Submitter : Kitty Vineyard **Date:** 10/10/2006

Organization : American Burn Association

Category : Health Care Professional or Association

Issue Areas/Comments

OPPS Impact

OPPS Impact

October 10, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS 1506 P
Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Ms. Norwalk,

The American Burn Association (ABA) sincerely appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System 2007 Proposed Rule. The American Burn Association represents the nation's burn surgeons, nurses, therapists, and other members of the burn team, and the nation's leading medical institutions with burn centers who together provide therapeutic and surgical services for burn patients and other patients diagnosed with extensive and/or life-threatening skin diseases.

Skin Replacement Surgery and Skin Substitutes (APCs 0024, 0025, 0027)

By way of background, the ABA initiated, developed and subsequently collaborated in the effort that culminated in the AMA acceptance and publication of the new 2006 skin substitute/replacement CPT codes.

The ABA has previously provided comments on the 2006 final rule in our letter to CMS dated January 9, 2006 and in our presentation to the APC Panel in March 2006.

Given that context and after review of the 2007 HOPPS proposed rule, the ABA would like to comment on the Proposed APC-Specific Policies regarding skin replacement surgery and skin substitutes.

The ABA appreciates CMS recognition of the APC Panel s recommendation that certain codes assigned to APC 0024 warranted placement in an APC with a higher median cost for 2007. We agree that skin substitute/replacement add-on codes (CPTs 15171, 15176, 15301, 15321, 15341, 15361, 15366, 15421, and 15431) should be placed in APC 0025.

Consistent with our previous letter and presentation to the Panel however, we respectfully disagree that (primary) code 15300 (Allograft skin for temporary wound closure, trunk, arms, legs; first 100 sq cm or less, or one percent of body area of infants and children) should be moved from APC 0027 to the lower median cost APC 0025 because it is not likely to require the greater hospital resources, including operating room time and special equipment, required for skin autograft and other procedures currently assigned to APC 0027.

Hospital Resource Utilization

The primary codes for skin substitute/replacement procedures proposed for assignment to APC 0025, including 15300, require use of specific resources and care/preparation that can be significant in advance of surgical application, such that they require utiliziation of time and resources similar to that for autografts. And, following preparation and application, they, like skin grafts and similar tissue transfer procedures, must be secured appropriately in place to prevent mechanical shearing by physical forces (e.g., caused by patient movement) and then dressed in a similar manner to safely secure them.

For these reasons and based on the judgment of our members involved in development of these CPT codes and their RVUs as well as on their clinical experience, we believe that primary codes 15170, 15175, 15300, 15320, 15340, 15360, 15365, 15420, and 15430 should be moved to APC 0027.
Thank you for the opportunity to comment on this final rule. The ABA looks forward to contributing its expertise to CMS in order to foster proper payment for 2006 and in the future. If you have any questions on the issues discussed in this comment letter, please contact us. We will be happy to provide the information you require.
Respectfully submitted,

John A. Krichbaum, JD
Executive Director
American Burn Association

CMS-1506-P-512-Attach-1.DOC

#512

American Burn Association

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October 10, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: CMS—1506—P
Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

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[1] Codes 15170-71, 15175-76, 15340-41, 15360-61, 15365-66

American Burn Association

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Thank you for the opportunity to comment on this final rule. The ABA looks forward to contributing its expertise to CMS in order to foster proper payment for 2006 and in the future. If you have any questions on the issues discussed in this comment letter, please contact us. We will be happy to provide the information you require.

Respectfully submitted,

John A. Krichbaum

John A. Krichbaum, JD
Executive Director
American Burn Association

American Burn Association

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Submitter : Dr. Joseph Bailes **Date:** 10/10/2006

Organization : American Society of Clinical Oncology

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-513-Attach-1.DOC

#513

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October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P Medicare Program; Proposed Changes in the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

These comments are submitted by the American Society of Clinical Oncology (ASCO) in response to the proposed changes to the Medicare hospital outpatient prospective payment system (OPPS) that were published in the Federal Register on August 23, 2006. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

Multiple Imaging Procedures

Although CMS has adopted a reduced payment for the second and subsequent imaging procedures in the same family when furnished in the physician office setting, CMS did not adopt that reduction under the OPPS in 2006. CMS is again proposing to defer implementation of any payment reduction pending additional analysis.

ASCO supports CMS's proposal to refrain from reducing payments for multiple imaging procedures. Any such reduction should be supported by definitive data demonstrating that the OPPS payment rates do not already take multiple procedures into account.

Specified Covered Outpatient Drugs

The statutory category of "specified covered outpatient drugs" includes most of the important drugs used in the treatment of cancer patients. Payment for these drugs is based on the estimated average acquisition cost plus pharmacy overhead costs, and CMS currently sets the payment amount at average sales price (ASP) +6%. CMS is proposing to reduce the payment amount to ASP+5%. The notice states that CMS based the proposed reduction in the payment rate on ASP data from the fourth quarter of 2005 and on the mean costs of drugs as calculated from 2005 hospital claims data.

2007 Annual Meeting
June 1–June 5, 2007
Chicago, Illinois

For more information about ASCO Meetings
Phone: (703) 631-6200
Fax: (703) 818-6425
Website: www.asco.org

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ASCO strongly urges CMS to retain the current payment rate of ASP+6%. It is well known that the use of hospital charges for expensive drugs, such as many cancer drugs, may not be an accurate method of determining the costs for those drugs when a standard cost-to-charge ratio is used to estimate costs. Hospitals' percentage mark-up on expensive drugs may be much smaller than for low-cost drugs, thus resulting in an inaccurately low estimate of the price paid by hospitals for expensive drugs when a standard cost-to-charge ratio is used.

Proper payment for expensive drugs is especially important to oncology. CMS should not reduce payment for these drugs based on questionable inferences from hospital charge data.

Radiopharmaceuticals

Radiopharmaceuticals are considered specified covered outpatient drugs under the statute, but CMS lacks ASP data on them since they are not paid under the ASP methodology in the office setting. For 2006, CMS therefore adopted an interim policy of paying for radiopharmaceuticals based on 2004 charges in each hospital's claims data, converted to costs. For 2007, CMS is proposing to base prospectively determined payment amounts on average costs for all hospitals as determined from 2005 claims data.

For the same reason that ASCO opposes the reduction in payments for the other specified covered outpatient drugs, we oppose the change in methodology for radiopharmaceuticals. Until there is clear evidence that hospital charge data can be reliably used to estimate the prices paid for expensive radiopharmaceuticals, the current payment method should be retained.

IVIG

A recent ASCO survey of its members indicated that there continues to be a serious problem in obtaining intravenous immune globulin (IVIG) due to shortages and, in addition, that the payment applicable in the office setting (ASP+6%) is not adequate to cover the purchase price. While the survey focused on physician offices, it seems likely that hospitals are also experiencing similar problems.

In 2006, Medicare has been making an extra payment to hospitals to help cover the pre-administration costs associated with acquiring IVIG, but CMS is proposing to eliminate that payment for 2007. Since the problems that led to adoption of the payment appear still to exist, ASCO urges that the payment be continued in 2007.

* * * * * *

Thank you for the opportunity to comment on the proposed changes.

Sincerely,

Joseph S. Bailes

Joseph S. Bailes, MD
Co-Chair, Government Relations Council

Submitter : Ms. Robert Reske **Date:** 10/10/2006

Organization : The University of Michigan Health Systems

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

See attached document.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Jenny Rodseth **Date:** 10/10/2006

Organization : Scripps Health

Category : Hospital

Issue Areas/Comments

OPPS Comments Indicator

OPPS Comments Indicator

I. Issue Identifier: "OPPS: 2 Times Rule" section E.2
1.) Comment Indicator "CH" is assigned to indicate one of two possible changes. It can signify that the HCPCS code has had a status indicator change. It can also indicate that the HCPCS code has had an APC assignment change. Could a Comment Indicator be limited to only a single change? This would readily facilitate the identification of the HCPCS code change and would minimize the need for visual comparison of two separate Addendum B files to determine what has actually changed. Currently we have to review the previous quarter's addendum B to the new addendum to identify which (Status Indicator or APC assignment) has incurred the changed.

OPPS Impact

OPPS Impact

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1.) Comment Indicator "CH" is assigned to indicate one of two possible changes. It can signify that the HCPCS code has had a status indicator change. It can also indicate that the HCPCS code has had an APC assignment change. Could a Comment Indicator be limited to only a single change? This would readily facilitate the identification of the HCPCS code change and would minimize the need for visual comparison of two separate Addendum B files to determine what has actually changed. Currently we have to review the previous quarter's addendum B to the new addendum to identify which (Status Indicator or APC assignment) has incurred the changed.
2.) Table 7 contains a list of APCs that are considered exempt from the "2 Times Rule". It includes APC 0111 and APC 0112 (pheresis related services) which may be services performed by contracted agencies outside of the hospitals because of the need for specialized equipment. The contracts with these agencies providing the services to our hospital patients are negotiated by the outside agency. The hospital provider's cost can vary greatly depending on how many agencies offer these services and location of the actual provider. The pricing and charges typically represent the cost so adding these APCs to be exempt from the "2 Times Rule" violation would exclude the facility from receiving additional payment if the cost outlier is met. Could you please remove these 2 APCs (0111 and 0112) from the "2 Times Rule" exempt list?
3.) Table 7 contains APC 0418 Insertion of Left Ventricular Pacing Electrode. Could the APC committee explain the rationale as to why APC 0418 should be exempt from the "2 Times Rule" and excluded from outlier payment? This procedure represents a biventricular generator whieh may result in a significant cost for the device and leads. Providers would not be eligible to receive additional payments for elevated costs associated with this expensive device and associated supplies (leads, etc.).

II. Issue Identifier: "Myocardial PET Scans"
1.) The proposed rule is recommending a reduction of $1,700.00 for multiple scans. It is proposing to reduce the 2 existing APCs down to a single APC for all PET scans. This will have a significant impact on reimbursement related to PET scans technology. Could the APC committee comment on the rationale as to how they feel this reduction in payment will not indirectly result in beneficiary s accessibility to these services in the future?

III. Issue Identifier: "Radiology Procedures"
1.) Did the analysis comparing CT median costs to CTA median costs come from different cost centers or the same cost center? If from the same cost center, how can they differentiate costs of these services to calculate the true / actual median of both services?

IV. Issue Identifier: "Device Dependent APCs"
1.) This year has been extremely challenging for pacemakers and defibrillators due to the complex and changing regulations surrounding device replacements, devices exchanged or upgraded as a result of a recall, token charges, device dependent edits, modifier FB, etc. All of these changes posed a tremendous burden for providers because of the impacts on hospital information systems, charge master files, encoding software, and billing systems. I am concerned with integrity of the data utilized to calculate the median cost data analysis and proposed 2007 APC payment assigned to defibrillator cases (G0297, G0298, G0299, G0300) for APCs 0107 and 0108. Our facility cost for defibrillators can range from $21,000 - $29,900.00. The 2007 national unadjusted payment for APC 0107 is $17,185.34 and for APC 0108 is $22,807.94. The reimbursement in the proposed payment for 2007 for the entire episode of care for these cases frequently does not even cover our facility's cost for the defibrillator device and leads. Errors in the integrity of the data collected or analysis of claims submit

Submitter : **Michelle Rainville** **Date: 10/10/2006**

Organization : **Charlotte Hungerford Hospital**

Category : **Nurse**

Issue Areas/Comments

Visits

Visits

see attached

CMS-1506-P-516-Attach-1.DOC

#516

October 11, 2006

As an Emergency Department Registered Nurse for fifteen years, I feel that I have a unique perspective on the recent CMS proposal to render reduced payments to less than 24 hour Emergency Departments. I have been employed in Northwest Connecticut for my entire nursing career, working to provide exemplary care to my patients as the number of Emergency Department visits has skyrocketed in number over the past few decades. The population in our relatively rural area has grown and we have attempted to grow with those numbers to accommodate a population that seeks care at the Emergency Department level at an ever increasing rate. It seems that at every turn, regulatory agencies increase the workload of caregivers via new rules and regulations, as reimbursement from those agencies and their affiliates decreases, in the face of ever expanding technology. We are held to high standards of care, yet are denied the level of reimbursement that allows such care to be maintained and expanded as our abilities evolve.

The recent proposal to cut the reimbursement level seems to be an illogical move on the part of those entrusted to care for those most likely to need Emergency Care, that is, the poor and the elderly. In an era where our Emergency Departments are asked to plan and prepare for bioterrorism, pandemics, and other cataclysmic disasters, to exclude the less than 24 hour Emergency Departments from appropriate funding flies in the face of preparedness for the events we are to respond to. As a 'part-time' Emergency Department, my facility deals daily with the same patients that present at full time Emergency Departments nationwide, providing life and limb saving care to any and all who arrive.

On the webpage of Medlineplus, a service of the U.S. National Library of Medicine and the National Institutes of Health (http://www.nlm.nih.gov/medlineplus/news/fullstory_39251.html), is an article detailing the problem of overcrowding in Emergency departments, as the number that remain open declines, causing "concerns about the capacity of EDs that continue to operate." The Centers for Disease Control, National Center for Health Statistics has also addressed this issue, releasing on September 27, 2006, a report that linked Emergency Department overcrowding to increased waits for treatment, diversion of ambulances to other facilities, delaying definitive treatment and overtaxing the EMS transport system, and also links the issue to the nursing shortage that threatens healthcare provision nationwide (http://www.cdc.gov/nchs/pressroom/06facts/hospitals.htm).

Thus, by our governmental agencies' own admissions, the current usage of emergency departments overwhelms the available resources and staff, and yet the CMS response to this is to deny the proper reimbursement to those facilities who have proactively expanded the availability and capacity of their Emergent Care milieu to serve additional areas and populations, effectively dealing a financially destructive blow to those facilities that are attempting to alleviate the problem, which has been caused in part by the structure and payment schedules of that same agency.

The Institute of Medicine and the National Academies' Committee on the Future of Emergency Care in the United States Health System released their report in June 2006 (http://www.iom.edu/CMS/3809/16107/35007.aspx) detailing its findings on this subject. Their examination of the future of Emergency Care in the United States Health System demonstrates some salient points:

"Not only has the hospital ED become the place that Americans turn to first when they have an illness or injury that demands immediate attention, but it has been given an increasing number of other responsibilities as well. EDs today provide much of the medical care for patients without medical insurance.....In some rural communities, the hospital ED may be the main source of health care for a large percentage of residents. EDs also play a key role in public health surveillance and in disaster preparation and response."

The report further states that in the period from 1993 to 2003, demand for emergency care as illustrated by the number of ED visits, has grown 26%. During the same period, the number of Emergency Departments available nationwide shrank by 425, and inpatient beds declined in number by 198,000. The number of hospitals available to provide care in the U.S. decreased by

703. The loss of these facilities and inpatient beds further exacerbates ED overcrowding...there is no place left to accept these patients other than the ED. Thus patients are held in the ED until an appropriate provider and place of care can be located. With an Emergency Department saturated with patients, their is little reserve left for responding to major events, whether it be pandemic influenza, bioterrorism, or natural disasters. This overcrowding leads to a domino effect on other Emergency Services. Ambulances are diverted in response to the overcrowding. IOM states in its report that in 2003, ambulances were diverted 501,000 times, an average of once every minute, resulting in delays that may mean the difference between life and death in some cases, and prolonging times of unavailability for ambulances seeking to turn over care of patients.

Culminating the report, IOM recommends increased funding for hospitals to compensate for the provision of uncompensated Emergency Care, as well as funding to prevent the future closings of hospitals and EDs struggling with the financial losses incumbent in providing care to all.

In closing, I would add my plea for the reasons detailed above---do not add to the National Emergency Care Crisis by further reducing funds available to legitimate Emergency Care providers in an attempt to control governmental health care costs. The needs of our citizens, including the uninsured and destitute without a voice, dictate availability of a system that is able to care for all of us, and to have the surge capacity to respond to times of crisis in our nation. Connecticut's satellite Emergency Departments should be lauded for their response to overcrowding, rather than punished by being reimbursed at inadequate rates.

Sincerely,

Michele Rainville RN

Team Leader, Hungerford Emergency and Medical Care

115 Spencer St.

Winsted, CT 06098

mrainville@hungerford.org

860-738-6610

Submitter : **Ms. Maya Bermingham** **Date: 10/10/2006**

Organization : **Pharmaceutical Research and Manufacturers Associat**

Category : **Drug Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-517-Attach-1.PDF

CMS-1506-P-517-Attach-2.PDF

#517-1

Conan P. Grames
Senior Vice President
General Counsel

PhRMA

October 10, 2006

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

Dear Dr. McClellan:

Enclosed please find the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding Solicitation of Comments on the proposed rule published by the Centers of Medicare and Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2007.

If you have any questions, please do not hesitate to call Maya Bermingham directly at (202) 835-3478.

Sincerely,

Conan P. Grames

Conan P. Grames

Enclosure

PhRMA

October 10, 2006

BY HAND DELIVERY AND EMAIL
http://www.cms.hhs.gov/eRulemaking

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

Re: **CMS-1506-P; Comments Regarding the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2007.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in ensuring that Medicare beneficiaries have access to the most appropriate therapies, both under the OPPS and in other settings. We believe the proposed rule has a number of provisions, such as those governing vaccines, antiemetics and elements of coding structure that can help to assure access to high-quality care under the OPPS. However, we are concerned by other provisions in the proposed rule that could set back the goal of promoting access. Among other things, we strongly encourage CMS to revise its proposal to reimburse certain drugs, including specified covered outpatient drugs (SCODs), at 105% of average sales price (ASP). As detailed below, CMS' does not provide a rationale or analysis that provides sound support for this payment amount and we are concerned that this payment may not cover hospital handling and acquisition costs and could therefore jeopardize beneficiaries' access to needed drugs; accordingly, PhRMA recommends that CMS, in the final OPPS rule for 2007,

[1] 71 Fed. Reg. 49506 (Aug. 23, 2006).

adopt the 106% of ASP payment rate that it applied to these drugs in 2006. We also believe that CMS has proposed an approach to radiopharmaceutical payments that would undercompensate hospitals for their handling and acquisition costs for radiopharmaceuticals in 2007. PhRMA therefore recommends that CMS revisit this proposal, and instead continue to use the current payment methodology for radiopharmaceuticals during 2007.

Our detailed comments on these payment proposals and other key issues raised by the proposed rule are set out below.

* * *

A. Proposed Payment for Specified Covered Outpatient Drugs

A SCOD is a drug for which a separate APC has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions).[2] The Social Security Act (SSA) requires that payment for SCODs in CY 2006 and subsequent years be equal to the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[3] If hospital acquisition cost data are not available, payment must equal "the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."[4]

Although last year CMS paid for SCODs at 106% of ASP, this year CMS proposes paying for them at 105% of ASP. To arrive at this figure, CMS compared two sources of data - - ASP data from the fourth quarter of CY 2005 and mean "costs [of drugs] derived from the CY 2005 hospital claims data."[5] CMS states that its data analysis indicates that using mean cost to set SCOD payment rates for drugs would be "equivalent to basing their payment rates, on average, at ASP+5 percent."[6] CMS states that a "MedPAC survey of hospital charging practices indicated that hospitals set charges for drugs . . . high enough to reflect their pharmacy handling costs as well as their acquisition costs. Therefore, the mean costs calculated using charges from hospital claims data converted to costs are representative of hospital acquisition costs for these

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2 SSA § 1833(t)(14)(B)(i). The term does not include drugs that first received pass-through payments on or after January 1, 2003 and drugs that have not been assigned a temporary HCPCS code.

3 SSA § 1833(t)(14)(A)(iii).

4 Id.

5 71 Fed. Reg. at 49584.

6 Id.

products, as well as their related pharmacy overhead costs."[7] Therefore, CMS concludes, "[P]ayment for drugs . . . and pharmacy overhead at a combined ASP +5 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products."[8]

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Given these problems, PhRMA is concerned that this proposed shift to payment at 105% of ASP may not adequately cover acquisition and handling costs, which could impede beneficiary access to important drug therapies. Associations of cancer care providers (and individual providers) voiced these same concerns during the most APC Panel meeting, and the Panel recommended that "CMS maintain the payment rates for drugs at their ASP plus 6 percent

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[7] Id.

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CMS also proposes paying 105% of ASP for clotting factors and drugs and biologicals that "were payable during CY 2005 or where HCPCS codes for products were created effective January 1, 2006, for which [CMS] do[es] not have CY 2005 hospital claims data."[12] Our objections and concerns regarding payment for SCODs at 105% of ASP apply here as well. We also note that in the final 2006 OPPS rule, which established clotting factor payment at 106% of ASP plus a furnishing fee, CMS stated that "similar resources [are used] to furnish clotting factors across all types of service settings" and that it "believe[s] it is appropriate" to pay for clotting factors under the OPPS and physician fee schedule rules at equivalent rates.[13] It is equally appropriate to do so this year.

B. Radiopharmaceuticals

CMS is required to pay for radiopharmaceuticals equal to their average acquisition costs and subject to any adjustment for overhead costs. Currently, CMS pays for radiopharmaceuticals under the OPPS based on each hospital's charge for each radiopharmaceutical adjusted to cost using each hospital's overall cost-to-charge ratio (CCR). This year CMS proposes to set fixed payment amounts for all radiopharmaceuticals -- a positive starting point -- but some significant adjustments need to be made to ensure that the payment levels account for radiopharmaceutical acquisition, overhead, and handling costs. In the final OPPS rule for CY 2006 (which was released in November 2005) CMS expressly advised hospitals that "it is appropriate for hospitals to set charges for these agents in CY 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients."[14] Hospitals incur special costs in shielding patients and staff from radiation exposure, and regulatory compliance costs in safe administration, transport, and disposal of radioactive isotopes used in therapeutic and diagnostic nuclear medicine procedures. This year, CMS proposes paying for radiopharmaceuticals based on 2005 charge data. Even if hospitals responded

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CMS' proposed method to determine radiopharmaceutical payment is a valuable starting point, but using the 2005 data is premature, and additional payment adjustments will be needed in the future. Use of mean costs, together with an adjustment for overhead/handling and overall hospital CCR rates would support appropriate payment for most radiopharmaceuticals in 2008. Some products, especially the most high cost radiopharmaceuticals, may require special methodologies to correct for charge compression, which has been a traditional concern with high cost products and may be contributing to the drops seen between the 2005 and the proposed 2007 payment levels. Until these significant adjustments can be made, we recommend, as did the APC Panel, the continuation of current payment methods for radiopharmaceuticals for one more year.

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CMS will continue to pay for influenza, pneumococcal pneumonia, and hepatitis B vaccines at reasonable cost. CMS began paying for vaccines on this basis to "take into account yearly fluctuations in the[ir] costs" so as to protect patient access to these important therapies. These considerations remain important today and thus PhRMA commends CMS for continuing to pay for these products at reasonable cost.

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CMS pays for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status by either packaging payment with the payments for associated items and services or providing a separate payment. Currently, CMS pays separately for drugs, biologicals, and radiopharmaceuticals with per-day costs that exceed a threshold amount and packages those with per day costs less than or equal to the threshold. Currently, per-day costs of a drug are generally determined by multiplying the average number of units of the drug used per-day by 106% of the drug's ASP. However, for CY 2007, CMS proposes using 105% of ASP to determine per-day costs, and states that its rationale for doing so is the same as with its SCOD payment proposal. Therefore, our same objections regarding gaps and flaws in this rationale apply here as well.

Also, we note that CMS proposes indexing the packaging threshold to inflation, which would raise it from $50 to $55 dollars for 2007.[15] CMS recognizes that packaging risks "insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services."[16] In addition, the APC Panel recently heard testimony requesting that the packaging threshold be eliminated, and recommended that "CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes."[17] PhRMA is concerned that CMS' proposal to increase the packaging threshold is moving in the wrong direction.

PhRMA supports CMS' proposal to continue to make separate payment for 5HT3 anti-emetics, regardless of whether per day costs meet the packaging threshold. We agree with CMS that anti-emetic use is often integral "to achieving maximum therapeutic benefit from chemotherapy and other therapies with side effects of nausea and vomiting," and that finalizing this proposal would "continue to ensure that Medicare payment rules do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician."[18] In the antiemetics proposal, CMS correctly recognizes that packaging some drugs but paying separately for others gives hospitals an incentive to choose therapies based on their reimbursement, not their clinical appropriateness for each patient. CMS should acknowledge that the same concerns apply to other drugs as well. To ensure that beneficiaries are able to receive the most appropriate drug for their condition, CMS should pay separately for all drugs with HCPCS codes, not just those that have a price per day above an arbitrary threshold. This approach also would help to protect access to care in the most appropriate setting by applying a consistent policy to payment for drugs in both hospital outpatient departments and physicians' office. Finally, paying separately for all drugs with HCPCS codes would encourage hospitals to code more accurately without increasing their administrative burdens. Hospitals currently follow CMS' guidance and code for many packaged drugs, and paying separately for all drugs with HCPCS codes would push hospitals to improve the accuracy of their coding.

E. Drug Administration Payments

In CY 2006, the CPT Editorial Panel revised the CPT codes for physician office setting drug administration services. In the CY 2006 OPPS final rule, CMS implemented many (but not all) of these drug administration CPT codes and created six new HCPCS C-codes similar to the CY 2005 CPT codes for the same services. This year, CMS proposes maintaining the same coding structure. PhRMA applauds CMS' recent efforts to make OPPS and physician office

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[17] APC Panel Report, 17.

[18] 71 Fed. Reg. at 49583.

drug administration coding more parallel; in general parallel coding across sites of service reduces unnecessary complexities and offers the same benefits as parallel payment amounts, as discussed above with respect to SCOD payments. To realize these benefits fully, CMS should fully adopt drug administration CPT codes for the OPPS. The APC Panel agrees, stating that CMS should "recognize only the AMA's CPT codes for outpatient hospital reporting of drug administration services in CY 2007."[19]

F. Echocardiography Imaging Drug Administration Issue

Echocardiography procedures are used to evaluate patients with various cardiac disorders. In approximately 20% of cases, echocardiographic images are suboptimal and repeat studies or additional testing may be required. In many of these cases, echocardiographic imaging drugs are used to enhance images, and clinical studies have shown that echocardiographic imaging drugs can salvage up to 58-91 percent of unevaluable images. Echocardiographic imaging drugs are administered intravenously. Although Medicare pays separately for echocardiographic imaging drugs, no separate payment is made for the intravenous administration of these drugs. Current coding edits do not allow providers to report the intravenous administration of these drugs separate from the imaging procedure. Unlike other imaging procedures involving contrast (e.g., computed tomography and magnetic resonance imaging), there are no codes that describe echocardiography procedures performed with contrast imaging drugs. Echocardiography procedure codes were developed before echocardiographic imaging drugs were approved by the FDA; none of these procedure codes mention use of contrast imaging drugs. The costs for intravenous administration of echocardiographic imaging drugs are not insubstantial, and none of these costs are reflected in the resources supporting the payment rates for echocardiography procedures. We urge CMS to remove any edits from the Outpatient Code Editor (OCE) and the hospital version of the Correct Coding Initiative (CCI) that package intravenous injection code(s) into codes for the associated echocardiography procedures. Deleting the OCE and CCI edits should remove financial disincentives limiting appropriate use of echocardiography imaging drugs and should encourage appropriate use of contrast enhancement, to help salvage images when the echocardiographic image is suboptimal.

* * *

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PhRMA hopes that these comments will be useful to CMS in developing the final OPPS rule for 2007. We look forward to further dialogue on enhancing beneficiaries' access to care in the hospital outpatient setting, and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Maya J. Bermingham
Assistant General Counsel

#517-2

Conan P. Grames
Senior Vice President
General Counsel

PhRMA

October 10, 2006

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

Dear Dr. McClellan:

Enclosed please find the comments of the Pharmaceutical Research and Manufacturers of America (PhRMA) regarding Solicitation of Comments on the proposed rule published by the Centers of Medicare and Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2007.

If you have any questions, please do not hesitate to call Maya Bermingham directly at (202) 835-3478.

Sincerely,

Conan P. Grames

Conan P. Grames

Enclosure

PhRMA

October 10, 2006

BY HAND DELIVERY AND EMAIL
http://www.cms.hhs.gov/eRulemaking

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

Re: **CMS-1506-P; Comments Regarding the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2007.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in ensuring that Medicare beneficiaries have access to the most appropriate therapies, both under the OPPS and in other settings. We believe the proposed rule has a number of provisions, such as those governing vaccines, antiemetics and elements of coding structure that can help to assure access to high-quality care under the OPPS. However, we are concerned by other provisions in the proposed rule that could set back the goal of promoting access. Among other things, we strongly encourage CMS to revise its proposal to reimburse certain drugs, including specified covered outpatient drugs (SCODs), at 105% of average sales price (ASP). As detailed below, CMS' does not provide a rationale or analysis that provides sound support for this payment amount and we are concerned that this payment may not cover hospital handling and acquisition costs and could therefore jeopardize beneficiaries' access to needed drugs; accordingly, PhRMA recommends that CMS, in the final OPPS rule for 2007,

[1] 71 Fed. Reg. 49506 (Aug. 23, 2006).

adopt the 106% of ASP payment rate that it applied to these drugs in 2006. We also believe that CMS has proposed an approach to radiopharmaceutical payments that would undercompensate hospitals for their handling and acquisition costs for radiopharmaceuticals in 2007. PhRMA therefore recommends that CMS revisit this proposal, and instead continue to use the current payment methodology for radiopharmaceuticals during 2007.

Our detailed comments on these payment proposals and other key issues raised by the proposed rule are set out below.

* * *

A. Proposed Payment for Specified Covered Outpatient Drugs

A SCOD is a drug for which a separate APC has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions).[2] The Social Security Act (SSA) requires that payment for SCODs in CY 2006 and subsequent years be equal to the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[3] If hospital acquisition cost data are not available, payment must equal "the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."[4]

Although last year CMS paid for SCODs at 106% of ASP, this year CMS proposes paying for them at 105% of ASP. To arrive at this figure, CMS compared two sources of data - - ASP data from the fourth quarter of CY 2005 and mean "costs [of drugs] derived from the CY 2005 hospital claims data."[5] CMS states that its data analysis indicates that using mean cost to set SCOD payment rates for drugs would be "equivalent to basing their payment rates, on average, at ASP+5 percent."[6] CMS states that a "MedPAC survey of hospital charging practices indicated that hospitals set charges for drugs . . . high enough to reflect their pharmacy handling costs as well as their acquisition costs. Therefore, the mean costs calculated using charges from hospital claims data converted to costs are representative of hospital acquisition costs for these

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2 SSA § 1833(t)(14)(B)(i). The term does not include drugs that first received pass-through payments on or after January 1, 2003 and drugs that have not been assigned a temporary HCPCS code.

3 SSA § 1833(t)(14)(A)(iii).

4 Id.

5 71 Fed. Reg. at 49584.

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products, as well as their related pharmacy overhead costs."[7] Therefore, CMS concludes, "[P]ayment for drugs . . . and pharmacy overhead at a combined ASP +5 percent rate would serve as the best proxy for the combined acquisition and overhead costs of each of these products."[8]

There are several flaws and gaps in this analysis. First, it confuses costs and charges. CMS reasons that because hospitals set charges for drugs high enough to "reflect" handling costs and acquisition costs, a payment rate determined by reducing charges to costs would be appropriate to cover handling and acquisition costs for these products. However, CMS' premise that charges are adequate to cover acquisition costs only suggests that payment at charges would be adequate. The MedPAC "survey" to which CMS refers to support the notion that payment at charges reduced to costs would be adequate likewise confuses costs and charges, stating, for instance, "Hospital officials and others told MedPAC staff that hospitals build handling costs for drugs, biologicals, and radiopharmaceuticals into the charges for the products themselves as part of the markup over costs. Therefore the original payment pool that CMS based on hospital charges (reduced to costs) reflected handling costs."[9] In addition, this MedPAC report's conclusions appear not to be based on a systematic survey, but instead on "numerous" informal MedPAC "consultations" with hospital pharmacy directors and administrators, which may or may not provide a representative sample of charging practices.[10] Second, CMS did not adequately explain how it determined its average reimbursement of 105% of ASP from charges reduced to costs. For instance, CMS stated that 105% of ASP for the fourth quarter 2005 was equal to the mean "costs [of drugs] derived from the CY 2005 hospital claims data" (i.e. charges reduced to costs), but did not specify whether all CY 2005 or only fourth quarter 2005 claims data were considered. Nor did CMS discuss the degree to which 105% of ASP matches (or does not match) costs determined from charges across a range of drugs. Thus, even assuming that costs reduced to charges cover acquisition and handling costs (which is unclear), additional questions would remain about the proposed methodology.

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PhRMA hopes that these comments will be useful to CMS in developing the final OPPS rule for 2007. We look forward to further dialogue on enhancing beneficiaries' access to care in the hospital outpatient setting, and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Maya J. Bermingham
Assistant General Counsel

Submitter : **Ms. Shannon Strickler** **Date: 10/10/2006**

Organization : **Iowa Hospital Association**

Category : **Hospital**

Issue Areas/Comments

CAHs: Emergency Medical Screening

CAHs: Emergency Medical Screening

See Attachment

GENERAL

GENERAL

See Attachment

OPPS: Rural SCH Payments

OPPS: Rural SCH Payments

See Attachment

Visits

Visits

See Attachment

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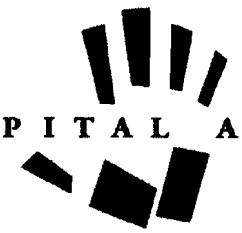

IOWA HOSPITAL ASSOCIATION

100 EAST GRAND DES MOINES, IOWA 50309-1835 515.288.1955 FAX 515.283.9366

October 10, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1506-P, Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Iowa's 35 hospitals reimbursed under the Medicare Outpatient Prospective Payment System (PPS), the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the CY 2007 Medicare Outpatient Prospective Payment System. Our comments are outlined by topic area below.

Visits

Hospital currently use the current procedural terminology (CPT) codes used by physicians to report clinic and emergency department (ED) visits and critical care services on claims paid under the OPPS. However, the CPT Evaluation and Management (E/M) codes reflect the activities of physicians but do not describe the range and mix of services provided by hospitals during visits of clinic and ED patients and critical care encounters. In addition, there are no national policies to determine the assignment of E/M codes so hospitals have to develop internal hospital guidelines to determine what level of visit should be reported for each patient.

CMS proposes to replace the current E/M codes with new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. IHA opposes the proposed creation of temporary level II G-codes while continuing to allow hospitals to apply their own internal guidelines to these codes. Instead, CMS should defer creation of new evaluation and management codes until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and published.

CMS has specified in an earlier outpatient PPS rule that they would not create new codes to replace existing the E/M codes until national guidelines were developed. This proposal contradicts that statement and will create additional, unnecessary administrative burdens on hospitals. Implementation of new codes in CY 2007 without implementation of national guidelines will require hospitals to evaluate their current internal guidelines and revise them to be consistent with the new codes. Then, when national guidelines are implemented in a subsequent year, hospitals may again need to revise their coding procedures.

OPPS: Rural SCH Payments

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that CMS conduct a study to determine if the cost of providing outpatient care in rural hospitals exceeded that of urban hospitals. The CMS analysis showed that rural Sole Community Hospitals (SCH) demonstrated significantly higher cost per unit than urban hospitals. CMS stated that its analysis showed that other rural hospitals did show some levels of higher cost per unit; however, CMS did not believe it was significant enough to justify an adjustment for other rural hospitals. Therefore, in CY 2006 provided an adjustment of 7.1% for SCHs but provided no adjustment for other rural hospitals. CMS proposes to continue this policy in CY 2007.

The MMA mandated report was intended to coincide with the scheduled expiration of hold-harmless payments for small rural hospitals on December 31, 2005. The payments were subsequently extended through December 31, 2008 with a gradual phase-down of the payment amount. IHA supports the continuation of the 7.1% adjustment for rural SCHs. IHA also urges CMS to revisit their analysis of the cost of providing outpatient care in rural hospitals and to propose an adjustment for other rural hospitals in CY 2008 or CY 2009 if justified by the analysis.

CAHs: Emergency Medical Screening

CMS proposes to revise the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel for emergency medical screenings. IHA strongly supports this proposal which will provide CAHs with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services. Iowa is a largely rural state and this change would be very helpful to those hospitals providing access to emergency services in rural areas.

Sincerely,

Shannon Strickler

Shannon Strickler
Director, Government Relations

Submitter : Mr. Matthew Eyles **Date:** 10/10/2006

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-519-Attach-1.PDF

#519

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Matthew D. Eyles
Assistant Vice President
Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

BY ELECTRONIC DELIVERY

October 10, 2006

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

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)

Dear Dr. McClellan:

Wyeth Pharmaceuticals welcomes the opportunity to comment on the CMS draft proposal of the Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates Proposed Rule (Proposed OPPS Rule). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and healthcare products companies with leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

Wyeth appreciates CMS' efforts to safeguard beneficiary access to drug and biological therapies in the hospital outpatient setting. To preserve patient access, it is critical for CMS to appropriately reimburse hospitals for both the costs of acquiring and providing the services necessary to administer drugs and biologics. To this point, Wyeth is particularly concerned about CMS' proposal to reduce payments for non-pass through drugs and clotting factors to average sales price (ASP) plus 5 percent. We believe that even small payment changes may potentially limit or hinder beneficiary access to certain life-saving therapies and recommend at least maintaining the current ASP+6% reimbursement system. By contrast, with respect to pass-through drugs and vaccines, we believe that CMS

Wyeth

has taken positive steps to guarantee access. Our specific concerns are highlighted and discussed in greater detail below.

Pass-Through Drugs

Wyeth supports CMS' proposal to continue paying for pass-through drugs in 2007 at no less than ASP+6%.

Consistent with prior calendar years, CMS proposes to reimburse pass-through drugs and biologics at ASP+6% unless that product is included in the Competitive Acquisition Program (CAP). CAP drugs and biologics will be reimbursed at the CAP rate.

Under the Proposed OPPS Rule, TYGACIL™ (tigecycline), Wyeth's novel I.V. antibiotic with a broad spectrum of antimicrobial activity indicated for the treatment of complicated skin and skin structure infections and for adults with complicated intra-abdominal infections, was included on the proposed list of drugs and biologics with pass-through status for 2007. TYGACIL™ qualified for a transitional pass-through payment on April 1, 2006, and may be used in the hospital outpatient setting when patients are discharged before their course of treatment is complete. Wyeth appreciates the inclusion of TYGACIL™ on the proposed pass-through list for 2007 and supports CMS' proposal to continue to reimbursement at no less than ASP+6%.

OPPS: Non pass-Through Drugs, Biologicals and Radiopharmaceuticals

Wyeth is concerned about CMS' proposal to reduce payments for non pass-through drugs to ASP+5% and recommends at least maintaining the ASP+6% reimbursement for policy consistency across Medicare providers.

Wyeth is concerned with CMS' proposed reduction in payment for non pass-through drugs and biologicals to ASP+5%. If hospital outpatient departments are not adequately reimbursed for the purchase and administration of these products, Medicare beneficiaries may be denied access to life-saving therapies in this important site of care.

Recent analyses have raised issues and questions about the adequacy of OPPS payments for handling and administration of drugs and biologics that are based on

Wyeth

broad averages.[1] While reducing the payment rate to ASP+5 % may seem like a small amount on the surface, Wyeth is concerned that the 2006 payment rate of ASP+6% is inadequate. After factoring in the costs of product acquisition, handling, overhead, administration and others costs, we are not confident that ASP+6% is sufficient for hospital outpatient departments. Any further reduction in payment rates could endanger beneficiaries' access to much-needed drug and biological therapies. At a minimum, Wyeth requests that CMS maintain the current payment rate of ASP+6%. Furthermore, for the sake of CMS policy consistency across various sites of beneficiary care and service, Wyeth believes ASP+6% is preferable.

Packaging Policies

Wyeth is concerned about CMS' proposal to update the packaging threshold to $55 and to adjust it annually by PPI for prescription preparation and recommends that all drugs and biologicals be reimbursed separately.

CMS proposes to increase the packaging threshold from $50 to $55 per day based on inflation. Wyeth encourages CMS to consider a different methodology when paying for packaging of services. We agree with the recent APC Panel recommendation that "CMS eliminate the drug packaging threshold for all drugs and radiopharmaceuticals with HCPCS codes."[2] We believe that separately reimbursing all drugs and biologicals with HCPCS codes will encourage hospitals to code for drugs utilized in packaged therapies. It may also remove the current disincentives to use packaged therapies currently built into the OPPS. Finally, all services provided in a hospital outpatient department would be more appropriately reimbursed if invoiced and paid for separately.

Clotting Factor Reimbursement

Wyeth opposes CMS' proposal to cut base clotting factor reimbursement to ASP+5% and recommends maintaining payments at no less than ASP+6%.

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[1] Medicare Payment Advisory Commission, *Report to Congress: Issues in a Modernized Medicare Program*, June 2005; Government Accountability Office (GAO), *Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services*, GAO-04-772, September 2004.

[2] Advisory Panel on Ambulatory Payment Classification Groups, August 23-24, 2006, Panel recommendations, 17

Wyeth

CMS' proposes to cut base clotting factor reimbursement to ASP+5%. With a cut in clotting factor reimbursement, hemophilia patients could be denied clinically appropriate access and may not receive prompt treatment for bleeds associated with their disease. In the 2007 proposed Physician Fee Schedule rule,[3] CMS proposes to increase the clotting factor furnishing fee by the percentage increase in the consumer price index (CPI) and we applaud this effort. However, Wyeth believes decreasing the base clotting factor reimbursement to ASP+5% in the hospital outpatient setting contradicts CMS' efforts to provide adequate access and reimbursement for these life saving drugs. For the sake of CMS policy consistency, at a minimum, Wyeth urges CMS to continuing base reimbursement for clotting factor at no less than ASP+6% across various sites of beneficiary care and service.

Vaccines

Wyeth applauds CMS' proposal to continue reimbursing influenza, pneumococcal pneumonia, and hepatitis B vaccines at reasonable cost.

CMS recognizes there are often annual fluctuations in vaccine costs and proposes to continue reimbursing for life-saving vaccines such as flu, pneumococcal pneumonia, and hepatitis B at reasonable cost. Appropriate access is particularly important to more vulnerable populations, including many Medicare beneficiaries. We applaud CMS for having the foresight to recognize that variations in annual vaccine supplies and costs are possible and for proposing to reimburse at reasonable cost.

OPPS: Drug Administration

Wyeth commends CMS for promoting consistency and transparency across sites of service and payment systems by adopting CPT coding in OPPS.

For 2007, CMS is proposing to maintain the same CPT coding structure for drug administration services in the physician office and OPPS settings as in the 2006 OPPS final rule. The current drug administration structure and the proposed 2007 structure include six drug administration codes. While Wyeth applauds CMS' efforts to promote consistency here, we believe that in order for OPPS providers

[3] CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)

Wyeth

to realize the full benefit of this consistency, CMS should adopt all drug administrations CPT in the OPPS.

Conclusion

Again, Wyeth appreciates the opportunity to comment on the essential issues outlined in the **CMS-1506-P** (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates) proposed rule. We look forward to our continued partnership with CMS to ensure that Medicare beneficiaries receive appropriate access to life-saving and life-improving drug and biological therapies. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,

Matthew D. Eyles

Matthew D. Eyles

Submitter : Mr. Robert Reske **Date:** 10/10/2006

Organization : The University of Michigan Health Systems

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

We have attempted to submit our document and have not been successful with the transmission. We will overnite our document and continue to attempt to submit UMHS' comments electronically.

Thank you for your understanding.

Submitter : Ms. Margaret VanAmringe **Date:** 10/10/2006

Organization : Joint Commission on Accreditation of Healthcare Or

Category : Health Care Industry

Issue Areas/Comments

Transparency of Health Care Information

Transparency of Health Care Information

Transparency of Healthcare Information (Section XXII)
? CMS is seeking comment on their transparency initiative efforts to provide more comprehensive information on quality and costs to the public.

Joint Commission Comments:
The Joint Commission agrees that the healthcare consumer is best served by readily available quality and price/cost information. We support any approach that would serve this objective, but we believe that significant groundwork is needed before CMS undertakes any initiative to advance the transparency of quality and pricing data. Specifically, we believe the Secretary of DHHS must develop or adopt a standardized, consumer-friendly taxonomy with easily understandable definitions and sufficient explanatory information to make it useful to the average consumer. Additionally, such information must be captured within a system that ensures all providers report this data in a consistent manner.

CMS-1506-P-521-Attach-1.DOC

#521

Joint Commission
on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

October 10, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
CMS-1506-P
CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Hospital Outpatient Prospective Payment System (OPPS) and Fiscal Year 2007 Rates; Promoting Effective Use of Healthcare Information Technology (HIT); Healthcare Information Transparency Initiative, and; Reporting Hospital Quality Data for FY2008 Inpatient Prospective Payment System (IPPS) and Annual Update Program

The Joint Commission on Accreditation of Healthcare Organizations welcomes the opportunity to comment on the outpatient quality reporting, hospital inpatient quality reporting, and healthcare information technology (HIT) issues contained within the Outpatient Prospective Payment System (OPPS) proposed rule released August 23, 2006. Established in 1951, the Joint Commission is an independent, not-for-profit organization that evaluates and accredits nearly 15,000 healthcare organizations in the U.S. These include hospitals, laboratories, ambulatory care and office-based surgery facilities, and assisted living, behavioral healthcare, home care, hospice, and long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and licensure purposes across all of the Joint Commission's accreditation programs.

The Joint Commission is a recognized and award winning international leader with a long proven ability to identify, test and specify standardized performance measures. We engage in cutting edge performance measurement research and development activities, and have established successful, ongoing, collaborative relationships with key performance

measurement entities. Furthermore, the Joint Commission presides over a growing, national, comparative performance measurement database that can inform internal healthcare organization quality improvement activities, external accountability efforts, and pay for performance (P4P) programs.

Hospital Quality Data: Reporting Quality Data Under the OPPS (Section XX)

- Overall, the Joint Commission agrees that the absence of hospital outpatient quality measures for Medicare beneficiaries creates an "issue of payment equity." Indeed, improved quality reporting for all healthcare services, regardless of setting, should be a top priority for CMS. Increasingly, evidence supports the use of value-based purchasing mechanisms to promote higher quality and more efficient healthcare services.
- Section XX of the proposed rule, contains statements that the Joint Commission find confusing and, at times, conflicting. This made it difficult for us to determine the specific outpatient reporting requirements hospitals must undertake to receive the full conversion factor update[1]. After discussions with other stakeholders, the Joint Commission determined that there could be two distinct interpretations: (1) hospital outpatient departments must report the IPPS measures for outpatient discharges, to prevent a 2.0 percent reduction in their FY2007 OPPS conversion factor update, or; (2) hospitals that report all the IPPS measures for inpatient discharges will automatically receive the full FY2007 OPPS conversion factor update. Because the Joint Commission is not clear on CMS' intent, our comments will address both of these interpretations.

Joint Commission Comments: Option One - CMS Requires Outpatient Departments to Report

Any way you interpret Section XX of the proposed rule, it is certain that CMS will initiate a Reporting Hospital Quality Data for Annual Payment Update under the OPPS (OPPS RHQDAPU) effective January 1, 2007. However, under the first interpretation, hospitals that are required to participate in the IPPS RHQDAPU will need to report these same 21 IPPS measures under the OPPS RHQDAPU for their outpatient discharges, in order to receive the full FY2007 OPPS conversion factor update. If this is the correct interpretation,

[1] The conversion factor update is a combination of a market basket increase, as well as budget neutrality and outlier threshold adjustments.

the Joint Commission strongly encourages CMS to develop a mechanism to test the use of the inpatient measures for services that are delivered in outpatient settings. The Joint Commission believes that the introduction of measures to the outpatient arena, which were developed for inpatient services, should not be undertaken without sufficient reliability and validity testing. The authority under section 1833(t)(2)(E) of the Social Security Act to make "adjustments as determined to be necessary to ensure equitable payments" is not a sufficient argument to implement such a burdensome, untested mandate. Hospital outpatient departments will not be able to prepare for, and participate in, this reporting requirement in such a short period of time. Additionally, the Joint Commission is concerned that the diversion of resources needed for the proposed OPPS reporting might negatively affect the ability of hospitals to report all the HQA-approved IPPS measures, possibly negating the improvement potential of both.

As an organization that has worked on quality measures for decades, the Joint Commission strongly cautions CMS on the assumption that the use of inpatient measures "reasonably represent the quality of care provided to hospital outpatients." How accountabilities might map from the inpatient to the outpatient setting in the context of measurement is, at best, unknown without specific empiric testing. A specific example of this inpatient/outpatient incompatibility involves the acute myocardial infarction (AMI) population in the inpatient setting, which is identified by an ICD-9-CM principal discharge diagnosis of AMI. In this proposed rule, it is noted that the seven inpatient AMI measures will likely serve as reasonable proxies for the quality of patients presenting to the hospital outpatient department, with chest pain related to a myocardial infarction, who commonly receive care along the continuum. Currently these measures have never been tested to ensure that the population in the outpatient setting can be reliably identified using the same methodology and the specified ICD-9-CM codes, which do not include codes for chest pain. Furthermore, it is unclear how the inpatient measure exclusions applicable to all measures, would be applied in the outpatient setting.

The Joint Commission believes that a substantial amount of research and field input, similar to what was necessary for the development of the IPPS measure set, should be expended on any measures that will be applied to the outpatient arena. Anything less rigorous would most likely impede quality improvement efforts in the provider community, not

enhance them. Furthermore, CMS should seek to consolidate the various silos of measures into a single set that promotes patient-centeredness, episodes of care, the continuum of care, and disease management. There also needs to be a national measurement framework for establishing the priorities for outpatient measures. And, before the implementation of these outpatient measures, that CMS proposes would happen in 2009, some testing, dry run or pilot expansion process should be pursued previous to public reporting of the findings.

Joint Commission Comments: Option Two – IPPS Reporting Alters OPPS Payment

If it is the intent of CMS to simply use the evidence of IPPS reporting to influence the OPPS conversion factor update for FY2007 and FY2008, then the Joint Commission supports the extra incentive for hospital quality reporting. As noted in the proposed rule, not all hospitals are currently participating in the IPPS reporting system, and have had their IPPS payment updates reduced accordingly. It is imperative that all hospitals participate in this avenue for accountability and quality improvement. Thus, basing a portion of OPPS payment on whether hospitals report their IPPS measures is warranted.

Health Information Technology (HIT): Promoting Effective Use of HIT (Section XXI)

- CMS is seeking comment on their statutory authority to promote the adoption and use of HIT, possibly through hospital conditions of participation (CoPs).

Joint Commission Comments:

The Joint Commission commends CMS for utilizing this proposed rule as a vehicle to energize the public dialogue about HIT. CMS' leadership is crucial if we are to bring information technology into the healthcare industry in an efficient and effective manner. The creation of a comprehensive HIT infrastructure is integrally linked to healthcare quality and patient safety improvement efforts, and is critically associated with their success. Within this framework, an important role for quality oversight and quality improvement organizations, such as the Joint Commission, is to develop information management standards, to apply these standards, and to use these standards to promote the adoption of proper HIT systems. In accordance with its mission to improve patient safety and quality among the nation's healthcare organizations, the Joint Commission supports the evolution of an HIT

infrastructure where performance measurement becomes a natural derivative of the care delivery process. It is only under these circumstances that measurement requirements can continue to evolve without creating undue burden on healthcare organizations.

The Joint Commission further suggests that interoperability, which enables authorized users to capture, share, and report information from any system, is essential for improving healthcare and reducing medical errors, as well as for encouraging consumer choice and portability. The impetus for interoperability and the foundation of a national healthcare information network should be built on the six quality aims set forth in the Institute of Medicine's, *"Quality Chasm"* report (i.e., healthcare should be safe, beneficial, patient centered, timely, cost efficient, and equitable.) For HIT systems to be truly interoperable, the context and connotation of the data must be identical as it moves between networks. Achieving this universal definition will require a common set of policies, procedures and standards for data collection and documentation. Although a variety of systems presently exist, they do not use standardized data – making comparisons of data between these systems, nearly impossible. A set of public, non-proprietary standards would define the performance expectations, structures and processes that must be in place.

Any HIT implementation effort, a certification process must be in place for quality assurance purposes. A third party, independent certification process should be used to promote evidence-based standards and policies, monitor compliance to the standards; and update/add standards in the future. Any certification process should involve an ongoing-self assessment program. The certification process should also include an educational component to support the regional networks' performance improvement activities.

In this section, CMS also suggests that linking HIT standards with hospital conditions of participation (CoPs) may be a mechanism to promote HIT adoption. The Joint Commission is supportive of systematic mechanisms that promote the interoperability of HIT systems, and acknowledge that the development of a CoP is one possible approach. We believe, however, that the Medicare hospitals CoPs should undergo a comprehensive update that reflects the use of HIT to promote safe quality healthcare. Under this approach, the Joint Commission and CMS can partner to ensure that the cultural changes, necessary to achieve the widespread redesign of care delivery that must accompany HIT adoption, are implemented by our nation's hospitals. As we have noted in previous correspondence, the Joint

Commission strongly believes that the Medicare hospital CoPs need to be revised in their entirety to reflect how inpatient care is actually delivered. The Joint Commission recognizes the political expediency of using a piece-meal approach that "carves out" particular CoPs for revision. Unfortunately, such a method only increases the fragmentation in the delivery system and undermines a more over-arching focus on increasing the quality and safety of patient care in our nation's hospitals.

Transparency of Healthcare Information (Section XXII)

- CMS is seeking comment on their "transparency initiative" efforts to provide more comprehensive information on quality and costs to the public.

Joint Commission Comments:

The Joint Commission agrees that the healthcare consumer is best served by readily available quality and price/cost information. We support any approach that would serve this objective, but we believe that significant groundwork is needed before CMS undertakes any initiative to advance the transparency of quality and pricing data. Specifically, we believe the Secretary of DHHS must develop or adopt a standardized, consumer-friendly taxonomy with easily understandable definitions and sufficient explanatory information to make it useful to the average consumer. Additionally, such information must be captured within a system that ensures all providers report this data in a consistent manner.

FY2008 IPPS RHQDAPU: Additional Quality Measures and Procedures for Hospital Reporting of Quality Date for the FY2008 IPPS Payment Update (Section XXIII)

- This section CMS is proposing the implementation of HCAHPS, SCIP and 30-day mortality measures, part of the final set of quality measures required by the *Deficit Reduction Act of 2005*, and detailed in the April 25, 2006 IPPS proposed rule.

Joint Commission Comments:

The Joint Commission has been an integral participant in the Hospital Quality Alliance (HQA), in the development and assessment of the HCAHPS, Surgical Care Improvement Project (SCIP), and the 30-day mortality measures discussed in this section. Because of this, the Joint Commission would like to use this opportunity to focus on processes to ensure the validity and reliability of inpatient quality data. Earlier in the year, the Joint Commission provided comments to CMS on a specific statement within the IPPS proposed rule asserting that CMS was "to develop an infrastructure that would facilitate the efficient transmission and storage of data." In our comments, we informed CMS that this "is a confusing mandate, because clarification is needed as to where this database would reside (e.g., CMS, AHRQ, QIOs, private vendors, etc.), and who has oversight and is responsible for the infrastructure." The Joint Commission hopes CMS would consult with healthcare stakeholders before determining where the quality data is housed.

CMS also suggested in the proposed IPPS rule that data can be transmitted to the QIO Clinical Warehouse by performance measurement system vendors. While this is true - and essentially represents the current method by which Hospital Compare data are derived - CMS does not have any contractual relationship with performance measurement system vendors. Rather, only the Joint Commission has such contractual relationships in place and the majority of the data currently being transmitted through the QNet Exchange is derived from Joint Commission-listed vendors. The integrity of data being transmitted to the QIO data warehouse is an essential element for success. Because the proposed quality reporting and value-based purchasing process is entirely dependent on a third party, vendor without having a formal relationship with that party, we suggest CMS create a private-sector mechanism to leverage the reporting benefit the Joint Commission is providing through its vendors, especially respecting attention to the quality of the data. For many years, the Joint Commission has had in place specific requirements for these performance measurement system vendors against which they are evaluated annually in order to be deemed a "listed system". The Joint Commission also verifies and validates whether the vendors have successfully embedded the standardized performance measures in accord with specific technical requirements, and maintains an ongoing oversight process for the systems.

Submitter : Mrs. Elizabeth Schinina **Date:** 10/10/2006

Organization : Adventist Health

Category : Hospital

Issue Areas/Comments

OPPS

OPPS

Visits: In reference to CMS' proposal of establishing new codes for ED and clinic visits. Adventist Health strongly recommends that CMS wait to adopt new codes until the associated criterion has been finalized to distribute along with new codes.

We also would strongly urge CMS to work with the AMA to develop CPT codes specifically for hospitals for clinic and ED visits so the hospitals do not have to adopt new HCPCS codes for just the Medicare beneficiary. To maintain different code sets for different payers represents a burden to the hospitals.

In working with the AMA, we would suggest eliminating the critical care verbiage and assigning a code for a 6th level of care reflecting the hospital resources.

Adventist Health strongly disagrees with comments made by CMS that any critical care provided at less than the first 30 minutes should be billed at a lower level of care. Our prices have been set to reflect the level of care provided to the patient and reducing the level of care would not reflect our actual costs. Adventist Health recommends reversing this directive and allowing hospitals to charge for the critical care level when the criteria used to make that determination indicates the patient should be at this level of care. If CMS created a 6th level of ED/Clinic care and eliminated the critical care terminology, this directive would be debatable.

If CMS chooses to keep the critical care verbiage for hospitals and disregard the request to create a 6th level of care, then Adventist Health would like to recommend to CMS that the additional time for critical care, currently represented by 99292, be changed to a payable status and not remain as bundled. This level represents the highest level of care provided to a patient and a facility should be reimbursed for the additional time spent with a very labor-intensive patient.

Submitter : **Date: 10/10/2006**

Organization :

Category : **Hospital**

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

IV. Issue Identifier: "Device Dependent APCs"
1.) This year has been extremely challenging for pacemakers and defibrillators due to the complex and changing regulations surrounding device replacements, devices exchanged or upgraded as a result of a recall, token charges, device dependent edits, modifier FB, etc. All of these changes posed a tremendous burden for providers because of the impacts on hospital information systems, charge master files, encoding software, and billing systems. I am concerned with integrity of the data utilized to calculate the median cost data analysis and proposed 2007 APC payment assigned to defibrillator cases (G0297, G0298, G0299, G0300) for APCs 0107 and 0108. Our facility cost for defibrillators can range from $21,000 - $29,900.00. The 2007 national unadjusted payment for APC 0107 is $17,185.34 and for APC 0108 is $22,807.94. The reimbursement in the proposed payment for 2007 for the entire episode of care for these cases frequently does not even cover our facility's cost for the defibrillator device and leads. Errors in the integrity of the data collected or analysis of claims submitted during the many changes over the past 2 years could impact our reimbursement for these cases and many others.

OPPS: Drug Administration

OPPS: Drug Administration

V. Issue Identifier: "OPPS: Drug Administration"
1.) I couldn't locate CPT code 90768 for Concurrent IV Infusions in the proposed 6 APCs for drug administration services in 2007. Will this continue to be a status indicator of B for 2007?

2.) Currently there are OCE edits requiring vaccination procedure codes when reporting vaccines that prevent claims from being processed. Are these edits going to continue for 2007? Vaccinations administered on a nursing unit to surgical patients, observation patients, inpatients, etc. are typically not reported with a specific CPT / HCPCS code and is not charged. It's problematic and difficult to implement a process to report these codes. Would it be possible to remove the vaccines from the OCE edit that requires an associated administration code since this is a nursing service not typically captured on patients who have room and board charges or observation hours charged?

Submitter : Mr Smit **Date:** 10/10/2006

Organization : Mr Smit

Category : Individual

Issue Areas/Comments

Impact

Impact

good

Submitter : Dr. Dennis Holmes **Date:** 10/10/2006

Organization : Norris Cancer Center/USC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-525-Attach-1.DOC

#525

Office of The Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1506-P; Medicare Program; Hospital Outpatient Prospective Payment System (OPPS) and CY 2007 Payment Rates

Dear Administrator,

I appreciate the opportunity to share my comments on the Center for Medicare and Medicaid Services' proposed rule, which was published in the Federal Register on August 22, 2006. I would like to share my concerns regarding the proposed reduction of the RVUs by 4 units when CPT code 19296 is performed by the Surgeon in the Hospital as well as the proposed reduction of the conversion factor by 5.1%. Further the proposed APC reassignment for the hospital for CPT codes 19296 and 19297 from New Technology APC (1524 & 1523) to Clinical APCs (030 & 029) will impact services due to the cost of the device (catheter) not being adequately captured in the clinical APC payment rate.

By reducing the RVUs it will negatively affect my ability as a Physician to treat Medicare patients with this important procedure in the hospital. The current proposal will have the catheter priced higher than the clinical APC rate and this may lead the hospital to not offer this procedure to Medicare beneficiaries. I will not be able to provide Medicare patients with the benefits of partial breast irradiation due to the reduction of RVUs and the conversion factor. Access to this procedure for Medicare patients with breast cancer will be severely impeded due to the reduction of RVUs for the Surgeon and the reassignment of the APC from New Technology to Clinical. It is very important to provide this service to those women who are eligible for breast conserving surgery and who would benefit from Partial breast irradiation. CMS needs to preserve the RVUs and continue the assignment of the New Technology APC for an additional year.

I strongly recommend that CMS maintain the current RVUs for CPT code 19296 when done in the hospital and lessen the degree of reduction of the conversion factor as well. I also recommend that CMS maintain the designation of CPT codes 19296 and 19297 to the New Technology APC for the hospital for at least another year until further research is completed. This way you will not have a disruption of breast cancer services for Medicare patients.

I appreciate your careful review of this matter and strongly urge CMS to reconsider the significant impact the proposal may have for your Medicare beneficiaries. Thank you for your time.

Sincerely,

Dennis Holmes, MD

Dennis Holmes, MD
Breast Surgeon andDirector of New Technology Development
Breast Fellowship Program University of Southern California/
Norris Comprehensive Cancer Center and Hospital Chief, Breast Service, LAC+USC Medical Center
1441 Eastlake Ave
Los Angeles, CA 90033

cc: Senator Barbara Boxer, CA (D)
Senator Diane Feinstein, CA (D)
Congresswoman Hilda Solis CA (D)

cc: Carol Bazell, MD, MPH, Director, Division Outpatient Services

cc: American Society of Breast Surgeons
Helen Pass, M.D. President American Society of Breast Surgeons

cc: American College of Surgeons
Mark A. Malangoni, MD, Chair, American College of Surgeons

Submitter : A B **Date:** 10/10/2006

Organization : A B

Category : Individual

Issue Areas/Comments

Medicare Contracting Reform Impact

Medicare Contracting Reform Impact

test

Submitter : R Reske **Date:** 10/10/2006

Organization : Univ of MI Health System

Category : Hospital

Issue Areas/Comments

OPPS Impact

OPPS Impact

UMHS comments on OPPS CY 2007

CMS-1506-P-527-Attach-1.DOC

#527

University of Michigan
Hospitals and
Health Centers

Accounting and Reimbursement Services
2500 Green Rd. Suite 100
Ann Arbor, Michigan 48105-1500
734-647-3321
734-647-0026 Fax

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P; CMS-4125-P
P.O. Box 8011
Baltimore, MD 21244-1850

October 10, 2006

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule
CMS-1506-P; CMS-4125-P
Federal Register Dated August 23, 2006

The University of Michigan Health System (UMHS) welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services regarding the proposed rule to update the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates.

Indirect Medical Education Adjustment

With the implementation of an Indirect Medical Education (IME) adjustment in the Inpatient Rehabilitation Facility prospective payment system (PPS) in the fall of 2006 each Medicare PPS except the Outpatient Prospective Payment System (OPPS) contains an IME adjustment factor. UMHS believes that the reasons cited by the Center for Medicare and Medicaid Services (CMS) as support for an IME adjustment for the Inpatient Prospective Payment System (IPPS) also apply to the OPPS. An IME adjustment is needed to reimburse providers for the higher costs incurred by major teaching hospitals to provide outpatient care services to Medicare beneficiaries. The CMS analysis titled "Impact of Proposed Changes for CY 2007 Hospital OPPS" projects that major teaching hospitals will be required to address the 23% shortfall to the market basket update ((2.6% - 3.4%)/ 3.4%).

UMHS recommends CMS implement an IME adjustment to the OPPS system as part of the CY 2007 payment rate updates.

Visits - Proposed Hospital Coding and Payments for Visits (Page 49,604)

The evaluation and management (E&M) codes are designed to record the physician activities and as a result do not provide the range and mix needed by hospitals to capture the activities performed during an encounter. As a result of the deficiency with the E&M codes, CMS has encouraged hospitals to use their internal guidelines (based on hospital resource use) to establish the CPT level code to report. UMHS believes that the CMS approach has resulted in coding inconsistencies between hospitals. In the proposed rule, CMS discusses its objective to implement national coding guidelines and the barriers to doing so, and concludes that national guidelines will not be implemented prior to calendar year 2008 because of its commitment to provide hospitals 6 – 12 months notice prior to implementation.

CMS specifically references the existing reimbursement limitation resulting from only three payment levels and proposes an expansion to five payment levels for calendar year 2007. CMS goes on to describe its intent to implement a coding system that will establish different reimbursement levels between new and established patients as well as differentiate between standard visits and consultation.

UMHS supports CMS' objective to implement national guidelines in an orderly yet timely manner that will reimburse hospitals for the efficient and effective provision of visits in hospital outpatient settings.

Wage Index (Page 49,539)

CMS believes and the UMHS agrees that using the IPPS wage index as the source of the adjustment factor for OPPS is a reasonable approach, given the integrated approach to the delivery of health care practiced at UMHS. The IPPS 2007 final rule (August 18, 2006 Federal Register page 48029) set the labor component at 69.7% of the DRG payment.

It is the UMHS' understanding that the data used to set the IPPS labor related adjustment factor does not separate inpatient and outpatient compensation. Therefore, UMHS believes that the IPPS labor related adjustment should be used by CMS to determine the reimbursement for outpatient services. At a minimum, UMHS requests that the OPPS labor-related share for 2007 be updated from the initial OPPS proposed rule of 60% (63 FR 47581, September 8, 1998), and be set at 63%, the labor-related percentage referenced by CMS in the preamble to both Table 5 and Table 6 of the 2006 OPPS final rule.

UMHS requests CMS to revise the 2007 OPPS labor related share from 60% currently proposed to 69.7%, consistent with the 2007 IPPS final rule.

Outlier Payments (Page 49,546)

With the 2006 OPPS final rule CMS set the size of the OPPS outlier pool at 1% of expected OPPS payments. In the 2007 OPPS proposed rule CMS proposes, for an

outpatient service or procedure performed by a hospital to qualify for an outlier payment, the cost of the procedure or service must exceed the OPPS reimbursement by 1.75 times plus $1,825 (the CMS set outlier fixed-dollar threshold). The hospital having incurred the outlier fixed dollar threshold would qualify for an outlier payment of 50% of the difference between the cost of the service and the computed payment for the service.

UMHS continues to believe that outpatient services that qualify for outlier payments should receive reimbursement at 80 percent of its costs above the threshold, rather than the current level of 50 percent. While teaching hospitals would incur significant non-reimbursed costs, increasing outlier reimbursement would help ameliorate the level of these losses that provide complex outpatient services. Increasing outlier reimbursement to 80% of provider cost would also make the OPPS outlier reimbursement policy consistent with the IPPS policy.

CMS proposes that for 2007, hospitals incur a 46% increase of $575 above the 2006 outlier fixed payment threshold before qualifying for outlier reimbursement. UMHS is concerned that the loss in reimbursement resulting from the increase in the outlier fixed payment threshold will be borne disproportionately by major teaching hospitals including UMHS. Analysis of 2004 and 2005 data demonstrates that outlier payments as a percent of total OPPS payments are substantially greater for major teaching hospitals than non-teaching hospitals. The concern that major teaching hospitals will suffer the majority of the proposed reduction in reimbursement was reinforced as a result of CMS not providing any analysis that would support the 46% increase in the outlier fixed dollar threshold.

UMHS recommends that CMS retain the outlier fixed payment threshold at the 2006 amount of $1,250. Further, UMHS recommends that CMS not implement an increase to the outlier fixed dollar threshold until CMS has published its conclusions and received public comments on its analysis.

Inpatient-Only Procedures (Page 49,621)

Under the Medicare regulations, providers that perform a procedure on an outpatient basis that is referenced on the Inpatient-Only procedure list, will not be reimbursed for that procedure.

CMS proposes that eight procedures would be removed from the Inpatient-Only Procedure list and therefore those procedures would qualify for OPPS reimbursement in 2007. CMS also requests hospitals review the procedures that remain on the list and as part of this comment process recommend those procedures that they feel appropriate for removal.

UMHS supports the reduction of procedures on the Inpatient-Only Procedures list. In addition UMHS believes that the determination of care and its setting (inpatient or outpatient) should reside with the physician and therefore believes that health systems that elect to perform the Inpatient-Only procedures that remain on the list should be reimbursed for the service.

Assuming the Inpatient-Only Procedure regulation is not rescinded in the 2007 OPPS final rule, these additional procedures are offered for CMS consideration for removal as part of the final rule.

CPT / HCPCS	Description
37182	Insert hepatic shunt (tips)
45563	Exploration/repair of rectum
61624	Occlusion / embolization cath

Myocardial PET Scans (Page 49,566)

CMS proposes that the reimbursement for the Positron Emission Tomography (APC 0307) be reduced from $2,484.88 in calendar 2006 to $721.26 for 2007. CMS cites the reason for the $1,763 (70%) proposed reduction: *"as myocardial PET scans are being provided more frequently at a greater number of hospitals than in the past, it is possible that most hospitals performing multiple PET scans are particularly efficient in their delivery of higher volumes of these services and, therefore, incur hospital costs that are similar to those of single scans, which are provided less commonly".*

UMHS recommends that CMS not implement the proposed 70% reduction until CMS has performed a comprehensive analysis of the appropriate reimbursement rate and received public comments on that analysis.

OPPS: Drug Administration (Page 49,599)

In 2005, CMS transitioned from using daily per visit drug administration Q codes to CPT codes. In the 2006 final rule, CMS implemented 20 of the 33 new 2006 CPT codes for drug administration. The 13 CPT codes that were not implemented included concepts such as initial, subsequent and concurrent administration, which were operationally problematic for hospitals to report. CMS instead created six HCPCS C codes that generally paralleled the 2005 CPT codes for the same services.

While hospitals were grateful for CMS' responsiveness to their concerns regarding the operational difficulties of implementing the full range of 2005 CPT codes for drug administration services, they nevertheless had to implement these CPT codes for non-Medicare payers. As such, hospitals have had to overcome those operational challenges while implementing two sets of codes for reporting certain drug administration services, depending on the payer.

UMHS recommends that in 2007, CMS implement the full set of CPT drug administration codes and eliminate the six HCPCS C codes created to parallel the 13 drug administration codes that were not implemented in 2006. This policy change eliminates the burden of having to apply and maintain two sets of codes for essentially the same services.

In addition, in 2005 and 2006 CMS provided special instructions to hospitals for the use of modifier 59 in order to ensure proper outpatient PPS payments, consistent with their claims processing logic. Since CMS did not expect any changes to coding structure for 2007, and because the agency has updated service-specific claims data from 2005, CMS no longer needs specific drug administration instructions regarding modifier 59. **UMHS supports CMS' proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other outpatient PPS services.**

CMS also proposes six new APCs in 2007 that are intended to better distinguish costs related to infusions of different types and furnished over different lengths of time. Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However, in 2005, codes used in the outpatient department distinguished between the first hour of infusion and additional hours of infusion. Using newly available 2005 claims data, CMS proposes to assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data. **UMHS supports CMS' proposal to create six new drug administration APC levels which will provide more accurate payment for complex and lengthy drug administration services.**

Additionally, as part of the implementation of new drug administration codes in 2006, CMS decided to no longer allow for the reporting of separate IV pushes of the same drug. This coding instruction created a situation in which no payment is made for packaged drugs that are given as separate IV pushes. The prime example is pain management where a patient may require multiple IV pushes of morphine, but only one drug administration code could be reported. Because morphine is a packaged drug, not only would the administration services involved in the subsequent IV pushes of morphine not be reimbursed, the drug itself would not be paid. UMHS does not believe CMS' intent was to discontinue payment for this drug when it is medically necessary. **UMHS recommends that CMS make payment for a second or subsequent IV push of the same drug** by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in 2007 so that an appropriate payment is made for this service.

Further, UMHS also recommends that CMS allow providers to use all available HCPCS codes for reporting drugs to reduce the administrative burden associated with reporting drugs using only HCPCS codes with the lowest increments in their descriptors.

OPPS: Observation Services (Page 49,620)

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. UMHS continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are

separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid. **Therefore, UMHS recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.**

Summary

Outpatient departments and clinics are critical components of teaching hospitals and the 2007 OPPS rule has a number of proposed changes that should be considered prior to implementation. Please contact me at (734) 647 2579 should you or your staff have any follow up questions.

Thank you again for your consideration of these comments.

Cordially,

Robert Reske

Robert Reske
Hospital Financial Services
University of Michigan Hospitals and Health Centers

Submitter : Mrs. Charlotte Buscher **Date:** 10/10/2006

Organization : University Medical Center

Category : Hospital

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

My hospital is an acute care hospital that provides inpatient and partial psychiatric services to a large rural area. This area is underserved by psychiatry and the partial program is a very needed level of care. The proposed rate cuts totalling 27.5% over a two year period have a very real potential to eliminate the partial program level of care. This loss will create a greater number of patients that will have to be served on a more costly inpatient basis who may have been served in the partial level. Outpatient appointments are few and far between due to the lack of services and the partial program helps to intervene to avoid more costly treatment. This also impacts the use of the medical benefit side of CMS dollars. It is proven that timely, appropriate mental health services for those who need it reduce the need for more costly medical visits and procedures. Everyone loses if this rate cut goes forward. A system needs to be developed for reimbursement based on realistic numbers that will allow a program to cover its costs.
I also serve on the board of the Association of Ambulatory Behavioral Healthcare and our association has sent in a request to relook at the payment methodolgy with providers and community organizations. Working together we feel that a fair payment rate can be accomplished and the partial hospital benefit preserved for the elderly and disabled that need it the most. Please consider the lives that will be affected by this change and the ultimate costs to our nation.

Submitter : **Date: 10/10/2006**

Organization :

Category : **Private Industry**

Issue Areas/Comments

OPPS: Drug Administration

OPPS: Drug Administration

See Attachment

OPPS: New HCPCS and CPT Codes

OPPS: New HCPCS and CPT Codes

See Attachment

CMS-1506-P-529-Attach-1.DOC

#529

GRIFOLS

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October 11, 2006

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

RE: CMS-1501-P
Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates" (71 Fed. Reg. 49506; hereinafter referred to as the OPPS Proposed Rule). CMS is to be lauded for its use of market-based payment methodologies across both the physician office and hospital outpatient clinic sites of service. Market-based reimbursement methodologies such as average sales price (ASP) offer many advantages over other methodologies. However, the implementation of a market-based methodology is not, in of itself, adequate to assure access to all drugs and biologics. As outlined more fully below, Grifols is concerned that proposed payment rates for intravenous immune globulin (IVIG) is not adequate to address current access problems associated with this life-saving biologic therapy.

Grifols believes that in order to restore access to all brands of IVIG, CMS must:

- **Continue the preadministration service fee throughout 2007,**
- **Establish separate HCPCS codes for each brand of IVIG,**

Grifols is a major producer of plasma therapies including hemophilia blood clotting factors, IVIG, human serum albumin and others. While we are concerned generally with the adequacy of the OPPS proposed payment rates, our comments relate primarily to IVIG. This is because from among those therapies we produce, IVIG is most often administered in the outpatient setting. More importantly, IVIG has been the subject of numerous reports of patient access problems since the implementation of the ASP payment methodology in the outpatient setting.

Establish Separate HCPCS Codes for Each Brand of IVIG

As noted above, Grifols applauds CMS for the use of ASP as a benchmark for payment rate setting. However, the current practice of including more than one IVIG preparation under a single HCPCS code will continue to exacerbate ongoing access to care problems. This is the result of the fact that the calculation of ASP across different branded therapies results in a payment rate that is below many of the products within the HCPCS code. Further the bundling of multiple branded therapies within a single HCPCS code makes all products in the class susceptible to anomalous market circumstances.

On December 15, 2004 Grifols submitted a request for a separate HCPCS code for our proprietary IVIG preparation, Flebogamma ®5%. The basis for this request was the unique formulation of Flebogamma®. Unlike other IVIG preparations, Flebogamma® is produced using sorbitol as a stabilizer rather than glucose, sucrose, or maltose. As a result, Flebogamma® has an adverse event risk profile different from other IVIG preparations with respect to the incidence of renal failure, stroke, and myocardial infarction. Grifols also presented its case for a separate HCPCS code at the June 14, 2005 HCPCS public meeting. This request was denied without explanation.

The selection of stabilizer in the production of IVIG is just one of many factors that dictates the unique biochemical profile of each branded IVIG preparation. Other characteristics that impact product tolerability include: volume load, osmolarlity, IgA content, and pH. Depending on the patient's individual health profile, one or more of these product characteristics may determine which product is most clinically appropriate. Thus, one patient may have an adverse reaction to one product that another patient tolerates perfectly well. Consequently, the process of selecting the appropriate product is often one of trial and error. Because of this unique patient and product matching it is important that access to all products be maintained free of artificial economic influences.

Establishing separate HCPCS codes based on national drug code (NDC) numbers will help maintain access to all brands of therapy because it would assure that the ASP benchmark is appropriate for each product. Under the current bundling schema, where multiple therapies are included in a single HCPCS code, the published ASP is too low to cover the acquisition costs of many products included in that code. As a result, affordability becomes an access limiting factor and ultimately can contribute to suboptimal clinical care.

CMS already has acknowledged that important distinctions exist among IVIG preparations by establishing separate HCPCS codes for liquid and lyophilized IVIG preparations (J1566 and J1577, respectively). While the distinction between liquid and lyophilized IVIG preparations is an important factor in terms of convenience and ease of preparation, it is clinically less significant that the chemical properties listed above.

Simply dividing IVIG products by liquid and lyophilized class does not go far enough to assure access to each branded therapy.

Moreover, establishing a separate HCPCS code for each branded therapy will not increase CMS total payments for IVIG. This is because the current ASP is a volume weighted average. By separating the HCPCS codes and multiplying the brand specific ASP by brand specific claims volume, the total spend for IVIG is equivalent to multiplying the total claims volume by the volume weighted average ASP. Thus, from an economic standpoint there is no benefit to bundling HCPCS codes for IVIG.

Finally, IVIG is one of very few therapies where branded products are bundled under a single HCPCS code. CMS standard practice is to establish separate HCPCS codes for each unique therapy. Notwithstanding the clinical and economic reasons, simply as a matter of policy, CMS should de-bundle the HCPCS codes for IVIG and establish a brand specific ASP payment method for each approved therapy.

Continue the Preadministration Service Fee Throughout 2007

As you are aware, in 2005 CMS established an IVIG preadministration fee of $75.00 in the hospital setting and $69.00 in the physician office setting. However, the OPPS Proposed Rule eliminates the preadministration service fee for 2007. The rationale for eliminating the preadministration service fee is vague at best; the OPPS Proposed Rule states simply that the fee "would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG." 71 Fed. Reg. at 49604.

The preadministration service fee payments were established to cover many of the unique expenses associated with acquiring IVIG. Some of the expenses to be covered included:

- monitoring and managing inventory,
- locating available IVIG products,
- rescheduling infusions according to product availability and patient need,
- implementing physician decisions regarding whether available formulations are appropriate for patients, and
- determining whether specific dosing adjustments are required.

70 Fed. Reg. 68649 (November 10, 2005). Further, in the 2006 OPPS Rule CMS stated that:

> [D]ue to the present significant fluctuations in the IVIG marketplace [the preadministration service fee] will ensure that Medicare beneficiaries depending on IVIG experience no adverse health consequences from the market instability for IVIG products.

70 Fed. Reg. at 68650. There is no evidence to suggest that these same conditions do not exist today. In fact, there is more concern about patient access to IVIG today than

ever before. Since implementation of the 2006 OPPS Rule IVIG access problems have been the subject of:

- an ongoing investigation by the Department of Health and Human Services (HHS) Office of the Inspector General (OIG),
- the initiation of a new access study by the HHS Assistant Secretary for Planning and Evaluation,
- a Congressional hearing by the Health Subcommittee of the House of Representatives Committee on Ways and Means.

In addition, numerous letters from members of Congress have been sent to HHS Secretary Leavitt and CMS, requesting that action be taken to alleviate reported IVIG access problems.

In light of this level of concern regarding IVIG access it is surprising that CMS would eliminate the preadministration service fee absent some compelling rationale. However regrettable, the fact remains that at present the elimination of the preadministration service fee would likely serve to further disrupt the IVIG marketplace. Continuation of the preadministration service fee is an integral part of assuring continued access to IVIG for the patients who rely on it.

Conslusion

Based on the foregoing, we respectfully request that CMS establish separate HCPCS codes for each brand of IVIG and continue the preadministration fee throughout 2007. These measures are essential to assuring continued access to IVIG and mitigating some of the patient access problems reported over the last eighteen months.

Thank you for the opportunity to comment on the 2007 OPPS Proposed Rule. If you have any questions about these comments or the information contained herein, please feel free to contact me.

Respectfully Submitted,

Christopher Healey
Vice President, Government and Public Affairs
Chris.healey@grifols.com

Submitter : **Mr. Tom Daulton** **Date: 10/10/2006**

Organization : **Mr. Tom Daulton**

Category : **Device Industry**

Issue Areas/Comments

OPPS Impact

OPPS Impact

See attached PDF.

CMS-1506-P-530-Attach-1.PDF

#530

Denver®
BIOMEDICAL

14998 W. 6th Ave., Bldg E-700
Golden, CO 80401

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-8011

RE: CMS-1506-P
Reassignment of CPT 32019 to APC 0652

Dear Sir or Madam:

We are Denver Biomedical, Inc. (DBI). We are a Colorado corporation and currently employ about 40 workers. We manufacture clinically-proven, patented Pleurx Pleural Catheters, Drainage Kits, and Vacuum Drainage Bottles used for the drainage of symptomatic, recurrent, pleural effusions and malignant ascites. We respectfully submit our comments to the proposed rule regarding the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates (CMS-1506-P), which was published on August 23, 2006 (71 Fed. Reg. 49506).

Specifically, we support and appreciate the proposed decision by the Centers for Medicare and Medicaid Services (CMS) to reassign CPT 32019 (insert pleural catheter) to APC 0652 (insertion of intraperitoneal catheters). Last year, we commented that CPT 32019 should be reassigned to APC 0652. CMS responded that it would examine the claims data for CPT 32019 because this code was new for CY 2004. We are grateful that CMS kept its word.

On behalf of over 40 hard-working families of DBI, we thank you for the opportunity to comment on the proposed rule. We hope that CMS will adopt this proposed change.

Sincerely,

Tom Daulton
Vice President and General Manager

Tel: (303) 279-7500 Toll Free: (800) 824-8454 Fax: (303) 279-7575 www.denverbiomedical.com

Submitter : Mr. Michael McAnder **Date:** 10/10/2006

Organization : Banner Health

Category : Hospital

Issue Areas/Comments

Visits

Visits

Please see attachement

CMS-1506-P-531-Attach-1.DOC

#531

Banner Health®

1441 North 12th Street, Phoenix, AZ 85006
602-495-4000
BannerHealth.com

October 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

VIA Electronic Mail - Original to follow via U.S. Post
http://www.cms.hhs.gov/eRulemaking.

RE: CMS-1506-P, Medicare Program: Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Federal Register, 49506, August 23, 2006.

Banner Health, a multi-hospital health care system that operates 20 hospitals in addition to other health care facilities, in 7 states, appreciates this opportunity to comment on CMS' Proposed Rule for the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates that was published on August 8, 2006. Specifically, Banner Health would like to comment on that portion of the rule related to the *CY 2007 Proposed Treatment of Guidelines* (49615-49614).

CY 2007 Proposed Treatment of Guidelines (49615-49614)

CMS proposes to implement a new set of 17 "G" codes to replace existing Evaluation and Management (E/M) codes to report hospital clinic visits and ED visits, effective January 1, 2007. However, CMS has indicated that it will not provide standardized, national coding guidelines to complement these new temporary codes, and that hospitals should use their existing internal guidelines to determine the level of service code for reporting, until such time as national guidelines for coding are implemented by CMS.

In the interim, CMS is requesting comments on the June 2003 version of the AHA/AHIMA Recommendation for Standardized Hospital Evaluation and Management Coding of Emergency Department and Clinic Services, as well as CMS' June 1, 2006 modified version of these recommended coding guidelines, in anticipation of future adoption of a refined version of these guidelines by CMS. The deadline for these comments as set forth in the proposed rule is October 10, 2006.

While CMS has requested comments on 8 specific areas of the AHA/AHIMA version of the coding guidelines, we found it impossible to provide reliable comment in each of the areas listed in the proposed rule, given the relatively short time-frame allowed for review and analysis of these complex, detailed documents, and the time required to obtain the needed input from all of the clinical and administrative areas at Banner Health that would be impacted by these guidelines. Thus, we concentrated our review on CMS' modified version of the guidelines, and limited our comments to the following areas:

Inappropriate Alignment of Interventions with Visit/ Acuity Levels: Listed interventions are not consistent with the level of clinical resource consumption, skill, risk, and time that would logically be associated with many of the levels of service. It is our overall impression that many of the interventions are undervalued and would result in a decrease in reimbursement for our services. We estimate that these guidelines, adopted in their current form, would result in a 40% decrease in revenue for our ED services alone.

For example, under Level 1 ED Interventions, "Tracheal suctioning via tracheostomy" is a procedure carrying a much higher risk (e.g. risk of hypoxia or cardiac dysarrhythmia), and thus a higher level of resource/skill/time than would logically be associated with a level 1 service. "First aid procedures" also under Level 1 ED Interventions, lists external body cooling or warming as an example of an intervention that qualifies for a Level 1 service. This again would represent an undervalued service in that external body cooling or warming is usually performed on hyperthermic or hypothermic patients – those that will require the application of special cooling blankets or warming of IV fluids and other treatment fluids. These interventions would clearly be appropriate for a higher level acuity patient and would require greater resources/time than would typically be associated with the lowest level of ED services.

Lack of Clarity of Interventions: There was no explanatory guidance for several of the interventions, which were in and of themselves, not well defined. For example, Level 1 ED Intervention, "Measurement/ Assessment of fetal heart tones" does not have a corresponding explanatory note. Does this intervention include monitoring of FHTs as well? If so, a higher level of service/acuity/skill/time would be more appropriate. We believe that more and better definitions of the interventions that comprise the proposed service levels are necessary to ensure accurate and consistent coding.

Complexity of Guidelines/Impact on Costs: The inherent complexity of the methodology proposed (i.e. "counting" interventions, assessing contributory factors) would increase the administrative time required to properly "code" the visit levels – nursing staff would no longer have the time necessary to accurately code/charge clinic/ED services. Should the final version of the clinic visit/ED coding guidelines follow the structure and methodology of the proposed versions, each of our facilities will be forced to increase staffing to accomplish appropriate coding of these services, thereby increasing our costs.

While we commend CMS for pursuing the development of a set of national guidelines that can be applied to a consistent coding methodology for hospital clinic and ED visits, we feel that the current models supplied for comment at this time are too complex and do not reflect clinically logical criteria consistent with incremental levels of service provided in these settings. It is our position that this model will require further and significant analysis and revision in order to serve as a legitimate guide to compliant coding and charging of hospital visit services.

Should CMS reconsider extending the timeline for accepting comments on these model guidelines, Banner Health would like to conduct a more thorough and inclusive review of the model guideline documents and be afforded the opportunity to expand upon our comments here, to assist CMS with the development of a viable system for determining the appropriate coding of hospital clinic and ED visits.

Thank you for providing us with an opportunity to respond to the proposed changes. If you should require any clarifications or further information, please feel free to contact Paul Dzurinda, System Director of Reimbursement, at 602-747-4157.

Sincerely,

Michael McAnder
Vice President, Systems

cc: Paul Dzurinda

Submitter : Mr. John McClanahan **Date:** 10/10/2006

Organization : Cochlear Americas

Category : Device Industry

Issue Areas/Comments

Device-Dependent APCs

Device-Dependent APCs

Cochlear" Americas, the world s largest manufacturer and distributor of cochlear implants, welcomes the opportunity to comment on CMS proposed rule, CMS-1506-P. Cochlear Americas appreciates the considerable effort put into the development of the outpatient prospective payment system (OPPS).

If adopted as proposed, payment for cochlear implantation (APC 0259; 69930; L8614) in calendar year 2007 would increase by 7%, which would augment payment for the procedure to $25,040. While we are grateful for the proposed increase this year, this would still result in payment below the 2005 OPPS payment level of $25,307 at a time when the actual device and procedure costs have continued to rise.

In an effort to better understand the OPPS process as it affects cochlear implantation, Cochlear Americas and Med-El Corporation, another cochlear implant manufacturer, each independently commissioned The Lewin Group to evaluate the effect of charge compression on Medicare payment rates for cochlear implantation devices and systems. Each of the three cochlear implant manufacturers also sent confidential average selling price information to Lewin so that an industry-wide average sales price for 2005 could be computed.

Using this confidential company data, Lewin determined that the average industry selling price for the cochlear implant device in 2005 was $24,342, which was up from $21,827 the prior year. An analysis of OPPS claims data conducted by Boston Scientific determined that the hospital facility fee for cochlear implantation in 2005 was $6,328. Hence the full procedure cost was $30,670, or $5,630 below the proposed payment OPPS level in 2007.

The Lewin Group was tasked with exploring the extent to which the proposed payment for APC 0259 (Level VI ENT, or cochlear implantation) is impacted by charge compression. Specifically Lewin explored whether hospital charge patterns for implanted cochlear devices for Medicare patients were inconsistent with charging patterns for other hospital products and services and what the impact was on Medicare payment rates. Lewin reviewed other device-dependent APCs (defined as when the device represents at least 80% of the APC). Ten such APCs were found and examined. Hospital charge patterns for implanted cochlear devices were found to be most inconsistent with charging patterns for other lower cost hospital products and services in the inpatient and outpatient setting. Charge compression for higher cost devices, compared to other items and services, were found to be the major reason. A copy of the Lewin study is attached to this submission. Cochlear Americas recommends the following:

(1) Due to the major impact of cost compression on cochlear implantation, we request that CMS supplement its claims data with sales information in computing the OPPS payment level for cochlear implantation. We suggest that a payment level of $30,670 would better reflect the actual cost of the device and procedure in the outpatient setting.

(2) We appreciate CMS efforts to address payment levels. Nonetheless, the existing environment in which payment has remained flat in the face of rising costs have made access to cochlear implantation increasingly difficult for the Medicare population. Few cochlear implant centers have opened in recent years, and existing centers must serve not only new patients but also the prior patient base which requires ongoing after surgical care a unique element of the cochlear implant procedure. The cost compression issue prevents hospitals from covering their minimum costs, which translate into losses and ultimately into reduced access for Medicare beneficiaries. CMS should study the issue in depth and conduct educational activities for hospitals aimed at the impact of cost compression on payment. Thank you for your attention and consideration in this matter.

Submitter : Ms. REBECCA THERIOT **Date:** 10/10/2006

Organization : LOUISIANA STATE UNIVERSITY

Category : Nurse

Issue Areas/Comments

OPPS Impact

OPPS Impact

THE DECISION TO CONTINOUE TO DECREASE COVERAGE TO THE MENTALLY DISABLED IN OUR SOCIETY IS A CONTINOUED ASSAULT ON THE MENTALLY DISABLED THAT ORIGINATED WITH THE DECISION FOR DEINSTITUTIONALIZATION.

HAVING WORKED IN THE MENTAL HEALTH ARENA IN BOTH INPATIENT AND OUTPATIENT FOR OVER 20 YEARS I HAVE LIVED THROUGH THE SHIFT OF MOVING OUR CHRONICALLY MENTALLY ILL FROM STATE INSTITUTIONS BACK INTO THE COMMUNITY.

I HELD MANY A PATIENT AS THEY CRIED ON MY SHOULDER BECAUSE THEY JUST WANTED TO GO HOME AND THE STATE HOSPITALS WERE THEIR HOMES.

BUT WE ARE A HUMAN SOCIETY AND WE TOLD OUR MENTALLY DISABLED THEY WOULD BE BETTER OFF BACK IN THE COMMUNITY. THIS MAY BE TRUE, BUT THE SYSYTEM FAILED TO PUT ALTERNATIVE HELP IN PLACE IN THE COMMUNITIES TO CARE FOR THE CHRONICALLY MENTALLY ILL.

NOW THAT THE SYSTEM BOTH PRIVATE AND PUBLIC HAS MADE GAINS IN PUTTING PROGRAMS IN PLACE TO ASSIST THESE CHRONICALLY MENTALLY ILL TO FUNCTION AND HAVE A QUALITY OF LIFE IN THE COMMUNITY, ONCE AGAIN THE fEDERAL GOVERMENT IS MAKING CHANGES THAT DECREASE THE AVAILABLE SUPPORT OF THESE INDIVIDUALS.

THE PATIENTS I SEE IN PHP AND OUTPATIENT PROGRAMS ARE THE SAME PATIENTS, THE CHRONICALLY DISABLED THAT IN 1984 WE ADMITTED TO THE STATE HOSPITALS FOR EXTENDED PERIODS OF TIME.

IT WAS WELL UNDERSTOOD BY THE PSYCHOLOGIST, PSYCHIATRIST,SOCIAL WORKERS, THERAPIST, AND NURSING STAFF at that time, that even at their highest base line that these patient's of ours, these ehronically mentally disabled, would always need help in the community.

That said, to decrease the funding is just another insult to those vulnerable populations in our society that need those of us in health cares help.
Where will these patients go this time?
Will the goverment fund and reopen the state beds? Will they just be homeless people left with no treatment and no quality of life.

The CMHC Act was put inplace specifically to address the mandate to deinstutionalize the chronically mentally ill.
Has everyone after 40 years forgotten that?

SO if the goverment is now going to change the CMHC act's mandate does that mean we will go back to institutionalizing our chronically mentally ill?

Sincerely
A Psychiatric Nurse Advocate
R Theriot RN, MSN

Submitter :

Date: 10/10/2006

Organization :

Category : Individual

Issue Areas/Comments

Policy and Payment Recommendations

Policy and Payment Recommendations

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