American Hospital Association

AHIMA
American Health Information Management Association

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October 10, 2006

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

RE: CMS-1506P MEDICARE Program: Hospital Outpatient Prospective Payment System and CY2007 Payment Rates, VISITS, 71 Federal Register 49506, August 23, 2006

Dear Dr. McClellan:

On behalf of the members of the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule that would establish new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year 2007 and hospital visit coding.

In January 2003, the AHA and the AHIMA convened the Hospital Evaluation and Management Coding Panel – also known as the expert panel – whose members had coding, health information management, documentation, billing, nursing, finance, auditing and medical experience. The panel developed recommendations for CMS on the 2004 hospital outpatient PPS rulemaking process. Based on the work of this panel, the AHA and the AHIMA in June 2003 recommended a hospital evaluation and management (E/M) visit guidelines model, also known as the AHA/AHIMA hospital visit model.

The AHA and the AHIMA have reconvened this panel, and it is ready to help CMS address public comments received regarding the development of national hospital visit codes and their corresponding guidelines.

Based on collective analysis, the AHA, the AHIMA and the independent expert panel recommend the following changes for the 2007 outpatient PPS.

BACKGROUND

Since April 2000, hospitals have been using current procedural terminology (CPT) and E/M codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that current E/M descriptors reflect the activities of physicians and do not adequately describe the range and mix of services provided by hospitals, CMS asked hospitals to develop internal guidelines to determine the level of clinic or ED services.

In the last several years, different national coding guideline models for reporting facility visits have been proposed and reviewed by CMS. In 2002, CMS specified that the agency would not create new codes to replace existing CPT E/M codes for reporting hospital visits until national guidelines were developed; this was a response to individuals who were concerned about implementing code definitions without national guidelines.

We appreciate that CMS is considering the recommendations of the independent expert panel and is posting this recommendation for wider public input. **While we have eagerly awaited national guidelines for hospital visits since the implementation of outpatient PPS, we continue to support CMS' commitment to provide a minimum of six to 12 months notice to hospitals prior to implementation of national guidelines.** Sufficient time is required so providers can make necessary system changes and educate staff on new coding and documentation requirements.

In 2005, CMS contracted with the Iowa Foundation for Medical Care to retrospectively code hospital medical records using the AHA/AHIMA model. The study was an attempt to validate the modified AHA/AHIMA guidelines and examine the distribution of services resulting from their application under outpatient PPS. CMS is concerned that the study revealed the AHA/AHIMA guidelines generate a different distribution of volume by code level, compared to current hospital reporting. What these findings do reflect, however, is that there are no national coding guidelines nor a standard methodology which hospitals can use to develop their own guidelines.

As stated by CMS, many different types of models are used to assign a visit code, each using a different variable to determine the differences in hospital resource use. Some use interventions, others use time, others use clinician skill level to determine complexity. In 2003, the expert panel compared different hospitals' methodologies when developing its initial set of recommendations. This review revealed considerable variability in the levels of services, depending on which methodology was used.

PROPOSED CODES AND CODING POLICY FOR 2007

Despite previous CMS assurances that the agency would not create new codes to replace existing CPT E/M codes until national guidelines were developed, CMS proposes to establish in 2007 new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of

EDs (Type A EDs, which are open 24 hours a day, seven days a week; and Type B EDs, which are not), and two critical care G codes. Until national guidelines are formally proposed and finalized, CMS said hospitals may continue to use existing internal guidelines to determine what visit would be reported using the new G codes, or adjust their guidelines to reflect the new codes and policies.

The AHA and the AHIMA continue to believe that CMS should not implement new codes for hospital clinic and ED visits unless accompanying national code definitions and national guidelines for their application are developed. Therefore, we oppose CMS' proposal to create temporary level II G codes while continuing to allow hospitals to apply their own internal guidelines to these codes. **Instead, we recommend that CMS support the continued use of the current five-level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are finalized.**

Creating temporary G codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. Instead, our approach would provide consistent coding policy, and allow CMS and stakeholders to focus instead on developing and fine-tuning a set of national guidelines that could be applied to a future set of hospital visit codes.

The AHA and the AHIMA recommend that once national guidelines are developed, a formal proposal should be presented to the American Medical Association CPT Editorial Panel to create CPT codes for hospital visits. These codes could then be widely reported by hospitals to all payers. We do not believe that creating temporary G codes would be effective or efficient as an interim step, and urge CMS to wait until the implementation of new CPT codes.

PROPOSED GUIDELINES AND CMS CONCERNS

CMS reviewed more than 10 sets of guidelines submitted since 2000. We are pleased that CMS believes the AHA/AHIMA guidelines provide the best platform for refinement and adoption, and we agree that any guidelines adopted will continue to require refinement after implementation. CMS used the AHA/AHIMA model to develop a modified version of the AHA/AHIMA model and CMS is seeking comment on both versions.

CMS identified eight general areas of concern regarding the AHA/AHIMA model. We will broadly address these areas in this letter, but will continue to review the models to develop specific recommendations for CMS in the near future.

Three Levels Versus Five Levels of Codes. To determine whether three levels of visit codes or five levels are appropriate, certain issues related to standardized national guidelines must be resolved. During the development of the visits model in 2003, the AHA/AHIMA expert panel concluded that "there was considerable difficulty in distinguishing the typical interventions performed in an ED and hospital clinic into more than three levels, once separately billable procedures were removed from the mix of interventions utilizing facility resources."

Clear guidance from CMS is required to determine what factors or interventions should or should not be included in determining the visit levels. For instance, may separately payable services be used as a proxy for intensity to drive level of service assignment? May time be taken into consideration? Having three levels versus five levels depends on the degree of specificity and discriminatory criteria associated with each level.

Lack of Clarity for Some Interventions. The AHA and the AHIMA agree that additional educational materials may be needed to provide greater clarity on interventions proposed in the model. The model submitted was an initial attempt to develop, on a very tight timeframe, a methodology around which hospital visit levels could be determined and that would address CMS' concerns with all other methodologies reviewed through 2002. The model was never intended as a stand-alone document, without explanations or supplementary educational materials.

Treatment of Separately Payable Services. While we will reconsider the inclusion of separately payable services as a proxy for patient acuity, the AHA and the AHIMA believe that this area requires further study and discussion. Coordination of services is certainly a resource-intensive activity for facility staff resources. However, not all separately payable services may reflect patient acuity; therefore, we believe the expert panel could determine which separately payable services are appropriate for inclusion.

Some Interventions Appear Overvalued. We would appreciate specific feedback from CMS regarding why the agency thought some interventions were overvalued. In determining the value for the different interventions included, the expert panel carefully evaluated the implications for facility resources for each intervention. The criteria included:

- The hospital staff time involved;
- The complexity of the intervention;
- The number of hospital staff members required to perform the intervention; and
- The skill level, qualifications or credentialing needed to perform the intervention.

Concerns of Specialty Clinics. We believe that a single set of clinic codes should be used by all types of clinics, rather than separate and distinct codes and guidelines for different types of clinics. To that end, specific facility services – not physician services – that are not currently identified in the clinic model should be identified and classified into a single clinic visit classification model. Such a classification model should appropriately recognize services for all patients, and not just the Medicare population.

Special Needs May Be in Violation of Americans with Disability Act. Unless carefully structured, proposals related to paying for patients with special needs may conflict with federal law governing discrimination. The AHA has evaluated this issue with legal counsel. The AHA/AHIMA model was intended to reflect the differences in service intensity – i.e., the type and amount of facility resources used in patient care – in order to support the appropriate assignment of a billing code for the level of services provided. It is clear that patients with special needs, such as altered mental status, language, cognitive and/or communications impairments, sometimes require increased resources in the form of additional staff time and/or specialized facility resources, and result in increased costs for the facility. While the AHA/AHIMA model was crafted so as to permit evaluation of facility resources used, it was not intended to affect the payment obligations of individual beneficiaries for items such as coinsurance. The AHA and the AHIMA would like to work further with CMS to evaluate how the Medicare program could adequately pay for its share of these increased costs without affecting individual beneficiary payment liability or otherwise raising concerns under federal law governing discrimination.

Differentiation Between New and Established Patients, and Between Standard Visits and Consultations. Differentiating hospital visit codes between new and established patients, or between standard visits and consultations, would add an unnecessary level of complexity and be difficult to implement. These distinctions should be eliminated. 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 services performed then are related to the current visit. 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. Every ED patient is treated using the same standard of care and the same work effort, regardless of whether the patient is new or established.

Lack of Distinction Between Type A and Type B EDs. This is not a coding issue. Hospital visit codes should be assigned on the basis of the services provided to a specific patient, and not related to a licensing issue. If there is a need to distinguish between Type A or Type B EDs, it should be done through the provider profile or some other methodology.

PROPOSED CRITICAL CARE CODING

We oppose the proposed structuring of critical care coding on the basis of time. Time is not a relevant factor to determine facility resources used and is inappropriate for hospital critical care codes for the following reasons:

- Most critical care patients are in the ED for 30 minutes or less. Typically, critical care patients are stabilized and transferred to the intensive care unit, which would then be billed as an inpatient service.

- Critical care codes in the outpatient setting most likely would apply to patients who died before they could be admitted or who were transferred to another facility.

- The goal of the ED is to stabilize the patient as quickly as possible. If a code is created that requires that a patient receive at least 30 minutes of critical care before the code can be used, then for any patient receiving less than 30 minutes of care the facility resources for these patients would not be recognized.

- Critical care patients require multiple hospital staff to be present simultaneously and may require a multidisciplinary team. It would be extremely burdensome and confusing to track time for those different individuals.

We will continue to do an in-depth review of the models and CMS' concerns. We also request CMS' assistance in a few key areas.

The AHA and the AHIMA request the opportunity to review the analysis of the AHA/AHIMA model conducted by the Iowa Foundation for Medical Care. Understanding the specific concerns and findings of this study will allow our expert panel to determine whether additional examples or education are needed and how best to modify the model. Examples of outstanding questions are whether the contractor had access and reviewed complete medical records, or only physician documentation. Typically, requests for hospital documentation by payers are answered with copies of the physician documentation and do not include nurses' notes or flow sheets. The entire medical record may provide additional information to support hospital staff interventions included in the AHA/AHIMA model that may not necessarily be part of the physician documentation.

We also would like to meet with CMS staff to understand the rationale for some of CMS' modifications of the AHA/AHIMA model. In some instances, it appeared that CMS may have considered interventions on the basis of the physician time/expertise involved, rather than the actions of hospital staff or facility resources. For example, it is unclear why patient education by hospital staff was deleted, while physician counseling of more than 60 minutes would be added. Preliminary testing of the CMS-modified model by two of the expert panel members raised concerns that the modified model did not allow their cases to go beyond a level one code. Removing other factors such as altered mental status and scheduling/coordination of ancillary services has a significant impact on the assignment of a level of service to patients who required substantial additional hospital resources. Understanding CMS' intentions will allow us to provide a more thorough review and detailed recommendations.

We agree that additional training, education and supplemental materials (e.g. vignettes) would be helpful to aid in the application of the guidelines. We believe that these should be developed only after national guidelines are established.

The AHA and the AHIMA appreciate the opportunity to comment on hospital visit coding. We look forward to working with CMS to resolve any remaining issues and assist in the development and implementation of standardized national coding guidelines for the reporting of hospital visits. If you have questions, please feel free to contact AHA's Nelly Leon-Chisen, RHIA, director of coding and classification for, at (312) 422-3396; or AHIMA's Sue Bowman, RHIA, CCS, director of coding policy and compliance, at (312) 233-1115.

Sincerely,

Rick Pollack
Executive Vice President
American Hospital Association

Dan Rode, MBA, FHFMA
Vice President, Policy and Government Relations
American Health Information
Management Association

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PPTA
Plasma Protein Therapeutics Association

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

Re: CMS-1506-P; CMS-4125-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates)

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule concerning the 2007 hospital outpatient prospective payment system ("OPPS") rates that was published in the Federal Register on August 23, 2006 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the hospital outpatient setting.

PPTA is the association that represents the commercial producers of plasma protein therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the plasma protein therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

PPTA commends CMS for its proposal to pay separately for additional hours, beyond the first hour, for intravenous infusions and urges CMS to finalize this proposal.

[1] 71 Fed. Reg. 49506.

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

At the same time, however, PPTA is very disappointed in the agency's proposal to reduce the payment rates for plasma protein therapies, especially IVIG, furnished in hospital outpatient departments. PPTA disagrees with the agency's rationale for proposing payment at average sales price ("ASP") plus 5%, and is extremely troubled by the differential it would create in payments between the hospital outpatient and physician office settings. Such a policy change will create another detrimental shift in site of service for beneficiaries seeking plasma protein therapies. If implemented, this reduction in reimbursement for the hospital outpatient setting will further dislocate Medicare beneficiaries because it will continue to impede their access to quality care. PPTA is also incredibly concerned about the proposed elimination of the preadministration-related services payment for IVIG. Such action by CMS would further reduce reimbursement in the hospital outpatient setting for IVIG, which would exacerbate the existing access problem for this therapy.

Moreover, PPTA strongly urges CMS to ensure the OPPS payment rates for IVIG do not continue to adversely impact beneficiaries seeking IVIG therapies. PPTA believes CMS can accomplish this by both creating separate Healthcare Common Procedure Coding System ("HCPCS") codes for each brand name IVIG therapy, and reconsidering the implementation of a payment adjustment for IVIG within the ASP plus 6% formula, similar to the precedent it established through its treatment, at Congress' direction, of blood clotting factor, which is also a plasma derived therapy.

DISCUSSION

PAYMENT FOR EXTENDED INFUSIONS ["OPPS Drug Administration"]

In the Proposed Rule, following the recommendation of the Ambulatory Payment Classification ("APC") Advisory Panel, CMS proposes to make separate payments for each additional hour of an intravenous infusion beyond the first hour. CMS recognizes that this policy is particularly appropriate for IVIG infusions, given the length and resource intensity of these infusions. 71 Fed. Reg. at 49603-04. PPTA appreciates the agency's recognition of these costs. We note also that this proposal rightly would treat hospitals like physician offices, as in the latter setting, CMS has long made separate payments for each additional hour (after the first hour) of an intravenous infusion. For these reasons, PPTA strongly recommends that CMS finalize its proposal to pay separately for each additional hour of an intravenous infusion beyond the first hour.

ENSURING ADEQUATE PAYMENT RATES FOR PLASMA PROTEIN THERAPIES ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

For 2007, CMS proposes to pay for drugs and biologicals that do not have pass-through status at ASP + 5%. The purpose of the current ASP + 6% payment methodology is to reimburse hospitals for both the acquisition and overhead costs incurred for drugs and biologicals. The basis for CMS' proposal to pay for such products at ASP + 5%, rather than the current ASP + 6% payment methodology is an evaluation of the mean costs of drugs using hospital claims data compared to the ASP data CMS receives on a quarterly basis. 71 Fed. Reg. at 49584-85. This analysis contains a number of fundamental flaws; thus, it cannot form the basis upon which CMS deviates from the current payment methodology.

Foremost among these flaws in evaluation is the reliance by CMS on hospital claims data. With the apparent exception of CMS, every other interested party recognizes that hospital claims data used for OPPS, particularly on drugs and biologicals, is highly problematic because of an inability to properly code for drugs and units. At virtually every APC Advisory Panel meeting, there are extensive discussions about the poor quality of the hospital claims data for this reason. The Panel members working in hospitals acknowledge this to be the case, so much so that the Panel created a Data Subcommittee to examine manners in which to improve the data that underlies OPPS. Earlier this year, the Data Subcommittee reported on its efforts, concluding that while CMS has made its best efforts, the problems with the data can only be solved at the individual hospital level, which has not been occurring.[2]

Moreover, the agency's proposed use of hospital claims data fails to consider the impact that charge compression has on such data at a time when the agency has engaged a contractor to study the charge compression issue for the inpatient prospective payment system. Specifically, the CMS contractor "will focus on methods of improving the accuracy of the adjustment of charges to cost to account for the fact that hospitals tend to markup high cost items to a lesser extent than they markup low cost items, a phenomenon known as charge compression."[3] The OPPS data on drugs and biologicals is subject to the same charge compression phenomenon CMS has decided to study because many of the products are high cost items that are subject to a lesser markup. PPTA believes that CMS should not rely on claims data to make an OPPS drug payment methodology change without a full consideration of the effect of charge compression on the data.

Another potential flaw in CMS' evaluation involves the inclusion of claims data from the 340B program, which provides price discounts for certain health care entities. These prices are excluded from the ASP calculation.[4] Likewise, when the Government Accountability Office ("GAO") conducted a study of drug purchase prices in hospital outpatient departments, it excluded these prices.[5] This exclusion is appropriate because, by the design of the program, prices to these entities are lower than is available to other hospitals. As a result, their inclusion could lower the identified costs. While the GAO recognized this, it is not clear that CMS did when conducting the

[2] *See* "Report of the Advisory Panel on Ambulatory Payment Classification (APC) Groups, March 1-2, 2006," p. 10, available at http://www.cms.hhs.gov/FACA/Downloads/March1-2Mtg.zip.

[3] The CMS announcement is available at http://www.hfma.org/hfmanews/ct.ashx?id=fbe23a25-4001-471a-8743-.

[4] *See* "Report on Sales of Drugs and Biologicals to Large Volume Purchasers" (2006), at p. 3, available at http://www.cms.hhs.gov/reports/downloads/LVP_RTC_2_09_06.pdf.

[5] *See* "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting" (Jun. 30, 2005), at p. 8, available at http://www.gao.gov/new.items/d05581r.pdf.

evaluation that led to the ASP + 5% proposal. To the extent that the agency included claims from the 340B program, that would make the data underlying the proposed ASP + 5% rate flawed.

In addition to these flaws, PPTA is troubled by the agency's proposed change from a policy perspective. Specifically, PPTA believes that creating a differential in the payment rates for products between the physician office and the hospital outpatient sites of service would be detrimental to beneficiary access to drugs and biologicals. CMS must remain consistent as it actually took this very position in last year's OPPS final rule, stating:

> We agree with the commenters' statements about the use of similar resources to furnish clotting factors across all types of service settings and believe that it is appropriate to adopt a methodology for paying for clotting factors under the OPPS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting. 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).

PPTA witnessed the negative impact of payment differentials in 2005, when physician offices were reimbursed at ASP + 6%, but hospital outpatient departments were paid based on the OPPS median cost methodology subject to certain average wholesale price floors and ceilings. This prompted changes in the site of service, most notably for IVIG (which has been documented by the Immune Deficiency Foundation), which caused disruption in treatment regimens and inconvenienced beneficiaries. Because of the lack of foundation for an ASP + 5% payment methodology, PPTA sees no valid reason for CMS to recreate this reimbursement environment and further jeopardize beneficiary access to life sustaining therapies such as IVIG.

In 2006, CMS made attempts to recognize the uniqueness of IVIG and address the ongoing patient access issue. Specifically, in both the third and fourth quarters of 2006, CMS took the measure of directly addressing IVIG in its quarterly updates of payment rates by highlighting the increased payment amount of 11.9 percent for lyophilized IVIG (J1566) and 3.5 percent for liquid IVIG (J1567) in the third quarter and an additional 1.5 percent for lyophilized IVIG and 0.7 percent for liquid IVIG for the fourth quarter.[6] The Proposed Rule counteracts these payment increases. Furthermore, by determining average acquisition costs to be equal to ASP + 5% based on surveys of all Medicare outpatient covered therapies, CMS is contradicting its recent trend by now choosing to ignore the uniqueness of IVIG.

Additionally, recent efforts by CMS to eliminate confusion for providers, contractors, and the general public by streamlining payment mechanisms notwithstanding, the Proposed Rule would reimburse drugs and biologicals based on different methodologies depending upon their status – nonpass-through drugs at ASP + 5%, drugs with specific HCPCS codes but no OPPS claims data at ASP + 6%, and

[6] *See* 2006 ASP Drug Pricing Files, Centers for Medicare & Medicaid Services, *available at* http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp (last modified Oct. 2, 2006).

pass-through drugs at either ASP + 6% or at a competitive acquisition program rate if applicable. PPTA believes that the added complexity of these various payment methodologies will be unnecessarily confusing for providers, contractors, and the general public – clearly a negation of the agency's recent progress in this area. Accordingly, PPTA urges CMS not to finalize its proposal to set payment rates for nonpass-through drugs at ASP + 5% in 2007.

CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES ["OPPS Drug Administration"]

IVIG is the only effective treatment for primary immunodeficiency disease and has also been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States-licensed IVIG products are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals afflicted with diseases or conditions treated with IVIG must depend on this life-saving therapy for the duration of their lives. Each individual patient requires maximum access to the specific formulation that not only best meets their unique needs, but also significantly limits the risk of exposure to serious and potentially life threatening complications.

As noted above, the proposal to pay for nonpass-through drugs at ASP + 5% would adversely impact access to this crucial therapy. Regrettably, that proposal is not the only aspect of the Proposed Rule that would diminish access to IVIG. PPTA is deeply troubled by the agency's proposal to discontinue the payment for the preadministration-related services for IVIG. In justifying its decision, CMS merely stated that continuing this payment "would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG." 71 Fed. Reg. at 49604. Currently, Medicare makes a $75 payment for preadministration-related services to ensure that hospitals are adequately reimbursed for furnishing IVIG to beneficiaries on an outpatient basis. See 70 Fed. Reg. at 68649. PPTA does not understand how CMS concluded that this payment is no longer necessary, when hospitals continue to struggle in providing the proper IVIG therapy to Medicare beneficiaries. Moreover, when also considering the possibility of reimbursement cuts for IVIG therapy in 2007, CMS must understand the horrendous position in which it is potentially placing beneficiaries seeking IVIG therapies in the hospital outpatient setting.

Recognizing the complexity of IVIG therapy, Department of Health and Human Services Secretary Michael O. Leavitt recently touted the CY 2006 preadministration payment as a manner in which CMS has sought to compensate providers for the additional resources associated with administering IVIG.[7] Secretary Leavitt cited this

[7] *See, e.g.*, Letter from Michael O. Leavitt, Secretary Dep't of Health and Human Services, to Rep. Ellen O. Tauscher, August 29, 2006. ["Attachment A"]

CMS action in response to a letter[8] authored by Representative Joseph R. Pitts (R-PA) and thirty-four other Members of Congress. Ironically, Secretary Leavitt's response letter to the Pitts letter signatories was dated August 29, 2006 – one week after CMS published the Proposed Rule. Disappointed with the "inadequate" response by Secretary Leavitt, Representative Charles Norwood (R-GA) recently submitted an extension of remarks in the *Congressional Record* requesting that CMS "rethink implementing any reimbursement change that has the potential to harm access and reduce medical outcomes."[9] PPTA agrees with Dr. Norwood's concern and urges CMS to make permanent this payment for preadministration-related services for IVIG administered in the hospital outpatient setting.

SEPARATE HCPCS CODES FOR IVIG PRODUCTS ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

As you know, the OPPS payment methodology is applied to items and services on a HCPCS code basis. While payment for many items and services is determined through the OPPS median cost methodology, currently, payments for drugs and biologicals are set based on the ASP methodology. This methodology compiles manufacturer information by HCPCS code and computes an average sales price. IVIG is somewhat uniquely situated in this regard in that it is one of the few sole source biologics for which there are multiple brand name therapies, but no generic products, in the code. PPTA believes that, in such unique circumstances, the ASP methodology does not generate representative payment rates for the different IVIG therapies.

While, as noted above, PPTA objects to the use of the proposed ASP + 5% payment methodology for setting payment rates for drugs and biologicals in 2007, we believe that, regardless of the applicable OPPS payment methodology, CMS must establish individual HCPCS codes for each brand name IVIG therapy. By basing the ASP rate for each therapy on their own ASP information, as is true with other biologicals, the OPPS payment rate will be set in a manner that is pertinent to each brand, which should enhance access to IVIG therapies. Simply dividing IVIG therapies by the liquid and lyophilized class does not go far enough in assuring that access to each unique brand is recognized by a free-standing HCPCS code that carries with it distinct reimbursement.

The following brands of IVIG are now broadly available in the United States market: Polygam® SD, Panglobulin® NF, Gammar® P I.V., Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, Iveegam® EN, and

[8] *See* Letter from Rep. Joseph R. Pitts (R-PA) et al., to Michael O. Leavitt, Secretary Dep't of Health and Human Services (May 31, 2006) (suggesting CMS consider, *inter alia*, both a payment adjustment and product specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access). ["Attachment B"]

[9] *See* 152 CONG. REC. E1937-38 (daily ed. Sept. 29, 2006) (statement of Rep. Charles Norwood). ["Attachment C"]

Gammagard® liquid. Establishing separate HCPCS codes for these therapies is appropriate because there are important clinical differences among them, such as:

- Some therapies contain no sugars, which is beneficial for diabetics;
- Some therapies have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some therapies contain sucrose, which can create a higher risk of renal failure;
- Some therapies contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some therapies have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Because of these differences, there are clinical reasons why physicians order one IVIG therapy in favor of another. CMS' coding of and payment for these therapies should also recognize these differences, which could be done by establishing separate HCPCS codes for each brand name IVIG therapy. Such a policy change would allow CMS to determine separate and more representative payments for each therapy. Moreover, new immune globulin products with different delivery methods (such as subcutaneous delivered immune globulin) should also be reimbursed by brand with a separate HCPCS code rather than bundling them into a class with other therapies.

PPTA recognizes that, in the final rule setting forth the 2006 payment rates, CMS considered establishing brand-specific HCPCS codes for IVIG, but did not find a "compelling" reason to override the standard practice of not establishing brand-specific codes. 70 Fed. Reg. at 68648. PPTA respectfully disagrees with the agency's assessment; therefore, we urge CMS to reconsider its position. Moreover, the standard practice for separately approved biologicals is for CMS to create separate HCPCS codes. Plasma protein therapies, including IVIG, are the exception to the standard practice of having separate codes for different biological products. Thus, PPTA suggests that CMS needs to articulate a "compelling" reason <u>not</u> to create separate codes for IVIG. Indeed, looking at the following statements made by CMS in its most recent OPPS final rule, it is difficult to fathom that the agency could demonstrate a compelling reason not to have separate HCPCS codes for IVIG therapies.

- "we continue to be concerned about CY 2005 reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG on a consistent basis to meet their patients' needs in the current marketplace." <u>Id.</u>;
- "The Secretary's Advisory Committee on Blood Safety and Availability has recommended immediate steps be taken to ensure access to IVIG so that patients' needs are being met." <u>Id.</u>;

For these reasons, PPTA requests that CMS establish separate HCPCS codes for IVIG therapies. Individual codes will not only improve the accuracy of the rate-setting for the various IVIG therapies, but also potentially enable CMS to reduce some of the complexity in the IVIG marketplace facilitating subsequent policy decisions on IVIG.

PAYMENT ADJUSTMENT FOR IVIG ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

In our comments on the 2006 OPPS proposed rule, PPTA advocated for an add-on payment for IVIG that captures the acquisition costs, as well as the direct and indirect handling costs associated with the therapy. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of hospital acquisition costs for IVIG, it nonetheless determined that Medicare should pay hospitals $75 for each administration of IVIG to compensate them for preadministration services related to IVIG. 70 Fed. Reg. at 68649-50.

PPTA appreciates the recognition by CMS of these additional costs incurred by hospitals in providing IVIG to beneficiaries. The prospect of the discontinuation of that payment, as discussed above, however, tempers that sense of appreciation. Even if CMS decides to continue the payment for preadministration-related services for IVIG, reimbursement for the therapy itself is currently insufficient to ensure continued access in the hospital outpatient setting. While that payment does reimburse hospitals for some of the costs that they incur related to IVIG, other costs would remain uncompensated.

PPTA believes a payment adjustment to the current ASP formula is required to ensure that providers are made whole on the purchase cost of the IVIG therapies so that they receive a fair return on their investments in care. This payment adjustment needs to be reflective of providers' true costs to make IVIG available to their patients in the hospital outpatient setting. Furthermore, the payment adjustment could be based on independent data from the two current IVIG access studies being conducted by HHS' Office of Inspector General and HHS' Assistant Secretary of Planning and Evaluation.

A payment adjustment precedent to life-saving plasma protein therapies has recently been effectuated by CMS when it implemented, at Congress' direction, a separate payment for blood-clotting factor because of its unique properties and the fragile needs of patients who rely on blood-clotting factors. See Social Security Act § 1842(o)(5)(A) (mandating a separate payment for items and services associated with the furnishing of blood clotting factor). This furnishing fee, which CMS directly incorporated into the payment rate, was $0.14 per unit in CY 2005, and is $0.146 per unit in CY 2006. Since the precedent setting blood-clotting factor furnishing fee was implemented, access to this life-saving plasma protein therapy has not been diminished, making this payment adjustment a successful mechanism in ensuring that the recent payment cuts did not adversely impact access. The same payment cuts, however, have resulted in providers' acquisition cost of IVIG for Medicare beneficiaries exceeding the reimbursement rates from CMS under the current ASP methodology. To this end, IVIG warrants the same acquisition furnishing fee considerations as blood clotting factor because it is similar in that both IVIG and blood clotting factor are plasma protein therapies that have highly unique characteristics that require complex manufacturing, storage, and distribution methods.

To ensure Medicare beneficiaries have the best available access to the life-saving IVIG therapies, CMS must provide a payment adjustment to the current ASP reimbursement methodology to enable providers in the hospital outpatient setting to cover the costs incurred for acquiring IVIG. The blood-clotting furnishing fee is a precedent-setting provision for plasma protein therapies, one which CMS has the authority to issue for IVIG. Without such a payment adjustment, patients will continue to be at risk of not being able to obtain the best possible access to care.

CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. We are deeply concerned about the impact the Proposed Rule could have on the lives of patients who depend upon plasma protein therapies, particularly IVIG. Regrettably, in many respects, the Proposed Rule represents a regression in efforts to ensure beneficiary access to these therapies. The proposed change to an ASP + 5% payment methodology is based on flawed data and policy, and must not be finalized. Similarly, the agency's proposal to discontinue payment for preadministration-related services in connection with IVIG lacks any foundation. CMS must continue to make this payment in 2007 so that the hospitals will continue to be reimbursed for the range of costs they incur in furnishing IVIG to Medicare beneficiaries. As you know, PPTA continues to be very concerned that reimbursement shortfalls continue to impede patient access to IVIG. We believe CMS could alleviate this concern to a significant degree by the establishment of both separate codes for each brand name IVIG therapy and an IVIG payment adjustment. PPTA urges CMS to implement these recommendations for its 2007 payments to hospitals. Finally, PPTA welcomes the agency's proposal to pay separately for the additional hours of an intravenous infusion, as this will help hospitals recoup their costs of furnishing a number of plasma protein therapies.

PPTA looks forward to working with CMS to ensure continued access to plasma protein therapies in the hospital outpatient setting. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Julie Birkofer

Julie Birkofer
Executive Director
PPTA North America

[Attachments]

Attachment A

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AUG 2 9 2006

The Honorable Ellen Tauscher
House of Representatives
Washington, DC 20515

Dear Ms. Tauscher:

Thank you for your letter expressing your concerns about Intravenous Immunoglobulin (IVIG) product supply and payment.

The Department of Health and Human Services, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration are closely monitoring access to and market developments for IVIG care. In addition, the IVIG manufacturers, the Plasma Protein Therapeutics Association, reports that the overall supply of IVIG is adequate and has increased in the past several months.

In accordance with a provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays for most Part B covered drugs and biologics administered in physicians' offices, based on 106 percent of the average sales price (ASP). Beginning in 2006, Medicare payment for Part B drugs, including IVIG, administered in hospital outpatient departments is also based on 106 percent of the ASP.

The Medicare payment rate, which is updated quarterly, is increasing by 11.9 percent for lyophilized IVIG and 3.5 percent for liquid IVIG in July 2006. We view these payment increases as an important development. The next quarterly update to the Medicare payment rates will occur in October 2006.

In light of the market conditions specific to IVIG, for 2006, CMS established a temporary add-on payment for physicians and hospital outpatient departments that administer IVIG to Medicare beneficiaries. This add-on payment is paid per day of IVIG administration and is for the extra resources expended on locating and obtaining appropriate IVIG products and on scheduling patient infusions during this current period where there may be potential issues in the IVIG market.

A number of components of HHS continue to work together, and to work with manufacturers, providers, patient groups, and stakeholders to understand the present situation and to assess potential actions that will help to ensure an adequate supply of IVIG and patients receiving appropriate and high quality care. To better understand the market for IVIG and evaluate access and reimbursement concerns from patients and physicians, HHS has commissioned an independent, expert study to assess these factors. HHS anticipates using the market analysis gained through this research to inform Departmental decision making related to IVIG in the future. In addition, we are actively exploring options that may be available to us under our legal and administrative authority to address IVIG concerns.

I appreciate your interest in this important issue. I also will provide this response to the cosigners of your letter.

Sincerely,

Michael O. Leavitt

Michael O. Leavitt

Congress of the United States
Washington, DC

May 31, 2006

The Honorable Michael Leavitt
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Dear Secretary Leavitt:

We understand that you have been working with the Centers for Medicare and Medicaid Services to address the shortfalls in the acquisition cost of IVIG and Medicare's reimbursement of this biological therapy in the physician office and hospital outpatient settings. This important patient access issue is also of great concern to us, and we wanted to take this opportunity to convey our commitment to working with the IVIG community to assure that this access issue is remedied through implementation of an immediate solution.

As you know, IVIG is a life-saving plasma-derived therapy, and, since the implementation of the MMA's new Medicare reimbursement methodologies, beginning in January 2005, patients have been migrating to the hospital outpatient setting because physicians were reimbursed at a rate lower than their purchase price. Beginning in January 2006, a similar occurrence with Medicare reimbursement in the hospital outpatient setting has taken place. We know you share the same desire to see these patients return to the physician office for treatment, and we are of the opinion that in order to achieve this goal, some type of payment adjustment, combined with product specific reimbursement, should be considered, in addition to any other mechanism that you deem necessary to resolve this patient access dilemma.

Thank you for your attention to the IVIG issue, to assuring Medicare beneficiary access to this therapy, and for working together with Congress to rectify the problems patients have reported in receiving care. We appreciate the opportunity to continue this dialogue with you and the IVIG community, and we look forward to the implementation of a permanent and comprehensive solution.

Sincerely,

Joseph Pitts
Rep. Joseph R. Pitts

Jim Ramstad
Rep. Jim Ramstad

Rep. John Sullivan

Rep. Mike Ferguson

Rep. Frank LoBiondo

Rep. Sue Myrick

Rep. Jim Gerlach

Rep. Ted Strickland

Rep. Kay Granger

Rep. John Shimkus

Rep. Tammy Baldwin

Rep. Ellen Tauscher

Rep. Henry Brown

Rep. Phil English

Rep. Shelley Moore Capito

Rep. Raul Grijalva

Rep. Pete Sessions

Rep. Michael Fitzpatrick

Rep. Virgil Goode

Rep. Thaddeus McCotter

Rep. C. L. "Butch" Otter

Rep. Dale Kildee

Rep. Sue Kelly

Rep. Jim Moran

Rep. David Hobson

Rep. Bill Young

Rep. Michael Burgess

Rep. William Jefferson

Rep. Jim Saxton

Rep. Gene Green

Rep. James Walsh

Rep. Silvestre Reyes

Rep. Charlie Norwood

Chip Pickering

Rep. Chip Pickering

Wally Herger

Rep. Wally Herger

More to the point, this treatment allows individuals to carry on normal daily-life activities. PID requires IVIG therapy every 3 to 4 weeks for the duration of an individual's life, but without such treatment the individual not only imposes additional medical costs on an already overburdened system, they cease to be active members of our society. Such an outcome is simply not acceptable. IVIG therapy is cost-effective and beneficial for the patient. As far as I am concerned, that should be enough to get CMS to rethink implementing any reimbursement change that has the potential to harm access and reduce medical outcomes.

In May of this year, thirty-five members of Congress, including myself, sent a letter to Secretary Leavitt of the Department of Health and Human Services expressing our concern over this matter and encouraged Secretary Leavitt to consider a payment adjustment, combined with product specific reimbursement. We also made clear that we would be open to any other mechanism he may have deemed suitable in order to resolve this patient access dilemma. Secretary Leavitt's response was, quite simply, inadequate. He failed to address our specific concerns or pose alterative remedies that would allow patients continued access to IVIG treatment.

I urge CMS to reconsider its actions in this case to ensure patient access to a necessary and legitimate medical treatment.

IN HONOR AND RECOGNITION OF THE 75TH ANNIVERSARY OF THE ST. SAVA SERBIAN SINGING FEDERATION

HON. DENNIS J. KUCINICH
OF OHIO
IN THE HOUSE OF REPRESENTATIVES
Friday, September 29, 2006

Mr. KUCINICH. Mr. Speaker. I rise today in honor and tribute to the 75th Anniversary of the St. Sava Serbian Singing Federation, and the local St. Sava Cathedral choir in Parma, Ohio.

Vjajko Lugonja founded the Serbian Singing Federation in 1931. His legend continues to thrive in the voices of the singers today. On a local and national level, the Singing Federation's member choirs contribute their Serbian cultural heritage through song and music. In Ohio alone, there are six member choirs. The group also boasts the largest collection of Serbian music, contained in its library, featuring the work of 96 Serbian composers.

The Serbian Singing Federation also supports local high school seniors trying to afford college tuition through its Paul Bielich Scholarships, given to multiple students for general studies, as well as the Petar and Minnie Sekulovich Scholarship awarded to a young member of the choir who wishes to study music in college.

In celebration of its 75th Anniversary, the Serbian Singing Federation is hosting a concert this Saturday, September 30, which will feature not only its 40–member ensemble, but also guest choirs, including the Kosovo Men's Choir of Cleveland and the Hamilton Ontario Choir.

Mr. Speaker and Colleagues, please join me in honoring the last 75 years of diversity the St. Sava Serbian Singing Federation has brought to Northeastern Ohio. They are an indispensable characteristic of Cleveland, and the Serbian community is one of the many groups that piece together this colorful city. By artistically perpetuating their culture through music, the choir offers a beautiful gift to all people.

IN RECOGNITION OF THE 10TH ANNIVERSARY OF FOX NEWS CHANNEL

HON. PETE SESSIONS
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES
Friday, September 29, 2006

Mr. SESSIONS. Mr. Speaker, I rise today to honor the 10th anniversary of Fox News Channel, which in celebration will present live audience shows from various locations across the country, including a live broadcast on September 22, 2006 from Southern Methodist University in Dallas, Texas.

Fox News Channel brings fair and balanced reporting to a national audience, and I am proud that they chose to broadcast live from one of Texas' and the Nation's premier institutions of higher learning, Southern Methodist University.

I would like to take this opportunity to express special recognition to Fox News Channel on the occasion of its 10th anniversary.

CONGRATULATING THE HONORABLE W. WILSON GOODE

HON. CHAKA FATTAH
OF PENNSYLVANIA
IN THE HOUSE OF REPRESENTATIVES
Friday, September 29, 2006

Mr. FATTAH. Mr. Speaker, I rise today to congratulate the Honorable W. Wilson Goode, 2006 recipient of the Purpose Prize, a new and exciting award by Civic Ventures that honors and promotes social entrepreneurs who are age 60 or older. Over 1200 people competed for five $100,000 gifts, creating publicity and support for programs developed to address society's biggest challenges.

Wilson Goode, former Mayor of Philadelphia, left government in 1992 after earning a Doctorate in Ministry, and moved into the nonprofit world. At age 62, he committed himself to helping the seven million children in America who have one or both parents in jail, on parole, or under state or federal supervision. Research shows that without intervention, 70 percent of these children are likely to follow their parents to jail. As Director of Amachi, Wilson Goode has championed a proven method of intervention, mentoring with a faith-based recruitment strategy. He has rallied pastors, particularly in the African-American community, to engage their members. Today, more than 240 programs in 48 states are connected with Amachi, and have helped more than 30,000 children.

Mr. Speaker, I also would like to commend Civic Ventures, along with Purpose Prize, the Atlantic Philanthropies, and the John Templeton Foundation, for their vision and generosity in creating this important stimulus for expanding citizen initiative for public good. The Purpose Prize joins Experience Corps as an important innovation by Civic Ventures, a nonprofit organization dedicated to generating ideas and programs to help society achieve the greatest return on the experience of older adults. I believe these programs will help transform society's view of aging, and lead to better investments in America's greatest untapped resource, which are experienced and engaged older adults.

Mr. Speaker, please join me in extending my heartfelt congratulations and appreciation to Wilson Goode, and wish him continued success.

IN MEMORY OF MONROE SWEETLAND

HON. EARL BLUMENAUER
OF OREGON
IN THE HOUSE OF REPRESENTATIVES
Friday, September 29, 2006

Mr. BLUMENAUER. Mr. Speaker, I rise today to celebrate and honor the life of Monroe Sweetland, along with my colleagues TOM LANTOS, ANNA ESHOO, and many other of Monroe's California friends.

The most important Oregonian most people have never heard of passed away earlier this month. Even though I knew Monroe would soon be leaving us, and even had quite a lucid farewell conversation with him shortly before, it's still hard to believe that he is gone.

Here's a man whose lifespan of active political life stretched from the Hoover administration to George Bush the second. Monroe engaged in every single important political debate of our times from economics to foreign-policy to civil rights: He was in Indonesia, during the year of living dangerously; was one of the most powerful men in Oregon during the Truman administration as a Democratic national committeeman for a Democratic administration when every elected leader was Republican; and, he had tremendous influence on appointments and policy decisions from judicial appointments and personnel decisions to policy direction. He was a journalist, an educator, and a politician but most of all a passionate advocate for making the world a better place.

From the time I first met Monroe Sweetland as a college student directing Oregon's campaign to lower the voting age, he was a steady presence in my political life and development. He always provided me good, sound advice, gentle but firm encouragement and tremendous support.

He knew everyone who had made a difference in his party for three quarters of a century. Monroe earned the respect and affection of principled opponents, including Senator Mark Hatfield who defeated Monroe when they ran against each other for Oregon Secretary of State in 1956. It was great to hear and feel the respect these two Oregon giants had for one another, and one hopes that someday that can come back into fashion.

As recently as 1998, Monroe ran for the State Senate mounting a close campaign against Verne Duncan, a longtime incumbent. To the end, Monroe conducted his campaign, as his entire career, with civility and affection, being able to point out differences with precision and civility that made people feel good about politics.

Most of all, Monroe was tireless and effective. He was gentle and kind but resolute in