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PhRMA

September 12, 2007

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

Acting Administrator Kerry Weems
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 1392-P; Comments Regarding the Proposed Hospital Outpatient Prospective Payment System Rule for Calendar Year 2008**

Dear Mr. Weems:

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 2008.[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. As a consequence, we are particularly concerned with two proposals in the CY 2008 Proposed Rule:

1) CMS' proposal to reimburse specified covered outpatient drugs (SCODs) at a payment rate of Average Sales Price (ASP) + 5 percent:

PhRMA is concerned that this payment may not cover hospital handling and acquisition costs and could therefore jeopardize beneficiaries' access to needed drugs. The Proposed Rule presents no new information suggesting that there is greater understanding of or confidence in the accounting of pharmacy overhead costs than in past years, or that an ASP + 5 percent

[1] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007) (the Proposed Rule).

payment rate would cover hospitals' acquisition costs for SCODs which was rejected in past years. CMS should therefore maintain the current ASP + 6 percent payment rate.

2) CMS' proposal to package all "diagnostic" radiopharmaceuticals and contrast agents.

This proposal is inconsistent with the rationale supporting CMS' packaging threshold approach for separately payable drugs in the OPPS and could result in underpayment for important radiopharmaceuticals and contrast agents.

Our detailed comments on the proposed rule are set out below.

* * *

A. Proposed Payment for Specified Covered Outpatient Drugs (SCODs)

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] By statute, payment for SCODs in CY 2006 and subsequent years must equal 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]

Although CMS currently pays for SCODs at ASP + 6 percent, CMS proposes a CY 2008 payment rate of ASP + 5 percent. CMS arrived at this figure using the same data analysis methodology that it employed in last year's proposed rule (and then rejected in the final rule). This method compares two sources of data: ASP data from the fourth quarter of CY 2006 and mean costs derived from the CY 2006 hospital claims data.[4] 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."[5]

CMS did not finalize the ASP + 5 percent rate in CY 2007. Instead, CMS decided "after carefully considering all comments and the recommendations of the APC [Ambulatory Payment Classification] panel, [to accept] the Panel's recommendation to continue to pay for separately payable drugs, biologicals, and their associated pharmacy handling in the hospital outpatient department for CY 2007 at a combined rate of ASP + 6 percent . . ."[6] The reasons that CMS

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2 Social Security Act (SSA) § 1833(t)(14)(B)(i). SCODs do 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 72 Fed. Reg. at 42736.

5 Id.

6 71 Fed. Reg. 67960, 68091 (November 24, 2006).

maintained the ASP + 6 percent rate for CY 2007 are as follows (as stated in the CY 2007 OPPS final rule):

- Although CMS' "final rule analysis indicated an average ASP-based payment of ASP + 4 percent [for separately payable drugs and biologicals]," CMS noted that this was "the same relative ASP-based amount that was comparable to the GAO purchase price data for a subset of drugs reviewed in our CY 2006 final rule with comment period, which did not include pharmacy overhead costs."[7] This finding suggests doubt on the part of CMS as to whether the CY 2007 final rule analysis properly accounted for pharmacy overhead costs.

- CMS "further believe[d] [that] maintaining stability in the payment levels for drug and biologicals should be considered in light of the inherent complexity in determining how best to account for pharmacy overhead costs."[8]

- CMS "believe[s] a better understanding of the full nature and magnitude of hospitals' costs related to these important [overhead and handling] activities is needed."[9]

- CMS "believe[s] that [the ASP + 6 percent rate] will ensure suitable payment for the hospital pharmacy overhead costs associated with drugs and biologicals, while [CMS] continue[s] to work with the hospital industry to understand the complex issues related to capturing and evaluating these overhead costs."[10]

In the CY 2008 Proposed Rule, CMS has adopted the same data analysis method for setting the separately-payable SCOD payment rate as in the CY 2007 Proposed Rule. Unlike the 2007 Proposed Rule, CMS did not even provide a theory as to why this method might account for pharmacy overhead costs incurred by hospital outpatient departments as well as drug acquisition costs.[11] CMS has also proposed a method to collect data on pharmacy overhead costs in the future, by having hospitals include pharmacy overhead costs on an uncoded revenue code line on the claim. However, the 2008 Proposed Rule does not provide any new information indicating that the circumstances that led to CMS maintaining the ASP + 6 percent payment rate for CY 2007 have changed for 2008. The proposal to collect overhead costs through revenue center coding will not produce OPPS data until the CY 2010 Proposed Rule. Until such time as

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7 Id. (emphasis added).

8 Id. (emphasis added).

9 Id.

10 Id.

11 In the CY 2007 proposed rule, CMS had theorized that mean costs from claims data (i.e., data on charges reduced to costs via cost to charge ratios(CCRs)) would capture pharmacy overhead costs because a MEDPAC Report had suggested that hospital charges (not charges reduced to cost via CCRs) reflected hospitals' pharmacy overhead costs. However, even if hospital charges did capture pharmacy overhead costs, this does not mean that charges reduced to costs via CCRs would capture pharmacy overhead costs as well as drug acquisition costs.

CMS has collected accurate data on pharmacy overhead costs, it should maintain the ASP + 6 percent payment rate for separately payable SCODs for all of the reasons outlined in the CY 2007 final rule -- i.e., uncertainty about whether pharmacy overhead costs are fully reflected in the drug claims data, the need for greater understanding of the "full nature and magnitude" of pharmacy overhead costs, and the need for suitable payment until better data is available with which to evaluate the effects of any payment reductions.

During the March 2007 APC meeting, the APC Panel recommended that "the overhead payments be made in addition to the current ASP + 6 percent payment rates for separately payable drugs."[12] If CMS is not prepared to accept the Panel's recommendation, for purposes of payment stability it should at least maintain the ASP + 6 percent payment rate until accurate claims data becomes available on pharmacy overhead costs.

If payment for SCODs were reduced to ASP + 5 percent for CY 2008, PhRMA is concerned based on the APC Panel recommendation and even CMS' concerns in the past, that this lower rate may not cover drug acquisition and handling costs, which could impede beneficiary access to important drug therapies and compromise the quality of care furnished to Medicare beneficiaries in the hospital outpatient setting. We urge CMS to maintain the current ASP + 6 percent rate for CY 2008 as it works to collect and evaluate accurate data on pharmacy overhead costs.

B. OPPS: Packaged Services -- "Diagnostic Radiopharmaceuticals" and Contrast Agents

CMS proposes to pay separately for most drugs, biologicals, and radiopharmaceuticals with per-day costs that exceed a threshold amount of $60, and to package those products with per day costs less than or equal to the $60 threshold. CMS has used this approach in the past to determine whether products are separately payable or packaged, but for CY 2008 CMS has increased the threshold from $55 to $60.

In addition to the cost-based approach to packaging that CMS proposes to continue for CY 2008, it is also proposing to package all "diagnostic" radiopharmaceuticals and contrast agents, regardless of the cost of the particular radiopharmaceutical or contrast agent. This proposed policy ignores the underlying rationale for the cost-based packaging threshold and would automatically package any agent that CMS describes as either a "diagnostic radiopharmaceutical" or a contrast agent. This is especially problematic because in establishing the proposed packaged payment rate for the combined radiopharmaceutical and procedure, CMS is using all claims for the procedures although a fairly significant number of claims may not include the necessary radiopharmaceuticals or contrast agent.

Separate payment for relatively costly drugs, biologicals, and radiopharmaceuticals traditionally has been designed to ensure that adequate payment for such agents is both available

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[12] 72 Fed. Reg. at 42735.

and predictable in the OPPS. Packaging under a prospective payment system such as the OPPS is appropriate for relatively inexpensive products and supplies that function to support the primary resources that are employed in an intervention, whether classified as either diagnostic or therapeutic. However, the proposed policy for 2008 would package "diagnostic" radiopharmaceuticals and contrast agents that have per day costs above the otherwise applicable packaging threshold -- and would risk inadequate payment for these products even if their costs are not properly reflected in the procedure code payment (into which the "diagnostic" radiopharmaceutical or contrast agent is packaged). Separate payment for SCODs above the current $55 packaging threshold is designed to guard against such problems.

To avoid access restrictions due to inadequate payment for advanced radiopharmaceuticals and contrast agents, CMS should continue a cost-based approach to packaging SCODs and should not rely on classifications such as "diagnostic" or "therapeutic" that could create access problems for relatively costly products in the OPPS. CMS has traditionally used a packaging threshold for high-cost drugs, biologicals, or radiopharmaceuticals because separate payment is needed to ensure that higher cost agents are accessible to Medicare beneficiaries. Nothing in the Proposed Rule undermines or supports a departure from this logic, which is fundamental to ensuring that Medicare beneficiaries receive the highest-quality, most appropriate care. PhRMA therefore urges CMS to apply its cost-based packaging approach consistently, instead of arbitrarily carving out "diagnostic" radiopharmaceuticals and contrast agents from the otherwise applicable packaging threshold.

* * *

PhRMA hopes that these comments will be useful to CMS in developing the final OPPS rule for 2008. We look forward to further dialogue on enhancing beneficiaries' access to care in the hospital outpatient setting. Please do 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

Diane E. Bieri
Senior Vice President and General Counsel

Ann Leopold Kaplan
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ST. MARY'S REGIONAL CANCER CENTER
Affiliated with Duke Comprehensive Cancer Center

Philip B. Lepanto, M.D.
Sanjeev Sharma, M.D.

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September 8, 2007

Carrie N. Weems
Administrator Designee
For the Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS - 1392-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

RE: Comments to the proposed rule (file code - CMS -1392-P)

Dear Administrator Weems:

My name is Sanjeev Sharma, MD. I work at St. Mary's Medical Center in Huntington, WV. I am a physician in charge of image guided robotic stereotactic radiosurgery and Cyberknife coalition member. I thank you for the opportunity to comment on the proposed rule for the hospital outpatient prospective payment system for the year 2008 - CMS - 1392-P.

At the present time the OPPS payment system groups SRS in three ambulatory payment classifications. The 2008 CMS has proposed to include two unrelated technologies with SRS in these APCs. We strongly disagree with this proposal because it does not maintain a degree of coherence in clinical and resource terms that CMS usually maintains and that is exhibited by other APCs. These two technologies are ultrasound ablation of uterine fibroids with magnet resonance guidance and magnetoencephalography. Neither of these two technologies is similar to SRS, and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

We support CMS's proposal for the continued use of HCPCS codes G0173, G0251, G0339, and G0340. I agree with the assessment that these codes are more specific in their descriptors than the available CPT codes, and their hospital claims data continue to reflect significantly different use of hospital resources. Adoption of a smaller set of CPT codes with less specific descriptors would not appropriately reflect the resource cost of these procedures to hospitals and would result in violations of the two times rule.

In summary I urge CMS to:

1. Not adapt its proposal to assign magnetoencephalography to the APCs for SRS.
2. Not adapt its proposal to assign ultrasound ablation of uterine fibroids with magnet resonance to the APCs for SRS.
3. Retain the SRS HCPCS codes G0173, G0251, G0339, and G0340.

Further, I request that CMS clarify the associated code descriptors to achieve the agency's goal of distinguishing image guided robotic stereotactic radiosurgery systems from **other LINAC systems**.

Sincerely,

Sanjeev Sharma

This document is electronically Approved
by Sanjeev Sharma, MD

SS/tn 9/10/07

Wooddale
MENTAL HEALTH

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September 12, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Subject: CMS-1392-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting Partial Hospitalization Programs. I am The Assessment Director at Wooddale Mental Health in Baton Rouge, Louisiana.

According to the *Report on Louisiana Healthcare Delivery and Financing System* prepared by Price, Waterhouse, Coopers, Louisiana was already suffering from limited ambulatory mental healthcare prior to Hurricanes Katrina and Rita. Providers were stretched to the limit of what they could provide its residents. According to Louisiana's the report, barriers to mental healthcare were:

- Gaps in community-based system of care;
- Lack of appropriately trained professionals;
- Service system fragmentation and lack of integration; and
- Insufficient funding.

The rate reduction in reimbursement proposed by CMS for Mental Health services will severely limit agencies' ability to provide even the most limited services. This includes psychiatry and outpatient therapy, which is reimbursed at a rate that makes breaking even under the current reimbursement levels a challenge.

Currently there is a lack of housing, group homes and facilities. The closing of one large freestanding mental health facility, DePaul Tulane, has also affected the availability of mental health services. Because of the displacement of some residents, many Louisianans have gone for long periods of time without their medications, making their current mental health conditions worse.

The result of the proposed cuts will be a population without access to necessary mental health services. Please do not burden our system anymore by enacting the proposed cuts.

1335-B Wooddale Boulevard ✢ Baton Rouge, LA 70806 ✢ Email: cmhcwmh@bellsouth.net
Phone: 225.928.4969 ✢ Fax: 225.928.4983

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to Partial Hospitalization Programs. As stated above, such provisions would be devastating!

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

S Tota, LCSW

Suzanne Tota, LCSW
Assessment Director

The National Pain Foundation

Advancing functional recovery through education.
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September 13, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

The National Pain Foundation has advocated for the estimated 75 million Americans living with chronic intractable pain since 1998. We provide unbiased, peer-reviewed educational materials and community support for people living with chronic pain. Currently, there are limited options available for clinically significant pain relief for many of these individuals and it seems their options are becoming even more limited.

As the chief executive officer of the National Pain Foundation, I'm writing to specifically request that CMS create a separate payment category for rechargeable neurostimulators to recognize the significant cost differences and patient quality of care differences between rechargeable and non-rechargeable neurostimulators.

Rechargeable neurostimulators are an important advancement for patients living with chronic neuropathic pain and improve patient care. Rechargeable neurostimulators last an average of five to nine years, allow physicians to better program the stimulators for optimal pain relief and enable continuous stimulation — even at high levels — to provide pain relief without concern for rapid battery depletion.

Non-rechargeable neurostimulators last an average of only two to five years, despite efforts to extend battery life by keeping stimulation levels lower. Thus, with non-rechargeable neurostimulators, patients receive a product that does not provide optimal pain relief and requires two to three more surgical procedures, which increases the patient's risk of infection or death. Furthermore, because they must be replaced more frequently, non-rechargeable neurostimulators lead to higher long-term costs for Medicare and hospitals.

While the procedures to implant both rechargeable and non-rechargeable neurostimulators are comparable both clinically and with respect to hospital resource use, the long-term costs of rechargeable neurostimulators are sufficiently different to warrant separate payment categories, not to mention the substantial clinical improvement for patients that rechargeable neurostimulators represent.

It's unfortunate for patients that the proposed outpatient reimbursement level might provide inappropriate financial incentives for hospitals to treat patients in the inpatient setting to better cover the cost of

rechargeable devices. This may lead to inefficient use of Medicare program dollars. This affects not only physicians' ability to offer rechargeable neurostimulators to eligible Medicare patients, but patients' quality of care. Rechargeable neurostimulators feature a long-life rechargeable battery that will greatly reduce the need for device replacement surgeries and reduce device-related complications, hospitalizations and clinic visits that are necessary when the device battery is depleted. Rechargeable neurostimulators ultimately generate long-term savings to the Medicare program while providing better pain relief for patients.

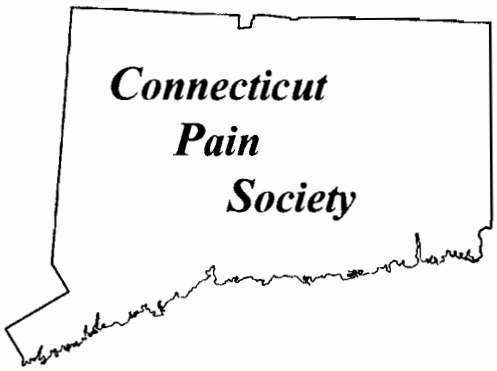
Let me repeat that key thought for emphasis. **Rechargeable neurostimulators ultimately generate long-term savings to the Medicare program while providing better pain relief for patients.**

I again ask you to consider my request that CMS create a separate payment category for rechargeable neurostimulators to recognize the significant cost differences and patient quality of care differences between rechargeable and non-rechargeable neurostimulators.

Creating a new payment category for rechargeable neurostimulators that covers the cost of this technology is important to the National Pain Foundation as it will allow eligible patients living with chronic pain to receive optimal pain relief and quality of care. I appreciate CMS' past recognition of the clinical benefits of rechargeable neurostimulators for Medicare beneficiaries and hope that you will consider my request. Please feel free to contact me at (303) 783-8899 should you have any questions or need additional information.

Sincerely,

Mark B. Rasmussen
President/Chief Executive Officer
The National Pain Foundation



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David Kloth MD
Executive Director
Connecticut Pain Society

Immediate Past President
Connecticut Pain Society

August 10, 2007

Department of Health and Human Services
Attn: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

To whom it may concern:

I am writing to you as a representative of the American Society of Interventional Pain Physicians, a national organization representing 4,000 interventional pain physicians throughout the United States.

On July 16, 2007, CMS issued its final and proposed rules on the new ASC payment system. As you are aware the ASC payment groups have been eliminated and ASC reimbursement will be based on a percentage of APC rates. This causes a number of problems but I would like to comment about one specific issue as it relates to coverage of a specific treatment modality and that is implantation of permanent spinal cord stimulator systems.

It has been brought to the attention of CMS in the past that there are now two different varieties of spinal cord stimulators, one being a rechargeable and one being a non-rechargeable. These two modalities have significant differences in costs for the actual equipment. At this time CMS has not made any allowance for this difference in equipment cost which would preclude physicians from using the rechargeable neurostimulators on our patients (proposed reimbursement would be less than the actual cost of the equipment). CMS has been asked to address this issue on a number of occasions and in 2006 and 2007 these devices were eligible for pass through payments which are intended to provide payments for the cost differential between technologies (the current pass through payment will expire 12/31/07). The net result of these changes would be that Medicare beneficiaries will not be able to receive rechargeable generators in an out patient hospital, or ASC setting.

As of the right now, ASC's receive reimbursement for rechargeable generators through the DME POS fee schedule (L8689-recharchable generator). With the current proposal, ASC reimbursements rates will be based on 100% of the device component and approximately 65% of the service component of the APC's. This is intended to account for the fact that the majority of the APC payment is for the equipment cost. If the device component, as determined from OPPS claims data, is based on a mix of rechargeable and non rechargeable device cost, the problem will magnify when carried over to the ASC setting. This will result in vast under reimbursement for the actual equipment (which costs the same in all settings). Each and every implant of a rechargeable device when performed in an ASC would then result in a significant loss of money to the facility just purely on the cost of the actual equipment. These issues need to be addressed by CMS in order to ensure long term and appropriate access for Medicare beneficiaries to this type of care.

Currently there are still several issues which are in flux including the final rates for hospital APC's for 2008. If these rates are significantly increased it may obviate some of these issues, but it would also result in significant overpayment in the hospital setting in order to obtain adequate coverage in the ASC setting, unless CMS splits the technology into separate APCs. We would urge CMS to try and find an alternative solution to resolve this issue.

At this time it is my understanding that CMS has not proposed a separate rechargeable APC for the outpatient payment system and therefore this differential reimbursement will not be available in the hospital or ASC setting.

Our society, as have multiple other physicians, has previously written to CMS explaining the importance of these rechargeable implantable neurostimulators. Long term these devices will save CMS significant money as there would be less need for replacement of depleted non-rechargeable pulsed generators. Cost analyses have previously been provided by a number of different sources to CMS and this was the basis in the past for CMS providing differential reimbursement for rechargeable and non-rechargeable systems with such mechanisms as add-on payments (for in patient) and pass through payments (for HOPD). We again urge CMS to re-look at this issue and include some of the same rationale in its long term pricing for these implanted spinal cord stimulator systems. The increased costs associated with a non-rechargeable vs. rechargeable system would include increased need for surgery, potential for post-op infections, increased surgical and facility fees, and other possible co-morbidities in this population of patients.

We are urging CMS to provide a separate out patient ambulatory payment classification (APC) for rechargeable neurostimulators. In addition we are asking CMS to ensure that the device and service components from the OPPS are appropriate and will provide adequate reimbursement when carried over to the ASC setting given that the service component will be reduced by 65%.

Thank you very much for giving this matter your attention. I look forward to working with you on this matter. If I can be of further assistance please do not hesitate to contact me or other physicians of our society.

Sincerely,

David Kloth, M.D.
Executive Director of Connecticut Pain Society
Board of Directors of the American Society of Interventional Pain Physicians
Past President of American Society of Interventional Pain Physicians
Medical Director of Connecticut Pain Care

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September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

Thank you for your consideration of these comments. The greatest concern is for the patients treated in our facility and isolating these procedures as proposed will cause an access to care issue for many Medicare beneficiaries and potentially cost the Medicare system more. Any questions or comments you have on this letter are welcome and thank you for your service to Health and Human Services and specifically the Centers for Medicare and Medicaid.

Sincerely,

Clinton Dillé, M.D., President

Christy Davies, Administrator

Southern Idaho Pain Institute

UPMC Cardiovascular Institute

Part of
University of Pittsburgh
Medical Center

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August 29, 2007

Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am a practicing cardiologist at the University of Pittsburgh Medical Center and I use echo contrast agents.

I am writing to express my serious concern over the plan to eliminate separate payment for the use of ultrasound contrast agents. These agents are critical to ensuring adequate diagnostic quality of echocardiograms in patients with suboptimal echo images. If separate payment for echo contrast agents is eliminated for hospital outpatients, I believe it will reduce patient access to echo contrast agents and ultimately compromise the quality of patient care. This can also ultimately be more costly, because technically inadequate echoes without the use of contrast will lead to more downstream use of additional imaging studies to get the needed clinical information.

Sincerely,

Flordeliza S. Villanueva, MD

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American Red Cross

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule [72 FR 148, August 2, 2007; Docket # CMS-1392-P]; OPPS: Blood and Blood Products, Blood Transfusions

Dear Sir or Madam:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Centers for Medicare and Medicaid Services' (CMS or agency) proposed rule titled *"Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates"* (hereafter, referred to as the proposed rule).

The Red Cross is an independent, nonprofit, tax-exempt, charitable organization, established pursuant to a charter granted to it by the United States Congress. The Red Cross, through its 35 Blood Services regions, supplies almost half of the nation's blood for transfusion needs. The Red Cross is committed to the safety of donors and patients, and to meeting the needs of the public we serve.

We are commenting specifically on CMS's proposed calendar year (CY) 2008 payment rates for blood and blood products, and its discussion of Medicare's transfusion payment policy under the Medicare hospital outpatient prospective payment system (OPPS). We discuss each of these issues below.

OPPS: BLOOD AND BLOOD PRODUCTS

The Red Cross appreciates CMS's longstanding acknowledgement of the importance of adequate reimbursement for maintaining an available and safe blood supply, as well as the agency's ongoing commitment to addressing the concerns about blood product reimbursement raised by the Red Cross, others in the blood banking industry, and the Advisory Panel on Ambulatory Payment Classification (APC) Groups. Additionally, the

Red Cross commends CMS for proposing to increase the APC payment rates for 24 blood products that account for the majority of blood utilization under OPPS. Increases in payment for key blood products are urgently needed in order to maintain adequate beneficiary access to the nation's blood supply, and represent an important step in the right direction toward ensuring that APC payment rates adequately reflect the costs of blood and blood products.

However, as the supplier of approximately 45 percent of the nation's blood supply, we know that there is still a gap between the proposed APC payment rates and the costs incurred by hospitals for the acquisition, management, and processing of blood and blood products. Specifically, the proposed APC payment rates for a number of high-volume products—including leukoreduced reduced red blood cells (P9016), which represent the single largest-volume blood product acquired by hospitals—are still below the direct acquisition costs for those products (that is, the fees that hospitals pay to their blood supplier). Therefore, given that the proposed rates for these products would not cover acquisition costs, they also would fail to reimburse hospitals for the overhead costs that facilities incur internally in the management and processing of those blood products. Examples of blood-related overhead costs—which are intended to be captured in the blood product APC payment rates—include critical activities such as in-hospital handling, storage, delivery, and inventory management.

We urge CMS to implement appropriate blood product payment increases so that the agency can continue to close the gap between costs and reimbursement under OPPS. The need for increased payment rates is driven by the fact that the costs of blood products continue to increase. As we have noted in previous comments to CMS, donor recruitment and retention are becoming significantly more expensive, driving up the costs associated with making blood available to patients in need. New safety measures, while improving the quality of blood products, create additional challenges and further increase the costs of maintaining an adequate blood supply.

In the past year alone, for example, the Red Cross implemented testing for Chagas' disease as well as strategies to mitigate the risk of Transfusion Related Acute Lung Injury (TRALI)—the leading cause of transfusion related deaths today. TRALI mitigation strategies for plasma products were focused on a move to predominantly male plasma, raising further the challenges of donor recruitment and retention. Over the next year, the Red Cross will be implementing TRALI mitigation strategies for platelets, which may have significant (and costly) impact both on donor recruitment requirements and testing costs. Hospitals and blood centers cannot absorb these rising costs, and appropriate reimbursement is critical to hospitals' and blood centers' ability to maintain the supply chain for a safe and adequate blood supply.

As the costs of blood and blood products continue to rise, it is important for CMS to ensure that APC payment rates keep pace with the technological advances, safety measures, and donor recruitment challenges that are driving the cost increases. Given the two-year lag inherent in the OPPS rate-setting process, the use of hospital claims data without adjustments likely will not reflect these rising costs in a timely manner. Therefore, we urge CMS to close the existing gap between blood product costs and

reimbursement rates—to ensure that hospitals receive adequate reimbursement and beneficiaries have continued access to the nation's blood supply.

BLOOD TRANSFUSIONS

In its proposed rule, CMS proposes to maintain its current OPPS payment policy for blood transfusions, which allows an APC payment for a transfusion procedure to be made only once per day. Over the last several years, numerous Red Cross hospital customers have expressed concerns that this policy does not adequately reimburse OPPS providers for the additional resources required for hospital outpatient visits involving multiple transfusions. Since there clearly are situations in which it is medically appropriate for a patient to receive more than one distinct transfusion, we urge CMS to revise its policy to allow payment for each distinct transfusion procedure, regardless of the number of units transfused or the timeframe during which the transfusions occur.

This change in payment policy could be operationalized by requiring hospitals to report modifier -59 (Distinct procedural service) or other appropriate modifier to indicate that the additional transfusions are distinct from the initial transfusion. We note that such a revised payment policy would not conflict with the descriptor for Current Procedural Terminology (CPT) code 36430 (Transfusion, blood and blood components)[1], since hospitals would report multiple units of the code only when they have performed more than one distinct transfusion.

* * * * *

The Red Cross appreciates this opportunity to provide public comments on the proposed rule. If you have any further questions about our comments, please contact Kamenna Lee, Director, Hospital Sales and Marketing, at 202-303-5443 (phone), or LeeKam@usa.redcross.org (email).

Sincerely,

Kamenna Lee

Kamenna Lee
Director, Hospital Sales and Marketing
Biomedical Services
American Red Cross

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American Hospital Association

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#205

September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007.

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar (CY) 2008 outpatient prospective payment system (OPPS).

The AHA is commenting on several OPPS proposals. Most importantly, we have serious concerns about the proposed packaging rules, partial hospitalization payment (PHP) cuts, changes to the critical access hospital (CAH) conditions of participation, separate billing for pharmacy overhead costs and requirements for outpatient quality measure reporting. In brief, the AHA makes the following recommendations:

- CMS should re-evaluate its new packaging proposal. We found problems in CMS' methodology and correcting these problems leads to different impact results by type of hospital. If CMS decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services.

- CMS should maintain the PHP per diem at the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services. In addition, we recommend CMS further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.

- CMS should rescind its proposal to require a CAH-operated provider-based facility created after January 1, 2008 to comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). The agency's proposal is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Such a policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

- CMS should withdraw its proposal instructing hospitals to bill separately the pharmacy overhead charge. The agency's proposal creates a huge administrative burden on hospitals and a morass of complexity that is unnecessary and excessive. Moreover, CMS should re-evaluate the recommendations of the Ambulatory Patient Classification Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

- CMS needs to refine several aspects of its new OPPS quality reporting program. First, the agency proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA) as the initial measures. We are pleased that CMS continues to align its choice of measures with the work of the HQA in the implementation of the hospital quality reporting programs; however, the HQA has only preliminarily approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. Therefore, we urge CMS to delay data collection until the measures have been thoroughly field-tested and received NQF endorsement, the data specifications have been finalized, and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when the hospitals and vendors are fully prepared to commence the program.

  We also urge CMS to modify its validation approach for the outpatient reporting program. We believe that, for 2009, data validation may be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold may be established at a lower level and then gradually raised to 80 percent, similar to the approach for inpatient PPS quality reporting.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

The American Hospital Association's Detailed Comments on the Proposed Rule for the 2008 Outpatient Prospective Payment System

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OPPS: PACKAGED PROPOSAL

Increasing Packaged Services
The outpatient prospective payment system (OPPS), unlike other prospective payment systems, employs only moderate packaging of services and generally makes a separate payment for each individual service provided during a patient encounter.

For 2008, CMS proposes to broaden the OPPS payment groupings – ambulatory payment classifications (APCs) – by packaging into the primary service provided seven categories of items and services that CMS considers to be typically ancillary and supportive. These services are currently billed separately. The agency believes that payment based on a larger group of services will provide an incentive for hospitals to furnish services in the most efficient way by allowing them to manage their resources with maximum flexibility.

The seven categories of items and services CMS proposes to package into primary diagnostic and therapeutic procedures with which they are performed include:

- Guidance services,
- Image processing services,
- Intra-operative services,
- Imaging supervision and interpretation services,
- Diagnostic radiopharmaceuticals,
- Contrast media, and
- Observation services.

CMS proposes to assign packaged codes either a payment status indicator "N" or "Q." Status indicator "N" is assigned to those codes for services that are always integral to the performance of the primary service with which they are billed. The costs for these codes are always packaged. Status indicator "Q" is assigned to those codes that are usually, but not always, integral to a primary service. These codes may sometimes be paid separately when no other separately paid primary service is provided during the hospital outpatient encounter.

CMS notes that the median cost of many APCs will change not only as a result of the increased packaging itself but as a result of the changes it makes in individual codes moving into and out of the APCs.

The AHA generally has supported efforts to package more services into larger payment bundles. We believe, like CMS, that appropriately sized bundles can provide incentives to improve efficiency and manage resources. However, we have concerns about CMS' proposal and the underlying analysis behind it.

First, while the agency estimates that the proposal would redistribute approximately 1.2 percent of the 2007 expenditures under the OPPS, analyses prepared by The Moran Company indicate that the seven categories in CMS' proposal represent 6 percent of outpatient costs. The reason

our analysis had a higher percentage of costs was because of the methodology for applying the status indicator "Q." The resulting impact reveals very different impacts by type of hospital than CMS' impact tables, and we are concerned that the implications of this policy are not fully understood.

Second, we have concerns about the proposal to package observation services. The billing and coding rules for observation have changed significantly since the implementation of the OPPS. Since CMS implemented separate payment for observation services in 2002 for selected medical conditions, hospitals have found the criteria and documentation requirements to be administratively burdensome and complex. During the past several years, the APC Advisory Panel has made multiple recommendations to CMS to simplify and/or clarify definitions and instructions for the reporting of observation services. Numerous operational hurdles had to be overcome to ensure compliance with all of the rules for reporting packaged observation charges versus separately payable observation APC charges. The requirements were not automated, difficult to track and involved multiple departments in order to ensure that the observation services were appropriate from both the clinical and billing perspectives. The confusion in billing observation led to incomplete data on separately billable observation services.

The impact of packaging observation at this time is likely to have the largest impact on those hospitals that understand and appropriately code for allowable observation services. Two hundred hospitals (or 5 percent) provided one-third of all separately payable observation services, according to The Moran Company's analysis of outpatient claims from 3,954 hospitals. Separately payable observation services are only covered for patients with three specific conditions: congestive heart failure, asthma and chest pain. These conditions are widely treated in the majority of America's hospitals and the concentration of observation services in a relatively small number of hospitals is likely due to the complexity and numerous changes of coding rules. To include observation services with such skewed claims data would be inappropriate at this time.

The AHA recommends that CMS re-evaluate its new packaging proposal in light of the methodological and data concerns. If the agency decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services and CMS' use of the Outpatient Claims Editor logic to automatically determine whether observation services on a claim are separately payable. Begun in 2002, this process resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services and continuation of this policy will lead to improved understanding of observation services and costs.

Composite APCs

CMS proposes to create a "composite" APC that would pay a single rate for larger bundles of major, and currently, separately paid, services that are commonly performed in the same hospital outpatient encounter (or as part of a multi-day episode of care). CMS believes this concept of "composite" APCs would create incentives for greater efficiency.

The two composite APCs proposed for 2008 are:

- APC 8001 (Low Dose Rate (LDR) Prostate Brachytherapy Composite) and
- APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite).

CMS' proposal begins to address the concept of the outpatient "episode" of care, and these new bundles may offer a cohesiveness of payment similar to the cohesiveness of the care. While CMS expects to develop additional composite APCs in the future as it learns more about major services that are commonly provided together during the same hospital outpatient encounter, **the AHA urges CMS to evaluate closely the impact of these new bundles on payment adequacy and access to care before expanding this new policy to other services.**

OPPS: Specified Covered Outpatient Drugs

The Medicare Modernization Act of 2003 (MMA) provisions require special classification and payment of certain separately paid drugs, biologicals and radiopharmaceuticals that had previously (or before December 31, 2002) received pass-through payments. In 2008, the law requires that payment for these specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs.

To set the proposed 2008 rates, CMS evaluated fourth quarter 2006 average sales price (ASP) data on about 500 drugs and mean costs derived from 2006 OPPS claims data. CMS concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be roughly equivalent to basing their payment rates at ASP plus 5 percent. The agency cites findings from a 2005 Medicare Payment Advisory Commission (MedPAC) study of pharmacy overhead costs to support its conclusion that ASP plus 5 percent is a sufficient level to cover drug acquisition and pharmacy overhead costs. The MedPAC survey results indicated that hospitals set charge levels for drugs to cover both drug acquisition and pharmacy overhead costs.

For 2008, CMS proposes to pay for the drug acquisition *and* pharmacy overhead costs of specified covered outpatient drugs at a *combined* rate of ASP plus 5 percent. This rate is lower than the ASP plus 6 percent rate for drugs furnished in physician offices. Lowering the payment percentage from 6 to 5 percent above ASP is a budget-neutral change to the OPPS and redistributes the additional 1 percent of payments to other outpatient services. However, reducing payment for separately payable drugs under the OPPS, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates inconsistencies in payment that could result in unintended and inappropriate incentives to treat patients in one setting over another. CMS should eliminate the inconsistency of paying differently for the same drugs based on the treatment setting.

Pharmacy Overhead Costs

CMS proposes to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim. This policy would apply to the reporting of charges for all drugs and

biologicals, including contrast agents, regardless of the item's packaged or separately payable status. CMS would not apply this policy to radiopharmaceuticals because it has previously instructed hospitals to include the overhead and handling charges in the charges for the radiopharmaceutical products.

CMS believes that this change would allow the agency to identify pharmacy overhead costs for drugs and biologicals and, in future years when the 2008 claims data become available, to package these overhead costs into payment for the associated procedure, likely a drug administration procedure. CMS also believes that this policy would not violate the "uniform charge" regulation that prohibits hospitals from charging Medicare differently from all other payers because under this proposed policy the same total charges would be provided to all payers.

However, CMS' proposal creates a huge administrative burden on hospitals and an unnecessary morass of complexity. During November and December, thousands of drugs and dosages would need to be evaluated and examined for the resources they consume in the operations of the pharmacy. Even large hospitals with sophisticated staff, resources and information systems – let alone small and rural hospitals – would find this task and the related timeframes unworkable. Because of the enormity of this task, hospitals would be forced to apply simple across-the-board overhead percentages which would undermine the validity and usefulness of the data.

CMS has vastly underestimated the difficulty of its proposal. The agency should withdraw its proposal, re-evaluate the recommendations of the APC Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

OPPS: QUALITY DATA

The Tax Relief and Health Care Act of 2006 mandated that CMS establish a program under which hospitals must report data on the quality of hospital outpatient care to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. Hospitals that fail to report outpatient quality data would incur a reduction in their annual outpatient payment update factor of 2.0 percentage points.

Quality Measures

To implement this legislative mandate, CMS proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA). We are pleased that CMS continues to align its choice of measures with the work of the HQA; however, the HQA has only *preliminarily* approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. We urge CMS to proceed in the same manner when the agency finalizes the rule.

Further, it is vital that all new measures undergo a rigorous field test to identify any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors. **We urge CMS to fund a thorough field test of the outpatient measures immediately.**

Regarding the other measures that CMS identifies for possible inclusion for CY 2010 or later, we reiterate our position that all measures included in hospital reporting programs should be NQF-endorsed and HQA-adopted.

Timing of Implementation

To be eligible for a full OPPS payment update in 2009, CMS proposes that hospitals submit quality data on these 10 measures effective with hospital outpatient services furnished on or after January 1, 2008. Before data collection can begin, hospitals will have to review the data specifications, become familiar with a new data collection tool, implement their reporting systems, develop any sampling methodologies and educate and train staff. Likewise, data vendors will have to develop the data abstraction and submission tools, test the software programs, create hospital educational materials and programs and work with hospitals to implement the software programs.

By contract and according to the CMS/Joint Commission Specifications Manual, data vendors are to have 120 days to complete this programming and prepare to collect the data. CMS released the data specifications for the outpatient measures on August 29; however, we understand that the specifications are still in fluctuation and may be changed as the measures go through NQF endorsement or are tested further. Developing the data collection tools and assisting hospitals with implementation by January 1 will be extremely challenging for the vendors; implementing these changes as the specifications are still evolving may be impossible.

Hospitals have told the AHA that the implementation timeline for outpatient reporting will be extremely difficult for them to meet, primarily due to the complexities around building the information technology infrastructure to begin data collection. The outpatient measures will require new documentation forms and criteria, and hospitals will face documentation issues that are different from those they have met for inpatient reporting. Hospital inpatient, emergency department and outpatient clinic information systems typically are separate from one another without common data interfaces. Even those hospitals with more established electronic health records may have different systems for inpatient and outpatient records, particularly with respect to outpatient clinic records. In addition, some data elements necessary for reporting will have to be obtained from billing records, similar to the inpatient measures. However, there currently is no mechanism available to collect this information from outpatient or physician claims.

Further, smaller hospitals may see their reporting burden increase dramatically with the implementation of the emergency department transfer measures. We generally applaud measures that allow smaller hospitals to fully participate, as many have been unable to report on some of the inpatient measures. However, these hospitals, which have fewer staff available and trained to

abstract data and fewer resources to implement electronic systems, may be overwhelmed trying to implement reporting on the outpatient measures in such a tight timeframe.

Hospitals support expanding the quality information available to the public and reporting on standardized outpatient quality measures. It is essential, however, to ensure that the information reported is valid and reliable. We would question the validity and reliability of any data that is reported before the measures are fully field-tested. Additionally, expecting hospitals to implement in less than four months a new program that is tied to payment is unduly burdensome. Therefore, we urge CMS to delay data collection on the outpatient measures until the measures have been fully field-tested and received NQF endorsement, the data specifications have been finalized and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when hospitals and vendors are fully prepared to commence the program.

Administrative Requirements of the Reporting Program
In the proposed rule, CMS outlines the administrative steps that hospitals must take to participate in the outpatient quality reporting program. The rule notes that hospitals must complete and submit a notice of participation form by November 15. We anticipate that there may be some confusion in the field around this requirement as hospitals were required to submit a similar form for participation in the inpatient quality reporting program in August. We urge CMS to communicate this requirement clearly and frequently to hospitals this fall and to work with its HQA partners so that all hospitals are aware of the steps they need to take to participate in the outpatient reporting program. We appreciate CMS' proposal that once a hospital has submitted a notice of participation, it will be considered an active participant of the program until the hospital indicates otherwise. This step will alleviate some of the administrative burden on hospitals, and we encourage CMS to adopt this policy in the final rule.

Data Submission Timeframe
The proposed data submission timeframe for the outpatient reporting program is 120 days, slightly shorter than the 135-day timeframe for the inpatient reporting program. If CMS chooses to adopt this shorter timeframe, the agency must be able to assure hospitals that updated data collection software will be available on the first day of the data submission period and that the necessary programming to receive the data at the data warehouse will have been completed and tested. Previously, delays in the availability of useable software for the inpatient reporting program have caused data submission delays for hospitals. Unless these recurring software problems can be resolved, CMS cannot shorten the timeline.

Data Validation
CMS is proposing data validation requirements for the outpatient quality reporting program. For 2009, CMS proposes randomly selecting for reabstraction five patient charts from each hospital from among those patients receiving services in January 2008. To pass validation, hospitals must meet a minimum of 80 percent reliability from the chart reabstraction.

The AHA opposes this proposal. Although hospitals have been collecting data for inpatient measures for several years, collecting data for the outpatient measures will involve the use of a new data collection tool with documentation criteria and forms that are different than the inpatient reporting program. The data likely will be collected by different staff. As with the implementation of any new program, there will be a learning curve as hospitals gain experience with the new program. Likewise, those staff members of the clinical data abstraction center with responsibility for the data reabstraction for validation will experience the same learning curve.

When the inpatient reporting program began, reabstraction and validation were used as learning tools for hospitals to improve their documentation and data collection. There was no minimum validation threshold determining whether or not hospitals received their full annual payment update. As the program evolved and hospitals gained experience with it, a minimum validation threshold was introduced and gradually raised to the 80 percent reliability rate. This was a thoughtful and deliberate approach to ensuring high reliability in the data used for the inpatient reporting program. **We urge CMS to undertake a similar approach for the outpatient program. For example, in 2009, data validation could be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold could be established at a lower level and then gradually raised to 80 percent.**

Reconsideration Process
For those hospitals that fail to meet the program requirements, CMS is proposing to implement a reconsideration process, similar to the one used for the inpatient reporting program. We believe that such a process is an essential component of the outpatient reporting program. CMS should establish a reconsideration process that is straightforward, transparent and timely.

ASCs: Quality Data

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ambulatory surgical centers (ASCs) in the outpatient quality reporting program. In the proposed rule, CMS delays implementing a quality reporting program for ASCs. The AHA encourages CMS to implement a quality reporting system for ASCs as soon as possible. All providers that perform the same services should be held to the same accountability standards with respect to the quality of the care they deliver.

OPPS: Partial Hospitalization

For the past two years, CMS has expressed concern that the median per diem cost derived from hospital and community mental health center (CMHC) claims data was too low to cover the cost of partial hospitalization programs (PHP) that typically span five to six hours per day. However, CMS still implemented a 15 percent decrease in the per diem for CY 2006 and then another 5

percent decrease in CY 2007. For CY 2008, CMS proposes another 24 percent drop in payments.

Cost-to-charge Ratios
For 2008, CMS proposes to adopt changes to its methodology for calculating PHP median costs using both hospital-based and CMHC PHP data. To more accurately estimate costs for PHP claims, CMS proposes to re-map 10 revenue center codes to a Primary Cost Center 3550, "Psychiatric/Psychological Services" or to a Secondary Cost Center 6000, "Clinic." In establishing the PHP median per diem rate, CMS proposes to calculate a separate per-diem cost for each day, rather than for each bill. **The AHA recommends that CMS conduct a similar analysis for CMHCs as PHP services are the highest-cost services they provide and may have statistically different cost-to-charge ratios than the overall CMHC cost-to-charge ratios.**

Median Costs
CMS analyzed the number of services being provided in a day of care as a possible explanation for the low per diem cost for PHP. It found that, despite its expectation that five or six services would be provided in a day, both hospital-based and CMHC PHPs have a significant number of days where three or fewer units of service were provided. Specifically, 34 percent of hospital-based PHP days contained three or fewer units of service, and 64 percent of CMHC PHP days contained three or fewer units of service.

CMS believes that its analysis of the number of units of service per day supports a lower per diem cost and thus, proposes to calculate the median per diem cost using all days, not just those with four or more units of service provided. Therefore, CMS proposes a per diem payment cost for 2008 of $178, which is 24 percent lower than the per diem cost of $233.37 for 2007.

CMS says that it did not propose separate rates for half-days and full-days because it believes the program was intended to cover a full day of service and that it was appropriate to set one rate that would be paid for all PHP days. The AHA, however, believes that there are circumstances that warrant less than a full day of services. For instance, when patients are transitioning out of the program or when there are other complicating physical ailments that require separate therapy. In addition, the partial hospitalization programs have evolved as the use of psychotropic drugs has increased and diminished the need for as much therapy. Even though a full day of services is not provided, such services are still valuable, necessary and warrant payment.

There is precedence for differentiating payments based on higher or lower utilization of services. For instance, under the home health PPS there is a low-utilization payment adjustment. Low-utilization payment adjustments are 60-day episodes with four or fewer visits where payment is based on a per visit basis. Following a similar pattern, CMS could set the PHP median per diem cost based on days when four or more services are provided and then pay a low-utilization payment adjustment amount for days when three or fewer services are provided. This approach would more accurately reflect resource intensity and ensure that those hospitals that provide more services per day are adequately paid. CMS could also put constraints around how

frequently three or fewer services could be billed to prevent the bulk of days furnished by a provider being low utilization. We urge CMS to further research the possibility of such a payment structure for CY 2009.

The vast majority of patient days in hospital-based units are high-intensity services that may avoid a hospital stay, or a continued hospital stay. If additional hospitals reduce or eliminate PHP services, there will be increased demand for inpatient psychiatric beds that are already in short supply and, likely, additional bottlenecks in the emergency departments.

The AHA recommends that CMS maintain the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services and further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.

NECESSARY PROVIDER CAHS

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

It is unclear in the rule to which provider-based entities CMS intends to apply this proposal. The provider-based regulations state that such determinations are not necessary for ambulatory surgery centers; comprehensive outpatient rehabilitation facilities; home health agencies; skilled nursing facilities; hospices; inpatient rehabilitation units; independent testing facilities; facilities, other than as parts of CAHs furnishing solely physical, occupational or speech therapy; ESRD facilities; ambulance providers; and rural health clinics (RHCs) with more than 50 beds. Thus, it is assumed that the proposal does not apply to these types of providers. It appears as if CMS intends the proposal to apply to psychiatric or rehabilitation distinct part units (even though rehabilitation units are on the list for which provider-based determinations are not necessary). It is unclear if CMS intended to include RHCs and outpatient departments. CMS should clearly state to which types of entities this policy applies.

Further, CMS' proposal will have detrimental effects on all CAHs, not just necessary provider CAHs. Two CAHs could be 40 miles apart, but their provider-based entities could be within 20 miles of the other hospital in a town midway in between the CAHs. This rule would prevent either hospital from serving this town through a provider-based entity.

a determination is made on the level of the credit. We believe that CMS should give hospitals the same options for reporting the HCPCS modifier under the OPPS.

OPPS: HOSPITAL VISITS

Since April 2000, hospitals have been using the American Medical Association's (AMA) Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors – designed to reflect the activities of physicians – did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In 2003, the AHA and the American Health Information Management Association (AHIMA) recommended hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency established new HCPCS level II G codes to distinguish visits provided by Type B EDs (not open 24 hours a day, seven days a week – 24/7).

Proposed Codes and Coding Policy for 2008
For 2008, CMS proposes to continue using CPT E/M codes for clinic visits including separate codes for new and established patients. The agency also proposes to cease paying for consultation E/M codes under OPPS and instead to instruct hospitals to bill a new or established visit code. Differentiating hospital visit codes between new and established patients, or between standard visits and consultations, adds an unnecessary level of complexity and is difficult to implement. **We support CMS' proposal to eliminate the consultation codes, but urge CMS not to implement the codes for new and established patient clinic visits.**

While current distinctions in the physician E/M codes exist, the same concepts do not apply to facility resources. From a physician's perspective, an established patient may require a shorter history and a less comprehensive physical exam. These same economies are not necessarily factors in determining facility resource codes. For example, a person may be an established patient to a facility because of previous visits to any number of outpatient settings, including the ED, a clinic, as an inpatient, for a diagnostic exam or for any other service. Previous services may or may not be related to the current visit, but it would be extremely burdensome for facilities to have to determine whether there was a previous encounter and whether previous services performed are related to the current visit. This determination is especially difficult for medium-sized hospitals and nearly impossible for small hospitals. For these hospitals, rural communities in particular, nearly every patient ever seen will have had some type of contact with the hospital.

The interventions performed during an encounter are determined by physician orders, but the actual performance of these interventions would be the same whether the patient was new or established. Current distinctions on new vs. established patients for hospital coding are based on whether the patient has a medical record number within the previous three years. **We believe that the clinic visits should be recognized on the basis of hospital resources utilized during a specific visit, and therefore, not determined by whether the patient has been seen by the hospital within the last three years. CMS should withdraw this proposal.**

ED Visits. We continue to be concerned about CMS' payment structure for Type A and B ED visits. Specifically, the new policy implemented by CMS' 2007 final OPPS rule led to significant confusion and concern about how hospital "fast tracks" are treated. Fast tracks generally function as a part of the ED that handles specialized cases (e.g. heart-related emergencies) or less emergent cases so that patient flow can be improved through a hospital ED. They can be physically adjacent or even located within the 24/7 ED but, hospitals often discontinue triaging patients to fast tracks during certain hours (e.g., the midnight shift).

Paying non-24/7 ED fast tracks at the clinic rate does not make sense from a national policy perspective. ED overcrowding and ambulance diversions are significant issues for America's health care system and fast tracks improve patient care, patient flow and patient satisfaction. CMS' policy has led many hospitals to consider closing these special units, a move that would exacerbate the nation's ED diversion and overcrowding problems.

The AHA believes CMS' policy can be improved to be clearer on the appropriate coding for fast track ED services. We recommend applying the following criteria.

If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is part of the Type A ED and can bill using the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as:

- **the fast track is a hospital-based facility which provides unscheduled episodic services to patients who present for immediate medical attention;**
- **the fast track area is physically located within the same building as the 24/7 ED; and**
- **the 24/7 ED and the fast track share a common patient registration system.**

ED Critical Care Visits. For 2007, CMS reaffirmed the criteria for payment for critical care services to require a minimum of 30 minutes of critical care services provided. From a facility perspective, a patient requiring at least 30 minutes of critical care would typically be admitted as an inpatient.

We recommend that the criteria for payment for critical care services be changed to a minimum of 15 minutes of critical care or the patient expires in spite of the administration of critical care services. Very significant hospital resources are utilized in the delivery of

critical care services, including multiple hospital staff members. These services are not appropriately recognized if the patient expires or is transferred before the completion of 30 minutes of service.

Proposed Treatment of Guidelines for 2008
CMS is not proposing to implement national visit guidelines for clinic or ED visits for CY 2008. In the proposed rule, CMS reiterated the set of principles it expects hospitals' internal guidelines should follow and requested comments on five additional principles.

The AHA is concerned that CMS is uninterested in developing or approving national guidelines for the reporting of hospital ED or clinic visits. Since the implementation of OPPS, the AHA has advocated for the development of national guidelines and unique codes to represent facility resources, rather than physician resources, used in the delivery of clinic and ED visits. CMS has poor data to calculate crucial APC reimbursement since there is no standard definition or standard application of E/M codes. Since hospitals are using different methodologies, (time, interventions, patient complexity or severity, etc.), each hospital's reported E/M levels reflect a different aspect of hospital resource utilization.

In the CY 2007 OPPS final rule, CMS indicated that "most commenters strongly supported creation of national guidelines." We are, therefore puzzled as to why CMS requested public comment as to whether there was still a pressing need for national guidelines. **The AHA continues to believe in the need for national guidelines for hospital ED and clinic visits.** The same reasons identified in previous comments from the AHA, as well as other providers, since 2001 regarding the need for national guidelines remain valid. In order to "play by the rules" a clear and detailed set of rules are needed. In the August 9, 2002 OPPS proposed rule, a summary of the comments received by CMS regarding the need for national guidelines included the following reasons:

- Facilities need to comply with HIPAA requirements (concern that use of E/M codes with different reporting rules and meanings when used by facilities would violate HIPAA requirements for using the standard code sets)
- To set up effective audit and compliance programs
- To minimize confusion on the part of coders
- To minimize inaccurate payments
- To prevent gaming of the system

The AHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA CPT Editorial Panel to create CPT codes for hospital visits. These codes then could be widely reported by hospitals to all payers.

While the set of principles that hospitals' internal coding guidelines are expected to follow may appear lofty and praiseworthy, in reality, they are worrisome because of the lack of specificity and definitions. We believe that if hospital guidelines are to be judged by these principles, it would be extremely difficult to satisfy these principles without additional guidance. The following issues and questions arise:

- How can guidelines follow the intent of the CPT code descriptors when the CPT E/M codes reflect intensity of resources that are not relevant factors in hospitals? For example, CPT E/M codes consider the history, physical examination and medical decision-making as the variable for determining physician resources. What would CMS consider appropriate variables to account for hospital resources in determining ED or clinic visits? Based on previous examples of hospital visit models submitted, some consider nursing interventions, time, diagnoses or complaints, patient acuity, or a combination of these.
- Principles such as "guidelines should be clear to facilitate accurate payments and be usable for compliance purposes and audits" are subjective and open to interpretation. A guideline may be clear to a coding professional but confusing to an auditor.
- Without national guidelines and unique codes and accompanying descriptors for hospital ED and clinic visits, guidelines cannot meet the HIPAA requirements. These requirements necessitate using codes based on the descriptors and definitions developed by the code set maintainer – the hospital. Current CPT codes describe physician services.
- What is the definition of great frequency? It is difficult for providers to meet a principle stating that guidelines should not change with great frequency when the definitions and concepts as to what may or not be specifically included in a clinic or ED visit code have changed since OPPS implementation. For example, hospitals may have had to redefine their ED visits or create new guidelines on the basis of last year's distinction between Type A and Type B ED visits. Another example is whether separately payable interventions may be included in the determination of a level. Initially, CMS was silent on this topic, but in 2002 commented that separately payable interventions should not be included. The list of packaged HCPCS codes can change annually, thereby necessitating their removal from the interventions included in the guideline. For example, bladder catheterization services were formerly packaged and then changed to being separately payable under certain circumstances.
- What is the definition of "readily available" in the principle regarding guidelines being readily available for fiscal intermediaries or Medicare administrative contractors? How should these guidelines be available?
- How will it be determined whether guidelines result in coding decisions that could be verified by other hospital staff as well as outside sources? Even with national standards and national definitions (such as with ICD-9-CM), there can sometimes be room for interpretation among coders and with outside sources requiring additional clarification and education.

Inclusion of Separately Payable Services in Visit Levels. In the CY 2007 proposed OPPS rule, CMS indicated that it was open to further discussion and welcomed public comments on the exclusion of separately payable services from the national visit guidelines. In the CY 2007 final OPPS rule, CMS agreed with commenters that there may be advantages to including separately payable interventions in the guidelines as examples because a measure of acuity may be lost in the absence of recognition of these procedures. In the absence of national guidelines, we urge CMS to clarify whether separately payable procedures may now be included in hospital-specific guidelines.

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September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (Vol. 72, No. 148), August 2, 2007.

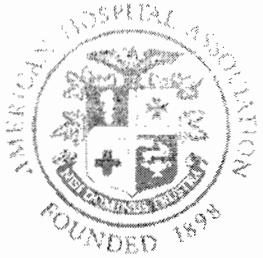
Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar (CY) 2008 outpatient prospective payment system (OPPS).

The AHA is commenting on several OPPS proposals. Most importantly, we have serious concerns about the proposed packaging rules, partial hospitalization payment (PHP) cuts, changes to the critical access hospital (CAH) conditions of participation, separate billing for pharmacy overhead costs and requirements for outpatient quality measure reporting. In brief, the AHA makes the following recommendations:

- CMS should re-evaluate its new packaging proposal. We found problems in CMS' methodology and correcting these problems leads to different impact results by type of hospital. If CMS decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services.

- CMS should maintain the PHP per diem at the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services. In addition, we recommend CMS further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.



- CMS should rescind its proposal to require a CAH-operated provider-based facility created after January 1, 2008 to comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). The agency's proposal is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Such a policy would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

- CMS should withdraw its proposal instructing hospitals to bill separately the pharmacy overhead charge. The agency's proposal creates a huge administrative burden on hospitals and a morass of complexity that is unnecessary and excessive. Moreover, CMS should re-evaluate the recommendations of the Ambulatory Patient Classification Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

- CMS needs to refine several aspects of its new OPPS quality reporting program. First, the agency proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA) as the initial measures. We are pleased that CMS continues to align its choice of measures with the work of the HQA in the implementation of the hospital quality reporting programs; however, the HQA has only preliminarily approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. Therefore, we urge CMS to delay data collection until the measures have been thoroughly field-tested and received NQF endorsement, the data specifications have been finalized, and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when the hospitals and vendors are fully prepared to commence the program.

  We also urge CMS to modify its validation approach for the outpatient reporting program. We believe that, for 2009, data validation may be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold may be established at a lower level and then gradually raised to 80 percent, similar to the approach for inpatient PPS quality reporting.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

The American Hospital Association's Detailed Comments on the Proposed Rule for the 2008 Outpatient Prospective Payment System

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OPPS: PACKAGED PROPOSAL

Increasing Packaged Services
The outpatient prospective payment system (OPPS), unlike other prospective payment systems, employs only moderate packaging of services and generally makes a separate payment for each individual service provided during a patient encounter.

For 2008, CMS proposes to broaden the OPPS payment groupings – ambulatory payment classifications (APCs) – by packaging into the primary service provided seven categories of items and services that CMS considers to be typically ancillary and supportive. These services are currently billed separately. The agency believes that payment based on a larger group of services will provide an incentive for hospitals to furnish services in the most efficient way by allowing them to manage their resources with maximum flexibility.

The seven categories of items and services CMS proposes to package into primary diagnostic and therapeutic procedures with which they are performed include:

- Guidance services,
- Image processing services,
- Intra-operative services,
- Imaging supervision and interpretation services,
- Diagnostic radiopharmaceuticals,
- Contrast media, and
- Observation services.

CMS proposes to assign packaged codes either a payment status indicator "N" or "Q." Status indicator "N" is assigned to those codes for services that are always integral to the performance of the primary service with which they are billed. The costs for these codes are always packaged. Status indicator "Q" is assigned to those codes that are usually, but not always, integral to a primary service. These codes may sometimes be paid separately when no other separately paid primary service is provided during the hospital outpatient encounter.

CMS notes that the median cost of many APCs will change not only as a result of the increased packaging itself but as a result of the changes it makes in individual codes moving into and out of the APCs.

The AHA generally has supported efforts to package more services into larger payment bundles. We believe, like CMS, that appropriately sized bundles can provide incentives to improve efficiency and manage resources. However, we have concerns about CMS' proposal and the underlying analysis behind it.

First, while the agency estimates that the proposal would redistribute approximately 1.2 percent of the 2007 expenditures under the OPPS, analyses prepared by The Moran Company indicate that the seven categories in CMS' proposal represent 6 percent of outpatient costs. The reason

our analysis had a higher percentage of costs was because of the methodology for applying the status indicator "Q." The resulting impact reveals very different impacts by type of hospital than CMS' impact tables, and we are concerned that the implications of this policy are not fully understood.

Second, we have concerns about the proposal to package observation services. The billing and coding rules for observation have changed significantly since the implementation of the OPPS. Since CMS implemented separate payment for observation services in 2002 for selected medical conditions, hospitals have found the criteria and documentation requirements to be administratively burdensome and complex. During the past several years, the APC Advisory Panel has made multiple recommendations to CMS to simplify and/or clarify definitions and instructions for the reporting of observation services. Numerous operational hurdles had to be overcome to ensure compliance with all of the rules for reporting packaged observation charges versus separately payable observation APC charges. The requirements were not automated, difficult to track and involved multiple departments in order to ensure that the observation services were appropriate from both the clinical and billing perspectives. The confusion in billing observation led to incomplete data on separately billable observation services.

The impact of packaging observation at this time is likely to have the largest impact on those hospitals that understand and appropriately code for allowable observation services. Two hundred hospitals (or 5 percent) provided one-third of all separately payable observation services, according to The Moran Company's analysis of outpatient claims from 3,954 hospitals. Separately payable observation services are only covered for patients with three specific conditions: congestive heart failure, asthma and chest pain. These conditions are widely treated in the majority of America's hospitals and the concentration of observation services in a relatively small number of hospitals is likely due to the complexity and numerous changes of coding rules. To include observation services with such skewed claims data would be inappropriate at this time.

The AHA recommends that CMS re-evaluate its new packaging proposal in light of the methodological and data concerns. If the agency decides to move forward with its proposal, we urge CMS to exclude observation services from its final packaging strategy at this time. The AHA supports the continuation of separately payable status for observation services and CMS' use of the Outpatient Claims Editor logic to automatically determine whether observation services on a claim are separately payable. Begun in 2002, this process resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services and continuation of this policy will lead to improved understanding of observation services and costs.

Composite APCs

CMS proposes to create a "composite" APC that would pay a single rate for larger bundles of major, and currently, separately paid, services that are commonly performed in the same hospital outpatient encounter (or as part of a multi-day episode of care). CMS believes this concept of "composite" APCs would create incentives for greater efficiency.

The two composite APCs proposed for 2008 are:

- APC 8001 (Low Dose Rate (LDR) Prostate Brachytherapy Composite) and
- APC 8000 (Cardiac Electrophysiologic Evaluation and Ablation Composite).

CMS' proposal begins to address the concept of the outpatient "episode" of care, and these new bundles may offer a cohesiveness of payment similar to the cohesiveness of the care. While CMS expects to develop additional composite APCs in the future as it learns more about major services that are commonly provided together during the same hospital outpatient encounter, **the AHA urges CMS to evaluate closely the impact of these new bundles on payment adequacy and access to care before expanding this new policy to other services.**

OPPS: Specified Covered Outpatient Drugs

The Medicare Modernization Act of 2003 (MMA) provisions require special classification and payment of certain separately paid drugs, biologicals and radiopharmaceuticals that had previously (or before December 31, 2002) received pass-through payments. In 2008, the law requires that payment for these specified covered outpatient drugs be equal to the average acquisition cost for the drug, subject to adjustment for pharmacy overhead costs.

To set the proposed 2008 rates, CMS evaluated fourth quarter 2006 average sales price (ASP) data on about 500 drugs and mean costs derived from 2006 OPPS claims data. CMS concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be roughly equivalent to basing their payment rates at ASP plus 5 percent. The agency cites findings from a 2005 Medicare Payment Advisory Commission (MedPAC) study of pharmacy overhead costs to support its conclusion that ASP plus 5 percent is a sufficient level to cover drug acquisition and pharmacy overhead costs. The MedPAC survey results indicated that hospitals set charge levels for drugs to cover both drug acquisition and pharmacy overhead costs.

For 2008, CMS proposes to pay for the drug acquisition *and* pharmacy overhead costs of specified covered outpatient drugs at a *combined* rate of ASP plus 5 percent. This rate is lower than the ASP plus 6 percent rate for drugs furnished in physician offices. Lowering the payment percentage from 6 to 5 percent above ASP is a budget-neutral change to the OPPS and redistributes the additional 1 percent of payments to other outpatient services. However, reducing payment for separately payable drugs under the OPPS, while maintaining drug payments at ASP plus 6 percent for drugs provided in physician offices, creates inconsistencies in payment that could result in unintended and inappropriate incentives to treat patients in one setting over another. CMS should eliminate the inconsistency of paying differently for the same drugs based on the treatment setting.

Pharmacy Overhead Costs

CMS proposes to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead charge on an uncoded revenue code line on the claim. This policy would apply to the reporting of charges for all drugs and

biologicals, including contrast agents, regardless of the item's packaged or separately payable status. CMS would not apply this policy to radiopharmaceuticals because it has previously instructed hospitals to include the overhead and handling charges in the charges for the radiopharmaceutical products.

CMS believes that this change would allow the agency to identify pharmacy overhead costs for drugs and biologicals and, in future years when the 2008 claims data become available, to package these overhead costs into payment for the associated procedure, likely a drug administration procedure. CMS also believes that this policy would not violate the "uniform charge" regulation that prohibits hospitals from charging Medicare differently from all other payers because under this proposed policy the same total charges would be provided to all payers.

However, CMS' proposal creates a huge administrative burden on hospitals and an unnecessary morass of complexity. During November and December, thousands of drugs and dosages would need to be evaluated and examined for the resources they consume in the operations of the pharmacy. Even large hospitals with sophisticated staff, resources and information systems – let alone small and rural hospitals – would find this task and the related timeframes unworkable. Because of the enormity of this task, hospitals would be forced to apply simple across-the-board overhead percentages which would undermine the validity and usefulness of the data.

CMS has vastly underestimated the difficulty of its proposal. The agency should withdraw its proposal, re-evaluate the recommendations of the APC Panel and consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs.

OPPS: QUALITY DATA

The Tax Relief and Health Care Act of 2006 mandated that CMS establish a program under which hospitals must report data on the quality of hospital outpatient care to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. Hospitals that fail to report outpatient quality data would incur a reduction in their annual outpatient payment update factor of 2.0 percentage points.

Quality Measures

To implement this legislative mandate, CMS proposes to use the 10 outpatient measures that have received preliminary approval from the Hospital Quality Alliance (HQA). We are pleased that CMS continues to align its choice of measures with the work of the HQA; however, the HQA has only *preliminarily* approved these measures because several of them have not yet been endorsed by the National Quality Forum (NQF), and all of them need work to further refine the specifications for data collection. The HQA will not proceed with measures that do not receive NQF endorsement or that are not fully specified and tested to ensure proper data collection can be achieved. We urge CMS to proceed in the same manner when the agency finalizes the rule.

Further, it is vital that all new measures undergo a rigorous field test to identify any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors. **We urge CMS to fund a thorough field test of the outpatient measures immediately.**

Regarding the other measures that CMS identifies for possible inclusion for CY 2010 or later, we reiterate our position that all measures included in hospital reporting programs should be NQF-endorsed and HQA-adopted.

Timing of Implementation
To be eligible for a full OPPS payment update in 2009, CMS proposes that hospitals submit quality data on these 10 measures effective with hospital outpatient services furnished on or after January 1, 2008. Before data collection can begin, hospitals will have to review the data specifications, become familiar with a new data collection tool, implement their reporting systems, develop any sampling methodologies and educate and train staff. Likewise, data vendors will have to develop the data abstraction and submission tools, test the software programs, create hospital educational materials and programs and work with hospitals to implement the software programs.

By contract and according to the CMS/Joint Commission Specifications Manual, data vendors are to have 120 days to complete this programming and prepare to collect the data. CMS released the data specifications for the outpatient measures on August 29; however, we understand that the specifications are still in fluctuation and may be changed as the measures go through NQF endorsement or are tested further. Developing the data collection tools and assisting hospitals with implementation by January 1 will be extremely challenging for the vendors; implementing these changes as the specifications are still evolving may be impossible.

Hospitals have told the AHA that the implementation timeline for outpatient reporting will be extremely difficult for them to meet, primarily due to the complexities around building the information technology infrastructure to begin data collection. The outpatient measures will require new documentation forms and criteria, and hospitals will face documentation issues that are different from those they have met for inpatient reporting. Hospital inpatient, emergency department and outpatient clinic information systems typically are separate from one another without common data interfaces. Even those hospitals with more established electronic health records may have different systems for inpatient and outpatient records, particularly with respect to outpatient clinic records. In addition, some data elements necessary for reporting will have to be obtained from billing records, similar to the inpatient measures. However, there currently is no mechanism available to collect this information from outpatient or physician claims.

Further, smaller hospitals may see their reporting burden increase dramatically with the implementation of the emergency department transfer measures. We generally applaud measures that allow smaller hospitals to fully participate, as many have been unable to report on some of the inpatient measures. However, these hospitals, which have fewer staff available and trained to

abstract data and fewer resources to implement electronic systems, may be overwhelmed trying to implement reporting on the outpatient measures in such a tight timeframe.

Hospitals support expanding the quality information available to the public and reporting on standardized outpatient quality measures. It is essential, however, to ensure that the information reported is valid and reliable. We would question the validity and reliability of any data that is reported before the measures are fully field-tested. Additionally, expecting hospitals to implement in less than four months a new program that is tied to payment is unduly burdensome. Therefore, we urge CMS to delay data collection on the outpatient measures until the measures have been fully field-tested and received NQF endorsement, the data specifications have been finalized and the data collection software is fully operational. There is no requirement in the statute that data collection begin on January 1, 2008. For CY 2009 payment purposes, data collection could begin later in 2008 when hospitals and vendors are fully prepared to commence the program.

Administrative Requirements of the Reporting Program
In the proposed rule, CMS outlines the administrative steps that hospitals must take to participate in the outpatient quality reporting program. The rule notes that hospitals must complete and submit a notice of participation form by November 15. We anticipate that there may be some confusion in the field around this requirement as hospitals were required to submit a similar form for participation in the inpatient quality reporting program in August. We urge CMS to communicate this requirement clearly and frequently to hospitals this fall and to work with its HQA partners so that all hospitals are aware of the steps they need to take to participate in the outpatient reporting program. We appreciate CMS' proposal that once a hospital has submitted a notice of participation, it will be considered an active participant of the program until the hospital indicates otherwise. This step will alleviate some of the administrative burden on hospitals, and we encourage CMS to adopt this policy in the final rule.

Data Submission Timeframe
The proposed data submission timeframe for the outpatient reporting program is 120 days, slightly shorter than the 135-day timeframe for the inpatient reporting program. If CMS chooses to adopt this shorter timeframe, the agency must be able to assure hospitals that updated data collection software will be available on the first day of the data submission period and that the necessary programming to receive the data at the data warehouse will have been completed and tested. Previously, delays in the availability of useable software for the inpatient reporting program have caused data submission delays for hospitals. Unless these recurring software problems can be resolved, CMS cannot shorten the timeline.

Data Validation
CMS is proposing data validation requirements for the outpatient quality reporting program. For 2009, CMS proposes randomly selecting for reabstraction five patient charts from each hospital from among those patients receiving services in January 2008. To pass validation, hospitals must meet a minimum of 80 percent reliability from the chart reabstraction.

The AHA opposes this proposal. Although hospitals have been collecting data for inpatient measures for several years, collecting data for the outpatient measures will involve the use of a new data collection tool with documentation criteria and forms that are different than the inpatient reporting program. The data likely will be collected by different staff. As with the implementation of any new program, there will be a learning curve as hospitals gain experience with the new program. Likewise, those staff members of the clinical data abstraction center with responsibility for the data reabstraction for validation will experience the same learning curve.

When the inpatient reporting program began, reabstraction and validation were used as learning tools for hospitals to improve their documentation and data collection. There was no minimum validation threshold determining whether or not hospitals received their full annual payment update. As the program evolved and hospitals gained experience with it, a minimum validation threshold was introduced and gradually raised to the 80 percent reliability rate. This was a thoughtful and deliberate approach to ensuring high reliability in the data used for the inpatient reporting program. **We urge CMS to undertake a similar approach for the outpatient program. For example, in 2009, data validation could be conducted as a learning tool for hospitals, but there should be no minimum reliability threshold required for the annual payment update. In subsequent years, a reliability threshold could be established at a lower level and then gradually raised to 80 percent.**

Reconsideration Process
For those hospitals that fail to meet the program requirements, CMS is proposing to implement a reconsideration process, similar to the one used for the inpatient reporting program. We believe that such a process is an essential component of the outpatient reporting program. CMS should establish a reconsideration process that is straightforward, transparent and timely.

ASCs: Quality Data

The Tax Relief and Health Care Act of 2006 mandated that the Secretary include ambulatory surgical centers (ASCs) in the outpatient quality reporting program. In the proposed rule, CMS delays implementing a quality reporting program for ASCs. The AHA encourages CMS to implement a quality reporting system for ASCs as soon as possible. All providers that perform the same services should be held to the same accountability standards with respect to the quality of the care they deliver.

OPPS: Partial Hospitalization

For the past two years, CMS has expressed concern that the median per diem cost derived from hospital and community mental health center (CMHC) claims data was too low to cover the cost of partial hospitalization programs (PHP) that typically span five to six hours per day. However, CMS still implemented a 15 percent decrease in the per diem for CY 2006 and then another 5

percent decrease in CY 2007. For CY 2008, CMS proposes another 24 percent drop in payments.

Cost-to-charge Ratios
For 2008, CMS proposes to adopt changes to its methodology for calculating PHP median costs using both hospital-based and CMHC PHP data. To more accurately estimate costs for PHP claims, CMS proposes to re-map 10 revenue center codes to a Primary Cost Center 3550, "Psychiatric/Psychological Services" or to a Secondary Cost Center 6000, "Clinic." In establishing the PHP median per diem rate, CMS proposes to calculate a separate per-diem cost for each day, rather than for each bill. **The AHA recommends that CMS conduct a similar analysis for CMHCs as PHP services are the highest-cost services they provide and may have statistically different cost-to-charge ratios than the overall CMHC cost-to-charge ratios.**

Median Costs
CMS analyzed the number of services being provided in a day of care as a possible explanation for the low per diem cost for PHP. It found that, despite its expectation that five or six services would be provided in a day, both hospital-based and CMHC PHPs have a significant number of days where three or fewer units of service were provided. Specifically, 34 percent of hospital-based PHP days contained three or fewer units of service, and 64 percent of CMHC PHP days contained three or fewer units of service.

CMS believes that its analysis of the number of units of service per day supports a lower per diem cost and thus, proposes to calculate the median per diem cost using all days, not just those with four or more units of service provided. Therefore, CMS proposes a per diem payment cost for 2008 of $178, which is 24 percent lower than the per diem cost of $233.37 for 2007.

CMS says that it did not propose separate rates for half-days and full-days because it believes the program was intended to cover a full day of service and that it was appropriate to set one rate that would be paid for all PHP days. The AHA, however, believes that there are circumstances that warrant less than a full day of services. For instance, when patients are transitioning out of the program or when there are other complicating physical ailments that require separate therapy. In addition, the partial hospitalization programs have evolved as the use of psychotropic drugs has increased and diminished the need for as much therapy. Even though a full day of services is not provided, such services are still valuable, necessary and warrant payment.

There is precedence for differentiating payments based on higher or lower utilization of services. For instance, under the home health PPS there is a low-utilization payment adjustment. Low-utilization payment adjustments are 60-day episodes with four or fewer visits where payment is based on a per visit basis. Following a similar pattern, CMS could set the PHP median per diem cost based on days when four or more services are provided and then pay a low-utilization payment adjustment amount for days when three or fewer services are provided. This approach would more accurately reflect resource intensity and ensure that those hospitals that provide more services per day are adequately paid. CMS could also put constraints around how

frequently three or fewer services could be billed to prevent the bulk of days furnished by a provider being low utilization. We urge CMS to further research the possibility of such a payment structure for CY 2009.

The vast majority of patient days in hospital-based units are high-intensity services that may avoid a hospital stay, or a continued hospital stay. If additional hospitals reduce or eliminate PHP services, there will be increased demand for inpatient psychiatric beds that are already in short supply and, likely, additional bottlenecks in the emergency departments.

The AHA recommends that CMS maintain the CY 2007 rate of $233 to ensure continued beneficiary access to PHP services and further study the possibility of differentiating payment based on the intensity of services provided during a day of PHP services for CY 2009.

NECESSARY PROVIDER CAHS

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). CMS believes that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. In the case of a necessary provider CAH that violates the proposed requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

It is unclear in the rule to which provider-based entities CMS intends to apply this proposal. The provider-based regulations state that such determinations are not necessary for ambulatory surgery centers; comprehensive outpatient rehabilitation facilities; home health agencies; skilled nursing facilities; hospices; inpatient rehabilitation units; independent testing facilities; facilities, other than as parts of CAHs furnishing solely physical, occupational or speech therapy; ESRD facilities; ambulance providers; and rural health clinics (RHCs) with more than 50 beds. Thus, it is assumed that the proposal does not apply to these types of providers. It appears as if CMS intends the proposal to apply to psychiatric or rehabilitation distinct part units (even though rehabilitation units are on the list for which provider-based determinations are not necessary). It is unclear if CMS intended to include RHCs and outpatient departments. CMS should clearly state to which types of entities this policy applies.

Further, CMS' proposal will have detrimental effects on all CAHs, not just necessary provider CAHs. Two CAHs could be 40 miles apart, but their provider-based entities could be within 20 miles of the other hospital in a town midway in between the CAHs. This rule would prevent either hospital from serving this town through a provider-based entity.

The AHA is unsure of CMS' motivation in making this proposal. There is nothing in the law to suggest that such an action is necessary. Nor, have we seen any recent direction from Congress to apply the mileage requirements, intended for the CAH itself, to its other lines of business. CMS is creating more burden for CAHs and potentially restricting access to care.

While there are payment advantages to CAHs under the inpatient and outpatient PPSs, there are no advantages for psychiatric and rehabilitation units. While the per visit limit for CAH-owned provider-based RHCs is waived, that is not unique to CAHs and is the case for any hospital with fewer than 50 beds. The location of provider-based entities nearer to the next hospital than the CAH itself does not pose an unfair market advantage compared to neighboring hospitals. Surrounding PPS hospitals are able to locate their provider-based entities wherever they chose as long as they continue to meet the provider-based criteria. Thus, if anything, this policy would put CAHs at a distinct disadvantage compared to their local PPS counterparts.

If CMS implements this policy, it may have broader effects on community access to care than the agency anticipates. CAH provider-based entities are located in different places for various reasons often unrelated to where the next hospital is located. Hospitals consider available land, natural boundaries, increased need, preference of physicians and other practitioners, etc. While community members may be willing to travel a distance to a hospital for urgent/emergent care or services not available elsewhere, beneficiaries want something closer to home for more routine visits, therapy, lab work, etc. By forcing the CAHs to have all services on-campus, CMS will be creating geographical bare patches that leave some communities members without access to services.

Additionally, clinics and distinct part units are often a way CAHs recruit physicians to practice in the area. By hiring a physician at one of the CAH's provider-based entities, the CAH guarantees that there is a physician in the area to serve on the medical staff. There are small communities nationwide within 35 miles of a CAH that would have no physician without a RHC. As older physicians retire or younger physicians relocate, the ability to set up a RHC would be critical to the continuation of basic medical care in rural areas. The hospitals that are affected by this rule are small and rural by their nature and all of them already have trouble recruiting and retaining physicians. CMS should not make it more difficult for CAHs to recruit and retain needed personnel.

Finally, the "grandfather" provision that extends only to provider-based entities that maintain the same location will inappropriately lock them into outdated facilities. Some CAHs are operating provider-based entities in very old buildings that need to be replaced, which often means relocation. Many hospitals are in the middle of planning or actively constructing new facilities. The financial viability of these projects revolves around provider-based status. Officially changing this requirement November 1 for January 1 implementation is simply not reasonable or feasible.

CMS should rescind this proposal. It is contrary to CMS' stated intention in the rule "to ensure access to essential health care services for rural residents." Moreover, CMS' policy

would make physician recruitment and retention in rural areas even harder and would jeopardize access to services in rural areas.

REPLACED DEVICES

In the 2007 OPPS final rule, CMS adopted a policy that reduces the APC payment to a hospital or ASC for selected device-dependent APCs when the hospital receives certain replacement devices without cost or receives a full credit for the device being replaced. The CY 2007 reduction policy does not apply to cases in which there is a partial credit toward the replacement of the device. For 2008, CMS proposes to expand the policy to require hospitals to report occurrences of devices being replaced under warranty or otherwise with a partial credit granted to the hospital so that the agency can identify systematic failures of devices or device problems through claims analysis and make appropriate payment adjustments.

CMS proposes to create a HCPCS modifier that would be reported in all cases in which the hospital receives a partial credit toward the replacement of one of the 31 medical devices listed in Table 39 of the proposed rule. CMS proposes to reduce the payment for the APC into which the device cost is packaged by one half of the amount of the offset amount that would apply if the device were being replaced without cost or with full credit when the amount of the device credit is at least 20 percent of the cost of the new replacement device being implanted.

Under the analogous policy adopted in the 2008 final inpatient rule, CMS only applies the reduced payment to cases in which the hospital receives a credit equal to 50 percent or more of the cost of the device. This ensures that the reduction in payment does not occur when the credit is nominal or relatively inconsequential in comparison to the overall payment for the case. **CMS should raise the proposed threshold from 20 percent to 50 percent in the final OPPS rule, as is the case under the inpatient PPS.**

We concur with CMS that requiring hospitals to reduce their charges in proportion to the partial credit or to provide paper invoices or other information to the fiscal intermediary (or Medicare administrative contractor) indicating the hospital's normal cost of the device and the amount of the credit received would impose an unacceptable administrative burden on hospitals. We urge CMS to exclude any such requirements in the final rule.

The AHA also is concerned about proper billing and the potential for payment delays that could occur while a returned device is being evaluated during a warranty service period. Hospitals frequently do not know whether a manufacturer will agree that a returned device is covered under the warranty or the amount of credit that will be granted. In the 2008 final inpatient rule, CMS acknowledged the validity of similar concerns and agreed that hospitals should have the options of either: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the inpatient PPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until

a determination is made on the level of the credit. We believe that CMS should give hospitals the same options for reporting the HCPCS modifier under the OPPS.

OPPS: HOSPITAL VISITS

Since April 2000, hospitals have been using the American Medical Association's (AMA) Current Procedural Terminology (CPT) evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors – designed to reflect the activities of physicians – did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services.

In 2003, the AHA and the American Health Information Management Association (AHIMA) recommended hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency established new HCPCS level II G codes to distinguish visits provided by Type B EDs (not open 24 hours a day, seven days a week – 24/7).

Proposed Codes and Coding Policy for 2008
For 2008, CMS proposes to continue using CPT E/M codes for clinic visits including separate codes for new and established patients. The agency also proposes to cease paying for consultation E/M codes under OPPS and instead to instruct hospitals to bill a new or established visit code. Differentiating hospital visit codes between new and established patients, or between standard visits and consultations, adds an unnecessary level of complexity and is difficult to implement. **We support CMS' proposal to eliminate the consultation codes, but urge CMS not to implement the codes for new and established patient clinic visits.**

While current distinctions in the physician E/M codes exist, the same concepts do not apply to facility resources. From a physician's perspective, an established patient may require a shorter history and a less comprehensive physical exam. These same economies are not necessarily factors in determining facility resource codes. For example, a person may be an established patient to a facility because of previous visits to any number of outpatient settings, including the ED, a clinic, as an inpatient, for a diagnostic exam or for any other service. Previous services may or may not be related to the current visit, but it would be extremely burdensome for facilities to have to determine whether there was a previous encounter and whether previous services performed are related to the current visit. This determination is especially difficult for medium-sized hospitals and nearly impossible for small hospitals. For these hospitals, rural communities in particular, nearly every patient ever seen will have had some type of contact with the hospital.

The interventions performed during an encounter are determined by physician orders, but the actual performance of these interventions would be the same whether the patient was new or established. Current distinctions on new vs. established patients for hospital coding are based on whether the patient has a medical record number within the previous three years. **We believe that the clinic visits should be recognized on the basis of hospital resources utilized during a specific visit, and therefore, not determined by whether the patient has been seen by the hospital within the last three years. CMS should withdraw this proposal.**

ED Visits. We continue to be concerned about CMS' payment structure for Type A and B ED visits. Specifically, the new policy implemented by CMS' 2007 final OPPS rule led to significant confusion and concern about how hospital "fast tracks" are treated. Fast tracks generally function as a part of the ED that handles specialized cases (e.g. heart-related emergencies) or less emergent cases so that patient flow can be improved through a hospital ED. They can be physically adjacent or even located within the 24/7 ED but, hospitals often discontinue triaging patients to fast tracks during certain hours (e.g., the midnight shift).

Paying non-24/7 ED fast tracks at the clinic rate does not make sense from a national policy perspective. ED overcrowding and ambulance diversions are significant issues for America's health care system and fast tracks improve patient care, patient flow and patient satisfaction. CMS' policy has led many hospitals to consider closing these special units, a move that would exacerbate the nation's ED diversion and overcrowding problems.

The AHA believes CMS' policy can be improved to be clearer on the appropriate coding for fast track ED services. We recommend applying the following criteria.

If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is part of the Type A ED and can bill using the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as:

- **the fast track is a hospital-based facility which provides unscheduled episodic services to patients who present for immediate medical attention;**
- **the fast track area is physically located within the same building as the 24/7 ED; and**
- **the 24/7 ED and the fast track share a common patient registration system.**

ED Critical Care Visits. For 2007, CMS reaffirmed the criteria for payment for critical care services to require a minimum of 30 minutes of critical care services provided. From a facility perspective, a patient requiring at least 30 minutes of critical care would typically be admitted as an inpatient.

We recommend that the criteria for payment for critical care services be changed to a minimum of 15 minutes of critical care or the patient expires in spite of the administration of critical care services. Very significant hospital resources are utilized in the delivery of

critical care services, including multiple hospital staff members. These services are not appropriately recognized if the patient expires or is transferred before the completion of 30 minutes of service.

Proposed Treatment of Guidelines for 2008
CMS is not proposing to implement national visit guidelines for clinic or ED visits for CY 2008. In the proposed rule, CMS reiterated the set of principles it expects hospitals' internal guidelines should follow and requested comments on five additional principles.

The AHA is concerned that CMS is uninterested in developing or approving national guidelines for the reporting of hospital ED or clinic visits. Since the implementation of OPPS, the AHA has advocated for the development of national guidelines and unique codes to represent facility resources, rather than physician resources, used in the delivery of clinic and ED visits. CMS has poor data to calculate crucial APC reimbursement since there is no standard definition or standard application of E/M codes. Since hospitals are using different methodologies, (time, interventions, patient complexity or severity, etc.), each hospital's reported E/M levels reflect a different aspect of hospital resource utilization.

In the CY 2007 OPPS final rule, CMS indicated that "most commenters strongly supported creation of national guidelines." We are, therefore puzzled as to why CMS requested public comment as to whether there was still a pressing need for national guidelines. **The AHA continues to believe in the need for national guidelines for hospital ED and clinic visits.** The same reasons identified in previous comments from the AHA, as well as other providers, since 2001 regarding the need for national guidelines remain valid. In order to "play by the rules" a clear and detailed set of rules are needed. In the August 9, 2002 OPPS proposed rule, a summary of the comments received by CMS regarding the need for national guidelines included the following reasons:

- Facilities need to comply with HIPAA requirements (concern that use of E/M codes with different reporting rules and meanings when used by facilities would violate HIPAA requirements for using the standard code sets)
- To set up effective audit and compliance programs
- To minimize confusion on the part of coders
- To minimize inaccurate payments
- To prevent gaming of the system

The AHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA CPT Editorial Panel to create CPT codes for hospital visits. These codes then could be widely reported by hospitals to all payers.

While the set of principles that hospitals' internal coding guidelines are expected to follow may appear lofty and praiseworthy, in reality, they are worrisome because of the lack of specificity and definitions. We believe that if hospital guidelines are to be judged by these principles, it would be extremely difficult to satisfy these principles without additional guidance. The following issues and questions arise:

- How can guidelines follow the intent of the CPT code descriptors when the CPT E/M codes reflect intensity of resources that are not relevant factors in hospitals? For example, CPT E/M codes consider the history, physical examination and medical decision-making as the variable for determining physician resources. What would CMS consider appropriate variables to account for hospital resources in determining ED or clinic visits? Based on previous examples of hospital visit models submitted, some consider nursing interventions, time, diagnoses or complaints, patient acuity, or a combination of these.
- Principles such as "guidelines should be clear to facilitate accurate payments and be usable for compliance purposes and audits" are subjective and open to interpretation. A guideline may be clear to a coding professional but confusing to an auditor.
- Without national guidelines and unique codes and accompanying descriptors for hospital ED and clinic visits, guidelines cannot meet the HIPAA requirements. These requirements necessitate using codes based on the descriptors and definitions developed by the code set maintainer – the hospital. Current CPT codes describe physician services.
- What is the definition of great frequency? It is difficult for providers to meet a principle stating that guidelines should not change with great frequency when the definitions and concepts as to what may or not be specifically included in a clinic or ED visit code have changed since OPPS implementation. For example, hospitals may have had to redefine their ED visits or create new guidelines on the basis of last year's distinction between Type A and Type B ED visits. Another example is whether separately payable interventions may be included in the determination of a level. Initially, CMS was silent on this topic, but in 2002 commented that separately payable interventions should not be included. The list of packaged HCPCS codes can change annually, thereby necessitating their removal from the interventions included in the guideline. For example, bladder catheterization services were formerly packaged and then changed to being separately payable under certain circumstances.
- What is the definition of "readily available" in the principle regarding guidelines being readily available for fiscal intermediaries or Medicare administrative contractors? How should these guidelines be available?
- How will it be determined whether guidelines result in coding decisions that could be verified by other hospital staff as well as outside sources? Even with national standards and national definitions (such as with ICD-9-CM), there can sometimes be room for interpretation among coders and with outside sources requiring additional clarification and education.

Inclusion of Separately Payable Services in Visit Levels. In the CY 2007 proposed OPPS rule, CMS indicated that it was open to further discussion and welcomed public comments on the exclusion of separately payable services from the national visit guidelines. In the CY 2007 final OPPS rule, CMS agreed with commenters that there may be advantages to including separately payable interventions in the guidelines as examples because a measure of acuity may be lost in the absence of recognition of these procedures. In the absence of national guidelines, we urge CMS to clarify whether separately payable procedures may now be included in hospital-specific guidelines.