Plasma Protein Therapeutics Association

August 31, 2007
Reference No.: FASC07059

Kerry Weems
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–1385–P (Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008)

Dear Administrator Weems:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the *Federal Register* on July 12, 2007 ("Proposed Rule").[1] As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies, which include albumin, blood clotting factor, alpha-1 antitrypsin, and intravenous immunoglobulin ("IVIG"), are used to treat a variety of orphan diseases and serious medical conditions for a very small, fragile patient population in the United States. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies is dependent on adequate physician reimbursement for the acquisition and administration of these biologicals. Because PPTA remains very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is insufficient, we applaud the Centers for Medicare and Medicaid Services ("CMS") for its proposal to

[1] 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 (July 12, 2007).

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continue to reimburse for IVIG preadministration-related services (G0332) for calendar year ("CY") 2008 at the current reimbursement rate. PPTA further supports the agency's proposal with regard to the future publication of the blood clotting factor furnishing fee update.

I. DISCUSSION

A. BACKGROUND

PPTA remains concerned with the access difficulties afflicting more than 10,000 Medicare beneficiaries who rely on regular infusions of IVIG therapies. PPTA has consistently argued that the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)) led to a reimbursement shortfall for IVIG therapies in the physician office setting. The MMA instituted the market-based manufacturer's average sales price ("ASP") for payment for most drugs under Medicare Part B, including IVIG when furnished by physicians and suppliers.[2] By shifting reimbursement methodology in this site of service for IVIG from 95 percent of the average wholesale price ("AWP") to 85 percent of the AWP in 2004, and then finally to 106 percent of the ASP in 2005, the MMA significantly reduced reimbursement levels for IVIG in the physician office.[3] When the ASP methodology went into effect in the physician office in 2005,[4] some physicians were unable to continue to offer IVIG therapies to their patients in this setting because 106 percent of the ASP does not adequately reimburse providers for the acquisition of IVIG.

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

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[2] *See* 42 U.S.C. § 1395w-3a (2007).
[3] *See* 42 U.S.C. § 1395u(o)(1)(E) (2007).
[4] *See* Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66236, 66299 (Nov. 15, 2004) (codified by 42 C.F.R. § 414.804 (2007)).
[5] *See* OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007) [hereinafter "ASPE Report"], at 4-22 (discussing reimbursement levels and noting difficulties Medicare beneficiaries confront in finding infusion sites); *see* OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007) [hereinafter "OIG Report"], at 15 (concluding that a significant percentage of sales of IVIG to hospitals and physicians were at prices at or above the Medicare payment rate for the third quarter of 2006).
[6] *See* IMMUNE DEFICIENCY FOUNDATION, ASSESSING THE IMPACT OF CHANGES IN REIMBURSEMENT REGULATIONS AND PRODUCT AVAILABILITY ON ACCESS TO INTRAVENOUS GAMMAGLOBULIN TREATMENT AMONG PRIMARY IMMUNE DEFICIENCY PATIENTS 17 (2006) (revealing that a significant majority of Medicare beneficiaries who use IVIG attribute access difficulties to poor reimbursement for these therapies).

the physician office to the hospital outpatient department.[7] The shift in site of service for those patients requiring IVIG has led to further access difficulties because of the allocation system for IVIG.[8] PPTA believes, however, that Medicare beneficiaries should be able to obtain IVIG therapies best suited for their individual needs in the most appropriate site of service, and more suitable reimbursement levels would effectuate such patient autonomy.

PPTA welcomes the attention given and action taken by CMS to address this very difficult patient access situation. We are especially grateful that the agency decided to grant new brand specific "Q" codes effective July 1, 2007 to four liquid IVIG therapies and two other immune globulin therapies in response to PPTA's February 21, 2007 request that IVIG products that were not on the market as of October 1, 2003 be assigned separate codes in order to be consistent with the ASP statute. PPTA further appreciates the agency's decision to implement an additional payment for IVIG preadministration-related services and the proposal to continue this payment at the current level. As we will discuss later, PPTA hopes your proposal to extend this payment through CY 2008 will be finalized. We believe such actions taken by the agency are a good first step to help improve patient access to IVIG therapies.

As the recent HHS studies illustrate, the ASP methodology does not reflect the true acquisition cost of IVIG therapies.[9] The Government Accountability Office ("GAO") has further argued that "a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP."[10] Additionally, in a 2005 study commissioned by PPTA, The Lewin Group determined there is an 8 percent shortfall for the acquisition of IVIG in the physician office. Such analysis by HHS and GAO should provide CMS with enough support to consider a payment adjustment to the ASP plus six percent in order to address the reimbursement shortfall providers experience in acquiring this critical therapy. The analysis from The Lewin Group could be used to provide guidance on what the appropriate amount may be.

In addition to the reimbursement for the product and preadministration-related services, CMS also reimburses providers for the costs of administering the infusion of

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

[8] *See* ASPE Report, *supra* note 5 at 2-29.

[9] *See, e.g*. OIG Report, *supra* note 5 at 9 (demonstrating that physicians are experiencing a significant reimbursement shortfall in acquiring IVIG therapies because the majority of IVIG sales to physicians in the third quarter of 2006 by the three largest IVIG distributors are at prices exceeding the reimbursement levels for that quarter).

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

IVIG. As you know, the Current Procedural Terminology ("CPT") codes of the American Medical Association ("AMA") are used for reporting medical services and procedures, including IVIG infusions. For example, the first hour of infusing IVIG is assigned to CPT code 90765, while the second hour of infusing IVIG is assigned to CPT code 90766.[11] For each CPT code, CMS assigns relative value units ("RVUs") to services that reflect (1) physician work, such as the time, skill, and intensity it takes to provide the service, (2) practice expenses, and (3) malpractice costs.[12] After the RVUs are adjusted for geographic variations in costs by the geographic practice cost indices ("GPCI"),[13] they are then converted into a dollar payment amount by a conversion factor, which for 2007 is $37.8975.[14] According to CMS, this conversion factor is scheduled to be reduced by 9.9 percent for CY 2008.[15] Without Congressional intervention, such a reduction could further hinder patient access to IVIG and other important drugs and biologicals.

PPTA would also like to comment on the CPT codes to which IVIG is assigned. PPTA respectfully disagrees with the inadequate work RVUs that CMS assigned to CPT codes 90765 and 90766 for CY 2007, and proposes for 2008. Although the AMA's Relative Value Update Committee ("RUC") recommends RVUs to CMS, CMS ultimately decides the pertinent figures comprising each RVU. While PPTA has not completed an analysis on the work RVUs assigned to CPT codes 90765 and 90766, we respectfully contend that assigning the first and additional hours of IVIG infusion to these codes is an oversight because the work RVUs fail to account for the complexities of infusing IVIG.

The MMA called for CMS to evaluate drugs according to the complexity of administration. The resulting statutory provision requires CMS to promptly evaluate drug administration codes for physicians' services to ensure accurate reporting and billing of those services, taking into account levels of complexity of the administration and resource consumption.[16] Although IVIG infusions are more complex and resource intensive than many other types of infusions currently reported using the same drug administration CPT codes 90765 and 90766, the RUC and CMS evidently believe IVIG infusions to be of low complexity, similar to a saline infusion. The resources required to administer IVIG, however, exceed reimbursement.

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[11] *See* Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; 71 Fed. Reg. 69623, 69974 (Dec. 1, 2006).
[12] *See* 42 U.S.C. § 1395w-4(c) (2007).
[13] *See* 42 U.S.C. § 1395w-4(e).
[14] In determining the administration payment for IVIG and other Part B drugs, one must use the following equation for each CPT code as appropriate: [(RVU work x budget neutrality adjustor x GPCI work) + (RVU PE x GPCI PE) + (RVU malpractice x GPCI malpractice)] x the conversion factor.
[15] *See* Letter from Thomas A. Gustafson, Ph.D., Acting Director, Center for Medicare Management, U.S. Dep't of Health & Human Servs., to Glen M. Hackbarth, Chair, Medicare Payment Advisory Commission (Feb. 28, 2007).
[16] 42 U.S.C. § 1395w-4(c)(2)(J).

For CY 2008, until CMS and the RUC can better evaluate the costs of the administration of IVIG, PPTA urges CMS to issue two "G" codes that will provide a more accurate reimbursement payment for the administration of an IVIG infusion -- one to account for the first hour of infusion and one to be used for each additional hour of infusion. In terms of resources required, PPTA believes the infusion of IVIG is most similar to the infusion of chemotherapy drugs and issuing this temporary payment code will help alleviate any problems that may arise in providing patients with safe and effective infusions of this lifesaving therapy.

Similar to the infusion of chemotherapy, an IVIG infusion requires the presence of a trained infusion nurse to administer the infusion and to monitor the patient during the entire infusion. As you may know, the infusion of IVIG has been associated with:

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

If CMS does not more accurately reimburse the administration of an IVIG infusion, patient safety could be compromised because providers may be forced to make a business decision to no longer continue to use these nurses to administer IVIG and monitor the patients receiving the infusion. The continued presence of a trained infusion nurse for the entirety of an IVIG infusion is essential to ensure that both IVIG is properly administered to Medicare beneficiaries and such patients are appropriately monitored for these adverse reactions. For example, IVIG must be administered at the minimum concentration available and the minimum rate of infusion practicable to those patients with a predisposition to acute renal failure. In addition, the nurse can monitor those patients at risk for thrombotic events, including those patients with hyperviscosity, atherosclerosis, and cardiovascular disease. PPTA implores CMS to consider these complexities and dangers associated with this infusion and, for CY 2008, assign the administration of IVIG infusion to more appropriate "G" codes.

B. CODING—PAYMENT FOR IVIG ADD-ON CODE : CMS SHOULD FINALIZE THE PROPOSAL TO CONTINUE THE SEPARATE PAYMENT FOR IVIG PREADMINISTRATION_RELATED SERVICES AND SHOULD MAKE THIS PAYMENT PERMANENT

IVIG therapies are single source, as defined by the ASP statute,[17] orphan drugs[18] that treat patients with immune deficiencies and other serious, chronic medical disorders. According to the IDF, these therapies are the only effective treatment for primary immune deficiency disease ("PIDD").[19] Currently, the FDA has approved existing IVIG therapies for six clinical indications, including treatment of: (1) PIDD; secondary immune deficiency diseases, such as (2) pediatric HIV and (3) B-cell chronic lymphocytic leukemia; (4) idiopathic thrombocytopenic purpura, which is an autoimmune bleeding disorder, (5) Kawasaki disease, and (6) bone marrow transplantation.[20] For indications such as PIDD, IVIG enhances the defective components of a patient's immunity to fight and protect against infection and complications of infection. Patients relying upon IVIG therapies usually require infusions every three to four weeks for the duration of their lives.[21]

As you know, CMS established a G-code (G0332), effective January 1, 2006, in order to address the significant resources necessary to manage inventory, locate and acquire product, reschedule infusions due to product availability and patient needs, and provide the proper therapy and dose to patients.[22] PPTA appreciates the recognition by CMS of these additional costs incurred by physicians in providing IVIG therapies to Medicare beneficiaries. We agree with the Secretary of HHS about the importance of this payment.[23]

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[17] 42 U.S.C. § 1395w-3(c)(6)(D) (2007) (specifying that a biological, which each IVIG therapy is, is a "single source drug or biological").

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

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

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

[21] *Id.* at 15.

[22] 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).

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

The Proposed Rule would continue payment for G0332 for CY 2008 at the current reimbursement rate, which is $71 in the physician office.[24] PPTA supports the agency's proposal, which is consistent with the position of the Secretary of HHS. While PPTA is grateful for the continuation at the current rate, we ask the agency to be mindful of the access issues facing Medicare beneficiaries seeking IVIG and respectfully urge CMS to consider increasing the payment amount for G0332 for CY 2008 if CMS is unable to provide a payment adjustment to the ASP plus six percent for the product as requested in section I: A of this letter.

We note that, in the Proposed Rule, CMS expresses a concern that continuing this payment could "further distort the [IVIG] market" or create incentives for inappropriate utilization.[25] In the more than 20 months that CMS has made payments for IVIG preadministration-related services, PPTA has seen no evidence that this payment has created market distortions or incentives for inappropriate utilization. Rather, PPTA believes that without this payment, a greater number of health care providers would have discontinued providing IVIG to Medicare beneficiaries. As a result, we see no foundation for the concerns raised by CMS and urge CMS to both finalize the proposal and make the additional payment permanent.

We believe maintaining G0332 for CY 2008 and beyond, as well as the agency's recent decision to provide brand-specific reimbursement for the four liquid IVIG therapies should play a significant role in improving patient access to IVIG therapies. This provision in the Proposed Rule to continue to reimburse G0332 in CY 2008 is another example of the tremendous effort CMS has undertaken to resolve the existing IVIG access barriers faced by Medicare beneficiaries that rely on these lifesaving therapies. PPTA does request that the agency, when finalizing the continuation of the payment for preadministration-related services for IVIG in CY 2008, please include G-0332 in Addendum B as it is not currently present in that location in the Proposed Rule. We again thank you for your commitment in this area.

C. ASP ISSUES: CMS SHOULD PROVIDE MORE GUIDANCE AND REVISIONS TO ITS PROPOSAL ON BUNDLED PRICE CONCESSIONS

In the interest of reimbursing physicians as accurately as possible for all physician-administered drugs, especially IVIG therapies, PPTA appreciates the efforts taken by CMS to provide additional guidance in calculating the ASP. PPTA, however, is seeking more guidance from the agency on not only the proposed definition of bundled arrangements, but also the proposed application of this definition in calculating the ASP. We are especially concerned that one may interpret the proposed definition to include any line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied

[24] 72 Fed. Reg. at 38146.
[25] *Id*.

together for the purpose of a discount. PPTA believes such a broad interpretation could actually further distort ASP calculations, rather than bring more clarity and accuracy to the process. Until more guidance is provided, PPTA urges CMS to continue to allow for manufacturers to make reasonable assumptions in accounting for price concessions in bundled arrangements in their calculation of the ASP for their products.

In response to a January 2007 report from the Medicare Payment Advisory Committee ("MedPAC"), *Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs*, CMS now believes it should define bundled sales arrangements and specify the methodology for manufacturers to use in allocating price concessions earned under such arrangements in calculating the ASP. CMS had proposed addressing this issue in its CY 2007 Physician Fee Schedule proposed rule,[26] but opted against including it in its final rule last year.[27] In the absence of any specific guidance from CMS on how to allocate price concessions in such arrangements, CMS directed manufacturers to "make reasonable assumptions in its calculations of the ASP, consistent with the general requirements and intent of the Act, Federal regulations, and its customary business practices."[28] Currently, the ASP must include price concession such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates, except for the Medicaid outpatient drug rebates.[29] Bona fide service fees are not considered price concessions for the purpose of calculating the ASP.[30]

Although the flexibility to use "reasonable assumptions" has been beneficial in some instances, PPTA agrees with both MedPAC and CMS that without clear guidance on how to treat bundled sales arrangements, the ASP for some Medicare Part B drugs may be inaccurate, which could potentially drive some products from the marketplace, and possibly create a reimbursement shortfall for physicians. In the case of IVIG, such a result would be very dangerous for patients. We further support CMS' desire that any definition of bundled sales arrangements under the ASP be consistent with the definition of "bundled sales" as recently proposed and finalized for the purpose of the average manufacturer's price ("AMP"). Without more guidance and revisions to the language, however, PPTA does not believe the proposed definition and proposed application of that definition in calculating the ASP, as drafted, will further the goals of MedPAC and CMS.

In the Proposed Rule, CMS summarizes the MedPAC Report and discusses the two proposals offered by MedPAC for consideration to achieve more accurate ASP calculations. The MedPAC report recommends that the CMS clarify ASP reporting requirements for bundled products to ensure that ASP calculations allocate discounts to

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[26] 71 Fed. Reg. at 49003.
[27] 71 Fed. Reg. at 69673.
[28] *Id*. at 69675.
[29] *See* 42 C.F.R. § 414.804(a)(2)(i).
[30] *See* 42 C.F.R. § 414.804(a)(2)(ii).

reflect the transaction price for each drug.[31] MedPAC further stated that CMS should ensure any guidance it issues with regard to the allocation of discounts be "clear" and can be implemented by manufacturers "in a timely fashion."[32] If CMS were to require manufacturer's to reflect contingencies in their sales contracts, MedPAC believes the ASPs for the drugs involved in a bundling arrangement that relies on contingencies will be more accurate.[33] CMS could also require manufacturers to allocate bundled discounts in proportion to sales of each drug sold under the bundled arrangement.[34] Although the latter recommendation is most consistent with the AMP calculation, as discussed below, it may not accurately account for contingency sales, according to MedPAC.[35]

According to CMS in its final rule on the AMP, which was issued pursuant to the Deficit Reduction Act of 2005 (Pub. L. 109-171, 120 Stat. 4 (2006)), a bundled sale is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[36] In accounting for such price concessions, the discounts must be "allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement."[37] When discounts are offered on multiple drugs in a bundled arrangement, however, "the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle."[38] CMS further believes that a "consistent methodology for addressing bundled sales in [both] the Medicaid and [the] Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP."[39] CMS echoes this sentiment throughout the Proposed Rule and proposes to adopt a definition for "bundled arrangements" under the ASP that is very similar to the above-mentioned definition of "bundled sales" under the AMP.[40]

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[31] *See* MEDICARE PAYMENT ADVISORY COMMISSION, REPORT TO CONGRESS: IMPACT OF CHANGES IN MEDICARE PAYMENTS FOR PART B DRUGS 9 (2007).
[32] *Id*.
[33] *Id*.
[34] *Id*.
[35] *Id*.
[36] *See* Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39240 to be codified in 42 C.F.R. § 447.502.
[37] *Id*.
[38] *Id*.
[39] *See* 72 Fed. Reg. at 39159.
[40] *See* 72 Fed. Reg. at 38151.

The Proposed Rule defines a "bundled arrangement" for the purpose of the ASP to mean "an arrangement, regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), *or where the resulting discount or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement."*[41] CMS further proposes that "the manufacturer must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement."[42] If multiple drugs are discounted under a single bundled arrangement, "the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement."[43]

PPTA appreciates CMS' efforts to provide clear guidance on bundled arrangements for the purpose of calculating the ASP. We are, however, concerned that this definition of bundled arrangement, similar to the definition of bundled sale for the purpose of the AMP, could be interpreted to mean that any contract that provides for discounts on multiple products, even when those discounts are not linked in any way, would qualify as a "bundled arrangement" for the purpose of calculating the ASP. Under the italicized language quoted above, such contracts could be viewed as bundled arrangements because they contain price concessions for a nine-digit NDC that are "greater than those that would have been available had the drugs or biologicals sold under [the contract] been purchased separately or outside [the contract]." If this definition of "bundled arrangement" is finalized as proposed and without additional guidance by CMS, PPTA believes that CMS could consider <u>any</u> line-item discount contract a "bundled arrangement" if such contract includes a price concession on more than one nine-digit NDC, even if such drugs are not tied together for the purpose of a discount. PPTA envisions an excessive administrative burden on manufacturers and the agency if all GPO contracts are considered "bundled arrangements" for the purpose of calculating the ASP and requests CMS to amend the definition as appropriate to clarify that those nine-digit NDCs that are not part of a contingency arrangement in larger contracts do not fall under the definition of a bundled arrangement for the purpose of calculating the ASP.

Such a broad definition also creates complications when allocating the price concessions across all sales in the bundle as would be required by the Proposed Rule. This could be especially problematic for lagged price concessions. As you know, data on price concessions is either available at the time of purchase of a product, or on a

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[41] *Id*. (emphasis added).
[42] *Id*.
[43] *Id*.

lagged basis. If the data on these price concessions are lagged, then the manufacturer is required to estimate costs attributable to these price concessions using the required estimation methodology.[44] A definition of bundled arrangement that requires reallocation of discounts that do not involve any contingencies, particularly where those discounts otherwise are not lagged, could be read to require the treatment of these discounts as lagged and not includable in the estimation methodology until the performance period for the bundled arrangement is completed, because only then will the universe of sales involved in the bundle be known so that the discounts can be allocated proportionately based on the sales involved in the bundle as the proposed rule requires. Without more guidance on how to reallocate lagged price concessions in transactions that would qualify as "bundled arrangements," it appears manufacturers would be required to reallocate all the price concessions, both lagged and non-lagged, across the entire universe of sales included in the arrangement, which could be one quarter, unless the sales contract specifies a longer or shorter duration. PPTA urges CMS to provide more guidance to clarify how to reallocate lagged price concessions in order to further the agency's goal of receiving the most accurate ASP calculations by manufacturers.

Because, under Section 1847A(d) of the Social Security Act, the AMP may be used as an alternative payment methodology for Part B drugs, PPTA further believes that definition of "bundled sales" for the purpose of the AMP and "bundled arrangements" for the purpose of the ASP should be consistent. The Proposed Rule, however, includes in the definition of a "bundled arrangement" as examples of a "performance requirement" both "purchasing patterns" and "prior purchases," neither of which are included in the definition of "bundled sales." In the interest of consistency and less administrative burden for manufacturers, PPTA respectfully urges you to remove "purchasing patterns" and "prior purchases" as possible conditions for bundling arrangements in calculating the ASP.

D. ASP ISSUES: PPTA SUPPORTS THE DECISION BY CMS TO DISCONTINUE PUBLISHING THE ANNUAL BLOOD CLOTTING FACTOR FURNISHING FEE UPDATE IN THE ANNUAL PHYSICIAN FEE SCHEDULE RULE, BUT INSTEAD POST THE RELEVANT INFORMATION ON THE CMS WEBSITE

As you know, the MMA established a furnishing fee for blood clotting factor,[45] which is currently $0.152.[46] We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor in the physician office since the ASP plus six percent went into effect in 2005. PPTA supports CMS' decision in the Proposed Rule, consistent with the Social Security Act,[47] to increase this payment according to the annual consumer price index for medical care ending in June 2007.

[44] *See* 42 C.F.R. § 414.804(a)(3).
[45] *See* 42 U.S.C. § 1395u(o)(5).
[46] *See* 71 Fed. Reg. at 69680.
[47] 42 U.S.C. § 1395u(o)(5)(C).

We further support the agency's proposal that, beginning in CY 2009, CMS will announce the blood clotting furnishing fee update using the applicable program instructions and posting on the CMS Web site.

CMS determined it is not necessary to announce the furnishing fee update as part of the rulemaking process because: (1) the timing of the rulemaking process makes it impossible to release the blood clotting factor furnishing fee for the upcoming year in the proposed rule because the annual CPI information for medical care is not available when CMS issues its proposed rule; and (2) the blood clotting factor furnishing fee is determined by statute and the CPI for medical care cannot be affected by the rulemaking process so it is not imperative that this information is released in such a manner. Moreover, removing the blood clotting factor furnishing fee update from the rulemaking process and issuing it through program instructions will expedite receipt of this information by the necessary stakeholders, who currently must wait until the issuance of the final rule, which is several months after the information could be made available. PPTA fully agrees with this rationale on how to proceed for CY 2009, and looks forward to the issuance of the blood clotting factor furnishing fee for CY 2008 in the forthcoming final rule for the physician fee schedule.

E. ASP ISSUES: CMS MUST BE CAUTIOUS IN CONSIDERING WHETHER IT IS APPROPRIATE TO APPLY THE WAMP AND AMP THRESHOLD IN REIMBURSING IVIG"

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") or the AMP by a percentage threshold, the OIG informs CMS and the agency, in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.[48] The OIG must conduct studies, which can include surveys, to determine the WAMP.[49] In the Proposed Rule, CMS proposes to continue to set the WAMP and AMP threshold at 5 percent for CY 2008.[50] While PPTA does not oppose this threshold generally, we caution CMS that any decision to apply this statutory provision to the reimbursement of IVIG could exacerbate existing difficulties a fragile patient population is experiencing in attempting to access these therapies in the physician office. Because, as the two recent studies by HHS has confirmed,[51] reimbursement for the acquisition of IVIG at 106 percent of the ASP is inadequate, any reduction from that reimbursement level would be devastating to these patients who rely upon these lifesaving therapies.

[48] 42 U.S.C. § 1395w-3a(d)(3).
[49] 42 U.S.C. § 1395w-3a(d)(1).
[50] 72 Fed. Reg. at 38152.
[51] *See* discussion, *supra* at Section I:A.

II. CONCLUSION

PPTA appreciates the opportunity to comment on the Proposed Rule. Again, we are especially grateful for your decision to continue to reimburse temporary code G0332. We urge CMS to consider carefully these comments, particularly those related to IVIG access. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me 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