

September 14, 2007
Reference No.: STKH07022

Kerry Weems
Acting 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-1392-P Medicare Program: Proposed Changes to the Hospital
Outpatient Prospective Payment System and CY 2008 Payment Rates**

Dear Administrator Weems:

Stakeholders within the community of patients who rely upon lifesaving plasma derived and recombinant analog therapies and the Plasma Protein Therapeutics Association (“PPTA”) appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services (“CMS”) proposed rule detailing proposed payment policies in the Hospital Outpatient Prospective Payment System (“OPPS”) for Calendar Year (“CY”) 2008 (“Proposed Rule”).¹ We are deeply committed to the health and safety of the patients we serve, and these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, plasma-based and their recombinant analog therapies (“plasma protein therapies”) in the hospital outpatient department setting.

Patient access to plasma protein therapies is dependent on adequate provider reimbursement for the acquisition and administration of these biologicals. Although we are quite appreciative of the proposal to continue to reimburse for IVIG preadministration-related services (G0332) for CY 2008, we, the undersigned stakeholders and PPTA, are deeply troubled by the proposal to reduce this applicable payment rate by almost 50%, especially because we remain very concerned that the manner in which hospital outpatient departments are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient. Similarly, we believe that the proposal to pay for the acquisition and pharmacy overhead costs of most drugs at

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

average sales price (“ASP”) + 5% is inadequate for plasma protein therapies. Indeed, there is extensive evidence demonstrating that ASP + 6% does not cover the acquisition costs incurred by hospitals for IVIG. In addition, it is our belief that hospitals are insufficiently paid for the resources expended for the administration of IVIG. We do support the agency’s proposal with regard to the future publication of the blood clotting factor furnishing fee update.

I. DISCUSSION

A. BACKGROUND

We remain concerned with the access difficulties afflicting more than 10,000 Medicare beneficiaries who rely on regular infusions of IVIG therapies. As a result of payment rate changes in 2005 stemming from the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”) (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)), physicians began to be under-reimbursed for IVIG therapies in the physician office setting. Specifically, when the ASP methodology went into effect in the physician office in 2005,² some physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG. Many of these patients migrated to the hospital outpatient department to receive their IVIG infusions in 2005.³ In 2006, however, CMS began to set the 2006 OPPS payment rates for most drugs, including IVIG, using the ASP +6% methodology.⁴

Both the U.S. Department of Health and Human Services (“HHS”)⁵ and the Immune Deficiency Foundation and (“IDF”)⁶ have issued recent reports that support PPTA claims that insufficient reimbursement is a leading factor in the difficulties patients face in accessing IVIG. This reimbursement shortfall resulted in patient migration from

² See Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66236, 66299 (Nov. 15, 2004) (codified by 42 C.F.R. § 414.804 (2007)).

³ See OFFICE OF THE ASS’T SEC. FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007) [hereinafter “ASPE Report”], at 4-31 (concluding that insufficient reimbursement caused the patient migration in 2005).

⁴ 70 Fed. Reg. 68516, 68642 (Nov. 10, 2005).

⁵ See ASPE Report, *supra* note 3 at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); see OFFICE OF INSPECTOR GENERAL, U.S. DEP’T OF HEALTH AND HUMAN SERV., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter “OIG Report”], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).

⁶ See IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the physician office to the hospital outpatient department.⁷ We believe it is imperative that Medicare beneficiaries should be able to obtain IVIG therapies best suited for their individual needs in the most appropriate site of service, and thus hospital outpatient departments must remain a viable option for beneficiaries to be able to receive IVIG. That will not occur unless reimbursement levels are adequate.

We welcome the attention given and action taken by CMS to address this very difficult patient access situation. We believe many of these recent actions are a good first step to help improve patient access to IVIG therapies, and hope that you will consider our comments to continue to improve patient access for Medicare beneficiaries requiring plasma protein therapies, including IVIG. We are especially grateful that the agency decided to grant new brand specific “Q” codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies in response to PPTA’s February 21, 2007 request that IVIG products that were not on the market as of October 1, 2003 be assigned separate codes in order to be consistent with the ASP statute. We further appreciate the agency’s decision to implement an additional payment for IVIG preadministration-related services and the proposal to continue this payment for CY 2008 for IVIG infused in the hospital outpatient department. As discussed in Section I(C) below, we believe that CMS should finalize its proposal to continue the IVIG preadministration-related services payment under OPPS at the current level.

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of IVIG. As you know, the Current Procedural Terminology (“CPT”) codes are used for reporting medical services and procedures, including drug administration services. For example, the first hour of infusing IVIG may be billed using CPT code 90765, while the second hour of infusing IVIG may be billed using CPT code 90766.⁸ CMS assigns OPPS rates to these CPT codes, and for CY 2007, it designated \$111.20 for CPT code 90765 and \$24.25 for CPT code 90766.⁹ While we support the agency’s proposal to increase the OPPS payment rates for these codes for CY 2008 to \$116.62 for CPT code 90765 and \$25.71 for 90766, we believe these codes, as a means of compensating for administering IVIG, remain undervalued, for reasons discussed in Section I(D) below. We are concerned that this also could impede beneficiary access to IVIG in the hospital outpatient setting.

⁷ See, e.g., Ricardo Alonso-Zaldivar, *Crucial But Costly Treatment Is Drying Up With Funding: Thousands Of Elderly Patients Who Need Intravenous Antibodies Are Hurt By Medicare Cutbacks - More Pain Could Be On The Way*, L.A. TIMES, February 28, 2006, at A8 (illustrating the challenges, including shifts in sites of service, patients must overcome to receive IVIG therapies because of the Medicare reimbursement cuts).

⁸ See Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Final Rule, 71 Fed. Reg. 67960, 68117 Table 32 (Nov. 24, 2006).

⁹ *Id.* at 68355.

B. CMS MUST CONTINUE TO PAY FOR DRUGS AND BIOLOGICALS WITHOUT PASS-THROUGH STATUS THAT ARE NOT PACKAGED AT ASP PLUS 6 PERCENT. [“OPPS SPECIFIED COVERED OUTPATIENT DRUGS”; “OPPS: BLOOD CLOTTING FACTORS”]

1. Background

Section 1833(t) of the Social Security Act (“SSA”) provides that, in 2006 and beyond, payment rates for specified covered outpatient drugs, which includes plasma protein therapies such as IVIG and blood clotting factors, shall be equal, subject to a provision on overhead costs,

“(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.”¹⁰

When setting the payment rate for these drugs under the OPPS for CYs 2006 and 2007, CMS opted to utilize the payment rate under section 1847A of the SSA pursuant to this statutory language.¹¹ For 2008, CMS proposes to pay for drugs and biologicals that do not have pass-through status at ASP +5%, reimbursing for hospital acquisition and pharmacy overhead costs.¹²

Because we believe that the reimbursement for the acquisition of IVIG and pharmacy overhead costs in the hospital outpatient department is insufficient to guarantee unencumbered patient access for Medicare beneficiaries requiring IVIG, we object to the agency’s proposal to further reduce that payment in this site of service to the ASP +5%.

2. The ASP +6% methodology is inadequate to preserve patient access for IVIG under the OPPS and must be increased, not decreased.

While we support continued use of the ASP methodology generally, the ASP +6% methodology, as the recent HHS studies illustrate, does not adequately compensate significant numbers of hospitals for just the acquisition cost of IVIG therapies. For example, the OIG found that, in the first, second, and third calendar

¹⁰ Social Security Act (“SSA”) § 1833(t)(14)(A)(iii) (2007).

¹¹ 71 Fed. Reg. at 68091; 70 Fed. Reg. at 68642.

¹² See 72 Fed Reg. at 42736.

quarters of 2006, 74.5%, 77.2%, and 44% of hospitals, respectively, purchased IVIG from distributors at prices that were greater than the OPPS payment rate.¹³ The Government Accountability Office (“GAO”) has further argued that “a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6% above ASP.”¹⁴ Additionally, in a 2005 study commissioned by PPTA, The Lewin Group determined there is a 9% reimbursement shortfall by Medicare in covering the acquisition of IVIG in the hospital outpatient department.¹⁵ These analyses collectively refute CMS’ view, at least with regard to IVIG, that the ASP + 5% methodology “would continue to provide accurate payments for average acquisition costs of Part B drugs and pharmacy overhead costs”¹⁶ given that they show that ASP + 6% fails to cover the acquisition costs for many hospitals, without even considering pharmacy overhead costs. Rather, the analyses indicate that CMS should increase the OPPS payment amount for IVIG beyond ASP +6%. The analysis from The Lewin Group could be used to provide guidance on what the appropriate amount may be.

Because of the current IVIG reimbursement shortfall for hospital outpatient departments with rates set at ASP + 6%, some of these providers have discontinued offering these services to Medicare beneficiaries. Accordingly, we urge CMS to provide an upward payment adjustment to the ASP + 6%, irrespective of its treatment of other drugs, in order to ensure these patients that require regular infusions of IVIG are able to receive such infusions in a hospital outpatient department.

3. CMS relies upon flawed data to reduce payments for specified covered outpatient drugs under the OPPS.

CMS’ proposal to set the CY 2008 payment rates for drugs and biologicals at ASP +5%, rather than the current ASP + 6% payment methodology, is based on an evaluation of the mean costs of drugs using hospital claims data for CY 2006 compared to the ASP data CMS received for the fourth quarter of 2006.¹⁷ This analysis by CMS contains a number of fundamental flaws and thus, it cannot form the basis upon which CMS deviates from the current payment methodology.

Foremost among these flaws is the reliance in this evaluation 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 code for drugs and units properly. At virtually

¹³ See, e.g. OIG Report, *supra* note 5 at 9.

¹⁴ See *Hearing on Medicare Reimbursement of Physician-Administered Drugs Before the House Comm. on Ways and Means Subcomm. on Health*, 109th Cong. (2006) (statement of A. Bruce Greenwald, Director, Health Care, GAO).

¹⁵ THE LEWIN GROUP, *ASSESSING THE COST OF IVIG INFUSION SERVICES IN PHYSICIAN OFFICES AND HOSPITAL PHARMACY DEPARTMENTS 3* (2005) (on file with author).

¹⁶ 72 Fed. Reg. at 42736.

¹⁷ *Id.*

every Ambulatory Payment Classification (“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 look into ways to improve the data that underlies OPPS. In early 2006, 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.¹⁸

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 is considering the findings of an outside contractor on the issue (related to the inpatient prospective payment system).¹⁹ The CMS contractor was tasked with focusing “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.”²⁰ The OPSS data on drugs and biologicals is subject to the same charge compression phenomenon CMS contracted to study because many of the products are high cost items that are subject to a lesser markup. We believe that CMS should not rely on claims data to make an OPSS 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 Drug Pricing Program, which requires a manufacturer to provide significant discounts on its covered outpatient drugs to certain federally funded grantees and other safety net health providers.²¹ These prices are excluded from both the average manufacturer’s price (“AMP”) calculation²² and the ASP calculation.²³ Likewise, when the GAO conducted a study of drug purchase prices in hospital outpatient departments, it excluded drugs purchased at or below the 340B ceiling price.²⁴ This exclusion is appropriate because, by the design of the 340B Program, prices offered to these covered entities are lower than is available to other hospitals. As

¹⁸ 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>.

¹⁹ 72 Fed. Reg. at 42740.

²⁰ The CMS announcement is available at http://www.cms.hhs.gov/ResearchGenInfo/downloads/IPPS_AnnouncementFinal.pdf (last visited September 13, 2007).

²¹ 42 U.S.C. § 256b (2007).

²² See Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39241 (July 17, 2007).

²³ 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 (last visited September 13, 2007); see also 42 C.F.R. 414.804(a)(4) (describing those sales manufacturers must exempt from their calculation of the ASP for their drugs).

²⁴ 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> (last visited September 13, 2007).

a result, the inclusion of transactions at or below the 340B ceiling price could inappropriately lower the identified costs for the purpose of calculating both the ASP and the AMP. While the GAO recognized this, it is not clear that CMS did when conducting the evaluation that led to this ASP + 5% proposal. To the extent that the agency included claims from the 340B program, such inclusion would make the data underlying the proposed ASP + 5% rate flawed.

4. As a matter of policy, the proposal by CMS to decrease reimbursement for specified covered outpatient drugs under the OPDS is counterintuitive.

In addition to these analytical flaws, we view CMS' proposed change to the ASP +5% as troubling from a policy perspective. We believe that creating a differential in the payment rates for products between the physician office and hospital outpatient department sites of service would be detrimental to beneficiary access to drugs and biologicals. We saw the negative impacts of payment differentials in 2005, when physician offices were reimbursed at ASP + 6% but hospital outpatient departments were paid based on the OPDS median cost methodology subject to certain average wholesale price floors and ceilings. This methodology prompted changes in the site of service for various products, including IVIG, which disrupted treatment regimens and inconvenienced beneficiaries. In recent years, CMS has underscored the importance of consistent payment methodologies for both the physician office and hospital outpatient department.²⁵ In addition to the recent trend and given the lack of foundation for an ASP + 5% payment methodology, we see no valid reason for recreating this unstable environment and further jeopardizing beneficiary access to lifesaving therapies, such as IVIG.

Finally, the agency has laudably attempted to streamline payment mechanisms to make them more straightforward and less confusing. The Proposed Rule would work in the opposite direction in that drugs and biologicals would be paid based on different methodologies depending upon their status – nonpass-through drugs at ASP + 5%, drugs with specific Healthcare Common Procedure Coding System (“HCPCS”) codes but no OPDS claims data at ASP + 6%, and pass-through drugs at either ASP + 6% or at a competitive acquisition program rate if applicable. We believe that the added complexity of these various payment methodologies will be unnecessarily confusing for providers, contractors, and the general public. Accordingly, we urge CMS not to finalize its proposal to set payment rates for nonpass-through drugs at ASP + 5% for CY 2008.

²⁵ See, e.g., 70 Fed. Reg. at 68661 (demonstrating the importance of establishing a consistent methodology for the furnishing of blood clotting factor in all sites of service); see also 71 Fed. Reg. at 68091 (concluding that the CMS would continue the ASP +6% for CY 2007, because, *inter alia*, CMS recognized that “difference in payment rates for drugs and biologicals across the hospital outpatient and physician office settings may result in an unexpected site of service shift that may be problematic for beneficiaries.”).

5. Even if CMS does move to adopt the ASP +5% for most drugs, it should continue to pay for plasma protein therapies at a level that is at least ASP +6%.

For the reasons discussed above, we believe that the agency's proposal to pay for separately billable drugs under OPPS at ASP + 5% is flawed and should not be finalized. Should the agency nonetheless proceed with such policy, we urge CMS to again recognize the uniqueness of plasma protein therapies (e.g., their critical importance to vulnerable patient populations that typically have limited other available treatment options) and ensure that the payment rates for these products are at least maintained at ASP + 6%. In establishing the CY 2003 rates for plasma protein therapies, when these products were no longer considered pass-through items, CMS "recognize[d] the importance of these drugs, and consequently included them" in a special dampening mechanism to mitigate the impact of the change in payment methodology.²⁶ The importance of plasma protein therapies has not waned and thus we ask CMS to ensure that the OPPS payment rates for these drugs remain at least at ASP + 6 % (with added consideration for IVIG as discussed earlier).

C. IVIG PREADMINISTRATION-RELATED SERVICES: CMS SHOULD CONTINUE IVIG PREADMINISTRATION PAYMENTS AT CY 2007 LEVELS

IVIG therapies are single source, as defined by the ASP statute,²⁷ orphan drugs²⁸ that treat patients with immune deficiencies and other serious, chronic medical disorders. According to the IDF, these therapies are the only effective treatment for primary immune deficiency disease ("PIDD").²⁹ Currently, the Food and Drug Administration has approved existing IVIG therapies for six clinical indications, including treatment of: (1) PIDD; secondary immune deficiency diseases, such as (2) pediatric HIV and (3) B-cell chronic lymphocytic leukemia; (4) idiopathic thrombocytopenic purpura, which is an autoimmune bleeding disorder, (5) Kawasaki disease, and (6) bone marrow transplantation.³⁰ There is also a significant amount of medically indicated, off-label use of this therapy.³¹ For indications such as PIDD, IVIG enhances the defective

²⁶ Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; Final Rule, 67 Fed. Reg. 66718, 66774 (Nov. 1, 2002).

²⁷ See SSA § 1847A(c)(6)(D) (2007) (specifying that a biological, which each IVIG therapy is, is a "single source drug or biological").

²⁸ An "orphan drug" is a drug used to treat a rare disease or condition that "affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." See 21 U.S.C. § 360bb(a)(2) (2007).

²⁹ See Immune Deficiency Foundation at http://www.primaryimmune.org/igivreimb/igivreimb_bkgnd.htm (last visited August 12, 2007).

³⁰ PRIMARY IMMUNODEFICIENCY COMMITTEE OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY, PRACTICE PAPER ON THE APPROPRIATE USE OF INTRAVENOUSLY ADMINISTERED IMMUNOGLOBULIN 6 (Jordan S. Orange, MD, PhD, ed., 2005) [hereinafter "Orange Paper"].

³¹ *Id.*; see also ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY, U.S. DEP'T OF HEALTH AND HUMAN SVCS., STATUS OF IMMUNE GLOBULIN INTRAVENOUS (IGIV) PRODUCTS, available at

components of a patient's immunity to fight and protect against infection and complications of infection. Patients relying upon IVIG therapies usually require infusions every three to four weeks for the duration of their lives.³²

As you know, CMS established a G-code (G0332), effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.³³ We appreciate the recognition by CMS of these additional costs incurred by physicians in providing IVIG therapies to Medicare beneficiaries. We agree with the Secretary of HHS about the importance of this payment.³⁴

The Proposed Rule would continue payment for G0332 for CY 2008 and reassign this HCPCS code from a New Technology APC 1502 to new clinical APC 0430. We agree that CMS should continue making payments to hospital outpatient departments for IVIG preadministration-related services in CY 2008, and indeed that such payments should be made indefinitely until it is clear that all IVIG access issues have been resolved.

We, however, are very concerned that CMS has proposed to cut the level of payments in the hospital outpatient setting significantly by using hospital claims data for G0332 and proposing a rate that is almost half of the current rate. We believe that this proposed change to the payment rate is based on flawed data and flawed policy.

On PPTA's behalf, The Moran Company, analyzed hospital claims for G0332 and there are a number of aspects of the findings of this review that call into question whether the data are robust enough for CMS to remove this code from new technology status. For instance, The Moran Company found that hospitals recorded a G0332 code on just 49 percent of the claim dates on which IVIG codes are recorded, meaning that the code is not being used on a majority of IVIG claims. Thus, the claims database

<http://www.hhs.gov/bloodsafety/igiv.html> (last visited Sept. 14, 2007) (indicating more than half of all IVIG utilization is actually for off-label use); compare ASPE Study, *supra* note 3 at 3-4 (expressing concern that off-label use of IVIG is driving demand) with TOMAS PHILIPSON & ANUPAM B. JENNA, THE UNIV. OF CHICAGO, THE IMPACT OF THE MEDICARE MODERNIZATION ACT REIMBURSEMENT CHANGES ON THE UTILIZATION OF INTRAVENOUS IMMUNE GLOBULIN 3 (2007) (finding that "while the majority of IVIG users in [its] data have claims for off-label indications, the *proportion* of off-label users has remained relatively unchanged from 1997 to 2005. Clearly, therefore, changes in off-label use do not explain shortfalls in IVIG access.").

³² See Orange Paper, *supra* note 30 at 15.

³³ 70 Fed. Reg. at 68649.

³⁴ See, e.g., Letter from Michael O. Leavitt, Secretary Dep't of Health & Human Servs., to Rep. Ellen O. Tauscher (Aug. 29, 2006) (on file with author) (demonstrating the agency's support for the preadministration payment in his response to a May 31st letter, which was led by Representative Joe Pitts and signed by 34 other Members of Congress, urging CMS to consider a both a payment adjustment and brand-specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access to this lifesaving therapy).

upon which a median cost would be determined under the OPSS methodology should be twice the size but is not because of hospital billing errors. We submit that because the G0332 code was new in 2006 and clearly was not well understood by many hospitals, it is premature to remove new technology APC status.

Another indicia of hospital difficulty in adapting to the new code is the wide variation in hospital charges that The Moran Company found. Specifically, it found that hospital charges varied widely with average charges at the hospital level for bills that appeared to be “single bills” according to CMS criteria ranging from just over \$3 to more than \$1,600. As a new code adopted late in 2005, hospitals may have had difficulty in assigning charge levels to the code for 2006 and that also warrants a continuation of new technology APC status for CY 2008.

In addition, as the table below demonstrates, The Moran Company found that the revenue codes hospitals chose to associate with G0332 code varied quite a bit resulting in a wide range of different Cost to Charge Ratios (“CCRs”) used to reduce charges to cost. As shown in the table below, 24 percent of hospitals billing for G0332 failed to associate a revenue code mapping to a department with a cost-to-charge ratio at all. The wide variation in revenue codes and resulting CCRs to be used likewise suggests that the data for G0332 was in a significant state of flux in 2006 and that such data cannot serve as a basis for moving the service out of a new technology APC.

Revenue Coding for G0332 (99% of Claims Reflected)

revenue	Cost Quintiles					Total Lines	Hospital Dept.	CCR	% Lines
	1st Quintile	2nd Quintile	3rd Quintile	4th Quintile	5th Quintile				
0250	79	244	80	31	118	552	Pharmacy		2%
0260	3893	2561	3362	4028	1448	15292	IV therapy		33%
0280		78	79	187	101	445	Oncology		1%
0510	199	571	715	626	1685	3796	Clinic		8%
0636	3667	2189	1529	1021	798	9204	drugs to patient		19%
0761	537	459	1100	923	3004	6023	observation/clinic		12%
0940	1271	3207	2873	2742	1725	11818	other not mapped		24%

Based on the wide variation in hospital charging and coding practices for G0332, We believe that it is premature to set preadministration-related payments for IVIG based on Medicare claims data. We therefore urge CMS to continue to assign G0332 to a new technology APC with a level of reimbursement at the current \$75 level. We believe that this amount will better serve to protect the access of Medicare beneficiaries to this important product.

We further believe that maintaining payment for preadministration-related services at the current level will be more in line with payments the agency has proposed in the physician office. Maintaining preadministration-related service payments at comparable levels across these sites of service will mitigate potential disruptions to the

sites of service where patients are now receiving care and allow the choice of site of care to be dictated by particular patient circumstances.

We believe maintaining G0332 for CY 2008 and beyond, as well as the agency's recent decision to provide brand-specific reimbursement for the four liquid IVIG therapies are an important first step toward improving patient access to IVIG therapies. We again thank you for your commitment in this area.

D. CMS SHOULD ESTABLISH NEW CODES TO FACILITATE MORE ACCURATE PAYMENT FOR THE SERVICE OF ADMINISTERING IVIG

As noted earlier, we are concerned that access to IVIG may be impeded by insufficient payments to hospitals for the resources expended in administering IVIG to beneficiaries. We recognize that increases are proposed to the payment levels for the CPT codes currently billed for furnishing IVIG and we support those increases. Even so, we believe that hospitals are not paid adequately for administering IVIG because the pertinent codes do not fully capture the resources expended by hospitals for this service. Similar to the infusion of chemotherapy drugs, an IVIG infusion requires the presence of a trained infusion nurse to administer the infusion and to monitor the patient during the entire infusion. As you may know, the infusion of IVIG has been associated with:

- renal dysfunction;
- acute renal failure;
- osmotic nephrosis;
- thrombotic events; and
- death.

If CMS does not more accurately reimburse the administration of an IVIG infusion in the hospital outpatient department, patient safety could be compromised because providers may make a business decision to no longer continue to use trained infusion nurses to administer IVIG and monitor the patients receiving the infusion. The continued presence of a trained infusion nurse for the entirety of an IVIG infusion is essential to ensure that both IVIG is properly administered to Medicare beneficiaries and such patients are appropriately monitored for these adverse reactions. For example, IVIG must be administered at the minimum concentration available and the minimum rate of infusion practicable to those patients with a predisposition to acute renal failure. In addition, the nurse can monitor those patients at risk for thrombotic events, including those patients with hyperviscosity, atherosclerosis, and cardiovascular disease.

We urge CMS to recognize these complexities and dangers associated with administering IVIG and, for CY 2008, issue two "G" codes that will facilitate a more

accurate reimbursement payment for the administration of an IVIG infusion -- one to account for the first hour of IVIG infusion and one to be used for each additional hour of IVIG infusion. In terms of the complexity of the infusion and resources required, we believe the infusion of IVIG is most similar to the infusion of chemotherapy drugs and issuing these temporary codes and setting appropriate payment rates will more accurately reimburse for the administration of IVIG and will help alleviate any problems that may arise in providing patients with safe and effective infusions of this lifesaving therapy. Under OPSS for CY 2008, CMS has proposed to assign values of \$155.27 for the first hour and \$52.93 for each additional hour to the two CPT codes for chemotherapy drug infusions. We ask that you consider using these CPT codes as benchmarks in determining OPSS rates for these new "G" codes.

E. THE STAKEHOLDERS AND PPTA SUPPORT THE DECISION BY CMS TO DISCONTINUE PUBLISHING THE ANNUAL BLOOD CLOTting FACTOR FURNISHING FEE UPDATE IN THE ANNUAL PHYSICIAN FEE SCHEDULE RULE, BUT INSTEAD POST THE RELEVANT INFORMATION ON THE CMS WEBSITE [“OPSS BLOOD CLOTting FACTORS”]

As you know, the MMA established a furnishing fee for blood clotting factor,³⁵ which is currently \$0.152.³⁶ We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor since 2005. We support CMS' decision in the Proposed Rule, consistent with the Social Security Act,³⁷ to increase this payment according to the annual consumer price index for medical care ending in June 2007. We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

CMS determined it is not necessary to announce the furnishing fee update as part of the rulemaking process because: (1) the timing of the rulemaking process makes it impossible to release the blood clotting factor furnishing fee for the upcoming year in the proposed rule because the annual CPI information for medical care is not available when CMS issues its proposed rule; and (2) the blood clotting factor furnishing fee is determined by statute and the CPI for medical care cannot be affected by the rulemaking process so it is not imperative that this information is released in such a manner. Moreover, removing the blood clotting factor furnishing fee update from the rulemaking process and issuing it through program instructions will expedite receipt of this information by the necessary stakeholders, who currently must wait until the issuance of the final rule, which is several months after the information could be made available. We fully agree with this rationale on how to proceed for CY 2009, and looks

³⁵ See SSA. § 1842(o)(5) (2007).

³⁶ See 71 Fed. Reg. at 68093.

³⁷ SSA § 1842(o)(5)(C).

forward to the issuance of the blood clotting factor furnishing fee for CY 2008 in the forthcoming final rule for the OPFS.

II. CONCLUSION

We appreciate the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your decision to continue to reimburse temporary code G0332, although the rate should stay at the current level. We are, however, deeply concerned about the impact the Proposed Rule could have on the lives of patients who depend upon plasma protein therapies. Regrettably, in some respects, the Proposed Rule would represent a step back 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. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. We urge CMS to carefully consider these comments, particularly those related to IVIG access.

We look forward to working with CMS to ensure continued access to plasma protein therapies in the hospital outpatient setting. Thank you for your attention to this very important matter.

Respectfully submitted,

Alpha-1 Association/Alpha-1 Foundation
GBS/CIDP Foundation International
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
Plasma Protein Therapeutics Association