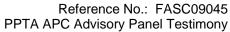


STATEMENT OF THE PLASMA PROTEIN THERAPEUTICS ASSOCIATION

BEFORE THE

ADVISORY PANEL ON AMBULATORY PAYMENT CLASSIFICATION GROUPS

AUGUST 5-7, 2009







The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to testify before the Advisory Panel on Ambulatory Payment Classifications ("APC Panel"). PPTA is the association that represents human plasma collection centers and the manufacturers of medicinal therapies, including albumin, alpha1-proteinase inhibitor, blood clotting factors, and immune globulin from this human plasma. Some of our members also use recombinant DNA technology to produce blood clotting factors. Collectively, these therapies – both plasma-derived and recombinant – are known as "plasma protein therapies."

PPTA is deeply troubled that the Centers for Medicare and Medicaid Services ("CMS") refused to accept the APC Panel's February 2009 recommendations for reimbursement of separately paid drugs and biologicals.¹ Continuing to reimburse these products at average sales price ("ASP") +4%, as the agency has proposed, will exacerbate existing patient access difficulties for several lifesaving plasma protein therapies. Plasma protein therapies are used in the treatment of a number of rare diseases.² Most of these disorders are genetic, chronic, life threatening conditions that require, as part of the standard of care, patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. Very often, plasma protein therapies are the only viable treatment option for these patients.

Nearly all plasma protein therapies³ rely on the donation of human plasma for the source material. In 2007, more than 85% of human plasma collected for use in the U.S. was source plasma,⁴ which cost about \$150 per liter in 2008.⁵ The cost of nucleic acid amplification technology testing for HIV and hepatitis A and B is included in this price.⁶ Threats of emerging pathogens will also increase the overall manufacturing costs of plasma protein therapies because manufacturers may have to develop new tests and viral inactivation and viral reduction procedures.

¹ See Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY2010 Payment Rates, 74 Fed. Reg. 35232, 35332 (July 20, 2009).

² The National Institute of Health Office of Rare Diseases generally defines rare diseases as those having a "prevalence of fewer than 200,000 affected individuals in the United States." *See* Office of Rare Diseases, U.S. Dep't of Health & Human Servs., Rare Disease and Related Terms, *at* http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1 (last visited May 12, 2009). Afibrinogenemia, alpha1-antitrypsin deficiency, B-cell chronic lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, Guillain-Barre syndrome, hemophilia A, hemophilia B, hyperimmunoglobulinemia E syndrome, hypofibrinogenemia, idiopathic thrombocytopenic purpura, Kawasaki syndrome, Lambert-Eaton myasthenic syndrome, multifocal motor neuropathy, multiple sclerosis, myasthenia gravis, primary immune deficiency disease, staphylococcal toxic shock syndrome, and von Willebrand disease are among the diseases that satisfy this definition.

³ Of the six brands of recombinant blood clotting factors available for consumption in the U.S., four brands contain traces of human plasma or a derivative (albumin).

⁴ See The Marketing Research Bureau, Inc., The Plasma Fractions Market in the United States 2007 14 (2008).

⁵ *Id.* at 40.

⁶ Id.





In order to recover these significant, unavoidable costs, manufacturers of plasma protein therapies must produce brands in multiple therapeutic classes from each liter of plasma that it fractionates. This economic necessity also provides incentives for plasma fractionators to invest in the research and development of therapies for treating diseases with extraordinarily low prevalence. For example, the Food and Drug Administration recently approved a biologics license application for a plasma-derived coagulation therapy used to treat Factor I protein deficiency, which afflicts only 300 people in the U.S.⁷ The CMS' proposal to continue to insufficiently reimburse plasma protein therapies will make such innovation cost prohibitive in the future.

For reasons discussed below, PPTA asks the APC Panel to recommend that CMS ensure that the hospital outpatient prospective payment system ("OPPS") rates for separately payable, non-pass-through drugs and biologicals in 2010 are set at least at the level of ASP +6%. In order to arrive at this payment level under the agency's current methodology, we urge the APC Panel to recommend that CMS remove from its rate-setting calculation data from hospitals that participate in the 340B Drug Pricing Program.

PPTA Recommendation: The APC Panel Should Recommend that CMS Ensure that the OPPS Rates for Separately Payable, Non-pass-through Drugs and Biologicals in 2010 Are Set at Least at ASP +6%. In Order to Arrive at This Payment Level Under the Agency's Current Methodology, We Urge the APC Panel to Recommend that CMS Remove from Its Rate-Setting Calculation Data from Hospitals that Participate in the 340B Drug Pricing Program.

I. The Effect of 340B Sales on CMS Rate Setting

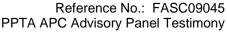
CMS' policy of using hospitals claims data in setting OPPS payment rates for drugs and biologicals is flawed because of its inclusion of drugs sold at or below the 340B Drug Pricing Program ceiling price. This program requires a manufacturer to provide significant discounts on its covered outpatient drugs to certain federally funded grantees and other safety net health providers. According to 2007 claims data, 340B hospitals account for approximately 35% of all billed drugs and biologicals by cost in the OPPS. The 340B ceiling price for a covered outpatient drug is determined by subtracting the Medicaid unit rebate amount ("URA") from the average manufacturer's

⁷ See Press Release, CSL Behring, CSL Behring Receives FDA Approval of RiaSTAP(TM), First and Only Approved Treatment of Acute Bleeding Episodes in Patients with Congenital Fibrinogen Deficiency (Jan 16, 2009) available at

http://news.prnewswire.com/ViewContent.aspx?ACCT=109&STORY=/www/story/01-16-2009/0004956268&EDATE (last visited May 26, 2009).

⁸ 42 U.S.C. § 256b (2008).

⁹ See Memorandum from Chris Hogan, Direct Research, LLC to Interested Parties 2 (July 27, 2008) [hereinafter "Hogan July Memo"].







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). For generic drugs, the URA is 11% of a product's AMP. The calculation of the URA for brand drugs and biologicals, including all plasma protein therapies, can be a bit more complicated.

Pursuant to section 1927(c)(1) of the Social Security Act ("SSA"), CMS calculates the Medicaid drug 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.¹² Brand name drugs may also be liable for an extra "penalty" rebate if the AMP for a product outpaces a specified inflation factor.¹³ 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, the BP calculation, and the ASP calculation for such drug. 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.

¹⁰ See 42 U.S.C. § 256b(a)(1)

¹¹ See SSA § 1927(c)(3) (2008).

¹² See SSA § 1927(c)(1)(B)(i).

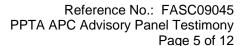
¹³ See SSA § 1927(c)(2). The "penalty" rebate can create a situation where a drug's URA becomes greater than its manufacturer reported AMP, which can result in a negative 340B ceiling price. In such instances, manufacturers are directed to charge a 340B ceiling price of one penny per unit, rather than the previous quarter's ceiling price. See OIG, HHS, REVIEW OF 340B PRICES 3, 14 (2006).

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

¹⁵ See SSA § 1927(c)(1)(C)(i)(I).

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).

¹⁷ 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 purchases at or below the 340B Drug Pricing Program ceiling price would provide an inaccurate average purchase price for a specified covered outpatient drug).





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 a further reduction to ASP +4% in CY 2009 and CY 2010, as proposed.

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. 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. 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, up from ASP +6.9% based on 2006 claims data.

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 more than 1100% from 1,223 to 14,706. As discussed in section II, Congress is currently debating legislation that would expand the program even further if enacted as well as establish a ceiling price that is, at minimum, 46% lower than the current level. If CMS continues to rely upon hospital claims data in setting the payment 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 1992, Congress created the 340B program in section 602 of the Veteran's Health Care Act of 1992²⁴ to protect federally funded clinics and hospitals from the unintended consequence of manufacturers ceasing to provide the large discounts they

²¹ See Hogan April Memo, supra note 18, at 2.

¹⁸ See Memorandum from Chris Hogan, Direct Research, LL to Interested Parties 2 (April 15, 2008) [hereinafter "Hogan April Memo"].

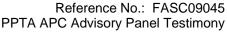
¹⁹ See Hogan July Memo, supra note 9, at 2.

²⁰ Id

²² 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 July 22, 2009).

²³ See e.g., H.R. 3200, 111th Cong.

²⁴ Pub. L. 102-585, Title VI, § 602(a), 106 Stat. 4967 (1992).







had previously given on outpatient prescription drugs sold to these purchasers prior to the implementation of the Medicaid Outpatient Drug Rebate Program one year earlier. Congress believed the "price controls" established by the 340B program would "enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

The 340B statute places no limitation on the price at which a covered entity can resell to a patient the covered outpatient drugs it purchases at the 340B discount, so covered entities are able to use this additional revenue to invest in more services for patients and at the very least, keep their doors open to serve the uninsured as well as many in the hemophilia community who obtain their blood clotting factor from hemophilia treatment centers. Lawmakers, however, 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.

CMS' decision to propose the CY 2010 payment rates for separately paid drugs and biologicals remain 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. We respectfully urge the APC Panel to recommend that CMS 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.

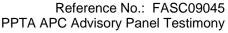
II. Potential Impact of Health Care Reform on 340B Sales

If certain legislative provisions in both the Senate Committee on Health Labor Education and Pensions' ("HELP") bill, the Affordable Health Choices Act, as reported out of committee on July 15, 2009, and the House of Representatives Committee on Energy and Commerce's bill, the America's Affordable Health Choices Act, currently in mark-up at the time of this submission, are enacted, manufacturers will be selling a

²⁵ See H.R. REP. No. 102-384, PART 2 (1992) (highlighting congressional hearing testimony describing canceled contracts and price increases to public hospitals following the implementation of the Medicaid Outpatient Drug Rebate Program). See also 102 Cong. Rec. S17882-S17902 (Oct. 8, 1992) (statement by Sen. Cranston); see also 102 Cong. Rec. S17724 (Oct. 8, 1992) (statement by Sen. Chafee) (illustrating that prior to the passage of the legislation creating the Medicaid Outpatient Drug Rebate Program in 1990, some Members of Congress expressed their concern regarding the impact of the program on the business practices of drug companies, and thus, federal purchasers).

²⁶ 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) (describing the legislative intent of protecting safety net hospitals from excessive price increases by drug manufacturers).

²⁷ H.R. Rep. No. 102-384, Part 2 (1992).





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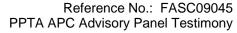
much larger volume of drugs and biologicals at a much lower price. On its own, these legislative policies create an unsustainable business model that will likely have an adverse effect on patient access. When considering the fact that CMS has proposed to continue to use its flawed rate setting calculation in establishing the OPPS payment level for most drugs and biologicals, the HOPD will no longer be an option for many Medicare beneficiaries to receive lifesaving plasma protein therapies. If this practice is not stopped and the OPPS payment restored to, at minimum, ASP +6%, reimbursement rates will continue to fall and patients will be driven into other sites of service that may not be ideal for their disease state, or convenient, especially in rural areas.

Congress is proposing to increase the minimum Medicaid rebate percentage for branded drugs and biologicals to as high as 23.1%, which would be more than a 53% increase from its current level. Such an increase is unprecedented, so anticipating the market response is difficult. Congress has, however, recognized that the initial 12.5% rebate level in 1991 led to cross-subsidization by drug manufacturers on drugs sold to the Department of Veterans Affairs, federally funded clinics, public hospitals, health maintenance organizations, and group purchasing organizations ("GPOs"). Because of the statutory link between the Medicaid rebate program and the 340B program, as discussed in section I of this testimony, a 53% increase in the rebate results in a 53% decrease in the 340B ceiling price.

In addition to driving down the 340B ceiling price, lawmakers are also proposing to dramatically increase: (1) the number of covered entity sites eligible for 340B pricing by adding critical access hospitals, sole community hospitals, and Medicare-dependant, small rural hospitals; (2) the volume of outpatient drugs sold at 340B pricing by requiring manufacturers to sell product to 340B covered entities; and (3) the volume of outpatient drugs sold at sub-ceiling 340B prices by providing DSH hospitals with the collective bargaining power of GPOs in certain instances. Such expansion will make accurate reimbursement impossible if 340B sales continue to be included in CMS' OPPS rate setting calculation.

Conclusion

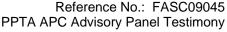
PPTA respectfully urges the APC Panel to recommend that for CY 2010, CMS ensure that the OPPS rates for separately payable, non pass-through drugs and biologicals are set at least at ASP +6%. In order to achieve this minimum payment level, PPTA would urge the APC Panel to once again recommend that CMS exclude drugs purchased at or below the 340B ceiling price from its evaluation of this hospital claims data. In doing so, PPTA strongly believes that CMS should continue to establish a single payment rate for all hospitals, including 340B hospitals. 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. For the reasons we







highlighted above, we believe this request is appropriate and sound policy. Thank you for the opportunity to present our request today. I would be pleased to answer any questions that the panel may have.



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Appendix: Insufficient Reimbursement Adversely Affects Access to the Plasma Protein Therapy Best Suited for the Individual Needs of the Patient in their Preferred Site of Service

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. 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, intravenous immune globulin ("IVIG").

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, 30 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. The majority of those patients that switched their site of service did so as a result of insufficient reimbursement. Many of these Medicare beneficiaries migrated to 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. By 2006,

²⁸ 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.").

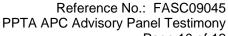
See Office of the Ass't Sec. for Planning & Evaluation, U.S. Dep't of Health and Human Servs. ["HHS"], Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV) 4-22 (2007) [hereinafter "ASPE Analysis of the IVIG Market"] (discussing reimbursement 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).

³⁰ 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"].

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)).

³² See IDF REIMBURSEMENT SURVEY, supra note 30, at 17 (revealing that 54% of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

See ASPE ANALYSIS OF THE IVIG MARKET, supra note 29, at 4-31 (concluding that insufficient reimbursement caused the patient migration in 2005).







there was nearly a 60% reduction from 2004 in the number of Medicare PIDD patients receiving their IVIG infusions in the physician's office.³⁴

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.³⁵ Generally, many hospitals were able to quickly adjust their contracts accordingly to account for their flood of new patients seeking IVIG.³⁶ 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 alpha₁-proteinase inhibitor, blood clotting factors, and IVIG, at ASP +6%.³⁷ PPTA respectfully urges the APC Panel to recommend that CMS restore this payment level to a minimum of ASP +6% for CY 2010. 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,³⁸ it is absolutely unreasonable for CMS to expect the current ASP +4% will adequately reimburse hospitals providing this critical service.³⁹

³⁴ See IDF REIMBURSEMENT SURVEY, supra note 30, at 16, fig, 10.

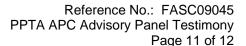
³⁵ See, e.g., ASPE ANALYSIS OF THE IVIG MARKET, supra note 29, at 2-29, 3-18 (illustrating the short term access challenges product allocation causes). In recent years, manufacturers have begun to enter into contracts with distributors based on historical utilization of IVIG in response to pressure from 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). See OIG REPORT ON IVIG, supra note 29, 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 29, 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).

See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, 70 Fed. Reg. 68516, 68642 (Nov. 10, 2005).

³⁸ See, e.g., OIG REPORT ON IVIG, supra note 9, at 29 Table 1.

³⁹ See Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Final Rule, 73 Fed. Reg. 68502, 68658 (Nov. 18, 2008).





Logically, one might expect the payment cuts for drugs furnished in the hospital outpatient department to drive patients back to the physician office setting. 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.⁴⁰ 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. 41 Medicare beneficiaries who require IVIG have continued to experience access difficulties over the last year and will have even fewer options now that the reimbursement level is at ASP +4% in the OPPS.⁴² Potentially further hindering patient access to IVIG is CMS' decision to eliminate the temporary payment for IVIG preadministration-related services for 2009.⁴³ Simply put, many hospital outpatient departments will not be able to afford to offer such services at this payment level, so it is unclear where patients are currently going for treatment.

Al Wight, a Medicare beneficiary suffering from alpha₁-antitrypsin deficiency, has experienced similar hardships when he faced a reimbursement level of ASP +5% for 2008, and will very likely face more difficulties at the new payment level of ASP +4%. Alpha₁-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 alpha₁-antitrypsin, which he had been receiving from his local hospital in Petaluma, California.

Unfortunately, those weekly infusions were discontinued for 2008 due to cuts in the Medicare OPPS payments to ASP +5%. Specifically, in late 2007, Petaluma Valley Hospital ("PVH") notified Mr. Wight that the hospital "would no longer be providing [his] life-sustaining [alpha₁-antitrypsin] infusion therapy after January 15, 2008" because of

⁴⁰ 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").

⁴¹ See OIG REPORT ON IVIG, supra note 29, at 9 Table 2 (averaging data for Q1 2006 through Q3 2006 to illustrate the insufficient Medicare reimbursement levels for doctors that purchase IVIG).

⁴² See Boyle Letter, *supra* note 40 (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).

⁴³ See 73 Fed. Reg. at 68581.





"inadequate reimbursement from Medicare." According to Mr. Wight, two other patients who had been receiving infusion therapy at PVH received similar cancellation letters from the hospital. 45

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," he has been forced to receive his weekly alpha₁-antitrypsin infusion treatments through Sutter Medical Center Hospital of Santa Rosa, California. 47

From a policy perspective, PPTA is quite troubled that CMS further cut OPPS reimbursement for specified covered outpatient drugs to ASP +4%. As we discuss below, the alpha₁-proteinase inhibitor and IVIG situations demonstrate the agency's application of flawed data 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. 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 CMS to have recreated this unstable environment and further jeopardize beneficiary access to lifesaving therapies, such as IVIG and alpha₁-proteinase inhibitor. Without an appropriate data set, PPTA believes that CMS should pay for non-pass-through drugs and biologicals at a minimum of ASP +6%. Hospital outpatient departments must remain a viable option for Medicare beneficiaries to be able to receive therapies like alpha₁-antitrypsin, blood clotting factors, and IVIG.

⁴⁶ 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.

⁴⁴ See Wight Letter to the Editor, *supra* note 28.

⁴⁵ Id

⁴⁷ 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.

⁴⁸ 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.").