatives from interested professional medical societies to eliminate barriers in hospital use of innovative sources. We welcome the opportunity to discuss these comments in more detail. If you have any questions, please reach me via the contact information listed below. Thank you for your consideration.

Sincerely,

Marga Ortigas-Wedekind
Vice President, Marketing and Sales
Xoft microTube, Inc.

CMS-1427-P-108

Submitter : Mr. Monroe Meyerson **Date & Time:** 10/01/2004 09:10:42

Organization : Radiology Corporation of America

Category : Health Care Industry

Issue Areas/Comments

Issues 1-10

New Technology APCs

Please see attached Comment Letter

CMS-1427-P-108-Attach-1.doc

7900 Glades Road TEL 561 477 3500
Suite 400 FAX 561 477 3620
Boca Raton, FL 33434 USA

RADIOLOGY
CORPORATION OF AMERICA

October 1, 2004

Sent Via Email

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

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 writing to you regarding Medicare's proposed payment rate for FDG positron emission tomography ("PET") procedures under the Hospital Outpatient Prospective Payment System for Calendar Year 2005. 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.). We are greatly concerned that the other proposed options would limit beneficiary access to PET services

RCOA is one of the leading mobile providers of PET services in Colorado, Delaware, Florida, Louisiana, Maryland, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Texas, and Washington. Many of our services are provided in rural communities such as Enid, Oklahoma; Pueblo, Colorado; Dover, Delaware; Milford, Delaware; Cumberland, Maryland; Santa Fe, New Mexico; Bryant, Texas; Tyler, Texas; Abilene, Texas; Wichita Falls, Texas; Denton, Texas; Vancouver, Washington; Silverdale, Washington; Loveland, Colorado; Greeley, Colorado; Puyallup, Washington; Everett, Washington; Renton, Washington; and Bellingham, Washington. We are the only provider of PET services in these areas.

PET is one of the most remarkable diagnostic imaging innovations in the past 20 years. It assists physicians in the diagnosis and treatment of tumors, cardiac disorders and neurological disorders. PET can eliminate unnecessary surgeries, reduce the costs of other diagnostic procedures and effectively diagnose and treat diseases.

While the clinical benefits of PET are significant, the costs should not be understated. The routes in rural America are far apart. Many of the routes are located from the top of a state to the bottom of a state resulting in mileage equal to 300 to 500 miles. Because of this, technologists and drivers have to be paid travel costs, remote hotel costs, and food allowance. In addition,

everything that supports these routes such as maintenance, fuel, delivery of FDG, etc., is more expensive. It is also very difficult and costly to recruit highly trained and dedicated staff for these positions in these rural areas. Additionally, RCOA provides PET services on a mobile basis, under contract with a medical provider. While we provide the equipment, FDG, and certain technical personnel, the medical provider must incur significant indirect costs to provide this service to their patients, such as space, utilities, scheduling, billing and other administrative services. Therefore if the rate reduction as suggested below becomes effective, it would not be economically feasible to service routes such as these and ultimately the patients, physicians and hospitals that depend on these services will be denied access to PET services.

I understand that the hospital cost and charge data that CMS uses to establish APC rates, if correct, appears to suggest that a lower rate would be appropriate. The drastic cuts suggested in options (2) and (3) would render our provider model (the most efficient and economic model) incapable of continuing and would bar access to patients and hospitals whose only alternatives are much more costly.

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 company'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 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.

We appreciate the opportunity to submit these comments to CMS. If you need additional information, please do not hesitate to contact us.

Sincerely yours,

Monroe Meyerson
Chairman of the Board

/d

Submitter : Mr. Thomas Walsh **Date & Time:** 10/02/2004 12:10:44

Organization : Advanced Bionics Corporation

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attached files.

CMS-1427-P-109-Attach-1.pdf

CMS-1427-P-109-Attach-2.pdf

ADVANCED BIONICS

Corporate Offices
Auditory Division
Pain Management Division
Pelvic Health Management Division

September 30, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1427-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

Issue Identifiers:
- **APC Relative Weights**
- **APC Groups**
- **2 Times Rule**

Dear Dr. McClellan:

On behalf of Advanced Bionics Corporation, we are pleased to submit the following comments on the proposed rule: "Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates," published in the Federal Register on August 16, 2004. Advanced Bionics Corporation is a leader in developing advanced technology, implantable devices. Specifically, Advanced Bionics markets the HiResolution Bionic Ear System and the Precision Spinal Cord Stimulation System.

Issue Identifier: APC Relative Weights

Payment for Cochlear Implantation

We are pleased to see the proposed increase in payment for cochlear implantation (APC 259 – "Level VI ENT Procedures") and recognize the progress this represents towards a level that appropriately pays for the device and its associated procedure costs. However, **the total 2005 proposed APC 259 payment of $23,686 is substantially less than a hospital's cost to acquire the cochlear implant device and deliver the associated implantation services.** It is well established that historically cochlear implantation has been significantly underpaid relative to actual costs for the device and procedure. This continues to be the case despite the proposed increase for 2005.

In 2002 the three cochlear implant manufacturers commissioned The Lewin Group to conduct an analysis of CY 2001 OPPS claims used to set CY 2003 OPPS payment rates

and presented those findings in their respective comments on the CY 2003 proposal. This year the three manufacturers again commissioned The Lewin Group to replicate the CMS methodology and proposed payment rate and conduct further analyses on the single claims data (see Attachment A). The Lewin Group used the same methods CMS has described that the Agency uses and arrived at a median device cost of $17,945 and a median APC cost of $23,686 (Attachment A, Table 1) which is consistent with costs reported by CMS. **The $17,945 median device cost which Lewin estimates based on OPPS claims is much lower than the hospital invoice price of cochlear implants. In fact, the average cost to hospitals, based on invoices, is $22,350 and very close to the L8614 median cost of $22,339 (Attachment A, Appendix C). Thus, we recommend that CMS substitute more accurate device cost data and recalculate the APC relative weight.**

The Lewin Group conducted additional analyses on the claims dataset to identify inconsistencies in the data. **The most striking finding resulted when they looked at claims in which the device (L8614) was coded (52% of claims) vs. claims in which the device was not coded. Including "pseudo" single claims (where the device was not coded) in the calculation of the APC median cost significantly reduced both the device median cost and the APC median cost. The results of this analysis shown in Table 1 below demonstrate astounding differences in the median device cost of $6,531 and in the median APC cost of $6,625 for claims with the device code vs. claims without the device code!**

	Device Median Cost	APC Median Cost
Device Coded Claims	$21,916	$27,660
Device Non-coded Claims	$15,385	$21,035
Difference	$6,531	$6,625

Table 1: Lewin Analysis – Claims With and Without HCPCS L8614 Coded

Other additional analyses noted the presence of many coding errors in claims contained within the dataset (Attachment A, Appendices A and B).

Thus, a major conclusion from The Lewin Group analysis is that properly coded claims containing the cochlear implant HCPCS code L8614 and CPT 69930 provided a more accurate representation of cochlear implant device costs when compared to actual hospital invoice costs for the device and by extension, a more accurate representation of APC costs. So, for device-dependent APC rate setting purposes, we recommend that CMS use only claims containing the appropriate device code as they provide more accurate data and will further support CMS' stated objective of being able to "use of all available single bill claims data to establish medians for device-dependent APCs." Further, because the claims data still include serious errors, we urge CMS to continue to accept external data to determine the validity of claims data.

To ensure the ability to obtain more accurate claims data, we recommend that CMS require reporting of L8614 on claims for cochlear implants. (See discussion below.)

Payment for Neurostimulation

The proposed significant decrease in payment for APC 222 – "Implantation of Neurological Device" to $11,845.60 is of great concern to us. Due to problems with the median cost for this APC, the imputed cost for the procedure is lower than the cost of the required devices for the procedure. Any reduction should be limited to 5% to restrict any negative impact on access to this technology. As stated above with respect to cochlear implants, we recommend that CMS require appropriate device coding on claims for implantation of neurostimulator generators and leads/electrodes. We urge CMS to move slowly to rely on claims data alone. CMS should continue to accept external data to assess the validity of claims data.

Although we are monitoring payments for neurostimulator implantation under APC 222, the claims in this APC do not reflect the costs of the Precision™ system which comprises a multiple channel device with independent current sources and a rechargeable battery and charging system. We believe the costs for this device should be paid separately through a new pass-through category for which we have recently submitted an application (see application under cover letter dated August 31, 2004).

III.C.1 – Proposed Adjustment of Median Costs for CY 2005: Device-Dependent APCs

As noted above, we support the use of device codes on claims to increase the accuracy of claims data and move towards CMS' objective of using "all available single bill claims data to establish medians for device-dependent APCs." Thus, we recommend that with device-dependent APCs, CMS use only data from claims containing the appropriate procedure, device AND revenue codes. Further, we recommend that the Agency continue to accept and review external data to determine the validity of claims data.

III.C.3 – Proposed Adjustment of Median Costs for CY 2005: Proposed Required Use of "C" Codes for Devices

We support requiring the use of device tracking codes ("C" codes) and believe such will result in more accurate claims data for rate setting purposes. However, cochlear implants do not have a "C" code and have used the HCPCS device code "L8614 – Cochlear Device/System" during the pass through period (HCFA PM-A-01-41) and since then (CMS PM-A-02-129). CMS PM-A-02-129 states: "The code for cochlear implant system, L8614, is a permanent HCPCS code that will not expire. Although the cochlear implant system device category will expire for pass-through payment purposes, the code may continue to be reported after December 31, 2002. Beginning January 1, 2003 charges reported with L8614 will be considered as charges attributable to a packaged device under OPPS." **Therefore, in order to accurately track data on the cochlear implant device, L8614 must be included among the required "C" codes listed on Table 20 of the proposed rule.**

The entry on Table 20 for APC 222 lists only one of three devices that are packaged into the costs for this particular APC. While the primary device in APC 222 is C1767 – "Generator, neurostimulator (implantable)," C1787 – "Patient programmer, neurostimulator" is used in all cases and in many cases, C1883 – "Adaptor/extension, pacing lead or neurostimulator lead (implantable)" is used in the procedure to facilitate generator placement. Capturing the costs of these devices and including these device costs in the single claims selected for rate setting will result in more accurate single claims cost data and a more accurate payment for this APC.

APC 040 – "Level II Implantation of Neurostimulator Electrodes" is device-dependent and was absent from Table 20. For the reasons stated above, we urge CMS to include APC 040 among those APCs for which device coding will be mandatory. While C1778 – "Lead, neurostimulator (implantable)" is the primary device for APC 040, in many cases, C1883 – "Adaptor/extension, pacing lead or neurostimulator lead (implantable)" is also used in the procedure to facilitate a device trial or device permanent placement.

The APCs listed in Table 2 below are device-dependent, but were either absent from the list of APCs on Table 20 for which mandatory device coding is proposed for CY 2005 or need modification as described above. While we support the use of device coding on claims for ALL device-dependent APCs, at a minimum, CMS should specifically add the following APCs and corresponding device codes to Table 20 in the final rule.

APC	Description	APC Status Indicator	Proposed Device Code	Device Long Descriptor
0040	Level II Implantation of Neurostimulator Electrodes	S	C1778 C1883	Lead, neurostimulator (implantable) Adaptor/extension, pacing lead or neurostimulator lead (implantable)
0222	Implantation of Neurological Device	T	C1767 C1787	Generator, neurostimulator (implantable) Patient programmer, neurostimulator
0259	Level VI ENT Procedures	T	L8614	Cochlear device/system

Table 2: Updates for Table 20 of the CY 2005 OPPS Proposal

Issue Identifier: APC Groups

Payment for Cochlear Implant-Related Procedures

APC 365 – "Level II Audiometry" combines audiologic function testing procedures with cochlear implant diagnostic analysis and programming procedures as shown in Table 3 below.

HCPCS CPT	Description
92557	Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)
92561	Bekesy audiometry; diagnostic
92577	Stenger test, speech
92579	Visual reinforcement audiometry (VRA)
92582	Conditioning play audiometry
92601	Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

Table 3: APC 365 CPT Codes and Descriptors

In clinical practice, general audiological services are typically separate from cochlear implant audiological services and are often provided by different audiologists. A brief comparison of CPTs 92604 and 92579 demonstrates the lack of clinical homogeneity:

> 92604: The audiologist re-determines thresholds for each electrode or electrode pair, then re-verifies maximum comfort levels for each electrode. The electrodes are then activated sequentially to ensure no undue loudness. The final program configuration is then transferred to the wearable speech processor.
>
> 92579: Frequency-specific sounds are presented to the child and behavioral reactions are observed. The loudness level is decreased until the child no longer responds. The minimum response level approximates the hearing threshold. The procedure is repeated for ongoing speech and narrow bands of noise.

A review of the procedures within APC 365 rank ordered by median costs in Table 4 below shows a clear violation of the two times rule with range from $51.89 for CPT 92577 to $163.35 for CPT 92561, a spread of 3.1 times.

APC 365		
HCPCS CPT	"Single" Frequency	"True" Median Cost
92577	80	$ 51.89
92579	467	$ 58.83
92582	198	$ 67.14
92557	59366	$ 74.04
92604	1611	$ 100.57
92602	16	$ 101.80
92603	209	$ 134.76
92601	15	$ 149.47
92561	8	$ 163.35
	APC median	$ 74.52

Table 4: APC 365 Procedures and Median Costs

Based on the above, we recommend that CMS split APC 365 into two APCs which would be clinically and economically more homogeneous than the current APC 365. The splits which we call "Split 365A" and "Split 365B" would have estimated, new median costs* as follows:

Split 365A		
HCPCS CPT	"Single" Frequency	"True" Median Cost
92604	1611	$ 100.57
92602	16	$ 101.80
92603	209	$ 134.76
92601	15	$ 149.47
92561	8	$ 163.35
*Estimated median cost for new split APC		$ 105.09

Table 5: Proposed Split 365A

Split 365B		
HCPCS CPT	"Single" Frequency	"True" Median Cost
92577	80	$ 51.89
92579	467	$ 58.83
92582	198	$ 67.14
92557	59366	$ 74.04
*Estimated median cost for new split APC		$ 73.87

Table 6: Proposed Split 365B

* Estimated median costs are determined as weighted averages of the median costs for each HCPCS code. These were taken from the files posted by CMS with the proposed rule. Calculation of the actual median costs for the split APCs would require access to the underlying claims files.

Issue Identifiers: APC Groups and 2 Times Rule
Payment for Neurostimulation-Related Procedures
APC 692 – "Electronic Analysis of Neurostimulator Pulse Generators" combines codes for analysis, with and without programming, of simple and complex neurostimulators as shown in Table 7 below.

HCPCS CPT	Description
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
95974	Electronic analysis of implanted neurostimulator pulse generator system (eg. Rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
95975	Electronic analysis of implanted neurostimulator pulse generator system (eg. Rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List seperately in addition to code for primary procedure)

Table 7: APC 692 CPT Codes and Descriptors

Despite the similarity of the descriptors for these procedures, there are significant differences in the resources required to provide these as reflected in the wide range of median costs.

A review of the procedures within APC 692 rank ordered by median costs in Table 8 below shows a clear violation of the two times rule with range from $63.96 for CPT 95970 to $202.60 for CPT 95973, a spread of 3.2 times.

APC 692		
HCPCS CPT	"Single" Frequency	"True" Median Cost
95970	605	$ 63.96
95971	743	$ 101.26
95974	1070	$ 125.09
95972	1567	$ 153.43
95975	61	$ 196.69
95973	140	$ 202.60
	APC median	$ 116.15

Table 8: APC 692 Procedures and Median Costs

We would recommend that CMS split APC 692 into two clinically and economically homogenous APCs--"Split 365A" and "Split 365B" with estimated, median costs* as follows:

Split 692A		
HCPCS CPT	"Single" Frequency	"True" Median Cost
95972	1567	$ 153.43
95975	61	$ 196.69
95973	140	$ 202.60
*Estimated median cost for new split APC		$ 158.82

Table 9: Proposed Split 692A

Split 692B		
HCPCS CPT	"Single" Frequency	"True" Median Cost
95970	605	$ 63.96
95971	743	$ 101.26
95974	1070	$ 125.09
*Estimated median cost for new split APC		$ 102.47

Table 10: Proposed Split 692B

* Estimated median costs are determined as weighted averages of the median costs for each HCPCS code. These were taken from the files posted by CMS with the proposed rule. Calculation of the actual median costs for the split APCs would require access to the underlying claims files.

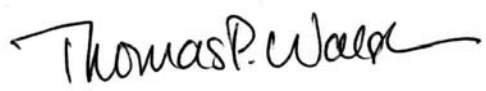
Summary

We appreciate CMS' work to establish an appropriate payment system for services paid under OPPS, and our comments on the proposed changes for OPPS in 2005 include:

- The proposed increase in payment for cochlear implantation under APC 259 to $23,686 remains well below the cost to provide this service.
- The proposed decrease in payment for APC 222 to $11,846 reduces the payment for this procedure even further below cost.
- The Lewin Group's analysis of cochlear implant claims found that claims coded with the appropriate HCPCS device code and CPT code more accurately reflected actual hospital costs than claims without device coding.
- We recommend that with device-dependent APCs, CMS use only data from claims containing the appropriate device, procedure and revenue codes as a step towards CMS' goal to rely on accurate, single bill claims data to establish device-dependent APC medians.
- We recommend that CMS continue to accept and review external data to determine the validity of claims data.
- We support requiring the use of device "C" codes, including L8614 for cochlear implants, on ALL claim forms for device-dependent APCs to track device costs and improve the accuracy of data in CMS' claims database.
- We recommend that APC 365 and APC 692 each be split on the basis of a 2 Times Rule violation into new APCs that are clinically and economically more homogenous than the existing APCs.

Advanced Bionics Corporation appreciates the agency's recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendations that we have submitted. If you require further information, please do not hesitate to contact me directly at 661-362-1721 or at Tom.Walsh@AdvancedBionics.com.

Sincerely,



Thomas P. Walsh
Manager, Strategic Reimbursement

Analysis of Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates for Cochlear Implantation Devices/Systems

Prepared for:

Advanced Bionics, Cochlear Americas, and Med-El Corporation

Prepared by:

The Lewin Group, Inc.

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Jessica Mireider, M.P.H.

September 13, 2004

Table of Contents

I. INTRODUCTION

Two years ago, The Lewin Group was commissioned separately by Advanced Bionics, Cochlear Americas, and Med-El Corporation to provide technical assistance in assessing the methodology used by The Centers for Medicare & Medicaid Services (CMS) to develop the proposed payment rates for cochlear implant devices/systems. The Lewin Group's initial analysis found that the proposed CY 2003 payment did not reflect the actual cost of the device due to provider miscoding of the device. Next, Lewin recalculated the median Ambulatory Payment Classification (APC) cost by substituting a weighted average device invoice price of prices individually provided by manufacturers for the device cost found on the claims. Ultimately, CMS revised the APC payment rate, and the final payment rate better reflected the cost of the device to hospitals.

This year Advanced Bionics, Cochlear Americas, and Med-El Corporation have again separately commissioned The Lewin Group to replicate CMS' methodology and the proposed payment rate for cochlear implant devices/system (APC 0259). On August 16, 2004 CMS published the proposed rule entitled Changes to the Hospital Outpatient System and Calendar Year 2005 Payment Rates in the *Federal Register*. In the NPRM, CMS lists a CY 2003 median APC cost of $24,086 and proposes a payment of $23,686 for CY 2005. Because hospitals have more experience coding under OPPS and because more data on hospital charges are available from CY 2003 claims, it is hypothesized that the proposed CY 2005 payment rate more adequately reflects actual hospital costs for the APC. The Lewin analysis will test this hypothesis by completing four primary tasks.

Specifically, Lewin was tasked with: (1) confirming the CMS estimate of the median cost for the APC covering the cochlear implantation procedure (APC 0259) by using the CY 2003 hospital outpatient claims; (2) estimating a median cost for the device (L8614) as reflected in the claims; (3) recalculating median APC 0259 costs using actual hospital device costs in order to estimate a "new" CY 2005 relative weight and a "new" CY 2005 payment rate for the procedure; and (4) identifying differences between claims that had coded devices and those that did not as well as to identify providers who were miscoding the device and the procedure.

II. SUMMARY OF RESULTS & FINDINGS

- CMS reports a median APC Cost of $24,086
- The Lewin Group duplicated CMS' analysis and arrived at a median APC cost of $23,686 and a median device cost of $17,945
- The Lewin Group also calculated a weighted average "hospital invoice price" of $22,350 for the cochlear implant device/system
- The recalculated median APC cost using the average hospital invoice price is $26,406
- Lewin calculated a "new" APC payment of $27,954 which more accurately reflects the cost of the device and the implied procedure cost

III. ANALYTIC METHODS

A. Overview

Before, performing the analyses Lewin had to create the working dataset from the CY 2003 Outpatient Prospective Payment System limited dataset of hospital outpatient claims. To create the working dataset, Lewin applied the methodology described by CMS in the proposed rule to remove "multiple procedures" claims, leaving claims with a single APC related to CPT 69930 (cochlear device implantation). We then created "pseudo" single claims from the previously removed multiple procedure claims by applying the methodology described in the *Federal Register*. First, bypass codes (*Federal Register,* August 16, 2004, Table 17) were eliminated from the claims. Next, date of service matching was used to create additional "pseudo" single claims. Single and pseudo single claims were then combined to create the APC working dataset. To finalize the APC working dataset non-packaged HCPCS codes (codes without a status indicator of "N") and non-packaged revenue codes (*Federal Register,* August 16, 2004, Table 18) were removed from the claims.

With the working dataset finalized, the first objective of our analysis was to determine the CY 2003 median cost for APC 0259, as well as the cost of the cochlear implant device/system. To estimate the median APC cost, we totaled the costs of the device and procedure as well as packaged HCPCS (codes with a status indicator of "N") and packaged revenue codes (*Federal Register,* August 16, 2004, Table 18) for each claim. Finally, we computed the median APC 0259 cost for all single and pseudo-single claims in our working dataset.

Our second objective was to determine the CY 2003 median cost of the device from the claims in our APC working dataset. Since, providers are no longer required to list the device separately on claims a two step process was used to identify device costs. First, device costs for claims listing L8614 were identified. Second, on the remaining claims we examined revenue codes 0270, 0272, 0274, and 0278 to identify additional devices that had not been separately coded. These revenue codes were selected for examination because the device, L8614, was frequently coded to these revenue codes when separately listed. If charges in excess of $20,000 for one unit or in excess of $40,000 for two units were found in any of these revenue codes they were included in our analyses. A unit device cost was computed for each claim by dividing total device costs by the number of device units. From the unit device costs, the median device cost was determined.

Our final objective was to recalculate the APC median and to determine a "new" APC payment rate using a weighted average "hospital invoice price". To achieve this objective we first calculated a weighted average "hospital invoice price" using confidential hospital invoice data supplied separately by each of the three manufacturers. We then substituted the weighted invoice price for the device cost in the CY 2003 claims and recalculated an APC cost based on this information. Finally, we compared invoice-based APC costs to APC costs derived from the CY 2003 claims and calculated a "new" CY 2005 APC payment amount.

B. Detailed Methods Discussion

1. Creating the Working Dataset

Our first step in creating a working dataset was to extract all claims involving CPT code 69930 (cochlear device implantation) and L8614 (the device code) from among the approximately 52.2 million records in the Limited Dataset (LDS) of Hospital Outpatient Department claims for CY 2003. This initial dataset contained a total of 822 claims. Claims that had the device L8614 coded, but did not have the corresponding, 69930, CPT code were then excluded. This created our original APC dataset which included 775 claims.

Next, we used the methodology described by CMS in the proposed rule to eliminate "multiple procedures" claims and to create "pseudo-single claims" from our original dataset, leaving only claims with a single APC related to CPT 69930 (cochlear device implantation). Two types of multiple major procedures claims were removed from the file:

- Claims in which ancillary costs cannot be associated with individual HCPCS codes because they are supportive of some or all services furnished to the patient – therefore, all claims with more than one procedure showing a status indicator of "S", "T", "V", or "X" were excluded; and
- Claims with packaged HCPCS codes coded with status indicator "N" that include more than one primary procedure (status code "S" or "T") were excluded.

In summary, in this step we extracted all of the "singleton" claims having only one primary procedure that could be grouped to an APC (aside from laboratory and incidentals such as packaged drugs and venipuncture). Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was a single primary procedure and a single APC. We also eliminated claims having a single procedure code but a zero charge. This step resulted in a dataset containing 253 true singleton claims.

After true singletons were identified the multiple procedure claims were evaluated to identify pseudo single claims. The first step in extracting pseudo-single claims from multiple procedure claims is to eliminate claim line items that contain CMS' bypass codes. The bypass codes are procedure codes found to include no packaged costs and their individual costs can, therefore, be eliminated from claims with CPT 69930. Included on this list of bypass codes were chest x-ray codes (HCPCS 71010 or 71020) and an EKG code (HCPCS 93005).

Next the dates of service were examined on the multiple procedure claims. Ultimately, pseudo single claims are claims on which multiple procedures occur but the dates of service are different for all procedures. In this case, a multiple procedure claim would have CPT 69930 on one date of service, but different procedures on other dates of service. To create pseudo-single claims from multiple procedure claims, the costs for the non-CPT 69930 procedure as well as any packaged costs associated with that procedure are eliminated. What remains are only the costs associated with CPT 69930. Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was now only a single primary procedure and a single APC.

The extraction of pseudo-single claims from the multiple procedure claims produced an additional 258 usable claims for a combined dataset containing 511 claims. The final step was eliminating line items from the 511 claims that were not in packaged revenue centers or did not contain either the device, the procedure, or packaged HCPCs (status indicator of "N").

Figure 1 on page 5 depicts the methodology employed to create the final APC working dataset.

2. Determining the CY 2003 Median APC Cost

The 511 claims Lewin extracted to the APC working dataset had to include the CPT code for the cochlear implantation procedure (69930). Using this APC working dataset, we computed the APC costs for each claim. These APC costs were then converted into logs and the geometric mean was calculated. Outliers, claims with log costs that were more than three standard deviations from the geometric mean, were eliminated from the calculation of the median APC cost. When outliers were excluded there were 498 claims in the dataset. (These results are essentially identical to those reported by CMS; CMS reports using a total of 499 claims to calculate the APC median cost.) From the remaining claims, Lewin calculated the range, mean, median and standard deviation of the CY 2003 APC cost.

3. Determining the CY 2003 Median Cochlear Implant Device/System Cost

Our second objective was to determine the median cost of the device from the claims. To calculate the median device cost, only claims with identifiable device costs were used (Figure 2, page 6). The claims we kept had to include both the CPT code for the cochlear implant procedure (69930) and a device cost which could appear in revenue centers 0270, 0272, 0274 or 0278 and was or was not additionally coded L8614. Specific device costs were identified either through their HCPCS code or through revenue center designation and were used to determine the total device cost for each claim. For example, a charge which appeared in revenue center 0270, 0272, 0274 or 0278 but was not coded as L8614 was determined to be a device cost (1) if the charge was in excess of $20,000 and the number of units listed was one or (2) if the charge was in excess of $40,000 and the number of units listed was two. The device working dataset included 417 claims. To calculate the median device cost, outliers were excluded based on the geometric mean and three standard deviations—this left 416 claims. Lewin then calculated the mean and median cost for the cochlear implant device/system for CY 2003.

Figure 1:
Methodology Used to Create APC Working Dataset

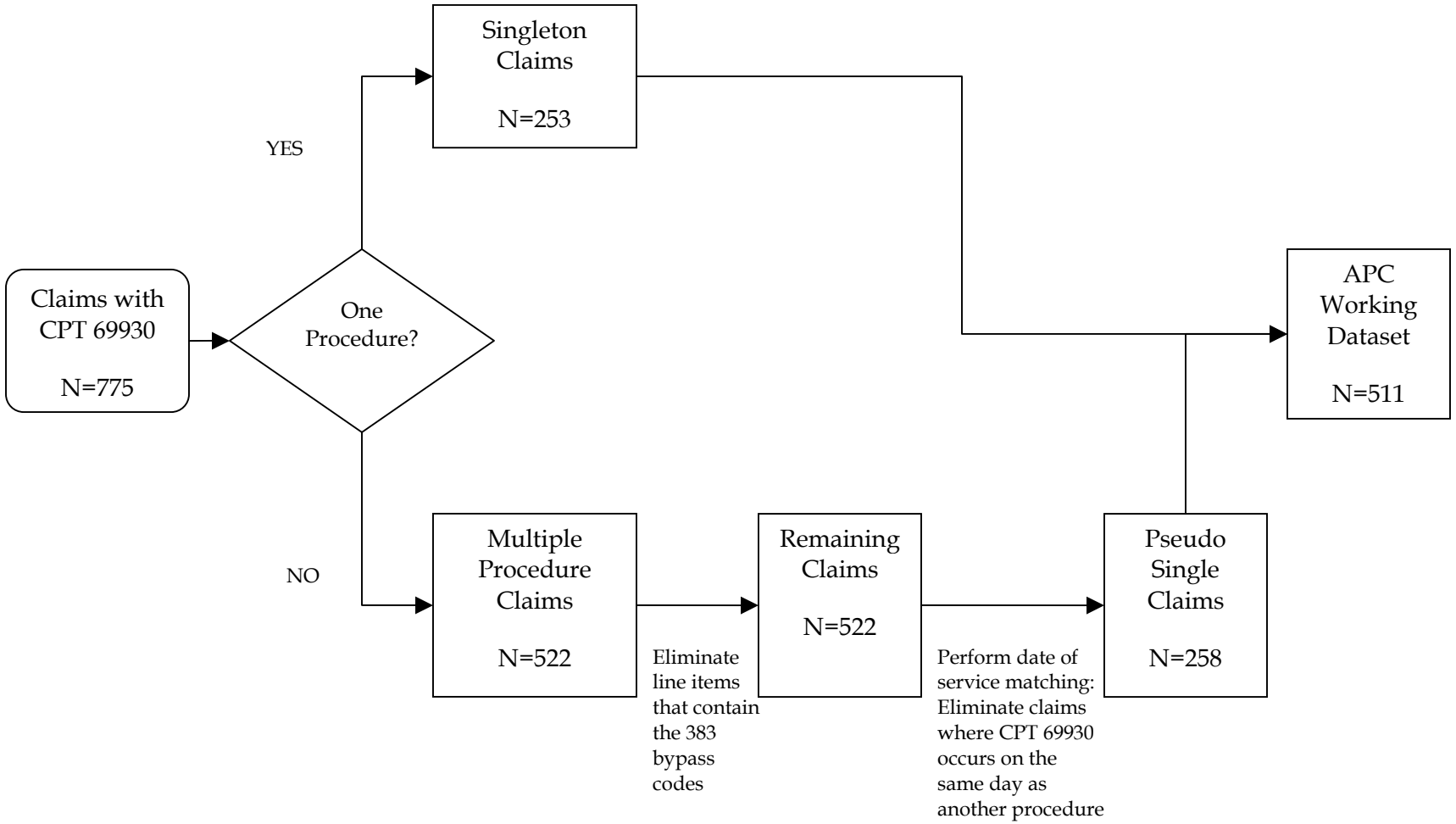
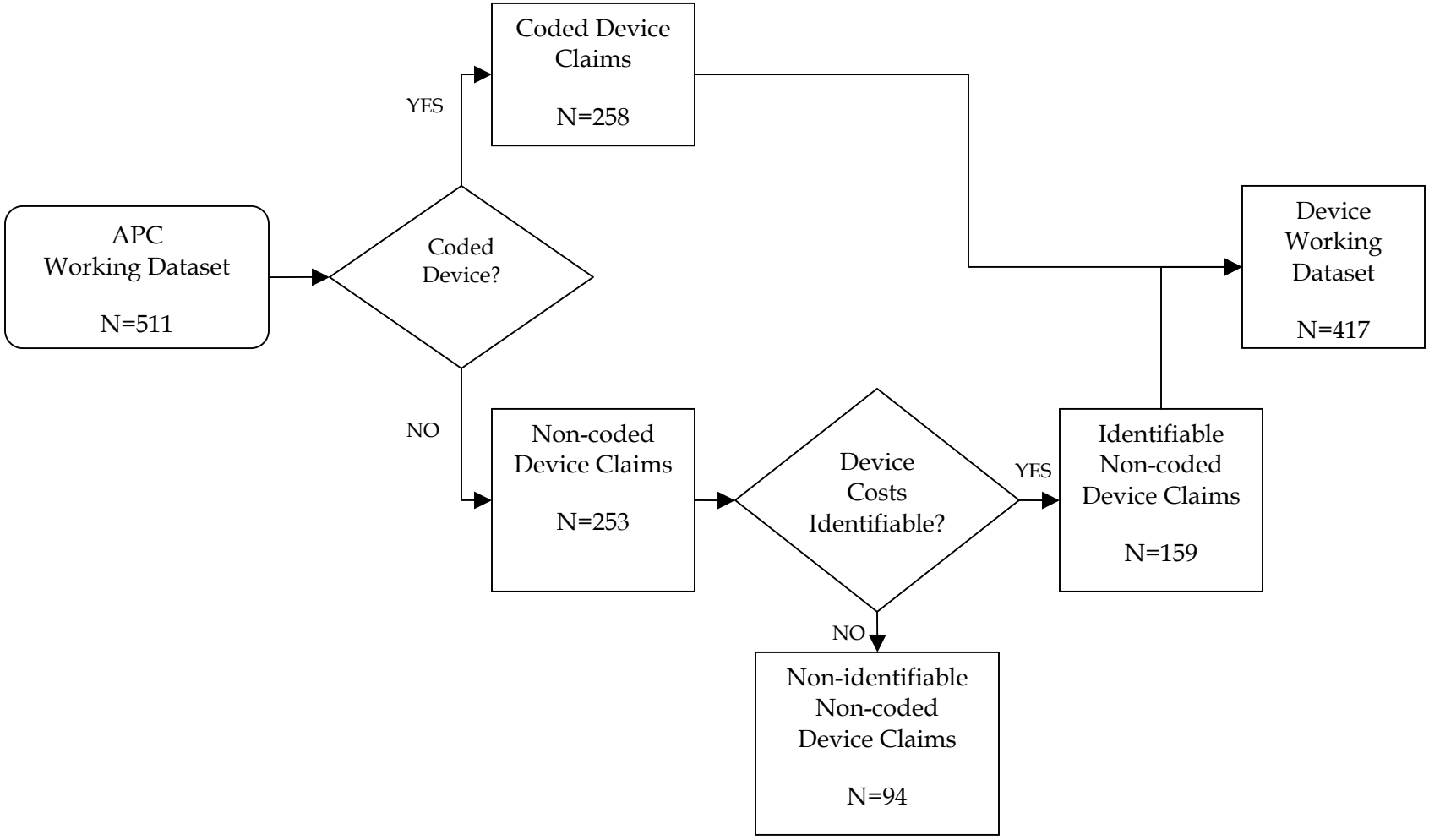


Figure 2:
Methodology Used to Create Device Working Dataset



4. Determining the CY 2003 Hospital Invoice Price

Next, Lewin calculated a weighted average hospital invoice price using confidential data supplied by the three manufacturers—Advanced Bionics, Cochlear Americas, and Med El Corporation.

5. Calculating the CY 2003 Median APC Cost Using the Weighted CY 2003 Hospital Invoice Price

Using the results of step four above, Lewin substituted the weighted hospital invoice price for the device cost in each claim in the device working dataset. Using the weighted hospital invoice price, Lewin recalculated the CY 2003 median APC cost.

6. Calculating a "New" APC Payment using a New Relative Weight and the CY 2005 Conversion Factor

The final step in the Lewin analysis was to derive a "new" CY 2005 APC payment rate. The new payment rate was derived by calculating a new relative weight and applying the CY 2005 conversion factor. To determine the new APC relative weight, Lewin first divided the APC cost calculated using the invoice price by the APC cost calculated from CY 2003 OPPS claims for each claim. This provided a ratio of these two costs for each claim. The median ratio was then identified and used to calculate a new relative weight. The "new" relative weight was then multiplied by the CY 2005 conversion factor to determine the "new" CY 2005 APC payment rate.

IV. RESULTS

Tables 1 - 4 below summarize the results of our analysis of the CY 2003 OPPS claims for the cochlear implant device/system.

C. Primary Results

In our analysis, we found the CY 2003 median APC cost to be $23,686, with a mean of $25,559 and a standard deviation of $14,721.[1] For the implant device, we found a median device cost of $17,945 in CY 2003, with a mean of $20,600. Table 1 illustrates these results.

Table 1:
Results of The Lewin Group Analysis of CY 2003 OPPS Claims

	APC Cost N=498	Device Cost N=416
range	$3,590 - $142,094	$2,896 - $84,444
mean	$ 25,559	$ 20,600
median	**$ 23,686**	**$ 17,945**
standard deviation	$ 14,721	$ 13,104

Table 2 reports the weighted average invoice price of the device as well as the results of the Lewin analysis using the weighted average invoice price of the device. The weighted device cost is $22,350 and when this invoice price is substituted for the device cost listed in the claims the new median APC cost is $26,406.

Table 2:
Results of The Lewin Group Analysis Using Hospital Invoice Price

	APC Cost N=408	Device Cost
range	$23,215 - $54,918	-
mean	$ 28,683	$ 22,350
median	**$ 26,406**	**-**
standard deviation	$ 6,968	-

1 Lewin Group analysis of CY 2003 OPPS claims

To compute the "new" Lewin payment rate, first the ratio of the invoice-based APC cost and the OPPS APC cost was calculated for each claim. The median of these cost ratios is 1.1802 (Table 3). Also, shown in Table 3 is the "new" Lewin APC relative weight.

Table 3:
Data Used to Calculate the "New" Lewin APC Payment Rate

Median of Claims Cost Ratios (Hospital Invoice APC Cost/OPPS APC Cost) (a)	2005 Proposed Relative Weight (b)	"New" Lewin Relative Weight (c) = (a) * (b)
1.1802	414.8416	489.5844

To determine "new" Lewin-derived payment found in Table 4 below, the "new" Lewin APC relative weight is multiplied by the CMS 2005 conversion factor—57.0965. The "new" Lewin APC payment rate is $27,954.

Table 4:
CMS Proposed CY 2005 APC Payment Rate and the "New" Lewin APC Payment Rate

	Proposed CY 2005 Payment Rate	"New" Lewin CY 2005 Payment Rate
2005 APC Payment Amount	$ 23,686	**$ 27,954**

D. Other Results

In addition to performing the analyses described above, The Lewin Group used the dataset of 498 claims to identify data inconsistencies:

- For claims in which the device was coded (N=258) the median device cost was found to be $21,916 when outliers were excluded. This is substantially different than the median device cost calculated from claims that did not have the device itself coded. For claims which did not have coded devices, we identified device costs on 159 claims. Of these 159 claims, 156 had non-coded device costs/charges linked to revenue center 0278. These 156 claims were then used to calculate the median device cost for non-coded devices. The result was a median device cost of $15,385—a difference of $6,531 ($21,916-$15,385).

- Claims with coded devices also differed from claims without coded devices with regard to median APC cost. Claims with coded devices had a median APC cost of $27,660, whereas claims with non-coded devices had a median APC cost of $21,035. This is a difference of $6,625 ($27,660-$21,035).

- Upon further analysis the primary difference between these two types of claims appears to be the incidence of multiple unit device costs. Claims that do not have coded devices have a

higher incidence of multiple unit device costs. On claims where the devices are coded, not one claim has multiple units of the device listed.

- One provider submitted eight claims in which device L8614 costs were assigned to revenue center 0272 (medical/surgical supplies-sterile supply). Another provider submitted four claims in which device L8614 costs were assigned to this revenue center. (Appendix A)

- Providers also coded the procedure incorrectly. One provider submitted 16 claims for CPT 69930 in which the costs/charges were assigned to revenue center 0490 (ambulatory surgical care – general). A different provider submitted eight claims on which CPT 69930 was listed, but linked to revenue center 0369 (operating room services – other). In total 49 claims were submitted in which the procedure was linked to an incorrect revenue center. (Appendix A)

- Almost thirty providers submitted fifty-one claims for device L8614 that were eliminated because the surgery did not match the device. One provider seemed particularly confused about what L8614 is, and included it in six claims for endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder. Other procedures with which device L8614 were listed include: tympanoplasty, unlisted procedure—esophagus, removal of cataract, retinal repair, among other surgeries. (Appendix B)

- In addition to analyzing the CY 2003 OPPS claims we also built two tables which compare costs for CY 2003 to costs for CY 2001. One chart presents costs by CPT (Appendix C) and the other displays costs by revenue center (Appendix C). The only difference that is remarkable is the change in median cost for L8614 from 2001 to 2003.

V. DISCUSSION

The 2002 Lewin analysis identified that the proposed CY 2003 APC payment rate was not high enough to cover the cost of the device alone. This was largely due to provider coding errors which were partially attributed to the newness of the OPPS system. Now that the OPPS system has been in place for several years, it is hypothesized that CMS' calculated payment rates will more accurately reflect hospital APC costs because more of the claims will be correctly coded.

This year's study, however, demonstrates that the proposed APC payment, although sufficient to cover the cost of the device, is too low to cover the hospital service costs related to the procedure as well. The proposed APC payment rate, $23,686, allows less than $1500 ($23,686 - $22,350) to cover hospital service costs. If the actual device cost was the median device cost calculated in the study, $17,945 (as opposed to the weighted invoice price of $22,350), the proposed CY 2003 payment would allow approximately $5,741 to cover the cost of hospital services related to APC 0259. The device cost, however, is not $17,945. As such, the "new" Lewin derived payment rate of $27,954 more accurately reflects the cost of the device and maintains the implicit cost of the procedure of approximately, $5,600 ($27,954 - $22,350).

Based on our analyses of the OPPS claims, it appears that CMS is underestimating the median APC cost by allowing claims with multiple units of the device to be included in their analysis. Doing so lowers the median device cost and thus, the median APC cost. When performing the analysis on only those claims that had the device coded and only one device unit, the median APC cost was $27,660. This median APC cost is closer to the Lewin-derived APC payment rate of $27,954.

VI. APPENDIX A

A. Providers Who Assigned Device L8614 To An Incorrect Revenue Center

Medicare Provider #	Hospital Name	State	# of Claims	Revenue Center	Revenue Center Description	Total Claims by Revenue Center
470003	Fletcher Allen Healthcare	VT	1	0270	Medical/surgical supplies-other	1
310051	Atlantic Health System	NJ	4	0272	Medical/surgical supplies-sterile supply	13
340053	Presbyterian Hospital	NC	1			
520177	Foedtert Memorial Lutheran Hospital	WI	8			
Total Number of Claims with Device L8614 Listed in an incorrect Revenue Center						14

B. Providers Who Assigned Procedure 69930 To An Incorrect Revenue Center

Medicare Provider #	Hospital Name	State	# of Claims	Revenue Center	Revenue Center Description	Total Claims by Revenue Center
030002	Good Samaritan Regional Medical Center	AZ	1	0361	Operating room services-minor surgery	16
030065	Desert Samaritan Medical Center	AZ	1			
060034	Swedish Medical Center	CO	4			
100022	Jackson Memorial Hospital	FL	3			
100087	Sarasota Memorial Hospital	FL	1			
330078	Sisters of Charity Hospital	NY	1			
330189	Albany Medical Center South Clinical Campus	NY	4			
450766	Zale Lipshy University Hospital	TX	1			
310051	Atlantic Health System	NJ	8	0369	Operating room services-other	8
040114	Baptist Health Medical Center	AR	2	0490	Ambulatory surgical care-general	25
070036	University of Connecticut Health Center	CT	1			
260065	St. John's Regional Health Center	MO	3			
280013	Nebraska Health System	NE	16			
310119	UMDNJ - University Hospital	NJ	2			
460009	University of Utah Hospital & Clinics	UT	1			
Total Number of Claims with Procedure 69930 Listed in an incorrect Revenue Center						**49**

VII. APPENDIX B

A. Providers Who Listed Device L8614, But Listed A Procedure Other Than 69930

Medicare Provider #	Hospital Name	State	# of Claims	CPT	Procedure Description	Total Claims by CPT
260021	Forest Park Hospital	MO	1	15100	Split graft (free skin graft)	1
490009	University of Virginia Medical Center	VA	1	43499	Unlisted procedure, esophagus	1
100220	Southwest Florida Regional Medical Center	FL	6	51715	Endscopic injection of impant material into the submucosal tissues of the urethra and/or bladder	6
450779	Harris Methodist Southwest	TX	1	52224	Cystourethroscopy, with fulguration of trigone, bladder neck, prostatic fossa, urethra or periurethral glands	1
100113	Shands at the University of Florida	FL	1	66930	Removal cataract	1
100220	Southwest Florida Regional Medical Center	FL	6	67108	Repair of retinal detachment	6
450135	Harris Methodist Fort Worth	TX	1	69421	Myringotomy including aspiration and/or eustachian tube inflation requiring general anesthesia	1
140051	Rush North Shore Medical Center	IL	2	69433	Tympanostomy	4
150042	Good Samaritan Hospital	IN	2			
140051	Rush North Shore Medical Center	IL	2	69436	Tympanostomy (requiring insertion of ventilating tube)	11
260021	Forest Park Hospital	MO	2			
450148	Walls Regional	TX	1			
450639	Harris Methodist HEB	TX	2			
450774	Tops Surgical Specialty Hospital	TX	2			
450779	Harris Methodist Southwest	TX	2			

Medicare Provider #	Hospital Name	State	# of Claims	CPT	Procedure Description	Total Claims by CPT
310011	Burdette Tomlin Memorial Hospital	NJ	1	69450	Tympanolysis, transcanal	1
450647	Medical City Dallas Hospital	TX	1	69502	Mastoidectomy, complete	1
500108	St. Joseph's Medical Center	WA	1	69633	Tympanoplasty without mastoidectomy, initial or revision; with ossicular chain reconstruction and synthetic prosthesis	3
520030	Wausau Hospital	WI	1			
520051	St. Mary's Hospital	WI	1			
450779	Harris Methodist Southwest	TX	1	69641	Tympanoplasty with mastoidectomy; without ossicular chain reconstruction	1
500141	St. Francis Hospital	WA	1	69642	Tympanoplasty with mastoidectomy; with ossicular chain reconstruction	1
500108	St. Joseph's Medical Center	WA	1	69643	Tympanoplasty with mastoidectomy;with intact or reconstructed wall, without ossicular chain reconstruction	1
240053	Methodist Hospital	MN	1	69660	Stapedectomy or stapedotomy with reestablishment of ossicular continuity, with or without us of foreign material	1
500108	St. Joseph's Medical Center	WA	2	69661	Stapedectomy or stapedotomy with reestablishment of ossicular continuity, with footplate drill out	2
140088	University of Chicago Hospital	IL	2	69714	Implantation, osseointegrated implan, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy	3
330024	Mount Sinai Hospital	NY	1			

Medicare Provider #	Hospital Name	State	# of Claims	CPT	Procedure Description	Total Claims by CPT
370028	Integris Baptist Medical Center	OK	2	69715	Implantation, osseointegrated implan, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy	3
370091	Saint Francis Hospital	OK	1			
220116	New England Medical Center	MA	1	69949	Unlisted procedure, inner ear	2
230019	Providence Hospital & Medical Centers	MI	1			
Total Number of Claims with Device L8614, but incorrect procedure						**51**

VIII. APPENDIX C

A. Costs by CPT/HCPCS Code: CY 2003 & CY 2001

(Note: Outliers have not been excluded)

CPT/ HCPCS	2003 Cochlear Claims							2001 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	**Median**	Standard Deviation	Freq	% of Claims (N=230)	Min	Max	Mean	**Median**	Standard Deviation
00120			$ -	$ -	$ -	**$ -**	$ -	2	1%	$ 94.68	$ 191.31	$ 143.00	**$ 143.00**	$ 68.33
36000	2	0%	16.72	16.72	16.72	**16.72**	-	1	0%	24.84	24.84	24.84	**24.84**	
69930	507	102%	240.92	20,583.47	2,265.05	**1,988.60**	1,517.28	230	100%	83.55	54,477.32	2,323.03	**1,894.10**	3,813.55
69990	1	0%	562.94	562.94	562.94	**562.94**		4	2%	-	-	-	**-**	-
94760	3	1%	13.12	28.93	23.66	**28.93**	9.13	2	1%	17.21	19.38	18.30	**18.30**	1.53
94761	4	1%	29.84	106.65	60.34	**52.44**	37.46	3	1%	9.10	27.32	15.56	**10.27**	10.20
94762	2	0%	74.70	74.70	74.70	**74.70**	-	1	0%	57.38	57.38	57.38	**57.38**	
99217	1	0%	111.55	111.55	111.55	**111.55**		1	0%	140.77	140.77	140.77	**140.77**	
99218	41	8%	20.16	863.61	134.12	**88.28**	146.96	4	2%	164.81	617.22	391.74	**392.47**	184.86
99219	2	0%	113.78	113.78	113.78	**113.78**	-	4	2%	627.42	884.53	747.33	**738.68**	109.45
99220	6	1%	25.20	138.67	84.33	**94.54**	46.67	1	0%	592.63	592.63	592.63	**592.63**	
99234	2	0%	141.86	141.86	141.86	**141.86**	-							
A6405	1	0%	4.09	4.09	4.09	**4.09**								
C1729								1	0%	27.45	27.45	27.45	**27.45**	
C1781								1	0%	55.09	55.09	55.09	**55.09**	
C6017								1	0%	171.93	171.93	171.93	**171.93**	
G0264	1	0%	267.64	267.64	267.64	**267.64**								
J0170	27	5%	0.74	15.21	6.32	**1.68**	5.77	4	2%	1.08	2.58	1.46	**1.08**	0.75
J0290								1	0%	8.17	8.17	8.17	**8.17**	
J0295	1	0%	16.57	16.57	16.57	**16.57**								
J0330	21	4%	0.64	8.24	3.61	**3.85**	1.66	16	7%	0.72	108.82	20.68	**7.48**	30.20
J0360	3	1%	6.59	15.89	10.64	**9.44**	4.76	2	1%	16.93	18.82	17.88	**17.88**	1.34
J0460	1	0%	3.76	3.76	3.76	**3.76**								
J0630	16	3%	3.60	16.96	6.13	**4.24**	4.46							
J0690	80	16%	1.09	156.49	13.42	**6.53**	21.10	22	10%	3.24	70.29	16.51	**15.49**	14.59

(Note: Outliers have not been excluded)

CPT/ HCPCS	2003 Cochlear Claims							2001 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	**Median**	Standard Deviation	Freq	% of Claims (N=230)	Min	Max	Mean	**Median**	Standard Deviation
J0696	11	2%	4.15	85.03	48.68	**42.51**	21.55							
J0697	2	0%	18.42	50.87	34.64	**34.64**	22.95	1	0.004348	4.60	4.60	4.60	**4.60**	
J0745	1	0%	10.44	10.44	10.44	**10.44**								
J1094	1	0%	10.28	10.28	10.28	**10.28**								
J1100	25	5%	1.63	16.07	5.95	**5.79**	3.65	3	0.013043	5.24	34.06	17.21	**12.33**	15.02
J1120	1	0%	13.96	13.96	13.96	**13.96**								
J1170	6	1%	1.52	4.71	3.40	**4.04**	1.28							
J1200	4	1%	0.94	1.86	1.47	**1.54**	0.41							
J1250								1	0%	62.64	62.64	62.64	**62.64**	
J1260	57	11%	2.88	94.29	25.04	**21.47**	14.18	17	7%	9.67	74.38	19.91	**16.47**	15.21
J1580	1	0%	0.97	0.97	0.97	**0.97**		1	0%	19.32	19.32	19.32	**19.32**	
J1650	2	0%	19.40	19.40	19.40	**19.40**	-	1	0%	102.79	102.79	102.79	**102.79**	
J1720	1	0%	13.53	13.53	13.53	**13.53**								
J1790	4	1%	2.59	10.44	5.81	**5.10**	3.42	8	3%	0.72	30.21	9.87	**6.73**	9.98
J1885	5	1%	4.71	13.02	9.62	**9.41**	3.49	1	0%	10.85	10.85	10.85	**10.85**	
J1940								1	0%	0.78	0.78	0.78	**0.78**	
J1956	2	0%	22.13	57.68	39.90	**39.90**	25.14							
J2000	29	6%	1.63	62.89	6.85	**4.06**	11.14	4	2%	1.05	18.28	7.40	**5.14**	7.72
J2175	17	3%	1.68	13.77	4.91	**4.11**	2.81	13	6%	1.81	32.94	17.11	**15.97**	10.56
J2180	1	0%	2.21	2.21	2.21	**2.21**								
J2250	53	11%	0.66	17.14	4.09	**3.85**	3.15	34	15%	0.83	25.45	8.22	**6.85**	6.14
J2270	61	12%	0.85	33.26	5.59	**3.94**	5.41	20	9%	0.60	17.54	7.07	**6.23**	5.35
J2275	8	2%	3.33	6.96	5.04	**4.89**	1.20	4	2%	5.20	7.17	5.71	**5.24**	0.97
J2310								2	1%	8.98	8.98	8.98	**8.98**	-
J2370	11	2%	0.88	7.63	4.09	**3.81**	1.62	2	1%	3.92	3.92	3.92	**3.92**	-
J2405	210	42%	5.29	295.22	34.64	**27.08**	32.27	67	29%	2.24	200.14	41.51	**33.30**	31.54
J2550	35	7%	1.75	19.51	5.54	**4.15**	4.37	21	9%	2.58	74.38	13.73	**7.48**	16.23
J2710	9	2%	3.07	19.19	8.76	**7.07**	4.42	3	1%	3.26	12.33	8.69	**10.48**	4.79
J2765	59	12%	0.22	19.10	5.72	**5.13**	3.88	22	10%	0.23	26.92	8.92	**7.28**	6.42
J2780	2	0%	2.33	5.54	3.94	**3.94**	2.27	1	0%	24.20	24.20	24.20	**24.20**	
J2930	2	0%	3.18	15.49	9.33	**9.33**	8.71	1	0%	3.76	3.76	3.76	**3.76**	
J3010	270	54%	0.31	56.09	9.54	**7.08**	8.05	89	39%	0.36	61.65	12.85	**10.73**	9.17
J3360	2	0%	2.58	7.10	4.84	**4.84**	3.20							

(Note: Outliers have not been excluded)

CPT/ HCPCS	2003 Cochlear Claims							2001 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	**Median**	Standard Deviation	Freq	% of Claims (N=230)	Min	Max	Mean	**Median**	Standard Deviation
J3370	1	0%	22.57	22.57	22.57	**22.57**								
J3410	3	1%	5.75	7.52	6.93	**7.52**	1.02							
J3480	3	1%	5.18	24.43	18.01	**24.43**	11.11	1	0%	0.85	0.85	0.85	**0.85**	
J3490	3	1%	4.85	9.62	6.44	**4.86**	2.75	4	2%	8.24	59.43	21.52	**9.20**	25.28
J7030								4	2%	12.31	21.46	19.17	**21.46**	4.58
J7042								2	1%	21.46	42.93	32.20	**32.20**	15.18
J7050								2	1%	7.48	21.46	14.47	**14.47**	9.89
J7120	12	2%	1.28	54.63	13.46	**7.07**	14.60	7	3%	8.73	42.93	25.04	**21.46**	10.93
J7317	3	1%	72.71	72.71	72.71	**72.71**	-							
J7501								1	0%	79.32	79.32	79.32	**79.32**	
L8613	2	0%	168.70	386.13	277.42	**277.42**	153.75							
L8614	263	53%	2,638.34	81,636.86	24,412.71	**22,339.08**	14,193.60	139	60%	1,548.61	57,841.10	17,403.85	**14,674.58**	11,555.52
L8699	2	0%	358.87	408.63	383.75	**383.75**	35.19	2	1%	6,734.84	10,404.53	8,569.69	**8,569.69**	2,594.86

Legend of Highlighted CPT/HCPCS Codes:

69930	Implant cochlear device
99218	Observation care
J0170	Adrenalin epinephrin inject
J0690	Cefazolin sodium injection
J2250	Inj midazolam hydrochloride
J2270	Morphine sulfate injection
J2405	Ondansetron HCL injection, per 1 mg
J2765	Metoclopramide HCL injection up to 10 mg
J3010	Fentanyl citrate injeciton
L8614	Cochlear device/system

B. Costs by Revenue Center: CY 2003 & CY 2001

(Note: Outliers have not been excluded)

Revenue Center	2003 Cochlear Claims							2001 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	**Median**	Standard Deviation	Freq	% of Claims (N=230)	Min	Max	Mean	**Median**	Standard Deviation
0250	595	119%	$ 0.10	$ 693.51	$ 118.76	**$ 80.66**	$ 122.85	250	109%	$ 0.49	$ 592.80	$ 135.85	**$ 105.75**	$ 127.52
0251	87	17%	0.88	192.75	34.24	**$ 12.95**	41.42	28	12%	0.87	200.50	25.55	**$ 10.32**	41.98
0252	46	9%	2.02	329.15	29.96	**$ 16.12**	51.18	28	12%	3.30	449.92	50.62	**$ 28.62**	83.80
0255	1	0%	37.53	37.53	37.53	**$ 37.53**		1	0%	9.83	9.83	9.83	**$ 9.83**	
0258	264	53%	0.69	286.87	48.25	**$ 39.83**	41.05	136	59%	0.72	281.88	49.93	**$ 29.50**	51.68
0259	91	18%	0.02	272.50	36.90	**$ 12.54**	51.33	13	6%	1.81	140.38	43.76	**$ 19.03**	51.26
0260								1	0%	16.88	16.88	16.88	**$ 16.88**	
0270	353	71%	1.73	37,000.56	1,841.20	**$ 340.05**	5,080.58	195	85%	2.19	49,461.35	1,912.60	**$ 298.27**	5,989.69
0271	91	18%	0.80	7,315.55	166.55	**$ 35.43**	768.07	27	12%	1.08	558.09	63.43	**$ 50.32**	106.61
0272	325	65%	0.74	48,454.21	2,910.49	**$ 665.48**	7,790.20	109	47%	1.11	49,461.08	865.20	**$ 304.50**	4,717.56
0274	86	17%	27.52	76,705.05	26,502.43	**$ 26,132.03**	15,092.31	99	43%	658.29	57,841.10	18,310.22	**$ 15,223.91**	11,781.40
0275	1	0%	6,692.33	6,692.33	6,692.33	**$ 6,692.33**			0%					
0278	429	86%	6.43	155,937.72	17,386.23	**$ 14,665.23**	16,611.98	112	49%	0.41	41,270.25	11,043.65	**$ 10,204.68**	7,918.37
0279	23	5%	0.39	19,901.29	1,464.13	**$ 173.49**	4,219.67	11	5%	6.23	243.13	37.29	**$ 6.86**	71.76
0360	459	92%	242.87	11,588.47	2,259.20	**$ 2,034.63**	1,186.26	216	94%	-	21,177.54	2,119.12	**$ 1,894.10**	1,645.85
0361	18	4%	16.72	20,583.47	4,007.19	**$ 2,481.87**	5,007.59	4	2%	-	54,477.32	13,880.11	**$ 521.57**	27,069.27
0369	8	2%	1,214.01	2,612.00	1,653.53	**$ 1,335.02**	558.74		0%					
0370	437	88%	8.31	1,358.44	272.62	**$ 211.83**	183.93	184	80%	17.67	942.43	258.65	**$ 208.12**	199.77
0372	1	0%	82.50	82.50	82.50	**$ 82.50**			0%					
0379	6	1%	10.61	69.33	38.85	**$ 43.58**	24.40		0%					
0440		0%						1	0%	83.55	83.55	83.55	**$ 83.55**	
0460	8	2%	13.12	74.91	44.39	**$ 29.90**	25.76	6	3%	9.10	57.38	23.44	**$ 18.30**	17.90
0469	1	0%	106.65	106.65	106.65	**$ 106.65**			0%					

(Note: Outliers have not been excluded)

Revenue Center	2003 Cochlear Claims							2001 Cochlear Claims						
	Freq	% of Claims (N=499)	Min	Max	Mean	**Median**	Standard Deviation	Freq	% of Claims (N=230)	Min	Max	Mean	**Median**	Standard Deviation
0490	25	5%	240.92	3,180.38	1,065.89	**$ 952.29**	687.02	13	6%	133.37	2,993.98	1,612.54	**$ 2,045.00**	1,173.02
0622								1	0%	18,497.71	18,497.71	18,497.71	**$ 18,497.71**	
0624								3	1%	15,735.74	17,014.92	16,588.53	**$ 17,014.92**	738.53
0636	920	184%	0.22	295.22	15.34	**$ 8.68**	21.39	339	147%	0.23	200.14	19.61	**$ 13.47**	22.22
0637	130	26%	0.32	174.32	13.81	**$ 5.26**	22.29	4	2%	2.89	37.59	21.69	**$ 23.15**	18.40
0710	477	96%	26.33	1,731.99	348.87	**$ 307.88**	222.84	201	87%	20.11	1,198.38	257.19	**$ 231.12**	154.66
0719	21	4%	57.03	400.45	226.53	**$ 263.49**	92.81	11	5%	130.15	363.30	204.49	**$ 194.80**	73.63
0760	9	2%	63.00	196.91	101.51	**$ 78.76**	43.04		0%					
0762	105	21%	6.65	863.61	192.02	**$ 131.08**	169.84	26	11%	45.46	884.53	359.29	**$ 311.22**	237.95
0920								1	0%	24.84	24.84	24.84	**$ 24.84**	

Legend of Revenue Center Codes

0250	Pharmacy-general
0251	Pharmacy-generic drugs
0252	Pharmacy-nongeneric drugs
0255	Pharmacy-drugs incident to radiology
0258	Pharmacy-IV solutions
0259	Pharmacy-other pharmacy
0260	IV therapy-general
0270	Medical/surgical supplies-general
0271	Medical/surgical supplies-nonsterile supply
0272	Medical/surgical supplies-sterile supply
0274	Medical/surgical supplies prosthetic/orthotic devices
0275	Medical/surgical supplies-pace maker
0278	Medical/surgical supplies-other implants
0279	Medical/surgical supplies-other devices
0360	Operating room services-general classification
0361	Operating room services-minor surgery
0369	Operating room services-other operating room services
0370	Anesthesia-general
0372	Anesthesia-incident to other diagnostic service
0379	Anesthesia-other
0440	Speech language pathology-general
0460	Pulmonary function-general
0469	Pulmonary function-other
0490	Ambulatory surgical care-general
0622	Medical/surgical supplies-incident to other diagnostic service -extension of 027x
0624	Medical/surgical supplies-medical investigational devices-extension of 027x
0636	Drugs requiring specific identification-detailed coding
0637	Self-administered drugs administered in an emergency situation
0710	Recovery room-general
0719	Recovery room-other
0760	Treatment or observation room-general
0762	Treatment or observation room-observation room
0920	Other diagnostic services-general

IX. APPENDIX D

A. Most Commonly Found Disallowed CPT/HCPCS Codes (Source: Multiple Procedure Claims)

CPT/HCPCS Code	Procedure Description	# of Claims on which CPT appears
95920	Intraoperative neurophysiology testing, per hour	105
95867	Needle electromyography; cranial nerve supplie muscle(s), unilateral	60
Q0081	Infusion therapy, using other than chemotherapeutic drugs, per visit	43
90784	Therapuetic, prophylactic or diagnositc injection; intravenous	28
94640	Pressurized of non-pressurized inhalation treatment for acute airway obstruction or for sputum induction for diagnostic purposes	19
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system, in the trunk or head	19
92516	Facial nerve function studies	18
99201	Office of other outpatient visit	16
92584	Electrocochleography	11
90782	Therapuetic, prophylactic or diagnositc injection; subcutaneous or intramuscular	10

B. Disallowed CPT/HCPCS Codes by Medicare Provider Number (Source: Multiple Procedure Claims)

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
010029	East Alabama Medical Center	AL	76000	2
010033	University of Alabama at Birmingham Health System	AL	94640	1
010056	St. Vincent's Hospital	AL	76375	2
			90784	3
			Q0081	1
030103	Mayo Clinic Hospital	AZ	95867	3
			95920	3
040055	Sparks Regional Medical Center	AR	90784	2
			Q0081	1
050108	Sutter Medical Center - Sacramento	CA	69641	1
050262	UCLA Medical Center	CA	92584	1
			95920	1
050454	UC San Francisco Medical Center	CA	69949	1
			92516	1
050502	St. Vincent Medical Center	CA	95920	20
			95927	19
050599	UC Davis Medical Center	CA	95867	3
			95920	3
060010	Poudre Valley Hospital	CO	64999	1
060024	University of Colorado Hospital	CO	69641	1
			95867	5
			95920	5
080001	Christiana Care Health Services	DE	92516	1
100007	Florida Hospital Medical Center	FL	90784	1
100113	Shands Hospital at The University of Florida	FL	92516	1
			93325	1
			95920	2
100128	Tampa General Hospital	FL	15770	2
			69310	1
			94664	1
			94799	1
100151	St. Luke's Hospital Association	FL	95920	1
110034	Medical College of Georgia Hospital	GA	20926	2
110161	Northside Hospital	GA	69310	1
130006	St. Luke's Regional Medical Center	ID	90784	1
			Q0081	2

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
140088	University of Chicago Hospitals	IL	94668	2
140091	Carle Foundation Hospital	IL	95920	3
140122	Hinsdale Hospital	IL	90782	1
			90784	1
			95867	5
			95920	5
140281	Northwestern Memorial Hospital	IL	95867	1
			95920	5
150017	Lutheran Hospital of Indiana	IN	95920	1
150056	Clarian Health Partners Inc.	IN	69949	1
			94664	1
160058	University of Iowa Hospital	IA	Q0081	1
170040	University of Kansas Hospital	KS	94664	3
170122	Via Christi Regional Medical Center	KS	90782	1
			90784	3
			94640	1
			Q0081	5
220075	Massachusetts Eye & Ear Infirmary	MA	20926	1
			92516	14
			95867	14
			95920	14
220077	Baystate Medical Center	MA	94640	3
220116	New England Medical Center	MA	Q0081	3
230019	Providence Hospital and Medical Centers	MI	94664	1
			95867	4
			95920	4
230038	Spectrum Health Hospitals	MI	92584	2
			95920	2
230046	University of Michigan Hospitals & Health Centers	MI	94799	4
250138	River Oaks Hospital	MS	90784	2
260017	Phelps County Regional Medical Center	MO	69631	1
260032	Barnes Jewish Hospital	MO	94799	1
260138	St. Lukes Hospital of Kansas City	MO	95867	1
			95868	2
			99201	3
280013	Nebraska Health System	NE	94640	1
283300	Boys Town National Research Hospital	NE	90784	2
			95867	1
			Q0081	2
300003	Mary Hitchcock Memorial Hospital	NJ	Q0081	1
330024	Mount Sinai Hospital	NY	95920	1
330078	Sisters of Charity Hospital	NY	Q0081	2

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
330241	University Hospital at Syracuse	NY	94640	2
			95920	4
340030	Duke University Medical Center	NC	93325	1
340053	Presbyterian Hospital	NC	95920	2
340061	University of North Carolina Hospitals	NC	69631	1
			J7317	4
360006	Riverside Methodist Hospitals	OH	Q0081	1
360051	Miami Valley Hospital	OH	76000	1
			94664	1
360085	The Ohio State University Hospital	OH	90784	1
360180	Cleveland Clinic Hospital	OH	20926	1
370091	St. Francis Hospital	OK	76499	2
390050	Allegheny General Hospital	PA	90782	2
390111	Hospital of The University of Pennsylvania	PA	69310	1
			94010	4
			94640	8
			95867	14
			95920	14
390164	UPMC - Presbyterian	PA	92584	5
			95867	5
			95920	5
420004	MUSC Medical Center	SC	92584	3
430027	Sioux Valley Hospital	SD	95867	3
440019	Baptist Hospital of East Tennessee	TN	90782	6
			90784	6
			94640	1
			Q0081	8
440048	Baptist Memorial Hospital	TN	95920	1
450021	Baylor University Medical Center	TX	94640	1
450040	Covenant Medical Center	TX	94010	1
450068	Hermann Hospital	TX	99201	2
450184	Memorial Hospital System	TX	99201	9
450388	Southwest Texas Methodist Hospital	TX	64999	2
			76375	1
			95920	6
			J7517	2
450647	Medical City Dallas Hospital	TX	69631	1
450766	Zale Lipshy University Hospital	TX	G0168	7
			J7317	5
460010	LDS Hospital	UT	95867	1
			95920	1

Medicare Provider #	Hospital Name	State	CPT	# of Claims on which CPT appears
490009	University of Virginia Medical Center	VA	92516	1
490032	Medical College of Virginia Hospital	VA	95920	2
			99201	2
490057	Virginia Beach General Hospital	VA	90784	1
500005	Virginia Mason Medical Center	WA	Q0081	8
500044	Deaconess Medical Center	WA	90784	4
			Q0081	8
500129	Tacoma General Allenmore Hospital	WA	15770	1
			94640	1
510001	West Virginia University Hospitals	WV	90784	1
510007	St. Mary's Hospital	WV	94664	1

Submitter : Mr. Roger Robertson **Date & Time:** 10/02/2004 12:10:00

Organization : Pitt County Memorial Hospital

Category : Hospital

Issue Areas/Comments

Issues 11-20

Blood and Blood Products

Blood and blood products are an essential commodity to providing healthcare. They are for the most part non-discretionary items. As such, reimbursement for these products needs to be adequate to insure that an adequate supply is available and that use of appropriate products in patient care will not result in financial losses to the providers. Blood and blood products should not be a "loss leader" for hospitals. Reimbursement below costs could lead to a rationing or witholding of product through erring on the side of not providing unless the situation is dire. This is not good medicine but could become a reality if it is not already so at some institutions.
I applaud your efforts to increase payment rates for some products. Thank you. On the other hand you propose to reduce rates for other products including those with low volume. I urge you to reconsider this position in view of what is best for patients and their access to these products. I encourage you to use external data in developing your payment rates to ensure that your rates are consistent with costs for the products. Finally, I encourage you to ehnance the billing process for blood products in order to capture better data.
Thank you.

Submitter : Dr. Ronald Gordon **Date & Time:** 10/02/2004 02:10:05

Organization : Mobile Hyperbaric Centers, LLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Secretary Tomm G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
PO Box 8010
Baltimore, MD 21244

RE: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

This comment concerns the Department of Health and Human Services Centers for Medicare & Medicaid services 2005 Hospital Outpatient Prospective Payment System proposed rule that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment.

I am the Co-President/CEO of Mobile Hyperbaric Centers, LLC, a new company contracted to provide exclusive hyperbaric oxygen therapy for the entire eastern region of the Cleveland Clinic Hospital System, in Cleveland Ohio. Production is near completion of our state of the art 11-place hyperbaric chamber, which will be located at Huron Hospital in East Cleveland, Ohio, and is slated to start treating patients on November 1, 2004. Currently, there is ONE monoplace chamber serving the entire cily of Cleveland. The eastern region hospitals of the Cleveland Clinic serve 53,000 patients with diabetes, of which 7,000 are estimated to suffer from diabetes related foot ulcers. Predictably, 900 of these patients will undergo amputation, if they are not able to receive hyperbaric oxygen treatments. Our company is going to be the lone provider of this long overdue service to this community.

The proposed changes to the reimbursement rate for hyperbaric oxygen will certainly threaten our ability to stay open, and provide access to this critical therapy for our community.

We support the Hyperbaric Oxygen Therapy Association's position and the Lewin Group's findings.

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.

2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47

3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

Thank you very much for the opportunity to express our opinions regarding this very important issue.

Sincerely,

Ronald S. Gordon, MD, FACEP
Co-President/CEO
Mobile Hyperbaric Centers, LLC
Suite 2400
Key Tower
Cleveland, OH 44115

Email: mobilehbot@aol.com

CMS-1427-P-112

Submitter : Mrs. Wanda Carey **Date & Time:** 10/02/2004 11:10:31

Organization : Mrs. Wanda Carey

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

Mammography

I am a radiographer who specializes in mammography. I have worked in the field of radiology for 34 years. I highly support any legislation that allows for an increase in the technical component of reimbursement for screening and diagnostic mammography performed in a outpatient hospital setting.

We are experiencing several issues in the field of mammography that will affect access to mammography in the coming years.

1. Centers are closing. It is no secret. Smaller offices can no longer afford to comply with all the stringent regulations and costs involved in performing mammography. In our community there has been a phenomenal consolidation of mammography providers. What we have left are a few hospital based mammography centers. The hospitals have traditionally been able to support services that do not break even. With declining reimbursement for all services, that is no longer the case. Nationally we have lost close to 1000 centers (10%) since the year 2000.
2. Aging radiographers (technologists). The computer age has drawn the younger generation away from healthcare and into jobs with better hours and pay. There are far fewer radiographers coming into the field of radiology than there are radiographers reaching the age of retirement.
3. Radiologists have seen their malpractice premiums skyrocket directly as a result of mammography lawsuits. Younger radiologists are joining radiology groups and specifying that they do not want to read mammography as a condition of employment.
4. As you know, mammography is the most HIGHLY regulated, MOST inspected imaging modality that exists. These regulations come at a great cost.
5. Women expect the best, latest and greatest technology. I read recently that health care providers will be expected to go to an electronic medical record. Many hospitals have converted to digital imaging technology to meet the demands of our ever changing health care environment. Yet, I can purchase a good film-screen mammography unit for $65,000-$70,000. A digital mammography unit with required viewing station will cost between $400,000 and $500,000. At the current reimbursement rate, most providers cannot afford to upgrade to this beneficial technology.

Some places in the country see long wait times to get screening and diagnostic mammography. It is not unusual to wait several months to get a screening appointment. I feel that increasing the technical reimbursement won't solve all our problems, but will slow the number of facilities that are closing and help keep access open for more women.

Submitter : Dr. Stephen Cummings **Date & Time:** 10/03/2004 01:10:56

Organization : Wound Recovery Center at Kent Hospital

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS-1427-P;APC 0659 HYPERBARIC OXYGEN THERAPY

My comments are directed to the HHS proposed rule on hyperbaric oxygen therapy (HBOT): 69FED. Reg. 50448; (Aug. 16, 2004)

I am director of the Wound Recovery Center (WRC), a tertiary care referral center for chronic wounds. HBOT is a major therapeutic asset to the wound healing therapies in use for our medicare patients who represent 50% of our total patient census. This is a hospital outpatient center at Kent Hospital, 300 bed community hospital, in Warwick RI. HBOT has become a very important and successful therapy at our institution for a large area of RI and adjacent sections of MA and CT. We have 24h per day call for HBOT emergencies many of which cover critically ill Medicare patients presenting locally or referred in with gangrene, compartment syndrome, CO poisoning, acute peripheral ischemia, crush injury. We are, in fact, the only provider of 24h/day emergency HBOT between Boston, MA, Springfield, MA. and Hartford, CT. We maintain a network with these instituions to ensure availability and mutual backup.

Our ability to provide HBOT emergency service to this wide geographic area encompassing several million people will be seriously undercut by the proposed reduction in HBOT APC reimbursement. We might squeeze by if we eliminate this service, as a neighboring HBOT facility has already been forced to do. If we do so the population of southeastern New England will suffer loss of a major medical resource. Our networking colleagues will certainly come under the same pressure.

Recently the Hyperbaric Oxygen Therapy Association (HOTA) presented the case for keeping reimbursement at its current level. CMS has received our recommendations via direct presentation by the Lewin Group. This organization is recognized in our industry as foremost in its expertise on HBOT finance. I urge CMS to adopt the HBOT payment rcommendation at $118.21 per 30 minute increment and apply the Lewin methodology to the 389 hospitals that reported HBOT claims for 2003. After extensive review with the finance department of Kent Hospital I submit that 2004 reimbursement levels are crucial to our ability to maintain our current level of service. We believe this would be evident in presenting our cost and cost-to-charge data which falls within the Lewin Group suggested CCR of .47.

On behalf of my staff and Kent Hospital Administration I thank you for consideration of these comments.

Stephen F. Cummings, MD
Director, Wound Recovery Center

Submitter : Dr. Brian Buinewicz **Date & Time:** 10/04/2004 12:10:38

Organization : Abuington Memorial Hospital Comprehensive Wound He

Category : Individual

Issue Areas/Comments

Issues 21-30

Cost-to-Charge Ratios

Dear sir,
Your proposed changes for payments for Hyperbaric Oxygen treatments wil effectively cause us to shut our center down, denying this unique treatment to patients. Please reconsider the change.
Brian Buinewicz MD

CMS-1427-P-114-Attach-1.txt

September 30, 2004

Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Proposed Changes to Hyperbaric Oxygen Therapy Reimbursement under the Medicare Hospital Outpatient Prospective Payment System (OPPS)

Dear Secretary Thompson:

I am writing in concern to the proposed rule (69 Federal Regulation 50448, 8/16/04) that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (HBOT). I am a wound expert in the Comprehensive Wound Healing Center affiliated with Abington Memorial Hospital, a suburban level one trauma center. Our center is the only center within a 15-mile radius to provide comprehensive wound consultation and care in addition to HBOT.

The use of HBOT as an adjunctive treatment is often the critical step in resolving long-standing complicated wounds. The presence of higher levels of oxygen in the bloodstream increases the ability of white blood cells to heal wounds. Healing wounds translates into fewer amputations and greater health care savings. If the proposed rates are finalized for 2005, it will limit our availability to provide HBOT to patients within our community that may otherwise require an amputation or chronic wound management.

HOTA, which represents the majority of hospitals in the country currently providing HBOT, commissioned the Lewin Group to study the methods used by CMS to develop the proposed payment rate and to assess its accuracy. The Lewin Group prepared a report that concluded that the CMS calculation was flawed and made several recommendations to ensure the necessary patient access to HBOT and control expenses.

Given the concerns raised by the CMS calculation and the impact of the reimbursement decrease on Medicare patients, I support consideration of the Lewin Group's suggestions:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has performed a calculation that will accurately assess HBOT costs and cost to charge ratio.

2. Adopt the overall cost to charge ratio of 0.47.

3. Apply the Lewin Group methodology to the 389 hospital that reported hyperbaric claims for the year 2003.

4. Adjust the HBOT rate to $118.21 per 30 minute increment.

I appreciate your consideration of the matter.

Sincerely,

Submitter : Mr. Jack Floyd **Date & Time:** 10/04/2004 03:10:27

Organization : MRI Mobile / Isoscan

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Providing imaging technology to enhance patient care and reduce the total medical cost of managing a disease is our stated purpose for being in the business.

With the advancements available with PET/CT, patient conditions can be detected earlier, treatment can be less radical, and total patient management costs can be significantly reduced. Clinical studies published and currently available to the public demonstrate these benefits.

As a provider of PET/CT service, the costs to deliver the technical component are significant: Major elements include equipment ($267,150 per year); manufacturer maintenance ($215,000); trained licensed personnel ($145,000); insurance and financing interest ($113,500); IT access and supplies ($86,000); facility rental, permits, and reporting ($81,750). Additionally, the business incurs FTE costs for scheduling, screening, preauthorizing, billing and collection, and transcription, totaling $62,800 per year. Taking these cost together with an average volume of 2.8 patients 5 days of week, results in per examination direct costs of $1380+ per patient, excluding FDG cost and related transportation cost to deliver the isotope.

Likewise, the costs to provide the FDG in our non-urban settings are substantial. With FDG itself in the range of $300 per dose, additional expense is incurred for delivery which can be incurred up to twice daily at between $150 to $600 per single visit depending on airfares and distances from the source of the isotope. With 2.8 patient averages, delivered FDG can range from $350 per dose to $515 per dose.

Being located and doing business in the Northwest, we do not operate in large metropolitan areas with high volume potential. If we stop providing the service, patients will either be force to drive hundreds of miles to locations like Salt Lake City, Utah or to Seattle, WA or not receive the service. Either way medical cost goes up for the patient and for CMS.

We feel the CMS should look at its data carefully: Remembering that large hospitals may be reporting only segments of their department costs; location, type of institution, age of equipment, volume potential, and so forth can have significant impact on cost levels; and can accordingly, lead to unintended and disparate treatment of patients.

We strongly support the position of leaving existing reimbursement fees unchanged until cost data can be validated and reviewed in light of the significant differences in the cost of doing business in various national and regional communities.

Issues 1-10

New Technology APCs

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Issues 21-30

Payment Rate for APCs

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We strongly support the position of leaving existing reimbursement fees unchanged until cost data can be validated and reviewed in light of the significant differences in the cost of doing business in various national and regional communities.

Submitter : Valerie Rinkle **Date & Time:** 10/04/2004 05:10:19

Organization : Asante Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1427-P-116-Attach-1.doc

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

The attachment to this document is not provided because:

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

Submitter : Dr. Alexander Ruthven **Date & Time:** 10/04/2004 07:10:36

Organization : Port Huron Hospital

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I support the recommendations of the HOTA. Please see attachment.

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

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CMS-1427-P-118

Submitter : Mr. Spencer Maidlow **Date & Time:** 10/04/2004 08:10:36

Organization : Covenant Medical Center, Inc.

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Secretary Thompson:

I would like to comment on the proposed 50.2% reduction in payment for hyperbaric oxygen therapy.

As CEO of a 700-bed referral hospital in Central Michigan, I have been impressed with the value of hyperbaric oxygen therapy for patients with difficult-to-heal wounds.

My hospital is the only regional provider for wound care, and I know the proposed payment reduction would challenge our ability to continue this service.

Please reconsider the proposed reduction.

Submitter : Ms. Rebecca Kane **Date & Time:** 10/04/2004 09:10:17

Organization : Association of Community Cancer Centers

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

please see attached

CMS-1427-P-119-Attach-1.pdf

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

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Submitter : Dr. Timothy Hullar **Date & Time:** 10/04/2004 10:10:24

Organization : Washington University School of Medicine

Category : Physician

Issue Areas/Comments

Issues 1-10

APC Relative Weights

The 2005 proposed payment for cochlear implants means that my hospital and others providing this service will continue to lose money on the procedure. We can not afford to do this. Asking those of us who have dedicated our lives to care of the deaf to lose money while doing so means essentially that the deaf will remain so. I sincerely urge you to consider reimbursing hospitals and health care providers enough to cover their costs (at a minimum) in providing this vital service.

Submitter : Mr. Fred Ford **Date & Time:** 10/05/2004 12:10:51

Organization : Sisters of Mercy Health System

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Groups

Proposed Treatment of Specified APC 0659 Hyperbaric Oxygen Therapy

CMS should consider a request to refrain from making the proposed payment changes to HCPCS code C1300, hyperbaric oxygen until clean claim data can be determined. There are many assumptions built into the proposed changes causing doubt in the accuracy of the proposed median cost. Hyperbaric Oxygen claims are few compared to other outpatient procedures and small inaccuracies in data can cause unnecessarily harmful changes. The payment impact to one of our facilities, St Johns Mercy Medical Center alone is estimated at $300,000 per year. Instead, I suggest that CMS continue to compile claim data as in the past and request a review by the APC Panel before implementing changes to this APC.

Inpatient List

CMS states that these are services that require inpatient care because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient. CMS considers moving an inpatient only procedure off of the list when CMS determines that the procedure is being performed in numerous hospitals on an outpatient basis. We would respectfully request and agree with your APC panel?s recommendations that the inpatient
only list be discarded and allow the physician to direct the appropriate plan of care for each patient based on the specific patient needs at the time as each patients recovery period is different and may not necessitate and Inpatient admission.

New Technology APCs

Proposed Movement of Procedures from New Technology APCs to Clinically Appropriate APCs:

CMS is soliciting comments related to PET scan payments. CMS is very concerned with access for this service therefore, has proposed 3 options:

a. Leave the PET scan HCPCS in the new technology APC 1516 with no payment change
b. Assign the PET scans to a clinically appropriate APC priced according to the median cost of the scans based on CY 2003 claims data. CMS would assign scans to APC 420 causing a payment decrease of $552 per scan
c. Transition assignment to a clinical APC in CY 2006 by setting payment in CY2005 based on a 50-50 blend of the median cost and the CY 2004 New Technology. This option would decrease payment by $300 per scan.

CMS did not provide details such as # of single items claims to support option b above. In the absence of such details, it is difficult for providers to understand the stability of the claim data. Instead, I request that CMS seriously consider option a above until data can be more thoroughly analyzed and published. To reduce the payment from $1450 to $899 would jeopardize access to this technology.

Issues 11-20

Drug Administration

Drug Administration

In the proposed rule, CMS has stated that it will be important for hospitals to use the correct CPT codes so that the data can be used for the 2007 APC rules and rate adjustments. CMS is proposing use of the CPT code 90780 (initial hour of IV therapy) and 90781 (subsequent hours of IV therapy ? up to 8 additional hours). This is a common service with varying length of time in a hospital outpatient area. The outpatient claim editor ? (OCE) used to adjudicate Medicare claims, will automatically group these CPT codes to APC 120 (reference your table 29 on page 186 of the proposed rule) which is a ?discounted? (status indicator = T) code as well as a ?once per visit code? regardless of the hours performed. This proposal would not allow for payment on a second or subsequent visit on the same date of service. If CMS allows for the OCE to roll these visits to ?1?, how will sufficient claims data be gathered for proper reporting the number of units and future rates established?
There was no clarification as to what is included in these codes as has been asked for by the public and promised by CMS. I would once again request information on what to include in IV therapy versus injections codes.

CMS-1427-P-121-Attach-1.doc

CMS-1427-P-121-Attach-1.doc

CMS-1427-P-121-Attach-1.doc

CMS-1427-P-121-Attach-1.doc

MERCY
SISTERS OF MERCY
HEALTH SYSTEM

October 4, 2004

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

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

The Sisters of Mercy Health System is an 18-hospital system operating in Missouri, Kansas, Oklahoma, and Arkansas. We perform a significant number of procedures in the outpatient setting and rely heavily on Medicare as a major payor for those services. We are writing to provide comments in areas of concern relating to the proposed rule. Thank you for considering our comments.

Specifically, we offer the following comments:

Drug Administration

In the proposed rule, CMS has stated that it will be important for hospitals to use the correct CPT codes so that the data can be used for the 2007 APC rules and rate adjustments. CMS is proposing use of the CPT code 90780 (initial hour of IV therapy) and 90781 (subsequent hours of IV therapy – up to 8 additional hours). This is a common service with varying length of time in a hospital outpatient area. The outpatient claim editor – (OCE) used to adjudicate Medicare claims, will automatically group these CPT codes to APC 120 (reference your table 29 on page 186 of the proposed rule) which is a *"discounted"* (status indicator = T) code as well as a *"once per visit code"* regardless of the hours performed. This proposal would not allow for payment on a *second* or *subsequent* visit on the same date of service. If CMS allows for the OCE to roll these visits to "1", how will sufficient claims data be gathered for proper reporting the number of units and future rates established?

2039 NORTH GEYER ROAD
ST. LOUIS, MO 63131
314-984-6100 ph.

There was no clarification as to what is included in these codes as has been asked for by the public and promised by CMS. I would once again request information on what to include in IV therapy versus injections codes.

Proposed Treatment of Specified APC 0659 – Hyperbaric Oxygen Therapy

CMS should consider a request to refrain from making the proposed payment changes to HCPCS code C1300, hyperbaric oxygen until clean claim data can be determined. There are many assumptions built into the proposed changes causing doubt in the accuracy of the proposed median cost. Hyperbaric Oxygen claims are few compared to other outpatient procedures and small inaccuracies in data can cause unnecessarily harmful changes. The payment impact to one of our facilities, St Johns Mercy Medical Center alone is estimated at $300,000 per year. Instead, I suggest that CMS continue to compile claim data as in the past and request a review by the APC Panel before implementing changes to this APC.

Proposed Movement of Procedures from New Technology APCs to Clinically Appropriate APCs:

CMS is soliciting comments related to PET scan payments. CMS is very concerned with access for this service therefore, has proposed 3 options:

a. Leave the PET scan HCPCS in the new technology APC 1516 with no payment change
b. Assign the PET scans to a clinically appropriate APC priced according to the median cost of the scans based on CY 2003 claims data. CMS would assign scans to APC 420 causing a payment decrease of $552 per scan
c. Transition assignment to a clinical APC in CY 2006 by setting payment in CY2005 based on a 50-50 blend of the median cost and the CY 2004 New Technology. This option would decrease payment by $300 per scan.

CMS did not provide details such as # of single items claims to support option b above. In the absence of such details, it is difficult for providers to understand the stability of the claim data. Instead, I request that CMS seriously consider option a above until data can be more thoroughly analyzed and published. To reduce the payment from $1450 to $899 would jeopardize access to this technology.

Inpatient Procedures

CMS states that these are services that require inpatient care because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient. CMS considers moving an inpatient only procedure off of the list when CMS determines that the procedure is being performed in numerous hospitals on an outpatient basis. We would respectfully request and agree with your APC panel's recommendations that the inpatient only list be discarded and ***allow*** the physician to direct the appropriate plan of care for each patient based on the specific patient needs at the time as each patients recovery period is different and may not necessitate and Inpatient admission.

Thank you again for considering my comments. Should you have additional questions you may contact Kathi Austin at 314-628-3693 or myself at 314-628-3706.

Sincerely,

Fred Ford
Vice President, Revenue & Decision Support

Submitter : Mr. Robert Hill **Date & Time:** 10/05/2004 01:10:03

Organization : Bethesda Memorial Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

5 October 2004
Dear Tommy Thompson:
Bethesda Memorial Hospital is a fully accredited, not for profit, 362 licensed bed community based hospital in Boynton Beach, Florida. We have been providing Hyperbaric Oxygen Therapy for over 7 years and are the largest provider of this service in southern Palm Beach County. The decrease in payment indicated by the proposed rule for APC 0659, hyperbaric oxygen therapy (HBOT) treatment, will not cover the cost of providing this service. This threatens our ability to provide this service.

The Hyperbaric Oxygen Therapy Association?s (HOTA) position is reasonable and we support the Lewin Group?s findings regarding the error in this payment rate. We support the Lewin Group?s alternatives:

 Apply the Lewin Group?s methodology to all hospitals that submitted HBOT claims in CY2003.
 Adopt the Lewin Group?s proposed reimbursement rate of $118.21 for the APC.
 Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.
 Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation.
Correcting this calculation would have a significant impact on our Hospital, even though using the Lewin Group?s estimate of $118.21 per half-hour would only change HBOT payments by $17 million.
Thank you for your time and attention and the opportunity to comment.

Sincerely yours,

Robert B. Hill, C.E.O.

Submitter : Ms. Diana Blair **Date & Time:** 10/05/2004 02:10:29

Organization : Wellmont Health System

Category : Nurse

Issue Areas/Comments

Issues 1-10

Devices

II. Section III-3 Proposed Required Use of 'C' Codes for Devices
I would like to encourage CMS to require device manufactors to place 'C' codes on device packaging. In this way, CMS would receive more uniform and accurate data from the providers in their billing.

Inpatient List

Issues 11-20

Drug Administration

I. Section V- H Proposed Coding and Payment for Drug Administration
This proposal for using CPT codes for chemotherapy drug administration and charges will create a increase in workload for providers. This will occur as a result of the education necessary for hospital staff to understand this significant change. These CPT codes have been difficult to use in the physician office arena, particularly the infusion codes based on time increments. The increased burden on hospital providers will not be offset by reimbursement for 2005. Physician offices currently receive payment for each chemotherapy drug given and for each drug given by IV push method. With the proposed rule hospitals will continue to be paid based on a per visit basis while the resources will have increased to ensure correct billing. The packaging of CPT infusion code 96412 for 1-8 hours also creates continued resource utilization with no additional reimbursement for providers for 2005.

Issues 21-30

E/M Services Guidelines

III. Section VII-F Hospital Coding for Evaluation and Management
CMS?s decision to delay their recommendation for E&M coding changes continues to impact providers due to the varying interpretation of available codes by providers and intermediaries. There has been no movement by CMS to adopt the AHA and AHIMA recommendations or at least provide some better direction to providers and intermediaries regarding the appropriate billing of E&M codes. Currently providers face many different interpretations from all payers of the guidelines they use for E&M coding. This variance in interpretation greatly impacts provider reimbursement

Inpatient Procedures

V. Section VII- E Procedures That Will Only Be Paid As Inpatient Procedures
CMS continues to receive feedback from providers about additional procedures that can be safely performed in the outpatient setting. Very few recommendations have been accepted by CMS. Please consider that physicians offer the best ability to determine whether the clinical condition of the patient would allow a procedure to be performed as an outpatient. Please note that most non-Medicare payers currently require some procedures to be done as an outpatient while these procedures continue to be on the CMS inpatient list.

Observation Services

IV. Section VII- D Observation Services
The lack of definitive guidelines on the observation discharge time continues to hamper the ability of providers to create a clear and concise policy for billing. The statement ?providers may not bill for observation time after all clinical treatment has been finished and the patient is waiting transportation home? continues to lack clarity for billing. What does CMS consider ?clinical treatment?? Is this when any additional clinical services (procedures/tests) are done? Or is this the ongoing need for continued services, such as the administration of medications? What guidelines will CMS provide to hospitals regarding the definition of clinical treatment?

Payment Rate for APCs

VI. Section III C-2.C Proposed recalibration of APC Weights for CY 2005
The decrease in payment in hyperbaric oxygen payment does not represent the resources and cost to the provider. CMS?s comment about `inconsistent billing patterns? requiring this change in payment seems inappropriate. Some of the issues of inconsistent billing may have resulted due to intermediary interpretation of `physician attendance? and several changes in billing guidelines over the past 2 years. I would like to have the decrease in payment reconsidered by CMS.

Section XVII Regulation Text- Addenda
It appears that CPT 13151 should be mapped to APC 0025 but, instead it is mapped to APC 0024. Why would a larger laceration repair (13151) be paid less than a smaller laceration repair (13150)?

CPT	APC	Description	National Payment
13150	0025	Repair,complex,eyelids,nose,ears and/or lips;1.0 cm or less	267.82
13151	0024	Repair,complex,eyelids,nose,ears and/or lips;1.1 cm to 2.5 cm	102.10
13152	0025	Repair,complex,eyelids,nose,ears and/or lips;2.6 cm to 7.5 cm	267.82
13153	0024	Repair,complex,eyelids,nose,ears and/or lips;ea addtl 5 cm/less	102.10

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

CMS-1427-P-123-Attach-1.rtf

Comments on OPPS Proposed Rule for 2005

I. Section V- H Proposed Coding and Payment for Drug Administration

This proposal for using CPT codes for chemotherapy drug administration and charges will create a increase in workload for providers. This will occur as a result of the education necessary for hospital staff to understand this significant change. These CPT codes have been difficult to use in the physician office arena, particularly the infusion codes based on time increments. The increased burden on hospital providers will not be offset by reimbursement for 2005. Physician offices currently receive payment for each chemotherapy drug given and for each drug given by IV push method. With the proposed rule hospitals will continue to be paid based on a per visit basis while the resources will have increased to ensure correct billing. The packaging of CPT infusion code 96412 for 1-8 hours also creates continued resource utilization with no additional reimbursement for providers for 2005.

II. Section III-3 Proposed Required Use of "C" Codes for Devices

I would like to encourage CMS to require device manufactors to place "C" codes on device packaging. In this way, CMS would receive more uniform and accurate data from the providers in their billing.

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CMS's decision to delay their recommendation for E&M coding changes continues to impact providers due to the varying interpretation of available codes by providers and intermediaries. There has been no movement by CMS to adopt the AHA and AHIMA recommendations or at least provide some better direction to providers and intermediaries regarding the appropriate billing of E&M codes. Currently providers face many different interpretations from all payers of the guidelines they use for E&M coding. This variance in interpretation greatly impacts provider reimbursement.

IV. Section VII- D Observation Services

The lack of definitive guidelines on the observation discharge time continues to hamper the ability of providers to create a clear and concise policy for billing. The statement "providers may not bill for observation time after all clinical treatment has been finished and the patient is waiting transportation home" continues to lack clarity for billing. What does CMS consider "clinical treatment"? Is this when any additional clinical services (procedures/tests) are done? Or is this the ongoing need for continued services, such as the administration of medications? *What guidelines will CMS provide to hospitals regarding the definition of clinical treatment?*

V. Section VII- E Procedures That Will Only Be Paid As Inpatient Procedures

CMS continues to receive feedback from providers about additional procedures that can be safely performed in the outpatient setting. Very few recommendations have been accepted by CMS. Please consider that physicians offer the best ability to determine whether the clinical condition of the patient would allow a procedure to be performed as an outpatient. Please note that most non-Medicare payers currently require some procedures to be done as an outpatient while these procedures continue to be on the CMS inpatient list.

VI. Section III C-2.C Proposed recalibration of APC Weights for CY 2005

The decrease in payment in hyperbaric oxygen payment does not represent the resources and cost to the provider. CMS's comment about 'inconsistent billing patterns" requiring this change in payment seems inappropriate. Some of the issues of inconsistent billing may have resulted due to intermediary interpretation of 'physician

attendance' and several changes in billing guidelines over the past 2 years. I would like to have the decrease in payment reconsidered by CMS.

VII. Section XVII <u>Regulation Text- Addenda</u>

It appears that CPT 13151 should be mapped to APC 0025 but, instead it is mapped to APC 0024. Why would a larger laceration repair (13151) be paid less than a smaller laceration repair (13150)?

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13153	0024	Repair,complex,eyelids,nose,ears and/or lips;ea addtl 5 cm/less	102.10

Respectfully,

Ms. Diana Blair, RN, BS, CPAR
APC Coordinator
Wellmont Health System
Business Affairs Department
diana_f_blair@wellmont.org

CMS-1427-P-124

Submitter : Dr. Robert Warriner **Date & Time:** 10/05/2004 02:10:14

Organization : UHMS

Category : Physician

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I am commenting in support of the Lewin Group analysis of the proposed payment rate for APC 659. I am the Chairman of the Federal Affairs Task Force of the Undersea and Hyperbaric Medical Society and have been involved in this analysis of collect hospital cost report data representing our professional society. Please refer to my detailed comments and letter attached.

CMS-1427-P-124-Attach-1.pdf

October 4, 2004

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018
www.cms.hhs.gov/regulations/ecomments

Re: CMS–1427–P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson:

I am the Chairman of the Federal Affairs Task Force of the Undersea and Hyperbaric Medical Society, the scientific professional organization regarding the practice of hyperbaric medicine. I also serve on the Society's Oxygen Therapy Committee and co-authored along with Dr. Harriett Hopf from the University of California San Francisco the Committee's evidence based review of the application of hyperbaric oxygen treatment for ischemic, hypoxic wounds, particularly diabetic foot ulcers. I was one of the primary representatives of our Society to CMS during the discussions that ultimately led to a coverage policy for hyperbaric oxygen treatment for diabetic foot ulcers meeting very specific medical requirements. I would like to express my concerns to the Department of Health and Human Services Centers for Medicare & Medicaid Services over the proposed 2005 Hospital Outpatient Prospective Payment System rule ("Proposed Rule") that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment ("HBOT"). 69 Fed. Reg. 50448 (Aug. 16, 2004).

I am particularly concerned that access to hyperbaric oxygen therapy will be compromised if the new proposed reimbursement takes effect. Only recently have sufficient hyperbaric medicine centers opened across the country to permit easier access of this important treatment modality, and now this access may indeed be compromised. Regarding efficacy, hyperbaric medicine is on a solid foundation and it would be unfortunate if Medicare recipients could not be adequately treated because existing hyperbaric medicine centers closed, or new centers could not open.

As Chairman of the UHMS Federal Affairs Task Force, I support the Hyperbaric Oxygen Therapy Association and the Lewin Group's findings, recently presented to CMS on September 9, 3004.. Given the data presented at this meeting, it seems reasonable for you to consider different proposals for future hyperbaric oxygen therapy reimbursement, including: (1) continuing the CMS 2004 reimbursement schedule pending a detail analysis of hyperbaric oxygen costs and cost-to-charge ratios; (2) Apply the Lewin Group methodology for hyperbaric oxygen therapy claims for 2003 to the 389 hospitals that submitted bills to CMS based on a more representative cost center; (3) Adopt the overall cost to charge ratio (CCR) of 0.47; or (4) Adopt the Lewin Group's recommendation to reimburse hospitals at $118.21 per 30 – minute increment of hyperbaric oxygen treatment.

I and other members of the hyperbaric medicine community practicing in acute care hospitals appreciate your consideration for this important request.

Sincerely,

Robert A. Warriner III M.D.

Robert A. Warriner, III, M.D., FACA, FCCP, ABPM/UHM,CWS
Chairman, Federal Affairs Task Force, and Treasurer, Undersea and Hyperbaric Medical Society
Chief Medical Officer, Praxis Clinical Services
1610 Woodstead Court, Suite 460, The Woodlands, TX 77381
(281) 298-1400 email: rwarriner@praxisusa.com

Submitter : Dr. Stephen Cummings **Date & Time:** 10/05/2004 03:10:48

Organization : Kent County Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Sir or Madam,
Please consider the attached letter urging CMS to modify decision regarding reduction of APC reimbursement for Hyperbaric oxygen therapy. It presnts our hospital's predicament if the reduction proceeds as announced.
Sincerely,
Stephen Cummings, MD
Director, Wound Recovery Center
Kent County Hospital
455 Tollgate Road
Warwick, RI 02886

CMS-1427-P-125-Attach-1.doc

VIA ELECTRONIC MAIL

www.cms.hhs.gov/regulations/ecomments

October 5, 2004

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Secretary Thompson,

We appreciate the opportunity to comment on the 2005 Hospital Outpatient Prospective Payment System proposed rule which sets forth a new reimbursement rate for hyperbaric oxygen therapy treatment (HBOT) 69 Federal Register No. 157 dated August 16, 2004.

Background:

Kent Hospital is a three hundred and fifty-nine (359) bed non-profit full service community hospital located in central Rhode Island. Our facility serves the acute health care needs of Rhode Island residents located in the primary service area of Kent County, and surrounding communities. Kent Hospital has admitted over 14,000 inpatients representing 80,992 patient days and has experienced outpatient volume in excess of 220,000 visits in the previous fiscal year.

The Hospital is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Commission on Accreditation of Rehabilitation Facilities (CARF), and participates as a provider in Medicare, Medicaid, Blue Cross and HMO insurance programs. The Hospital is also a member of Voluntary Hospitals of America Inc. (VHA) and is an affiliate organization of the Care New England Health System.

Clinical Program:

Kent Hospital has been operating a Hyperbaric Oxygen therapy program (HBOT), as part of our comprehensive Wound Recovery Center (WRC), since April, 2002 as a primary or adjunctive therapy for patients with necrotizing fasciitis, acute peripheral arterial insufficiency, crash injury, diabetic wounds of the lower extremities, compromised skin graft, carbon monoxide poisoning, and refractory osteomyelitis.

We have treated over 100 patients covering 1,862 visits including 340 inpatient HBOT treatments in the past fiscal year. Kent Hospital is only one of two facilities in Rhode Island offering Hyperbaric oxygen therapy services, and our clinical reach has extended into both Connecticut and Massachusetts. We are the only provider of 24h emergency HBOT for the region bordered by Boston, Springfield and Hartford with whose hospitals we maintain coordinated full time coverage. Access to full time emergency HBOT is a vital element of our service and commitment to the several millions population in this area for CO poisoning, crush injury, compartment syndrome, gas gangrene, post operative graft complication. This includes critically ill patients.

The Hospital utilizes three (3) 34"monoplace hyperbaric chambers housed in approximately 1,300 square feet. Each unit is designed to achieve maximum patient visibility to reduce the risk of claustrophobia. The Hospital has also incorporated an open space plan to further reduce confinement anxiety and to ensure that our patients receive optimal therapeutic value through successful adherence to treatment protocols.

Reimbursement:

We submit that the proposed APC payment rate is insufficient to cover the fully allocable costs of a hospital-based hyperbaric oxygen therapy program. The operating and capital costs associated with the HBOT program outweigh the proposed APC unadjusted reimbursement rate of $82.91 per 30 minute interval, which would represent almost a fifty percent reduction (50%) from current payment levels. While we support the recalibration of APC payment rates to reflect reasonable cost levels, we object to the proposed reduction in reimbursements based on imprecise and disparate departmental RCC data to establish final payment rates.

With a twenty-five percent (25%) Medicare utilization rate, the proposed APC payment rates shall have an adverse impact on our HBOT program, particularly the 24h emergency coverage that is disproportionately expensive to maintain..

Recommendations:

We have followed closely and endorse the following recommendations made by the Hyperbaric Oxygen Therapy Association (HOTA) and the Lewin Group's findings which examined specific hospital cost survey data:

(a) Retain the current payment rate methodology, until CMS has an opportunity to develop a payment rate that accurately reflects HBOT costs and cost to charge ratios.

(b) Adopt the Lewin Group's approach, which would revise the APC payment rate for code C1300 to $118.21 per thirty (30) minute increment.

We are grateful for the opportunity to respond to the CMS proposal during this comment period and urge you to reconsider the proposed APC payment rate of $82.91 that would go into effect on January 1, 2005, and either defer the implementation of the final rule proposing a reduction in the HBOT payment rate or adopt the Lewin Group's approach to scale back the calendar 04 reimbursement to $118.21 per thirty (30) minute increments.

If you have any questions related to this comment letter, please contact me directly. You may reach me at (401) 737-7010, extension 4646, or by e-mail: cummingss@kentri.org.

Yours Truly,

Stephen Cummings M.D.
Medical Director
Kent Hospital Hyperbaric Oxygen Therapy Program

CMS-1427-P-126

Submitter : Dr. Fredrick Hagemeister **Date & Time:** 10/05/2004 03:10:35

Organization : UTMD Anderson Cancer Center

Category : Physician

Issue Areas/Comments

Issues 11-20

New Drugs, Biologicals, and Radiopharmaceuticals Pass-Throughs

As a leading physician who treats patients with lymphoma at a major cancer center in the United States, I believe that patients with lymphoma should receive the most appropriate treatment based on clinical considerations. Reimbursement should not dictate whether a patient has access to the most appropriate treatment, especially a patient whose main source of medical cost reimbursement or ability to pay is through Medicare services. However, a recently proposed rule for hospital outpatient reimbursement creates a reimbursement barrier for patients eligible for Medicare that I believe will severely limit the availability of and choice for leading edge treatment for patients with lymphoma.

The treatments affected, Bexxar and Zevalin, are complex therapies that involve both radiolabeled and non-labeled antibodies over a period of seven to ten days. Each therapeutic dose is tailored to the needs of each individual patient. Because of the complexity of these products, only certain individuals at hospitals with selective training have the ability to provide these treatments.

The reimbursement provided under the proposed rule is significantly below the actual cost of the hospital to obtain and administer Bexxar therapy and likewise reduces reimbursement for Zevalin. The reimbursement amount for these products are below the acquisition price of the product, with no reimbursement available to the hospital to pay for the costs of administering or compounding each patient?s dose. Each therapeutic dose of radioimmunotherapy requires a specialized facility and professionals to manage patients who receive these drugs.

These shortfalls in reimbursement mean that patients with lymphomas may not be able to access such leading edge therapy and may be limited to therapies that could be less effective. At best, Medicare patients may be denied treatment options available to those not eligible for Medicare.

I ask that CMS revisit the reimbursement available for Bexxar and Zevalin to ensure that product reimbursement is at least the actual cost of the product and that reimbursement is available for the necessary administration of these medications.

Submitter : Mr. Edward Bruff **Date & Time:** 10/05/2004 03:10:09

Organization : Covenant HealthCare

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson,
Covenant HealthCare is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates. In the proposed rule, the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment dropped more than half to $82.91 from $164.93.

Covenant is a 700 bed hospital located in Saginaw, Michigan and we are the only regional provider for wound care in central Michigan. This decrease in payment will prevent our ability to provide this proven modality for treating otherwise expensive wounds.

Covenant HealthCare concurs with the Hyperbaric Oxygen Therapy Association and The Lewin Group?s understanding of how CMS has inappropriately applied cost-to-charge ratios to HBOT charges, understating median costs. We believe this needs to be corrected, as suggested by The Lewin Group, by one the following alternatives:
1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY2003.
2. Adopt The Lewin Group?s proposed reimbursement rate of $118.21 per 30-minute increment for HBOT.
3. Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. Because there is currently no standardization for which cost center HBOT costs and charges are located, CMS will be unable to appropriately determine the correct cost-to-charge ratio to apply to claims.
4. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will appropriately reflect HBOT costs.
This issue will have a significant adverse impact on our facility and we appreciate your attention to this matter.

Sincerely,
Edward G. Bruff
Executive Vice President/COO
Covenant HealthCare

CMS-1427-P-128

Submitter : Mr. Bernard Wess **Date & Time:** 10/05/2004 03:10:07

Organization : ProtonCare USA

Category : Health Care Industry

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Please consider our comments as attached.
Bernard P. Wess, Jr.
Managing Director
ProtonCare USA

CMS-1427-P-128-Attach-1.doc

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

The attachment to this document is not provided because:

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

Submitter : Mr. Eric Barber **Date & Time:** 10/05/2004 03:10:04

Organization : Riley Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy Thompson:

Riley Hospital is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates set forth in the proposed rule (69 Fed. Reg. 50448, Aug.16, 2004). Our comments are related to the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment. In the proposed rule, median cost at $82.91 is just over half of the CY 2004 payment of $164.93.

We are a 180-bed acute care hospital in Meridian, Mississippi. We have been providing HBOT for almost three years to the people of Lauderdale County. This incredible drop in the payment rate will not cover the cost of providing this service and will threaten patient?s access to this proven modality of treating painful and otherwise expensive non-healing wounds.

We support the Hyperbaric Oxygen Therapy Association?s (HOTA) position and the Lewin Group?s findings regarding the error in this calculation. We understand CMS has inappropriately applied each Hospital?s Respiratory Therapy department?s cost-to-charge ratio (CCR) to HBOT charges, regardless of the department that actually contains the HBOT charges. If left uncorrected, this error may prevent us from continuing to provide this service.

We support any one of The Lewin Group?s four recommendations, but especially numbers (3) and (4):

? (1) Apply the Lewin Group?s methodology to all hospitals that submitted HBOT claims in CY2003.

? (2) Adopt the Lewin Group?s proposed reimbursement rate of $118.21 for the APC.

? (3) Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.

? (4) Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation.

Although we understand using any of the above suggestions would change overall HBOT payments by millions of dollars, failure to rectify this situation will have a significant impact on our Hospital?s ability to provide the necessary care to the people of our community.

We appreciate your careful review of our comment.

Respectfully Submitted,

Eric Barber
Chief Operating Officer
Riley Hospital

CMS-1427-P-129-Attach-1.txt

Dear Tommy Thompson:

Riley Hospital is pleased to have this opportunity to comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates set forth in the proposed rule (69 Fed. Reg. 50448, Aug.16, 2004). Our comments are related to the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment. In the proposed rule, median cost at $82.91 is just over half of the CY 2004 payment of $164.93.

We are a 180-bed acute care hospital in Meridian, Mississippi. We have been providing HBOT for almost three years to the people of Lauderdale County. This incredible drop in the payment rate will not cover the cost of providing this service and will threaten patient's access to this proven modality of treating painful and otherwise expensive non-healing wounds.

We support the Hyperbaric Oxygen Therapy Association's (HOTA) position and the Lewin Group's findings regarding the error in this calculation. We understand CMS has inappropriately applied each Hospital's Respiratory Therapy department's cost-to-charge ratio (CCR) to HBOT charges, regardless of the department that actually contains the HBOT charges. If left uncorrected, this error may prevent us from continuing to provide this service.

We support any one of The Lewin Group's four recommendations, but especially those marked here in red:

- Apply the Lewin Group's methodology to all hospitals that submitted HBOT claims in CY2003.
- Adopt the Lewin Group's proposed reimbursement rate of $118.21 for the APC.
- Calculate the reimbursement rate for HBOT using each hospital's overall cost-to-charge ratio. CMS's rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.
- Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation.

We appreciate your careful review of our comment.

Respectfully Submitted,

Eric Barber
Chief Operating Officer
Riley Hospital

Submitter : Ms. Gail Daubert **Date & Time:** 10/05/2004 03:10:22

Organization : Ms. Gail Daubert

Category : Device Industry

Issue Areas/Comments

Issues 1-10

APC Groups

385 and 386

APC Relative Weights

APC 385 and APC 386

Issues 21-30

Payment Rate for APCs

APC 385 and APC 386

CMS-1427-P-131

Submitter : **Date & Time:** **10/05/2004 04:10:10**

Organization :

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See attached

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

The attachment to this document is not provided because:

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

CMS-1427-P-132

Submitter : **Date & Time:** **10/05/2004 04:10:46**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attached

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

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Submitter : Mr. Stephen Wolfe **Date & Time:** 10/05/2004 05:10:22

Organization : Indiana Regional Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Indiana Regional Medical Center (IRMC) is pleased to have this opportunity to provide comment on the proposed changes to the Medicare Hospital OPPS and CY2005 Payment Rates. In the proposed rule, the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment dropped more than half from $164.93 to $82.91.

We began offering HBOT as an adjunctive treatment for our wound center patients on June 22 of this year. As a rural, 162-bed hospital in Western Pennsylvania, we have sole provider status in Indiana County, and are the only provider of HBOT within a 60-mile radius. We have experienced great success thus far with HBOT. The proposed decrease in payment will adversely affect our ability to provide this proven modality for treating otherwise expensive wounds.

IRMC concurs with the Hyperbaric Oxygen Therapy Association and The Lewin Group's understanding of how CMS has inappropriately applied cost-to-charge ratios to HBOT charges, understating median costs. We believe this needs to be corrected, as suggested by The Lewin Group, by one the following alternatives:

1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY2003.

2. Adopt The Lewin Group's proposed reimbursement rate of $118.21 per 30-minute increment for HBOT.

3. Calculate the reimbursement rate for HBOT using each hospital's overall cost-to-charge ratio. Because there is currently no standardization for which cost center HBOT costs and charges are located, CMS will be unable to appropriately determine the correct cost-to-charge ratio to apply to claims.

4. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will appropriately reflect HBOT costs.

This issue will have a significant impact on our facility. Thank you for allowing our hospital to comment on this critical issue.

Respectfully Submitted,

Stephen A. Wolfe, CEO
Indiana Regional Medical Center

Submitter : Mr. Nick Grubbs **Date & Time:** 10/05/2004 06:10:38

Organization : Mon Health System

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson:

Monongalia General Hospital is pleased to have this opportunity to comment on proposed rule 69 Fed. Reg. 50448, Aug. 16, 2004: specifically, the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment, which is proposed dropping to $82.91 from the CY 2004 payment of $164.93.

We are a 207 bed acute care hospital located in Morgantown, West Virginia. We just invested in HBOT for our patients in June, 2004 as part of the therapy offered through our wound healing center, the only center of its kind in Monongalia and Preston Counties, WV; Greene & Fayette Counties, PA; and Garrett County, MD. This huge drop in the payment rate will not cover the cost of providing this service and will threaten patient?s access to this proven method for treating wounds that are both painful and otherwise expensive.

The Hyperbaric Oxygen Therapy Association?s (HOTA) position is reasonable given the report by The Lewin Group. The Lewin Group?s proposals for fixing this appear very reasonable: Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to perform a corrected calculation; or Apply the Lewin Group?s methodology to all hospitals; or Adopt the Lewin Group?s proposed reimbursement rate of $118.21 for a half-hour of treatment; or Calculate the reimbursement rate for HBOT using each hospital?s overall cost-to-charge ratio. CMS?s rules for calculating the median cost indicate if the cost-to-charge ratio cannot be calculated, the overall hospital cost-to-charge ratio is to be used.

Correcting this calculation would have a significant impact on our Hospital, even though using the Lewin Group?s estimate of $118.21 per half-hour would only change HBOT payments by $17 million.

Your serious consideration of this information is appreciated. We?re looking forward to a revised APC.

Very truly yours,

Nick Grubbs
CFO
Monongalia Health System
1200 J.D. Anderson Drive
Morgantown, WV 26505

Submitter : John McClanahan **Date & Time:** 10/05/2004 07:10:17

Organization : Cochlear Americas

Category : Device Industry

Issue Areas/Comments

Issues 1-10

2 Times Rule

Issue Identifier: APC Groups
Payment for Cochlear Implant-Related Procedures
APC 365 ? ?Level II Audiometry? combines audiologic function testing procedures with cochlear implant diagnostic analysis and programming procedures as shown in Table 3 below.

HCPCSCPT Description
92557 Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)
92561 Bekesy audiometry; diagnostic
92577 Stenger test, speech
92579 Visual reinforcement audiometry (VRA)
92582 Conditioning play audiometry
92601 Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming
92602 Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent reprogramming
92603 Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604 Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
Table 3: APC 365 CPT Codes and Descriptors

In clinical practice, general audiological services are typically separate from cochlear implant audiological services and are often provided by different audiologists. A brief comparison of CPTs 92604 and 92579 demonstrates the lack of clinical homogeneity:

92604: The audiologist re-determines thresholds for each electrode or electrode pair, then re-verifies maximum comfort levels for each electrode. The electrodes are then activated sequentially to ensure no undue loudness. The final program configuration is then transferred to the wearable speech processor.

92579: Frequency-specific sounds are presented to the child and behavioral reactions are observed. The loudness level is decreased until the child no longer responds. The minimum response level approximates the hearing threshold. The procedure is repeated for ongoing speech and narrow bands of noise.

A review of the procedures within APC 365 rank ordered by median costs in Table 4 below shows a clear violation of the two times rule with range from $51.89 for CPT 92577 to $163.35 for CPT 92561, a spread of 3.1 times.

APC 365
HCPCS CPT ?Single? Frequency ?True? Median Cost
92577 80 $ 51.89
92579 467 $ 58.83
92582 198 $ 67.14
92557 59366 $ 74.04
92604 1611 $ 100.57
92602 16 $ 101.80
92603 209 $ 134.76
92601 15 $ 149.47
92561 8 $ 163.35
APC median $ 74.52
Table 4: APC 365 Procedures and Median Costs

Based on the above, we recommend that CMS split APC 365 into two APCs which would be clinically and economically more homogeneous than the current APC 365. The splits which we call ?Split 365A? and ?Split 365B? would have estimated, new median costs* as follows:

Split 365A

HCPCS	CPT	?Single? Frequency	?True? Median Cost
92604	1611		$ 100.57
92602	16		$ 101.80
92603	209		$ 134.76
92601	15		$ 149.47
92561	8		$ 163.35
*Estimated median cost for new split APC			$ 105.09

Table 5: Proposed Split 365A

Split 365B

HCPCS	CPT	?Single? Frequency	?True? Median Cost
92577	80		$ 51.89
92579	467		$ 58.83
92582	198		$ 67.14
92557	59366		$ 74.04
*Estimated median cost for new split APC			$ 73.87

Table 6: Proposed Split 365B

*Estimated median costs are determined as weighted averages of the median costs for each HCPCS code. These were taken from the files psoted by CMS with the proposed rule. Calculation of the actual medican costs for the split APCs would require access to the underlying claims files.

Submitter : Ms. Ann Marie Benzinger **Date & Time:** 10/05/2004 07:10:15

Organization : Alpha 1 Advocacy Alliance

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

?h Alpha 1 Advocacy Alliance is a patient member organization providing education and support through our website at www.alpha1advocacy.org and programs for patients, the medical community and the families of those effected by Alpha 1 Antitrypsin Deficiency.
?h Currently, there are three alpha-1 proteinase inhibitors commercially available to patients. Until 2003 and the introduction of Aralast and Zemaira, there was only one product available to patients, Prolastin. Prior to this time, there was never an adequate supply of Prolastin to serve the entire patient community with full doses and patients underwent shortages and were often denied access to the therapy.
?h It is absolutely necessary that patients have sufficient supplies of the augmentation therapies consistently available for the regularly scheduled infusions to maintain vital lung function.
?h The majority of Medicare beneficiaries receive this IV therapy in outpatient hospital settings.
?h The proposed 2005 payment rate for APC901/J0256 when applied to all products, would result in serious access issues for many Medicare patients with Alpha 1 Antitrypsin Deficiency requiring this augmentation therapy.
?h To insure access to all three products now available and alleviating the previous shortages, the payment rate under the Hospital Outpatient Prospective Payment System must be sufficient to cover the hospital!|s cost of obtaining these orphan products. Failure to increase the proposed rates will jeopardize the health of patients due to this inability to access this vital medical therapy.

Thank for the willingness of your office to consider the well-being of our fellow Alpha 1 Antitrypsin Deficiency patients first so that we will be able to continue to have access to all three products. The addition of the two products in 2003 was a welcome relief to our patient community. Patients were often denied access to the product until another patient died, freeing up inventory while existing patients were instructed to take lower doses or, even worse, told to skip doses to ensure they would have Prolastin during flu season and when suffering from any respiratory infection. It is heart breaking to hear the stories from patients who have endured this treatment due to shortages. Please, consider these patients when examining the price permitted for 2005.

CMS-1427-P-137

Submitter : Ms. Mary Hirsch **Date & Time:** 10/05/2004 07:10:09

Organization : MATRIX Health Services, LLC

Category : Health Care Provider/Association

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

This comment letter concerns the Department of Helath and Human Services Centers for Medicare and Medicaid Services' 2005 Hospital Outpatient Prosepctive paument System proposed rule tha sets forth new reimbursement rates for hyperbaric oxygen therapy treatment(HBOT). 69 Fed. Reg. 50448 (Aug 16, 2004).

MATRIX Health Services, LLC is a rather new company made up of nurses and administrators with extensive experience in wound care and hyperbaric medicine. We provide management and consulting services to hospitals that wish to provide advanced wound care services to their community. We decided to start this company because of our belief that all patients with chronic non-healing wounds deserve access to the types of treatment that can make a real difference in healing. Hyperbaric medicine does make a difference. It reduces the number of amputations, or the level of amputation needed, thus reducing healing time and rehabilitation costs.

If the proposed rates are the finalized rates for 2005 many hospitals will be forced to shut down their services, denying patients access to care that could save limbs. Further, smaller, rural hospitals that are considering offering this care to patients in their own communities will be unable to. do. Transportation is always a major concern for many of these patients. We should be trying to make care more accessible not less. so.

MATRIX Health Services supports the Hyperbaric Oxygen Therapy Association (HOTA) position and the Lewin Group?s findings. We support consideration of the following four alternatives:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio (CCR) of .47
3. Apply the Lewin Group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
4. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

We appreciate your consideration for this very important matter.

Very sincerely.

Mary Hirsch, RN, MHSA, ACHRN, CWS and Becky Toups, RN, MBA
MATRIX Health Services, LLC

CMS-1427-P-138

Submitter : Mr. William Peaks **Date & Time:** 10/05/2004 08:10:05

Organization : Garden Park Medical Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

Dear Tommy G. Thompson,

Garden Park Medical Center is pleased to have this oppurtunity to comment on the proposed changes to Medicare Hospital OPPS and CY2005 payment rates. In the proposed rule, the median cost for APC 0659, hyperbaric oxygen therapy (HBOT) treatment dropped more than half to $82.91 from $164.93.

We have been providing hyperbaric oxygen therapy for approximately three years. We are a 130 bed hospital in south Mississippi. This decrease in payment wil prevent our ability to provide this proven modality for treating otherwise expensive wounds.

Garden Park Medical Center concurs with the Hyperbaric Oxygen Therapy Association and The Lewing Group's understanding of how CMS has inappropriately applied cost to charge ratios to HBOT charges, understanding median costs. We believe this needs to be corrected, as suggested by The Lewin Group, by one of the following alternatives:

1. If CMS has sufficient time, apply The Lewin Group methodology to all hospitals that submitted HBOT claims in CY2003.

2. Adopt The Lewin Group's proposed reimbursement rate of $118.21 per 30 minute increment for HBOT.

3. Calculate the reimbursement rate for HBOT using each hospital's overall cost-to-charge ratio. Because there is currently no standardization for which cost center HBOT costs and charges are located, CMS will be unable to appropriately determine the correct cost-to-charge ratio to apply to claims.

4. Leave the HBOT reimbursement rate at CY2004 levels until CMS has an opportunity to develop and perform a calculation that will appropriately reflect HBOT costs.

This issue will have a significant impact on our facility and I appreciate your time.

Sincerely,

William Peaks, CEO

Submitter : Mr. David Covert **Date & Time:** 10/05/2004 09:10:10

Organization : Chandler Regional Hospital

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

October 5, 2005

Dear Tommy G. Thompson:

Chandler Regional Hospital is a 238-bed hospital located in Chandler, Arizona. We are opposed to the proposed changes to the Medicare Hospital OPPS Payment Rates, in the 69 Fed. Reg. 50448, which have the median cost for APC 0659, hyperbaric oxygen therapy treatment declining to $82.91 from the 2004 payment of $164.93.

The hospital recently made a significant commitment to provide hyperbaric oxygen therapy (HBOT) to our community and will be the sole provider of this service in the Chandler service area. Hyperbaric oxygen therapy is an integral component of our newly established comprehensive program for the management of chronic wounds. The proposed lower payment will have a dramatic impact on our ability to provide this care and may threaten our patient?s access to this effective and efficient treatment.

The Lewin Group?s report indicates that Respiratory Therapy?s cost-to-charge ratio was applied in determining the proposed reimbursement. Clearly, this will not be the same situation with hyperbaric therapy provided with our wound program.

I am hopeful that CMS will reconsider their proposed rate structure revisions.

I appreciate your time in reviewing my concern.

Very Truly Yours,

David G. Covert
President, East Valley Service Area
and Chandler Regional Hospital

CMS-1427-P-140

Submitter : Mrs. Vicky Hicks **Date & Time:** 10/05/2004 09:10:24

Organization : Bloomington Hospital Wound Healing Center

Category : Hospital

Issue Areas/Comments

Issues 21-30

Payment Rate for APCs

I am the Lead Hyperbaric Technologist for our hospital's Wound Healing Center. We are the only Hyperbaric Oxygen therapy provider in South-Central Indiana. The proposed rate reduction would have a serious economic effect on our Center's ability to provide HBO therapy to patients in our area. I am sending you this comment to let you know that our hospital supports The Hyperbaric Oxygen Therapy Association's position and the Lewin group's findings. We support consideration of the 4 possible alternatives which have been presented to your office. These include; leave the HBOT reimbursement rate at CY 2004 levels until your office has had the opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios, adopt the overall cost to charge ration (CCR) of .47 due to the differences in which hospitals have reported costs, apply the Lewin group methodology to the 389 hospitals that reported hyperbaric claims for the year 2003, or adopt the Lewin group approach @ $118.21 per 30 minute increment.
I hope that your office can give serious consideration to this problem. We are gravely concerned that the severe reduction in reimbursement rates may force us to close our Hyperbaric program. Thank you very much for your attention to this concern.

Submitter : Mrs. Joy Blattner **Date & Time:** 10/05/2004 09:10:14

Organization : Milwaukee Comprehensive Wound Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

RE:CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Sir,
I am writing because I have concerns about the Department of Health and Human Services Centers for Medicare and Medicaid Services' 2005 Hospital Outpatient Prospective Payment System "Proposed Rule" that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment(HBOT). 69 Fed. Reg. 50448(August 16, 2004). I am a hyperbaric nurse, and I work at the Milwaukee Comprehensive Wound Healing Center. Our clinic is affiliated with St. Joseph's Hospital in Milwaukee, Wisconsin. We are located in the St. Joseph's Outpatient Center and are a part of the Covenant Healthcare system. We are the only Covenant Healthcare facility in the Milwaukee area that delivers HBOT to patients. We have five monoplace hyperbaric chambers with the ability to treat up to fifteen patients per day. Any patient needing HBOT from any of the Covenant Healthcare hospitals come to us. Primarily, we treat patients with wounds that are currently covered as "billable" by Medicare. Our patients see great improvement in their wounds after a given number of treatments. If the proposed rates for 2005 become the finalized rates, I fear that our clinic would not have the revenue to stay afloat and may potentially have to close. Hyperbaric treatments are not the only "bread and butter" of our clinic, but they dramatically increase the patient's chances to get better, as sometime HBOT is their only, or last, hope.
I realize that with everyone needing to have a budget, there will be cuts in reimbursement here and there. But this potential cut, I believe, will be very detrimental not only to our patients, but also to our clinic, and even to our building. However, I do support the Hyperbaric Oxygen Association's position, and the Lewin Group's findings. I feel that our clinic could still be successful and still be a benefit to our patients if one of the following four alternatives were used:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.
2. Apply the Lewin Group's methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.
3. Adopt the Lewin Group's approach at $118.21 per 30 minute increment.
4. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio of .47.

I, along with the rest of the clinic staff, strongly urge you to consider this proposal and not to go ahead with the new "Proposed Rule". We greatly appreciate your consideration on this very important matter.

Very Sincerely,
Joy Blattner, RN, BSN
Hyperbaric Nurse

CMS-1427-P-142

Submitter : Mr. Cecil Terry **Date & Time:** 10/05/2004 09:10:52

Organization : BJC HealthCare

Category : Hospital

Issue Areas/Comments

Issues 1-10

APC Relative Weights

On behalf of Barnes-Jewish Hospital, a member of BJC HealthCare, we are pleased to submit the following comments on the proposed rule CMS-1427-P published in the Federal Register on August 16, 2004. We are pleased to see the proposed increase in payment for cochlear implantation (APC 259, 69930) and recognize the progress this represents.

Barnes-Jewish Hospital has been performing cochlear implants since 1987. Last year the Hospital implanted 26 patients. Barnes-Jewish Hospital is one of the very few hospitals providing this service in the metropolitan St. Louis area, also providing this service to patients in the nearby rural areas of Missouri and Illinois. Approximately one third of the Hospital?s cochlear implant patients are Medicare beneficiaries.

The 2005 proposed payment under the outpatient prospective payment system (OPPS), however, is less than our hospital?s cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the 2003 data analyzed by CMS is not representative of the costs of the device and procedure.

We are also concerned about the billing and coding errors made by hospitals. While there has been some improvement, we urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for cochlear implant devices and other technology. In addition to using L8614, hospitals need to be educated on how to report charges for cochlear implants utilized in the outpatient department.

In addition, the Advisory Panel on Ambulatory Classification Groups has recommended a 5% cap rather than the increase proposed by CMS. It is well established that cochlear implantation has been significantly underpaid relative to the actual costs for the device and procedure. Therefore, we oppose the Advisory Panel's recommendation as arbitrary and a hindrance to CMS' goal to ultimately rely on accurate, claims data to establish rates for device-dependent APCs.

In conclusion, the proposed increase in payment for APC 0259 is based upon available data. Based upon the proposed rate, it is anticipated our hospital will lose over $10,000 per Medicare cochlear implant surgery in 2005. We ask CMS to improve educational outreach programs to hospitals. Similarly, we oppose arbitrary measures such as the APC Panel's 5% recommendation to cap increases at 5%.

Barnes-Jewish Hospital appreciates the agency's recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendations that we have submitted. If you require further information, please do not hesitate to contact me at 314-362-0637.

Sincerely,
For Barnes-Jewish Hospital
Cecil E. Terry
Manager of Billing & Reimbursement Compliance
BJC HealthCare

Submitter : Mrs. Joy Blattner **Date & Time:** 10/05/2004 09:10:11

Organization : Milwaukee Comprehensive Wound Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

CMS-1427-P-143-Attach-1.doc

Milwaukee
Comprehensive
Wound Healing Center

201 North Mayfair Road
Milwaukee, Wisconsin 53226

February 22, 2005

Secretary Tommy G. Thompson
Center for Medicare & Medicaid Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-8018

Re: CMS-1427-P; APC 0659 Hyperbaric Oxygen Therapy

Dear Sir:

I am writing because I have concerns about the Department of Health and Human Services Centers for Medicare and Medicaid Services' 2005 Hospital Outpatient Prospective Payment System "Proposed Rule" that sets forth new reimbursement rates for hyperbaric oxygen therapy treatment (HBOT). 69 Fed. Reg. 50448 (August 16, 2004). Our clinic is affiliated with St. Joseph's hospital, as we are located in the St. Joseph's Outpatient Center and are part of the Covenant Healthcare System. We are the only Covenant Healthcare facility in the Milwaukee area that delivers HBOT. We have five monoplace hyperbaric chambers with the ability to treat up to fifteen patients per day. Any patient needing HBOT from any Covenant Healthcare hospital comes to us. We primarily treat patients with wounds that are currently covered as "billable" by Medicare. Our patients see great improvement in their wounds after a given number of treatments. If the proposed rates for 2005 become the finalized rates, I fear that our clinic would not have the revenue to stay afloat and may potentially close. Hyperbaric treatments are not only the bread and butter of our clinic, but they dramatically increase the patient's chance to get better, as sometimes HBOT is their only or last hope.

I realize that with everyone needing to have a budget, there will be cuts in reimbursement here and there. This potential cut, I believe, will be very detrimental not only to our patients, but also to our clinic, and even our building. However, I do support the Hyperbaric Oxygen Therapy Association's position, and the Lewin Group's findings. I feel that our clinic could still be successful and still be a benefit to our patients if one of the following four alternatives were used:

1. Leave the HBOT reimbursement rate at CY 2004 levels until CMS has an opportunity to develop and perform a calculation that will accurately detail HBOT costs and cost-to-charge ratios.

2. Apply the Lewin Group's methodology to the 389 hospitals that reported hyperbaric claims for the year 2003.

3. Adopt the Lewin Group approach at $118.21 per 30 minute increment.

4. Due to the differences in which the hospitals have reported costs, adopt the overall cost to charge ratio of .47.

I, along with the rest of the clinic staff, urge you to consider this proposal and not to go ahead with the new "Proposed Rule". We greatly appreciate your consideration on this very important matter.

Very Sincerely,

Joy Blattner, RN, BSN, Hyperbaric Nurse