August 27, 2014

Marilyn Tavenner
Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ELECTRONIC DELIVERY
Re: CMS–1613–P (Hospital Outpatient Prospective Payment System Calendar Year 2015 Proposed Rule)

Dear Administrator Tavenner,

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule, Calendar Year (CY) 2015 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Policy Changes and Payment Rates.¹

PPTA represents the innovators and manufacturers of plasma-derived therapies predominantly used to treat rare, chronic and life-threatening diseases and disorders, including alpha-1 proteinase inhibitor deficiency, hemophilia, von willebrand disease, and primary immune deficiency (PID) diseases. Therapies include albumin, alpha-1-proteinase inhibitor, antithrombin III, plasma-derived and recombinant blood clotting factors,² C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, prothrombin complex concentrate, and protein C concentrate.³ Collectively, these therapies are known as “plasma protein therapies.” PPTA’s U.S. manufacturer membership includes Baxter BioScience, Biotest, CSL Behring, Grifols, and Kedrion.

PPTA member companies are committed to ensuring that patients have timely and appropriate access to lifesaving plasma protein therapies. In furtherance of this

¹ Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs
79 Fed. Reg. 38,365 (July 14, 2014)
² Recombinant blood clotting factor therapies are those created using recombinant DNA technologies, which entail the integration of genes coding for the production of human blood clotting factor proteins into laboratory cell cultures. The cell cultures produce the blood clotting factor proteins, which are subsequently collected, purified, and further refined into safe and effective biologic medicines.
³ 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 (2005, 2006).
commitment, PPTA recommends that CMS finalize several of the proposed changes the Agency is considering as part of the update to the OPPS, including:

1. Paying average sales price (ASP) + 6% for separately payable, non-pass-through drugs and biologicals in CY 2015; and
2. Continuing the 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.

If implemented as proposed, these recommendations will preserve access to the plasma protein therapy best suited for the individual needs of each patient.

**Overview: Unique by Nature**

Plasma protein therapies comprise a unique class of biologicals within the biopharmaceutical industry. From the human-derived plasma starting material, through the complex manufacturing process, to final physician-administration, plasma protein therapies and the rare disease patients that rely on these therapies for their lifesaving treatment consistently face distinct challenges and particular regulatory treatment. For example, nearly all plasma protein therapies treat rare diseases, and certain therapies treat extremely rare diseases that feature prevalence rates of fewer than 100 patients. As a result of the extraordinarily rare nature of many of these diseases and conditions, patients’ access to specialist providers with the distinct expertise necessary to effectively treat their rare disease can be tenuous, and in the past, due to changes in reimbursement, patients have experienced difficulties in accessing treatments in their preferred site of care. Accordingly, it is especially important that reimbursement for plasma protein therapies is established at rates that maintain patient access to these lifesaving therapies.

Additionally, manufacturers employ different fractionation processes to derive each distinct brand within the plasma protein therapeutic class. Due to the distinct manufacturing processes used by the industry, plasma protein therapies are non-interchangeable, sole source biologicals that produce different therapeutic outcomes on a patient-by-patient basis. The non-interchangeable nature of plasma protein therapies underscores the importance of reimbursement rates that ensure appropriate, timely, and uninterrupted access to all brands of plasma protein therapies.

The industry is further differentiated by the reliance on human donated plasma as the starting material for therapeutic production. The collection of human donated plasma from about 430 collection centers dispersed across the United States is a time- and resource-intensive system that adds multiple layers of complexity and regulation, resulting in a 7-9 month production process, highlighting the need for regulations and reimbursement mechanisms that protect patient access to these therapies.

---

Discussion

I. PPTA Urges CMS to Finalize Its Proposed Payment Level of ASP + 6% for Separately Payable, Non-Pass-Through Drugs and Biologicals under OPPS

Maintaining stable Medicare reimbursement rates that preserve patient access to therapeutic interventions is critical to protecting the health and improving outcomes for rare disease patients. As it did for CY 2014, CMS is proposing to set the payment for separately paid drugs and biologicals without pass-through status at ASP + 6% for CY 2015. We commend CMS for this proposal and recommend that CMS finalize the proposed payment rate and mechanism for separately payable, non-pass-through drugs and biologicals under OPPS.

By continuing to reimburse for separately payable, non-pass-through drugs at ASP + 6%, CMS is preserving patient access to plasma protein therapies in the hospital outpatient setting. Both the U.S. Department of Health and Human Services (HHS)\(^5\) and the Immune Deficiency Foundation (IDF)\(^6\) issued reports in 2007 that concluded insufficient reimbursement was a leading factor in the difficulties patients faced in accessing IVIG. At that time, reimbursement differences resulted in patient migration from the physician office to the hospital outpatient department. As evidenced by this experience, the establishment of different rates in these two settings has the potential to disrupt patient care. It is imperative that Medicare beneficiaries be able to obtain IVIG and other plasma protein therapies best suited for their individual needs in the most appropriate site of service, and thus hospital outpatient departments must remain a viable option for beneficiaries to receive their treatments.

For these reasons, we strongly support the proposal to pay hospital outpatient departments at ASP + 6%, in parity with physicians’ offices. Just as CMS has correctly decided to pay the same furnishing fee for blood clotting factors in physician offices and hospital outpatient departments to establish parity in outpatient settings, so too should CMS set payments at ASP + 6% in hospital outpatient departments. By establishing payment equity across settings, CMS helps to ensure that the choice of setting will be driven by clinical considerations.

II. PPTA Urges CMS to Finalize Its Proposal to Continue Its Longstanding Policy of Applying the Furnishing Fee for Blood Clotting Factors under the OPPS

PPTA strongly supports CMS’ proposal to continue paying for blood clotting factors at ASP + 6%, plus a furnishing fee using an updated amount based on the Consumer

\(^5\) OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, U.S. DEPT’ OF HEALTH AND HUMAN SERVS., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV): FINAL REPORT (2007), at Section 4 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites). OFFICE OF INSPECTOR GENERAL, U.S. DEPT’ OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007), at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices equal to or above the Medicare payment rate for the third quarter of 2006).

\(^6\) IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMA GLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).
Price Index (CPI) for medical care for the 12-month period ending with June, 2013.\(^7\) Since 2006, CMS has paid hospitals the same furnishing fee paid to physicians and again provides for a furnishing fee for hospital outpatient departments in the Proposed Rule. In arriving at its original decision to also provide for the furnishing fee under OPPS, CMS determined that similar resources were required to furnish blood clotting factors “across all types of service settings.”\(^8\) 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 with the agency’s conclusion that the furnishing fee is an effective method for ensuring patients have access to blood clotting factors in the hospital outpatient setting of care. Accordingly, PPTA urges CMS to finalize its proposal and continue the furnishing fee for blood clotting factors administered in the hospital outpatient department in CY 2015.

**Conclusion**

PPTA greatly appreciates the opportunity to provide comments to CMS on its proposed rule implementing payment policies in the OPPS for CY 2015. We strongly support the agency’s proposal to adopt a payment level for separately payable, non-pass through drugs and biologicals of ASP + 6%. We also appreciate and support the agency’s proposal to continue the furnishing fee for blood clotting factors administered or dispensed in the hospital outpatient department. Thank you for your time and consideration of PPTA’s comments. If you have any questions or require any additional information, please contact Carrie Fiarman Zlatos, Assistant Director of Federal Affairs at (202) 789-3100, CFiarman@pptaglobal.org.

Sincerely,

Carrie Fiarman Zlatos  
Assistant Director, Federal Affairs  
Plasma Protein Therapeutics Association

\(^7\) 79 Fed. Reg. at 41003  
\(^8\) 70 Fed. Reg. at 68661  
\(^9\) Id.