

August 30, 2011

Reference No. FASC11047

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

ELECTRONIC DELIVERY

Re: CMS–1525–P (Hospital Outpatient Prospective Payment System Calendar Year 2012 Proposed Rule)

Dear Administrator Berwick,

The Plasma Protein Therapeutics Association (“PPTA”) appreciates this opportunity to comment on the proposed rule that the Centers for Medicare & Medicaid Services (“CMS”) has promulgated detailing proposed payment policies in the Hospital Outpatient Prospective Payment System (“OPPS”) for Calendar Year (“CY”) 2012 (“Proposed Rule”).¹ Our comments on the Proposed Rule are intended to ensure that all Medicare beneficiaries that require plasma protein therapies as part of their treatment regimen have access to the full range of therapies in each therapeutic class. PPTA respectfully urges CMS to take the following action:

1. Continue its longstanding 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; and
2. Modify its rate setting methodology so that the OPPS payment rate for separately payable, non-pass-through drugs and biologicals in CY 2012 are set at least at ASP +6%.

PPTA believes these recommendations, if implemented in the final rule, will preserve access to the plasma protein therapy best suited for the individual needs of each patient.

PPTA represents human plasma collection centers and the manufacturers of lifesaving medicinal therapies, including albumin, alpha₁-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, fibrin sealant, immune

¹ See Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment System, 76 Fed. Reg. 42170 (July 18, 2011).

globulin, hyperimmune immune globulin, and protein C concentrate, from this human plasma.² 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.” The manufacturer membership of PPTA in the United States (“U.S.”) currently includes Baxter, Biotest, Cangene, CSL Behring, Grifols, and Kedrion.

Excluding albumin and fibrin sealant, plasma protein therapies are solely approved for marketing in the U.S. by the Food and Drug Administration for the treatment of rare diseases, disorders, and conditions. In the U.S., a “rare disease or condition” is generally defined as a disease or condition that affects less than 200,000 people.³ The majority of the rare conditions that require treatment with plasma protein therapies are genetic, chronic, and life threatening, including alpha-1 antitrypsin deficiency, chronic B-cell lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy (“CIDP”), hereditary angioedema, hereditary antithrombin III deficiency, protein C deficiency, primary immune deficiency diseases (“PIDDs”) (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, DiGeorge syndrome, Wiskott-Aldrich syndrome, Nezelof’s syndrome, severe combined immunodeficiency, and graft-versus-host diseases), and bleeding disorders (e.g., hemophilia A, hemophilia B, congenital fibrinogen deficiency, Von Willebrand’s disease, and factor XIII deficiency. Cytomegalovirus disease associated with transplant patients, hepatitis B reinfection in liver transplant patients, idiopathic thrombocytopenic purpura (“ITP”),⁴ infant botulism, Kawasaki’s disease, rabies, rhesus incompatible pregnancies, and tetanus are examples of acute rare conditions that are treated with plasma protein therapies.

As representatives of a segment of the drug industry with considerable experience in treating rare diseases, disorders, and conditions, PPTA recognizes the importance of adequate reimbursement levels for maintaining access to rare disease therapies. Previous reimbursement cuts for Medicare Part B drugs have resulted in some rare disease patient populations experiencing access difficulties. For example, it is well documented that PIDD patients requiring regular infusions of intravenous immune globulin (“IVIG”) have experienced treatment delays and shifts in site of service due to previous Medicare reimbursement cuts. Additionally, providers have switched some patients that require regular infusions of IVIG from a brand on which they had been stabilized because of the unintended consequences payment reductions. Because of the rare, chronic, life threatening nature of PIDDs and other rare diseases like alpha-1 antitrypsin deficiency and hemophilia, such impediments to treatment are particularly dangerous. PPTA believes adequate reimbursement levels will prevent future patient access issues for users of plasma protein therapies.

² Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. See Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, in 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209.

³ See 21 U.S.C. § 360bb(a)(2) (2006).

⁴ ITP can also be a chronic condition.

I. PPTA Applauds CMS for Continuing Its Longstanding Policy of Applying the Furnishing Fee for Blood Clotting Factors under the OPSS

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.⁵ Pursuant to the statute, this fee is updated annually according to inflation for medical care.⁶ The fee for CY 2011 is \$0.176 per unit.⁷

Since 2006, CMS has rightly paid hospitals the same furnishing fee⁸ and again provides for it in the Proposed Rule.⁹ In arriving at its original decision to also provide for the furnishing fee under the OPSS, CMS determined that similar resources were required to furnish blood clotting factors “across all types of service settings.”¹⁰ As such, the agency concluded that, moving forward, “it is appropriate to adopt a methodology for paying for clotting factors under the OPSS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting.”¹¹

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 OPSS to date. We urge CMS to finalize its proposal and continue the furnishing fee for blood clotting factors administered in the hospital outpatient department in CY 2012.

II. PPTA Urges CMS to Modify Its Rate Setting Methodology to Allow it to Set the Payment Level for Separately Payable, Non-Pass-Through Drugs and Biologicals at No Less Than ASP +6% in the OPSS

Adequate Medicare reimbursement is vital to preserve patient access to therapeutic interventions for rare diseases. It affects not only existing therapies, but also decisions by manufacturers to invest in the research and development required to improve formulations and routes of administration for existing therapies or to bring new therapies to market. CMS has proposed, however, to set the payment level for separately payable, non-pass-through drugs and biologicals at ASP +4% for CY 2012¹² -- a reduction from the current level of ASP +5%.

⁵ See MMA, 117 Stat. 2066, 2252 (2003); Social Security Act (“SSA”) § 1842(o)(5) (2006).

⁶ SSA, § 1842(o)(5)(C).

⁷ CMS, HHS, Blood Clotting Factor Furnishing Fee, https://www.cms.gov/McrPartBDrugAvgSalesPrice/20_ClotFactorFurnishFee.asp (last visited Aug. 10, 2011). In addition, the CY 2012 furnishing fee was recently announced as \$0.181 per unit. See CMS Transmittal 2279, available at <http://www.cms.gov/transmittals/downloads/R2279CP.pdf>.

⁸ 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)

⁹ See 76 Fed. Reg. at 42263.

¹⁰ 70 Fed. Reg. at 68661.

¹¹ *Id.*

¹² See 76 Fed. Reg. at 42262.

Pursuant to section 1833(t)(14)(A)(iii)(II) of the Social Security Act (“SSA”), CMS has broad statutory authority to set the payment level for specified covered outpatient drugs administered or dispensed in the hospital outpatient department. This broad authority has resulted in the reimbursement level for separately payable, non-pass-through drugs and biologicals constantly changing over the last several years – ASP +6% in CYs 2006 and 2007, ASP +5% in CY 2008, ASP +4% in CYs 2009 and 2010, and ASP +5% in 2011. For CY 2012, CMS arrived at its proposal of ASP +4% by determining total cost of separately payable, non-pass-through drugs and biologicals and comparing those costs to second quarter 2011 ASP dollars (ASP multiplied by drug or biological units in CY 2010 claims data) and then applying an overhead adjustment methodology.

Continuing the rate setting methodology it used in 2010 and 2011, CMS has determined that the total estimated cost, including acquisition and pharmacy overhead, of separately payable, non-pass-through drugs and biologicals is ASP -2%.¹³ In arriving at this number, the agency calculated mean unit costs by using CY 2010 claims data from all hospitals, including 340B hospitals, and compared this data to reported ASP for the second quarter of 2011 multiplied by the units of the separately payable drugs and biologicals in the claims data.¹⁴ By statute, manufacturers are to exclude 340B sales from its calculation of ASP. The CMS cost estimates do not reflect the actual cost of acquiring and preparing drugs and biologicals at most hospitals because the 340B data significantly skews the numbers. Simply put, CMS is inappropriately comparing two unrelated data sets. PPTA does, however, appreciate that the agency has determined that ASP -2% is not a sufficient payment level for separately payable drugs and biologicals.¹⁵

The agency made that determination after evaluating more data. For example, the total estimated aggregate cost, including acquisition and pharmacy overhead costs, for packaged drugs and biologicals with a Healthcare Common Procedure Coding System (“HCPCS”) code for which manufacturers report ASP data is ASP +188%.¹⁶ The total estimated cost for both packaged drugs and biologicals with a HCPCS code and separately payable drugs and biologicals for which they have ASP data, including acquisition cost and pharmacy overhead, is ASP +11%.¹⁷ Just as the agency recognized in CY 2010 and CY 2011, ASP -2% may not be sufficient for separately payable drugs and biologicals while ASP +188% may overstate the combined acquisition and pharmacy overhead costs of packaged drugs and biologicals; thus, CMS is again proposing its overhead adjustment methodology, which redistributes \$200 million (adjusted for inflation) in costs from packaged drugs with an ASP and uncoded packaged drugs.¹⁸ After the adjustment for inflation, CMS has determined that \$161

¹³ *Id.* at 42260.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See 76 Fed. Reg. at 42260.

million in overhead costs from coded packaged drugs and biologicals with reported ASP data and \$54 million in overhead costs from uncoded packaged drugs and biologicals without an ASP will need to be redistributed to separately payable drugs and biologicals.¹⁹ This redistribution of \$215 million will result in a payment rate for separately payable drugs and biologicals of ASP +4% for CY 2012.²⁰

As we will discuss in more detail below, PPTA believes the agency could arrive at a more appropriate payment level of no less than ASP +6% by doing the following:

- Redistribute the same percentage of costs from the coded and uncoded packaged drug pools to separately payable drugs and biologicals; and
- Exclude data from 340B hospitals in its rate setting calculation.

Again, a payment level of no less than ASP +6% is critically important to maintain unencumbered patient access to plasma protein therapies.

A. CMS Should Modify Its Pharmacy Overhead Adjustment Methodology

PPTA appreciates the proposal by CMS to increase the redistribution of additional pharmacy overhead costs to \$215 million – \$161 million from coded packaged drugs and \$54 million from uncoded packaged drugs – to cover the pharmacy overhead costs of separately payable drugs and biologicals. We do, however, urge the agency to consider increasing even further the amount of this reallocation based on an analysis of the data CMS published in Tables 31 and 32 of the Proposed Rule.

Although after the adjustment for inflation, the proposed redistribution of pharmacy overhead falls within parameters previously established by CMS, the proposed overhead pool only accounts for 10.9% of the costs associated with all drugs (both packaged and separately payable). In arriving at this percentage, one must use the following formula: (\$461 million (the overhead for coded packaged drugs) + \$54 million (the amount transferred from the total costs of uncoded packaged drugs))/ \$4,683 million (the total cost of all drugs).²¹ A pool of that size does not adequately reflect the actual costs of pharmacy services and handling for all drugs, which the Medicare Payment Advisory Commission has previously estimated to be approximately 25% of the total hospital outpatient pharmacy cost.²² In other words, the agency's starting point for its redistribution methodology is not appropriate.

¹⁹ *Id.* at 42261

²⁰ *Id.*

²¹ The total overhead pool is \$515 million (\$461 million (the overhead for coded packaged drugs) + \$54 million (the amount transferred from the total costs of uncoded packaged drugs)). The total cost of all drugs is \$4683 million (\$502 million (uncoded packaged) + \$705 million (coded packaged) + \$3,476 (separately payable)).

²² See MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO THE CONGRESS: ISSUES IN A MODERNIZED MEDICARE PROGRAM 140 (2005).

CMS proposes to reallocate \$161 million from the \$461 million in overhead for coded packaged drugs. The overhead pool of \$461 million for coded package drugs is determined by subtracting total ASP dollars in claims data (\$244 million) from the total cost of drugs and biologicals in claims data (\$705 million). This redistribution amounts to 35% of the overhead for coded packaged drugs, which is “within the redistribution parameters established in the CY 2010 OPPS/ASC final rule with comment period of roughly one-third to one-half of overhead cost in coded packaged drugs and biologicals.”²³ For uncoded packaged drugs, the CMS proposal to reallocate \$54 million of the \$502 million in total cost of uncoded packaged drugs equals 11% of the total cost, which is also consistent with the well-established adjustment methodology of redistributing no less than 8 percent of the total cost of uncoded packaged drugs.

For the purpose of consistency, PPTA recommends that CMS examine the redistribution from both the coded and uncoded packaged drugs in terms of percentage of total costs. The proposed reallocation of \$161 million from coded packaged drugs is 23% of the total cost of coded packaged drugs; the proposed reallocation of \$54 million from uncoded packaged drugs is 11% of the total cost of uncoded packaged drugs. If CMS would modify its overhead adjustment methodology to apply it in an equitable manner for both coded packaged drugs and uncoded packaged drugs by increasing the redistribution percentage for the total cost of uncoded packaged drugs from 11% to 23%, the payment level for separately payable, non-pass-through drugs and biologicals would be at a level consistent with the payment for these products in the physician office setting – at ASP +6%. The agency would now reallocate \$115 million from uncoded packaged drugs (23% of \$502 million) and would continue to reallocate \$161 million from coded packaged drugs (23% of \$705 million). The total amount reallocated would be \$276 million, which if added to the total cost of separately payable drugs and biologicals in claims data (\$3,476 million) would equal \$3,752 million. In order to determine the ratio of cost to ASP, the agency would then divide the total cost of separately payable drugs and biologicals based on CY 2010 claims data after the adjustment of pharmacy overhead (\$3,752 million) by the total ASP dollars for separately payable drugs and biologicals in claims data (\$3,536) to get 1.06, which yields a payment rate of ASP +6%.

B. CMS Should Exclude Data From 340B Hospitals in Its Rate Setting Calculation

Congress established the 340B Drug Pricing Program as part of title VI of the Veterans’ Health Care Act of 1992, which President George Bush signed into law on November 4, 1992.²⁴ The 340B program requires a participating manufacturer to enter into a pharmaceutical pricing agreement (“PPA”) with the Secretary of HHS. The statute provides the terms of the PPA, which requires a manufacturer to offer and sell covered outpatient drugs to 340B covered entities at no more than the 340B ceiling price.²⁵

²³ *Id.* at 42261.

²⁴ Pub. L. No. 102-585 (1992).

²⁵ See 42 U.S.C.S. § 256b(a)(1) (LexisNexis 2011).

The 340B ceiling price for most branded covered outpatient drugs is a 23.1% discount from the average manufacturer's price – this figure is generally well below ASP, which is why it is statutorily excluded from ASP reporting. According to the most recent data from the Office of Pharmacy Affairs within the Health Resources and Services Administration, there are currently 4,427 hospital sites that are enrolled in the 340B program and eligible for this discount. It is important to note that a single hospital may have multiple sites enrolled in the 340B program.

The hospitals eligible for 340B pricing must be publicly owned or non-profit and are limited to the following categories: subsection (d) hospitals with a disproportionate share ("DSH") adjustment percentage of more than 11.75%, non-prospective payment system children's hospitals with a DSH adjustment percentage of more than 11.75%, non-prospective payment system free standing cancer hospitals with a DSH adjustment percentage of more than 11.75%, critical access hospitals, sole community hospitals with a DSH adjustment percentage of at least 8%, and rural referral centers with a DSH adjustment percentage of at least 8%.²⁶

The number of 340B hospitals has grown at a staggering rate in recent years. The number of subsection (d) hospitals has more than doubled in the last seven years from 1,476 in the third quarter of 2004 to the current enrollment of 3,062.²⁷ The Affordable Care Act added the aforementioned children's hospitals, free standing cancer hospitals, critical access hospitals, sole community hospitals, and rural referral centers as new categories of 340B hospitals. There are 147 children's hospital sites, five free standing cancer hospital sites, 941 critical access hospital sites, 200 sole community hospital sites, and 72 rural referral center sites, bringing the total number to 4,427 hospital sites enrolled in the 340B program.²⁸ This figure is more than twice the amount of 340B hospital sites that were enrolled just three years ago (2,213 in the fourth quarter of 2008).²⁹

This program growth is significant because of its effect on the volume of 340B sales found in the hospital claims data that CMS uses in establishing the payment level for separately payable drugs and biologicals in the OPSS. Although sales to 340B covered entities are statutorily exempt from a manufacturer's calculation of ASP, CMS continues to set payment for separately payable drugs and biologicals by comparing their total costs from an analysis of claims data that do not exclude 340B sales with reported ASPs that do exclude 340B sales. As a result, the agency's cost estimates do not reflect the actual costs of acquiring and preparing these separately payable drugs and biologicals at most hospitals because the 340B data artificially lowers the estimates. If the agency were to exclude the 340B hospitals from its rate setting analysis, the mean unit cost of separately payable drugs and biologicals would rise, providing a more accurate picture of the actual costs of acquiring and preparing these

²⁶ *Id.* at § 256b(a)(4)(L)-(O).

²⁷ See OPA 340B Database, <http://opanet.hrsa.gov/opa/CESearch.aspx> (last visited Aug. 11, 2011).

²⁸ *Id.*

²⁹ *Id.*

drugs and biologicals at most hospitals. PPTA respectfully urges CMS to exclude data from 340B hospitals in its rate setting methodology if it continues to use it to establish the payment level for separately payable drugs and biologicals in the OPPS.

The fundamental purpose of the 340B program is for the 340B covered entities to use the savings from the 340B discount to “better serve their patients.” Specifically, Congress said that “[i]n giving these ‘covered entities’ access to price reductions, the Committee [on Energy and Commerce] intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³⁰ Congress did not intend the program to harm the ability of non-340B hospitals to provide certain drugs and biologicals due to the negative impact 340B sales are having on Medicare reimbursement levels for these products. If CMS implements PPTA’s recommendation to excludes data from the 340B hospitals, we want to be clear that we strongly believe that the agency should continue to establish a single payment rate for all hospitals, including 340B hospitals. Reducing Medicare payments to 340B hospitals for separately paid drugs and biologicals would severely undermine the purpose of the 340B program.

III. Conclusion

PPTA greatly appreciates the opportunity to provide comments to CMS on its proposed rule implementing payment policies in the OPPS for CY 2012. Although we are appreciative of the proposal to continue the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department, we are very concerned about the agency’s proposal to reduce the payment level for separately payable drugs and biologicals to ASP +4%. If the agency were to properly account for pharmacy overhead costs and exclude 340B hospital outpatient data from the data used for OPPS ratesetting, as it does for ASP, CMS would set a payment level for separately payable drugs and biologicals at no less than ASP +6%. We ask CMS to take such action. PPTA would like to underscore the importance of appropriate reimbursement levels for ensuring patient access to rare disease therapies like alpha₁-proteinase inhibitor, blood clotting factors, and intravenous immune globulin. The hospital outpatient department must remain a viable site of service for patients suffering from rare disorders like alpha-1 antitrypsin deficiency, bleeding disorders, chronic B-cell lymphocytic leukemia, CIDP, ITP and PIDDs. Please do not hesitate to contact me at 202-789-3100 or by email (jgreissing@pptaglobal.org) if you have any questions.

Sincerely,



John E. Greissing
Sr. Director, Federal Affairs

³⁰ H.R. REP. NO. 102-384, PART 2 (1992).