PPTA
Plasma Protein Therapeutics Association

September 2, 2008
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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 -1404 – P (Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Changes to the Ambulatory Surgical Payment System and CY 2009 Payment Rates; Proposed Rule)**

Dear Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates 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") 2009 ("Proposed Rule").[1] We are the association that represents human plasma collection centers, the manufacturers of lifesaving therapies derived from this human plasma, as well as some manufacturers that produce blood clotting factors by using recombinant DNA technology. The therapies manufactured from human plasma by our members include albumin, alpha$_1$-protenaise inhibitor, which is also known as alpha$_1$-antitrypsin, blood clotting factors, and immune globulin. Collectively, these therapies – both plasma-derived and recombinant – are known as "plasma protein therapies." With the exception of albumin, plasma protein therapies are used to treat "orphan" patient populations with debilitating diseases and chronic medical conditions.[2] Generally,

[1] Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Rule, 73 Fed. Reg. 41416 (July 18, 2008).

[2] An orphan drug patient population is one in which patients suffer from a rare disease or condition that "affects less than 200,000 persons in the United States." *See* 21 U.S.C. § 360bb(a)(2)(A) (2008). Nearly all disease states requiring plasma protein therapies could qualify for orphan drug status if the manufacturer of a therapy sought such a designation. For example, the Immune Deficiency Foundation reports that approximately 50,000 patients in the United States suffer from primary immune deficiency disease ("PIDD"), Centers for Disease Control and Prevention reports that approximately 18,000 patients in the U.S. suffer from hemophilia, and the Alpha-1 Foundation reports that approximately 100,000 patients in the U.S. suffer from alpha$_1$-antitrypsin deficiency.

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these patients require regular infusions or injections of the appropriate plasma protein therapy for the duration of their lives as part of their treatment plans.

Our comments on the Proposed Rule are intended to ensure that all Medicare beneficiaries have full access to the complete range of lifesaving, Food and Drug Administration ("FDA") approved plasma protein therapies in the hospital outpatient department setting. Although PPTA is very grateful for the agency's proposals to continue reimbursing providers for the "furnishing fee" for blood clotting factors in the OPPS and to increase the drug administration payment for the initial hour of intravenous immune globulin ("IVIG") infusion to $126.58,[3] we are deeply troubled by its proposals to discontinue paying for IVIG preadministration-related services, and to further cut reimbursement for separately payable, non-pass-through drugs and biologicals to average sales price ("ASP") +4%. In order to guarantee that hospital outpatient departments remain a viable treatment setting option for Medicare beneficiaries requiring plasma protein therapies, PPTA respectfully urges CMS to take the following action:

1. Continue its policy for payment of the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department at the same level as in the physician office setting;
2. Ensure that the OPPS rates for separately payable, non pass-through drugs and biologicals in 2009 are set at least at ASP +6%; and
3. Continue paying separately for IVIG preadministration-related services (Healthcare Common Procedure Coding Systems ("HCPCS") Code G0332).

## DISCUSSION

### I. PPTA APPLAUDS CMS FOR ITS DECISION TO MAINTAIN THE FURNISHING FEE FOR BLOOD CLOTTING FACTORS UNDER THE OPPS

Section 303(e) of The Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) established a "furnishing fee" for blood clotting factors provided in the physician office.[4] Pursuant to statute, this fee is updated annually according to inflation for medical care.[5] The fee for CY 2008 is $0.158 per unit.[6] Since 2006, CMS has rightly paid hospitals the same furnishing fee and again provides for it in the Proposed Rule.[7]

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[3] *See* Medicare Program: Proposed Changes to the Hospital Outpatient Perspective Payment System and CY 2009 Payment Rates, 73 Fed. Reg. 46575, 46578 (Aug. 11, 2008).
[4] *See* MMA, 117 Stat. 2066, 2252 (2003); Social Security Act ("SSA") § 1842(o)(5) (2008).
[5] SSA, § 1842(o)(5)(C).
[6] *See* 73 Fed. Reg. at 41492.
[7] *See* Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).

In arriving at its original decision to also provide for the furnishing fee under the OPPS, CMS determined that similar resources were required to furnish blood clotting factors "across all types of service settings."[8] As such, the agency concluded that, moving forward, "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."[9]

PPTA agrees that the agency's conclusion continues to be the correct one. Indeed, we believe this furnishing fee has been instrumental in preserving patient access to blood clotting factors since its inception in the physician office in 2005; thus, PPTA appreciates CMS' inclusion of the furnishing fee under OPPS to date. We urge CMS to finalize its proposal[10] and continue the furnishing fee for blood clotting factors administered in the hospital outpatient department in CY 2009.

## II. CMS MUST NOT SET THE PAYMENT LEVEL FOR SEPARATELY PAYABLE, NON-PASS-THROUGH DRUGS AND BIOLOGICALS AT ANY LESS THAN ASP +6%.

Adequate Medicare reimbursement is imperative for the preservation of patient access. CMS proposes, however, to pay for the acquisition and pharmacy overhead costs of separately payable non-pass-through drugs and biologicals at ASP +4% for CY 2009.[11] PPTA believes that Medicare beneficiaries should be able to obtain drugs and biologicals, especially plasma protein therapies, best suited for their individual needs in the most appropriate site of service. Hospital outpatient departments must remain a viable option for beneficiaries to be able to receive therapies such as $alpha_1$-antitrypsin, blood clotting factors, and IVIG. The Proposed Rule's plan to further reduce reimbursement in the OPPS may significantly limit the patient's ability to choose the site of service from which to obtain their lifesaving plasma protein therapy.

Our analysis below controverts CMS' view that payment of anything less than a minimum of ASP +6% "would continue to provide accurate payments for average acquisition costs of Part B drugs and pharmacy overhead costs"[12] given, as discussed below, that ASP + 6% fails to even cover just the acquisition costs of some drugs for many hospitals. Moreover, PPTA also refutes CMS' assertion that the use of hospital claims data in setting the OPPS payment level for specified covered outpatient drugs "is the best currently available proxy for average hospital acquisition cost and associated

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[8] *Id*.
[9] *Id*.
[10] *See* 73 Fed. Reg. at 41492.
[11] *Id*. at 41490.
[12] *See* Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule, 72 Fed Reg. 42628, 42736 (Aug. 2, 2007).

pharmacy overhead costs."[13] Because of the patient access issues that will result if CMS cuts the payment level for specified covered outpatient drugs based on these flawed data, PPTA respectfully requests that CMS provide payment parity between the physician office and the hospital outpatient department by setting the payment level under the OPPS at no less than ASP +6%.

### A. Further Payment Cuts for the Acquisition of Plasma Protein Therapies Will Exacerbate Existing Patient Access Challenges

Physicians and hospital administrators continue to cite insufficient Medicare reimbursement for making difficult business decisions to discontinue offering certain drugs to Medicare beneficiaries for infusion.[14] Such decisions have the potential to be fatal to the vulnerable patient populations that require regular infusions or injections of plasma protein therapies for the duration of their lives. Additionally, the U.S. Department of Health and Human Services ("HHS") published two reports in 2007 that suggest insufficient reimbursement is a leading factor in the difficulties patients face in accessing one particular biological, IVIG.[15]

IVIG is the only treatment option for patients suffering from primary immune deficiency disease ("PIDD"). According to 2006 survey data from the Immune Deficiency Foundation ("IDF"), 32% of Medicare beneficiaries with PIDD have switched their site of service since 2005,[16] which is when CMS set the reimbursement level for most drugs and biologicals administered in the physician office at ASP +6% pursuant to the MMA.[17] The majority of those patients that switched their site of service did so as a result of insufficient reimbursement.[18] Many of these Medicare beneficiaries migrated to

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[13] 73 Fed. Reg. at 41490.

[14] *See, e.g.*, Al Wight, Letter to the Editor, *Death Notice From PVH*, ARGUS COURIER, Dec. 12, 2007, http://www1.arguscourier.com/article/20071212/OPINION02/71211036 [hereinafter "Wight Letter to the Editor"] (describing two letters – one from June 2007 and one from October 2007 – from Petaluma Valley Hospital executives in which the hospital announced it would no longer offer infusions of alpha-1 antitrypsin, which the patient required weekly, because of "inadequate reimbursement from Medicare.").

[15] *See* OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS. ["HHS"], ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) 4-22 (2007) [hereinafter "ASPE ANALYSIS OF THE IVIG MARKET"] (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); OFFICE OF INSPECTOR GENERAL ["OIG"], HHS, INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY 9 (2007) [hereinafter "OIG REPORT ON IVIG"] (describing an unsustainable business model with data that show, in the first, second, and third calendar quarters of 2006, 74.5%, 77.2%, and 44% of hospitals, and 89.5%, 96.5%, and 41.4% of physician offices, respectively, purchased IVIG from distributors at prices that were greater than the Medicare payment rate).

[16] *See* IMMUNE DEFICIENCY FOUNDATION ["IDF"], ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 15, fig. 9(2006) [hereinafter "IDF REIMBURSEMENT SURVEY"].

[17] *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 at 42 C.F.R. § 414.904 (2007)).

[18] *See* IDF REIMBURSEMENT SURVEY, *supra* note 16, at 17 (revealing that 54% of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the hospital outpatient department to receive their IVIG infusions in 2005 because hospital outpatient departments were paid based on the OPPS median cost methodology subject to certain average wholesale price floors and ceilings.[19] By 2006, there was nearly a 60% reduction from 2004 in the number of Medicare PIDD patients receiving their IVIG infusions in the physician's office.[20]

Hospital outpatient departments were initially ill-equipped to handle the sudden patient migration from the physician office because manufacturers generally allocate IVIG to authorized distributors and group purchasing organizations based on the historical utilization of these therapies by the customers of these entities.[21] Generally, many hospitals were able to quickly adjust their contracts accordingly to account for their flood of new patients seeking IVIG.[22] Yet, the very next year, a change in the reimbursement level in the OPPS went into effect.

Beginning in 2006, CMS began to use the ASP-based payment methodology pursuant to its broad statutory authority under section 1833(t)(14) of the Social Security Act ("SSA"), and set the 2006 OPPS payment rates for most drugs and biologicals, including alpha$_1$-antitrypsin, blood clotting factors, and IVIG, at ASP +6%.[23] CMS must restore this payment level to a minimum of ASP +6% for CY 2009. Although the HHS reports decisively demonstrate that ASP +6% is an insufficient payment level to compensate significant numbers of hospitals for even just the acquisition cost of IVIG therapies,[24] it is absolutely unreasonable for CMS to expect the current ASP +5%,[25] or

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[19] *See* ASPE ANALYSIS OF THE IVIG MARKET, *supra* note 15, at 4-31 (concluding that insufficient reimbursement caused the patient migration in 2005).
[20] *See* IDF REIMBURSEMENT SURVEY, *supra* note 16, at 16, fig, 10.
[21] *See, e.g.,* ASPE ANALYSIS OF THE IVIG MARKET, *supra* note 15, at 2-29, 3-18 (illustrating the short term access challenges product allocation causes). In recent years, manufacturers have begun to enter into contracts with distributors based on historical utilization of IVIG in response to pressure from Congress and HHS to address a shortage of this therapy more than a decade earlier. *See Public Health 2000: Immune Globulin Shortages – Causes and Cures: Hearing Before the Subcomm. On Human Resource of the House Comm. on Government Reform and Oversight*, 105th Cong. 2, 16 (1998) (statement of Rep. Shays, Chairman, Subcomm. on Human Resources of the House Comm. on Government Reform and Oversight) (suggesting that proper allocation of IVIG, as recommended by HHS's Advisory Committee on Blood Safety and Availability, should prevent future IVIG shortages if manufacturers acquiesce).
[22] *See* OIG REPORT ON IVIG, *supra* note 15, at 13-14; *see also* Letter from Daniel R. Levinson, Inspector General, U.S. Dep't of Health & Human Servs., to Rep. Nathan Deal, Chairman, Subcomm. on Health, House Comm. on Energy & Commerce, June 7, 2006 (illustrating that hospitals ultimately adjusted to the significant IVIG patient migration from the physician office to the hospital outpatient department in 2005 through data that show manufacturers allocated 41% of their IVIG therapies to group purchasing organizations (up from 17% in 2004), compared to 38% to distributors (down from 62% in 2004) during that year. *But c.f.,* ASPE ANALYSIS OF THE IVIG MARKET, *supra* note 15, at 4-12, Table 4-9 (describing at least one hospital that received less IVIG than it requested in 2005. It is, however, unclear if that overall amount of IVIG received by that particular hospital was more than it had received in 2004).
[23] *See* 70 Fed. Reg. at 68642.
[24] *See, e.g.*, OIG REPORT ON IVIG, *supra* note 15, at 9 Table 1.
[25] *See* Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Final Rule, 72 Fed Reg., 66580, 66763 (Nov. 27, 2007).

the proposed ASP +4% will adequately reimburse hospitals providing this critical service.

Logically, one might expect the payment cuts for drugs furnished in the hospital outpatient department to drive patients back to the physician office setting. Each provider, however, has an individual business model, so one should not draw such a simplistic conclusion. For example, patient migration from the physician office to the hospital outpatient department for IVIG treatment even continues today because the ASP +6% reimbursement level in the physician office remains inappropriate for this therapy in that setting.[26] Those physician offices that discontinued providing IVIG when the ASP went into effect will not resume such services because the ability to purchase less than 25% of IVIG from distributors at a price at or below the Medicare reimbursement level remains a bad business model, especially when nearly 44% of the purchases above that payment level are at more than 10% above that level.[27] Medicare beneficiaries who require IVIG have continued to experience access difficulties over the last year and will have even fewer options to obtain therapy if reimbursement is cut to ASP +4% in the OPPS.[28] Simply put, hospital outpatient departments will not be able to afford to offer such services at this payment level, so it is unclear where patients will go for treatment if CMS finalizes its proposal.

Al Wight, a Medicare beneficiary suffering from alpha$_1$-antitrypsin deficiency, has experienced similar hardships in the last year at a reimbursement level of ASP +5%, and will very likely face more difficulties if the Proposed Rule is finalized. Alpha$_1$-antitrypsin deficiency is a serious genetic disorder that can result in life-threatening lung disease – emphysema in the case of Mr. Wight. The lung destruction associated with this condition is often misdiagnosed as either asthma or chronic obstructive pulmonary disease. Additionally, this condition can also result in significant liver damage. In order to treat this affliction, Mr. Wight requires regular, weekly infusions of alpha$_1$-antitrypsin, which he had been receiving from his local hospital in Petaluma, California.

Unfortunately, those weekly infusions were discontinued due to cuts in the Medicare OPPS payments to ASP +5% for this therapy. Specifically, in late 2007, Petaluma Valley Hospital ("PVH") notified Mr. Wight that the hospital "would no longer be providing [his] life-sustaining [alpha$_1$-antitrypsin] infusion therapy after January 15,

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[26] *See* Letter from Marcia Boyle, President & Founder, IDF to Kerry Weems, Acting Administrator, CMS (Aug. 8, 2008) [hereinafter "Boyle Letter"] (revealing that, according to a summer 2008 patient survey conducted by IDF, Medicare beneficiaries requiring IVIG "continue to be shifted from their physicians' offices for their infusions").

[27] *See* OIG REPORT ON IVIG, *supra* note 15, at 9 Table 2 (averaging data for Q1 2006 through Q3 2006 to illustrate the insufficient Medicare reimbursement levels for doctors that purchase IVIG).

[28] *See* Boyle Letter, *supra* note 26 (revealing that 45% of Medicare patients requiring IVIG to treat PIDD have, in the last 12 months, faced impediments such as postponed treatments, increased time between treatments, reduced dosage, and an inability to receive the brand best suited for their individual needs from their provider).

2008" because of "inadequate reimbursement from Medicare."[29] According to Mr. Wight, two other patients who had been receiving infusion therapy at PVH received similar cancellation letters from the hospital.[30]

In its notification to Mr. Wight, the hospital suggested that he either find another hospital to obtain his weekly infusions, or use a home infusion service. As you know, however, Medicare Part B would not cover the drug provided as part of a home infusion service. Although it was "Mr. Wight's desire to continue treatment at PVH because it is his local hospital and he feels it is their duty provide service to all Petaluma residents," as well as the fact that "it is a hardship for him to travel weekly to receive this service at another location,"[31] he has been forced to receive his weekly alpha$_1$-antitrypsin infusion treatments through Sutter Medical Center Hospital of Santa Rosa, California.[32]

From a policy perspective, PPTA is quite troubled by the CMS proposal to further cut OPPS reimbursement for specified covered outpatient drugs to ASP +4%. As we discuss below in section II.B of this letter, the alpha$_1$-antitrypsin and IVIG situations demonstrate the agency's application of flawed data on charges and costs of drugs and biologicals in determining their OPPS payment rate. The above examples also serve to illustrate the unintended consequences of drug payment disparity between the physician office and the hospital outpatient department sites of service.

In recent years, CMS has underscored the importance of a uniform drug payment level between the physician office and hospital outpatient department.[33] The economic reality of the ASP +6% methodology for IVIG notwithstanding, such parity preserves patient access by protecting patient choice. Given that fact and the lack of foundation for an ASP + 4% payment methodology, we see no valid reason for recreating this unstable environment and further jeopardizing beneficiary access to lifesaving therapies, such as IVIG and alpha$_1$-antitrypsin. Without an appropriate data set, PPTA believes that CMS should pay for non-pass-through drugs and biologicals at a minimum of ASP +6%.

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[29] *See* Wight Letter to the Editor, *supra* note 14.
[30] *Id*.
[31] Minutes of the November 29, 2007 Regular Meeting of the Petaluma Health Care District Board of Directors, *available at* http://www.phcd.org/Minutes/brdmins11-29-07.pdf.
[32] *See* Minutes of the January 10, 2008 Regular Meeting of the Petaluma Health Care District Board of Directors, *available at* http://www.phcd.org/Minutes/brdmins1-10-08.pdf.
[33] *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 See* Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Final Rule, 71 Fed. Reg. 67960, 68091 (Nov. 24, 2006) (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.").

## B. The Use of Hospital Claims Data to Set OPPS Drug Rates is a Flawed Methodology

CMS has been using hospital claims data to set the payment level for specified covered outpatient drugs in the OPPS since January 1, 2008. PPTA believes that determining OPPS payment rates based on these data is inappropriate because of flaws in the data. Furthermore, this use of hospital claims data also fails to consider the impact that charge compression has on such data.[34]

Charge compression is "the practice of applying a lower charge markup to higher-cost services and a higher charge markup to lower-cost services."[35] For drugs, charge compression essentially undervalues high cost products and overvalues low cost products. This is especially problematic for separately covered outpatient drugs, including all plasma protein therapies, because of their relatively high costs and lower pharmacy overhead charge by the hospital. The agency's own contractor, RTI International, confirmed what commenters have long told CMS about hospital charging practices:

> RTI determined that hospitals billing a greater percent of drug charges under revenue code 0636 (Drugs requiring detail coding) out of all revenue codes related to drugs had a significantly higher CCR for cost center 5600 (Drugs Charged to Patients). "These findings are consistent with the a priori expectation that providers tend to use lower markup rates on these relatively expensive items, as compared with the other items in their CCR group."[36]

In its final report, RTI stated that the impact of charge compression could be addressed by using regression-based cost to charge ratios, which would result in costs being roughly 17% higher.[37] Thus, CMS' reliance on data on drugs and biologicals that are biased because of charge compression causes the median costs of these products to be significantly understated.

Moreover, CMS' policy of using hospitals claims data in setting OPPS payment rates for drugs and biologicals is flawed because of its inclusion of drugs sold at or below the 340B Drug Pricing Program ceiling price. This program requires a manufacturer to provide significant discounts on its covered outpatient drugs to certain federally funded grantees and other safety net health providers.[38] According to 2007 claims data, 340B hospitals account for approximately 35% of all billed drugs and

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[34] 72 Fed. Reg. at 42740.
[35] 73 Fed. Reg. at 41429.
[36] *Id.* at 41490.
[37] RTI Final Report at p. 91, available at http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf.
[38] 42 U.S.C. § 256b (2007).

biologicals by cost in the OPPS.[39] The 340B ceiling price for a covered outpatient drug is determined by subtracting the Medicaid unit rebate amount ("URA") from the average manufacturer's price ("AMP") for the quarter that is two quarters prior to the quarter for which the ceiling price is being calculated (i.e., the Q1 AMP and URA will determine the Q3 340B ceiling price).[40] For generic drugs, the URA is 11% of a product's AMP.[41] The calculation of the URA for brand drugs, which include all plasma protein therapies, can be a bit more complicated.

Pursuant to section 1927(c)(1) of the SSA, CMS calculates this rebate amount as the greater of the minimum rebate percentage of AMP or the difference between the AMP and the best price ("BP"). Because most plasma protein therapies are sold under long term contracts with distributors, most will be subject to the minimum rebate percentage rather than rebates based on BP discounts. The basic URA for these therapies would likely then be 15.1% of their AMP.[42] Brand name drugs may also be liable for an extra "penalty" rebate if the AMP for a product outpaces a specified inflation factor.[43] The basic URA and additional URA are then added to determine the total URA for the purposes of both the Medicaid drug rebate and the 340B ceiling price.

Because the mandatory price concessions to 340B covered entities, such as disproportionate share hospitals, can be so large as to inappropriately distort data, transactions at or below the 340B ceiling price are excluded from the AMP calculation,[44] the BP calculation,[45] and the ASP calculation for such drug.[46] By providing for this exclusion in these instances of price reporting, CMS and Congress have made an unambiguous distinction between mandated government discounts and traditional manufacturer discounts. Likewise, when the Government Accountability Office ("GAO") conducted a study of drug purchase prices in hospital outpatient departments, it also excluded drugs purchased at or below the 340B ceiling price.[47]

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[39] *See* Memorandum from Chris Hogan, Direct Research, LLC to Interested Parties 2 (July 27, 2008) [hereinafter "Hogan July Memo"] (Attachment A).
[40] *See* 42 U.S.C. § 256b(a)(1)
[41] *See* SSA § 1927(c)(3) (2008).
[42] *See* SSA § 1927(c)(1)(B)(i).
[43] *See* SSA § 1927(c)(2). The "penalty" rebate can create a situation where a drug's URA becomes greater than its manufacturer reported AMP, which can result in a negative 340B ceiling price. In such instances, manufacturers are directed to charge a 340B ceiling price of one penny per unit, rather than the previous quarter's ceiling price. *See* OIG, HHS, REVIEW OF 340B PRICES 3, 14 (2006).
[44] *See* Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39241 (July 17, 2007).
[45] See SSA § 1927(c)(1)(C)(i)(I).
[46] See SSA § 1847A(c)(2)(A) (2008) (exempting sales that are exempt from the calculation of BP, which statutorily excludes drugs sold at or below the 340B ceiling price under SSA § 1927(c)(1)(C)(i)(I)); 42 C.F.R. § 414.804(a)(4) (2007). *See also* MICHAEL O. LEAVITT, SECRETARY,HHS, REPORT ON SALES OF DRUGS AND BIOLOGICALS TO LARGE VOLUME PURCHASERS 3 (2006), *available at* http://www.cms.hhs.gov/reports/downloads/LVP_RTC_2_09_06.pdf (last visited August 1, 2008).
[47] *See* Letter from A. Bruce Steinwald, Dir., Health Care, Government Accountability Office ["GAO"] to Michael O. Leavitt, Secretary, HHS 8 (June 30, 2005) (demonstrating that GAO believes that including

Exclusion of purchases at or below the 340B ceiling price is appropriate in the AMP, BP, and ASP calculations as well as GAO analysis because, by the design of the 340B Program, prices offered to 340B covered entities are lower than is available to other hospitals. As a result, the inclusion of transactions at or below the 340B ceiling price could inappropriately lower the identified costs for the purpose of calculating the AMP, BP, and ASP and distort the GAO's drug purchase price analysis. While this is a longstanding policy of CMS and GAO, CMS failed to exclude drugs purchased at or below the 340B ceiling price when conducting its hospital claims data evaluation that led to an initial payment cut to ASP +5% in CY 2008 and its proposal for further reduction to ASP +4% in CY 2009.

An April 2008 study of 2006 hospital claims data by Chris Hogan of Direct Research revealed that the inclusion of 340B hospitals reduces the estimated mean unit cost of separately covered outpatient drugs to ASP +3.4%, which is consistent with CMS' hospital claims data evaluation in setting the payment level for CY 2008.[48] In July 2008, Hogan updated his study with analysis of 2007 hospital claims data, which revealed that number increased to ASP +4%, which is the agency's proposal for CY 2009.[49] Hogan's analysis concludes that if CMS were to exclude 340B hospitals from its claims data analysis, the estimated mean unit cost of separately payable outpatient drugs would more appropriately be ASP +7.6% based on the 2007 claims data,[50] up from ASP +6.9% based on 2006 claims data.[51]

The variance in the data, which grew from -3.5% in 2006 to -3.6% in 2007, will continue to increase as the 340B Program continues to expand. Over the last decade, the number of these covered entities participating in the 340B Drug Pricing Program has increased by nearly 1100% from 1,223 to 13,205. [52] Meanwhile, the number of those entities that are eligible for the program has increased nearly 500% from 3,574 to 17,836 during that same period.[53] Current legislation in both the United States House of Representatives and the United States Senate would expand the program even further if enacted.[54] If CMS continues to rely upon hospital claims data in setting the payment

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purchases at or below the 340B Drug Pricing Program ceiling price would provide an inaccurate average purchase price for a specified covered outpatient drug).

[48] *See* Memorandum from Chris Hogan, Direct Research, LL to Interested Parties 2 (April 15, 2008) [hereinafter "Hogan April Memo"] (Attachment B).

[49] *See* Hogan July Memo, *supra* note 39, at 2.

[50] *Id*.

[51] *See* Hogan April Memo, *supra* note 48, at 2.

[52] *Compare* OIG, HHS, AUDIT OF THE UTILIZATION OF THE PUBLIC HEALTH SERVICE 340B DRUG PRICING PROGRAM 3 (1998) *with* OFFICE OF PHARMACY AFFAIRS,HHS, LIST OF COVERED ENTITIES, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last visited Aug. 13, 2008).

[53] *Id*.

[54] *See* S. 1376, 110th Cong.; H.R. 2606, 110th Cong. Both bills would not only expand the program to cover drugs purchased for use in the hospital inpatient setting, but also expand the type of covered entities eligible for the program to include children's hospitals, critical access hospitals, rural referral

level under the OPPS, the continued alarming growth of the 340B Program will soon result in the reimbursement of hospitals at levels below ASP.

In creating the 340B program, it was the intent of Congress to "establish price controls to limit the cost of drugs to Federal purchasers and to certain grantees of Federal agencies."[55] Congress believed such protection against excessive pharmaceutical prices would "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[56] Lawmakers never intended these deep discounts for these entities to adversely affect access to care for patients of non-340B hospitals by driving down the Medicare payment level.

In conclusion, CMS' proposal to set the CY 2009 payment rates for separately paid drugs and biologicals at ASP +4%, rather than at ASP + 6% is absolutely inappropriate because the methodology is flawed. In using claims data as it does, the agency is incorrectly disregarding the impact of drugs sold at or below the 340B ceiling price on hospital claims data, and the impact of charge compression on hospital claims data. We respectfully urge CMS to restore OPPS reimbursement to ASP +6% because the data CMS uses to set the OPPS rates for drugs and biologicals is flawed. In the absence of suitable data, PPTA believes payment at the same rate as physician office payment rates will serve the important policy of maintaining the same payment rates across sites of service so that there will not be financial incentives to furnish drugs and biologicals in one setting rather than another.

If CMS, however, continues its faulty policy of setting the reimbursement level for specified covered outpatient drugs using claims data, PPTA urges the agency to exclude drugs purchased at or below the 340B ceiling price from its evaluation of this hospital claims data, or separately calculate two amounts based on the two distinct patient populations. As a matter of policy, accurate reimbursement for each product is essential to preserving patient access, which is especially critical for Medicare beneficiaries that require lifesaving plasma protein therapies as these vulnerable patient populations typically have strict limitations on the type of efficacious treatment options afforded to them.

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centers, and sole community hospitals that meet the DSH requirements. H.R. 2606 would also expand the program to cover mental health facilities, substance abuse centers, Medicare-dependent small rural hospitals, and facilities, in addition to hemophilia treatment centers, that receive grants from the Maternal and Child Health Bureau.

[55] *See* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992: Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289 (May 7, 1993).

[56] H.R. REP. NO. 102-384, PART 2 (1992).

## III. CMS SHOULD CONTINUE PAYING FOR IVIG PREADMINISTRATION-RELATED SERVICES

CMS proposes to discontinue its current policy of making separate payments to hospital outpatient departments for IVIG preadministration-related services, HCPCS code G0332, by now accounting for "the hospital resources required to locate and obtain the appropriate IVIG products and to schedule patients' infusions…through the OPPS payment for the associated drug administration services."[57] PPTA appreciates CMS's past recognition of the need for this temporary payment since 2006 to combat the challenges patients face in obtaining IVIG in the hospital outpatient department. It should be noted that while patients have experienced access problems in recent years, CMS, the HHS Advisory Committee on Blood Safety and Availability, and the FDA Center for Biologics Evaluation and Research have all concluded that IVIG supply is sufficient.[58]

As you know, CMS established the payment, effective January 1, 2006, in order to address the significant resources necessary for hospital staff to "monitor and manage their inventory, locate available IVIG products, reschedule infusions according to product availability and patients' needs, and implement physicians' determinations regarding whether the available formulations are appropriate for patients and whether specific dosing adjustments are required."[59] Moreover, with regard to ensuring patients are obtaining the brand of IVIG best suited for their individual needs, staff must also evaluate "product-specific factors…in light of patients' clinical indications for the IVIG infusions, their underlying medical conditions, and their past reactions to various IVIG products."[60] After this evaluation, staff "must locate appropriate doses of IVIG products in light of these considerations."[61] We worry that if the proposal to eliminate this preadministration payment becomes final, this new policy could have a significant impact on patient access to IVIG, as hospitals in 2008 continue to expend these same resources that prompted CMS to establish this payment in the first place. Some Members of Congress share our concern.[62]

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[57] 73 Fed. Reg. at 41456 – 41457.
[58] *See Medicare Reimbursement of Physician Administered Drugs: Hearing Before the Subcomm. On Health of the House Comm. on Ways & Means*, 109th Cong. (2006) (statement of Herb Kuhn, Director, Centers for Medicare and Medicaid Services); ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY, HHS, STATUS OF IMMUNE GLOBULIN INTRAVENOUS (IGIV) PRODUCTS, *available at* http://www.hhs.gov/bloodsafety/igiv.html (last visited Sept. 2, 2008); CTR. FOR BIOLOGICAL RESEARCH & EVALUATION, HHS, BIOLOGICAL PRODUCT SHORTAGES, *at* http://www.fda.gov/cber/shortage/shortage.htm (last visited Sept. 2, 2008).
[59] *See* 70 Fed. Reg. at 68649.
[60] *Id.*
[61] *Id.*
[62] *See, e.g.,* Letter from Sen. John Ensign, Member, S. Comm. on Finance to Kerry Weems, Acting Administrator, CMS (July 28, 2008) (Attachment C).

The agency bases its proposal to package G0332 with the administration payment on the premise that the IVIG market has stabilized, as demonstrated by lower IVIG prices, increased IVIG utilization, and increased Medicare reimbursement for IVIG. Additionally, CMS contends that the transient conditions prompting the initial creation of G0332 no longer exist.[63] These rationales for discontinuing the IVIG preadministration-related services payment are flawed, as we explain below. This payment has proven successful in preventing difficulties for Medicare beneficiaries as they attempt to access IVIG in this site of service, so it is counterintuitive that the agency would discontinue this critical separate payment, particularly when it proposes to again cut payments for the acquisition and pharmacy overhead costs of IVIG to ASP +4%.

### A. Market Stability

In the Proposed Rule, after reviewing the history of the preadministration-related services payment, CMS provides its rationale for its plan to eliminate this payment. The agency references the April 2007 Office of Inspector General Report ("OIG Report") as proof that the IVIG marketplace has had "stability" since the third quarter of 2006. PPTA believes these same data are evidence of volatility in the IVIG marketplace.

Specifically, CMS views that the data illustrating that 56% of IVIG sales to hospital outpatient departments by distributors occurred at prices below the Medicare payment during the third quarter of 2006 as evidence that the IVIG marketplace is stabilizing.[64] The agency makes this analytical leap based on the data in the OIG Report that illustrates that during the fourth quarter of 2005, and the first and second quarters of 2006, only 37.3%, 25.5% and 22.8%, respectively, of IVIG sales to hospital outpatient departments were at prices below the Medicare payment level.[65] When CMS initially reviewed the OIG Report, the agency more appropriately referred to this improvement as an "important development."[66] PPTA agrees it is an important development but finds it is misleading for the agency to argue that market stability can be found in a market where 44% of hospitals are unable to purchase this lifesaving therapy at or below the Medicare payment rate. Moreover, more than 76% of that 44% were actually paying between 5% and 10% <u>above</u> this payment level.[67]

CMS has changed its position from last year on the value of these empirical data presented in the OIG Report. Specifically, CMS gave careful consideration to these data when it decided to continue to pay for preadministration-related services in the OPPS for CY 2008. The agency provided comments on this data not only in Appendix B of the report, but also in the CY 2008 Physician Fee Schedule Proposed

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[63] *See* 73 Fed. Reg. at 41457.
[64] *Id*.
[65] OIG REPORT ON IVIG, *supra* note 15, at 9.
[66] *Id*. at Appendix B.
[67] *Id*. at 9.

Rule.[68] In finalizing its decision to continue the preadministration-related services payment for the OPPS in 2008, CMS stated that it "would reevaluate the appropriateness of separate payment for IVIG preadministration-related services for the CY 2009 OPPS rulemaking cycle."[69] Such a reevaluation would presumably contain data different from that which the agency examined last year, which is why CMS' proposal to now eliminate G0332 without offering any new data to substantiate its elimination strikes us as illogical. PPTA agrees with the agency's previous stance that further examination by the OIG of certain components of the IVIG access issue is necessary,[70] and urges CMS to allow this to occur before making any changes to the payment for IVIG preadministration-related services.

CMS also states that IVIG drug HCPCS code revisions have led, in part, to increased payments for IVIG therapies resulting in a more stable marketplace.[71] Again, PPTA greatly appreciate that CMS finally gave a proper reading to the ASP statute and now computes the ASP payment rate of all IVIG entering the marketplace after October 1, 2003 based solely on the individual ASP information of that therapy – a process that is best facilitated by these HCPCS code revisions.[72] We do not, however, see a clear connection between the coding revisions and a more stable marketplace. Moreover, by statute, brand-specific reimbursement is not available for every brand of IVIG in the marketplace.

When advocating for appropriate IVIG reimbursement pursuant to the ASP statute, it was always PPTA's position that Medicare beneficiaries that require IVIG must be able to access the brand best suited for their individual needs because each brand is unique. IVIG therapies are unique not only because of the unique production processes, but also because of the "substantial variation in manufacturing, fractionation, and bottling process times that may also influence the biological activity of the final product," as well as formulation, volume load, sodium content, sugar content, osmolality, immunoglobulin A ("IgA") content, and pH.[73] For example, physicians may prefer prescribing IVIG therapies: (1) without sugar for diabetics; (2) with low osmolality and low volume for those patients with congestive heart failure or compromised renal function; (3) with less IgA for those patients with IgA deficiencies; (4) with lower pH for those patients with small peripheral vascular access or a tendency toward phlebitis. In addition, therapies with sucrose may create a higher risk of renal failure in some patients. Because IVIG is not an interchangeable, "one-size-fits-all" therapy, patient

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[68] *See* Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38122, 38146 (Jul. 12, 2007).
[69] *See* 72 Fed Reg. at 66698.
[70] *See* OIG REPORT ON IVIG, *supra* note 15, at Appendix B.
[71] *See* 73 Fed. Reg. at 41457.
[72] *See* SSA § 1847A(c)(6)(C) (2008).
[73] *See* ASPE ANALYSIS OF THE IVIG MARKET, *supra* note 15, at 2-17.

outcomes may be adversely affected if physicians fail to administer the IVIG therapy best suited for the individual needs of a patient.[74]

The HCPCS code revisions, which went into effect on July 1, 2007, ensure providers will prescribe IVIG therapies that had been assigned to discontinued HCPCS code J1567 based on safety and efficacy reasons.[75] There is no evidence that these HCPCS coding revisions had an effect on the availability of any specific IVIG therapy. Moreover, it is not clear if the cited increases in IVIG payment rates that CMS noted in the CY 2009 OPPS Proposed Rule were caused by the coding changes or just reflected the quarter to quarter variability in ASP payment rates. Thus, while the creation of new HCPCS codes for IVIG was welcome by the entire IVIG community, nothing about that decision lends support to the notion that the IVIG marketplace has stabilized over the past year.

CMS also states that the slight increase in utilization of IVIG and its corresponding preadministration code from 2006 to 2007 suggests that pricing of and access to IVIG may be improving, thereby indicative of a more stable market.[76] Although there was a slight increase, we do not believe that this increase demonstrates an improvement in the stability of the marketplace. There are other reasons that may have led to the slight increase; for example, an increase in the number of Medicare beneficiaries that require the therapy. As a result, the reported, but unanalyzed increase in utilization of IVIG from 2006 to 2007 does not signify a need to discontinue payment for IVIG preadministration-related services.

### B. Transient Market Conditions

CMS concludes its comments on the preadministration-related services payment by stating that it now believes that the "transient market conditions that led us to adopt the separate payment for IVIG preadministration-related services have improved."[77] Based on a review of the final rule in which CMS adopted the preadministration-related services payment, PPTA respectfully disagrees, as many of the initial conditions that led CMS to create the payment still exist.

In that final rule, the agency referenced "reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG products on a consistent basis to meet their patients' need in the current marketplace."[78] CMS seemed to believe that

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[74] *Id.* at 2-18 (describing the recommendations of the Clinical Immunology Society of the appropriate IVIG therapy for certain patient risk factors).
[75] *Id*. (suggesting that providers may argue a degree of substitutability exists among IVIG therapies to justify their preference to purchase or prescribe certain IVIG therapies for economic reasons).
[76] 73 Fed. Reg. at 41457.
[77] *Id*.
[78] 70 Fed. Reg. at 68648

this marketplace condition occurred, at least in part, because most brands of IVIG were put on allocation by manufacturers in 2005.[79] The OIG Report also provided discussion on the impact of allocation on the IVIG marketplace.[80] Currently, just as they did in 2005, manufacturers allocate to customers and providers the amount of IVIG they receive based on historical usage in order to satisfy their contractual obligations. To the extent that CMS viewed IVIG allocation as a "transient market condition" that warranted the establishment of the IVIG preadministration-related services payment, this market condition remains.

Further, in concluding that it will implement a preadministration payment in the CY 2006 OPPS Final Rule, CMS stated that the patterns of utilization of IVIG are different than for other drugs and biologicals due to the many indications that it treats.[81] The agency also discussed emerging indications for IVIG that distinguish this therapy from most other drugs and biologicals.[82] We agree with CMS' statement and appreciate that CMS has historically recognized the many treatment options that IVIG provides for Medicare beneficiaries. These market conditions have not changed; IVIG is still used to treat many conditions and is being studied to treat many more. The "unusual" utilization patterns that existed when CMS established the IVIG preadministration-related services payment have actually increased in recent years.[83]

Lastly, CMS also cited an increase in IVIG infusion days from CY 2002 through CY 2004 to further support its decision to create a preadministration-related services payment for IVIG.[84] Specifically, CMS stated that "[i]n the face of growing demand for IVIG in the absence of significant changes in the prevalence of medical conditions for which there is high quality evidence regarding the effectiveness of IVIG therapy, we are concerned that all patients with medical need for IVIG continue to have access to this expensive and valuable therapy."[85] Demand for IVIG remains high today, as evidenced by the record setting distribution by IVIG manufacturers for CY 2007 of 34,188 kg. While PPTA understands that CMS intended the additional payment to be temporary, we do not believe that relying upon increased utilization of IVIG from 2004 to 2006 to justify the establishment of G0332, and then using the identical policy rationale, specifically that IVIG utilization increased since 2006, to validate its proposal to eliminate this important payment is an appropriate policy position for CMS to take.

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[79] *See id.* at 68648-68649.
[80] *See* OIG REPORT ON IVIG, *supra* note 15, Appendix B.
[81] 70 Fed. Reg. at 68648-68649.
[82] *See id.* at 68649.
[83] *See* 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).
[84] *See* 70 Fed. Reg. at 68649.
[85] *Id*.

Nearly three years ago, CMS rightly began to make a payment for IVIG preadministration-related services. This additional payment amount has allowed the hospital outpatient department to remain a viable site of service for the thousands of Medicare beneficiaries requiring IVIG as part of their treatment plan. PPTA urges CMS to continue to pay for this service under the OPPS for CY 2009 and beyond until it analyzes new data that demonstrates it is no longer necessary to preserve patient access to IVIG.

### C. Packaging the IVIG Preadministration-Related Services Payment with the IVIG Administration Payment Will not Promote Access to IVIG

PPTA has been pleased to work with the agency in recent years to ensure that hospitals can acquire IVIG and provide access to this critical therapy for the Medicare beneficiaries that they treat. The fruit of these efforts include the establishment of the IVIG preadministration-related services payment. The idea that packaging the IVIG preadministration-related services payment will continue to promote access to IVIG in the hospital outpatient setting is misplaced, especially given the proposed reduction in payment for IVIG.

Hospitals furnishing IVIG to their patients encounter the same costs and difficulties now that they did when the agency first established the IVIG preadminstration-related services payment. Only those hospitals that furnish IVIG, however, are able to receive this payment. Packaging the cost for IVIG preadministration-related services into the drug administration service payment spreads this cost to all hospitals in almost immeasurable amounts. As a result, those hospitals that have furnished IVIG and have utilized the preadministration-related services payment to offset the added costs related to IVIG would see their payment for such costs virtually disappear to the betterment of those hospitals that furnish intravenous drugs other than IVIG. That is likely to undo the progress in ensuring access to IVIG in hospital outpatient departments that the agency has made in recent years. Accordingly, we urge CMS to continue to make a separate payment for IVIG preadministration-related services.

## CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your proposal to continue the blood clotting factor furnishing fee in the OPPS for CY 2009 and urge the agency to finalize it with the pertinent update for CY 2009. We also hope the agency finalizes its proposal to increase the drug administration payment for the initial hour of IVIG infusion. We are, however, very concerned with the agency's proposals to reduce the payment for separately covered outpatient drugs to ASP +4% and to eliminate the payment for IVIG preadministration-related services. As such, PPTA urges CMS to carefully consider these comments, particularly those related to patient access to plasma protein therapies. Please contact Jay Greissing (jgreissing@pptaglobal.org) or Jon McKnight (jmcknight@pptaglobal.org) 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
Vice President, North America

Attachments.

**Memorandum**

**To:** **Interested parties**
**From:** **Christopher Hogan, Direct Research, LLC**
**Subject:** **Update of 4/15/2008 memo on 340B hospitals and Medicare OPPS mean drug costs.**
**Date:** **7/27/2008**

This analysis uses the OPPS 2009 Proposed Rule file to estimate the impact of the Section 340B drug price discounts. It is an update of a prior analysis using last year's file. Results using the most recent file (2007 claims) are essentially identical to results from last year's file.

- The 340B hospitals' share of drug cost increased from 34 percent to 35 percent.
- The 340B hospitals' drug costs averaged 8 to 9 percent below other hospitals' costs.
- The 340B discounts reduce OPPS drug costs, on average, by about 3.5 percentage points (prior analysis) or 3.6 percentage points (current analysis).

## Summary of Background and Methods

- The Section 340B program is a federally-administered program that allows certain health care providers to obtain access to Medicaid-level drug discounts.
- To estimate the effect of these discounts, I extracted a list of the current 340B hospitals from the DHHS HRSA website, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx. Most hospitals were readily identified based on the CMS hospital ID embedded within HRSA's identifier. Others were matched to the CMS provider-of-services listing to obtain the hospital identifier necessary for use in analyzing the claims data. I identified a total of 802 Section 340B hospitals. These hospitals tended to be large, urban public hospitals.
- I processed the 2009 Proposed Rule file using CMS's methods to calculate mean cost per drug unit for each OPPS-paid drug. I calculated these separately for the 340B and non-340B hospitals. These mean unit costs were then used in the calculation of the markup of cost over ASP, that is, the X in the equation Cost = ASP + X%, again using the same methods as CMS.
- My overall estimate of ASP + X from the claims is slightly different from the CMS 2008 OPPS Final Rule calculation or 2009 Proposed Rule calculation. I re-based mine to match the CMS calculation when I included all hospitals in the calculation.

## Summary of Prior and Current Results

The 340B share of all drug costs rose slightly, from 34 percent to 35 percent of OPPS file drug costs (Table 1).

**Table 1: Cost Share and Average Cost Index, OPPS Drugs, by Hospital 340B Status**

| | All | Non-340B | 340B |
|---|---|---|---|
| | | | |
| **2008 File Analysis (2006 claims)** | | | |
| Total cost ($billions) | $ 2.8 | $ 1.8 | $ 0.9 |
| Percent of total cost | 100% | 66% | 34% |
| **2009 File Analysis (2007 claims)** | | | |
| Total cost ($billions) | $ 3.1 | $ 2.0 | $ 1.1 |
| Percent of total cost | 100% | 65% | 35% |
| | | | |

Source: Analysis of OPPS 2008 proposed rule file (CY 2006 claims) and OPPS 2009 Proposed Rule File (2007 claims)

The overall impact of 340B discounts on OPPS average drug costs increased from a 3.5 percentage point reduction to a 3.6 percentage point reduction (Table 2). That is the difference in costs that occurs when the 340B hospitals are excluded from the calculation of average costs. On this table, the first column replicates CMS's results, showing that cost is ASP plus 3.4 percent (last year) or ASP plus 4 percent (this year), for separately paid drugs. The second and third columns show the impact of separating the 340B hospitals from others. The difference between those two columns shows the net 340B discount. It appears to average between 8 and 9 percentage points. That is true whether the analysis looks at all drugs or only at the separately-paid drugs.

| Table 2: Markup of Cost Over ASP (the X in Cost = ASP + X%), by Hospital 340B Status | | | |
|---|---|---|---|
| | **All hospitals** | **non-340B** | **340B** |
| **2008 File Analysis (2006 claims)** | | | |
| All Identified Drugs | 13.0% | 16.1% | 8.8% |
| Separately-Paid Drugs Only | 3.4% | 6.9% | -1.7% |
| **Memo: 340B impact on average cost** | **-3.5%** | | |
| **2009 File Analysis (2007 claims)** | | | |
| All Identified Drugs | 12.5% | 16.0% | 7.4% |
| Separately-Paid Drugs Only | 4.0% | 7.6% | -1.1% |
| **Memo: 340B impact on average cost** | **-3.6%** | | |
| | | | |
| Source: Analysis of OPPS 2008 proposed rule file (2006 claims) and CMS 2008 Final Rule drug medians, and October 2007 ASP files (prior year analysis); and OPPS 2009 Proposed rule, CMS 2009 proposed rule drug medians, and April 2008 ASP file (current year analysis). | | | |

As was the case last year, the apparent drug discounts were far from uniform. The ratio of 340B to non-340B average cost varied across drugs. The table above captures only the weighted average effect of the discounts.

ATTACHMENT B

Memorandum

To: Interested parties
From: Christopher Hogan, Direct Research, LLC
Subject: Effect of 340B hospitals on Medicare OPPS mean drug costs.
Date: 4/15/2008

This brief memo summarizes an analysis of OPPS drug costs compared to Average Sales Price (ASP), including and excluding hospitals participating in the Section 340B drug discount program.

## BACKGROUND

A good plain-language description of the Section 340B program may be found at this URL: http://pssc.aphanet.org/pdfs/340b_handbook.pdf. In a nutshell, 340B is a federally-administered program that allows certain health care providers to obtain access to Medicaid-level drug discounts.

This memo shows the effect of the 340B drug discounts on the average cost (charge times cost-to-charge ratio) for drugs billed under the Medicare OPPS.

## METHODS

- A list of current 340B hospitals was extracted from the HRSA website: http://opanet.hrsa.gov/opa/CE/CEExtract.aspx
- There are more then 2000 lines in the listing, but many are multiple entities within a hospital (e.g., both a hospital OPD and a hospital-based home health agency).
- For about three-quarters of the hospitals, the 340B identification number is just the CMS hospital provider number plus a few additional characters. These were identified by extracting the provider number and verifying it by match to the CMS provider-of-services file.
- The remaining hospitals were matched to the CMS provider-of-services file by name, address, and ZIP. This gave a clear match for all but a handful (roughly 20) entries on the file.
- In total, 802 340B hospitals were identified by Medicare provider number.
- These provider numbers were used to flag the 340B hospitals on the 2008 OPPS proposed rule file (2006 claims).
- Drug lines on the 2008 OPPS proposed rule file (2006 claims) were extracted, trimmed, and averaged to yield average (mean) cost per unit, following the CMS methodology.
- The mean costs and units were calculated for all hospitals, then separately for the 340B and non-340B hospitals.
- These mean unit costs were then used in the calculation of the markup of cost over ASP, that is, the X in the equation Cost = ASP + X%, again using the same methods as CMS.
- Because this is based on the Proposed Rule file, my calculation of ASP + X from the claims was slightly different from the CMS 2008 OPPS Final Rule calculation. I re-

based mine to match the CMS calculation when I included all hospitals in the calculation.

**RESULTS**

I identified a total of 802 Section 340B hospitals. These hospitals tended to be large, urban public hospitals. All together, the Section 340B hospitals accounted for almost exactly one-third of all billed drugs (by cost) in the OPPS file (Table 1).

| **Table 1: Cost Share and Average Cost Index, OPPS Drugs, by Hospital 340B Status** | | | |
|---|---|---|---|
| | **All** | **Non-340B** | **340B** |
| | | | |
| Total cost ($billions) | $ 2.8 | $ 1.8 | $ 0.9 |
| Percent of total cost | 100% | 66% | 34% |
| | | | |
| Source: Analysis of OPPS 2008 proposed rule file (CY 2006 claims) | | | |

Inclusion of the 340B hospitals reduces the estimated markup of drug cost over ASP (Table 2). The first column replicated CMS's results, showing that cost is ASP plus 3.4 percent, on average, for separately paid drugs, for all hospitals. The second and third columns show the impact of separating the 340B hospitals from others. Excluding the 340B hospitals, the cost of the separately-paid drugs was ASP plus 6.9 percent. For the 340B hospitals alone, the cost of the separately-paid drugs was ASP minus 1.7 percent. Similar differences were found when all identified drugs (separately-paid and packaged) were included in the analysis.

| **Table 2: Markup of Cost Over ASP (the X in Cost = ASP + X%), by Hospital 340B Status** | | | |
|---|---|---|---|
| | **All hospitals** | **non-340B** | **340B** |
| | | | |
| All Identified Drugs | 13.0% | 16.1% | 8.8% |
| Separately-Paid Drugs Only | 3.4% | 6.9% | -1.7% |
| | | | |
| Source: Analysis of OPPS 2008 proposed rule file (2006 claims) and CMS 2008 Final Rule drug medians, and October 2007 ASP files. | | | |

It is worth noting that the apparent drug discounts were far from uniform. The ratio of 340B to non-340B average cost varied across drugs. The table above captures only the weighted average effect of the discounts.

## CONCLUSION

Section 340B uses the power of Federal law to grant certain providers access to Medicaid-like drug discounts. This is thought to serve a public purpose, as these discounts are restricted to hospitals serving a large volume of poor and uninsured patients.

The 340B discounts affect drug payments under the Medicare OPPS. The 340B providers appear to have drug costs that average about 8 percent below the costs of non-340B hospitals. Because the 340B hospitals account for about a third of OPPS drug costs, this reduces the average cost for all hospitals to roughly 3 to 3.5 percent below the cost for the non-340B hospitals.

This raises a potentially difficult policy issue for OPPS payment. The (indirect) Federal subsidy to the 340B hospitals, in the form of legally-mandated drug price reductions, results in payment below cost for the remaining unsubsidized (non-340B) hospitals. And, correspondingly, payment above cost for the 340B hospitals.

When the 340B program was passed, it was almost certainly not the intent of the Congress to inflict financial harm on the non-340B hospitals. Yet that seems to be a clear side-effect of the interaction of the 340B drug discounts with the OPPS rate calculation process. The 340B discounts reduce payments to non-340B hospitals, as CMS uses the average of all hospitals when calculating OPPS drug payments.

**JOHN ENSIGN**
NEVADA

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July 28, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Weems:

I am writing to express my concern regarding the Centers for Medicare and Medicaid Services (CMS) proposal to discontinue payments for pre-administration-related services for intravenous infusion of immunoglobulin (IVIG) as part of the Medicare Physician Fee Schedule for 2009 and the Hospital Outpatient Prospective Payment System for 2009. Such a change could significantly reduce patient access to IVIG.

As you know, CMS established a temporary pre-administration-related service payment in 2006 for physicians and hospital outpatient departments that administer IVIG to Medicare beneficiaries. This add-on payment, which has been available for three years now, is intended to help cover the effort required to locate and acquire adequate IVIG product during a period of market instability.

I recognize that the pre-administration payment was intended to be temporary; however, I am seriously concerned that the CMS proposal to discontinue these payments could negatively impact Medicare beneficiaries who suffer from Primary Immune Deficiency Disorder and other life-threatening ailments. This could result in patients experiencing delays in treatment and being shifted to more expensive care settings.

In the past, the HHS Office of the Inspector General and the HHS Assistant Secretary for Planning and Evaluation studied IVIG and concluded that payment problems exist. Although studies on IVIG payment issues have not been published since April 2007, CMS has apparently reviewed national claims data for IVIG drug utilization to develop its proposal to discontinue pre-administration payments. According to the proposed rule, national claims data "show modest increases in the utilization of IVIG drugs and the pre-administration-related service code which suggests that pricing and access may be improving." I would appreciate a more thorough description of the data CMS reviewed which led the Agency to propose to discontinue pre-administration payments.

In closing, I urge you to reconsider your proposal to discontinue payments for pre-administration-related services for IVIG. A change of this nature could significantly reduce patient access to this life-saving therapy. Thank you in advance for your prompt attention to this important matter.

Sincerely,

John Ensign

JOHN ENSIGN
United States Senator