Plasma Protein Therapeutics Association

July 16, 2018

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 600E
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The Plasma Protein Therapeutics Association (PPTA) appreciates the opportunity to provide comments on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information (RFI).[1]

PPTA is the trade association and standards-setting organization for plasma donation centers and the manufacturers of plasma protein therapies used to treat rare conditions. These conditions are often genetic, chronic, and life-threatening, and require individuals to receive regular infusions of plasma protein therapies for the duration of their lives. PPTA and its members are committed to ensuring that individuals who depend on vital plasma protein therapies continue to have appropriate access to them. Our North America membership includes Bio Products Laboratory, CSL Behring, Emergent BioSolutions, Grifols Inc., Kedrion SpA, and Shire.

The RFI asks stakeholders for feedback on issues in the areas of increased competition, better negotiation, incentives to lower list prices, and reduced out-of-pocket costs. PPTA urges the administration to consider reforms in all of these areas against a backdrop of preserving access to essential treatments such as plasma protein therapies. PPTA asks that HHS consider the following suggestions:

- HHS should not shift reimbursement for protein plasma therapies from Medicare Part B to Medicare Part D because doing so would reduce patient access without achieving savings.

[1] 83 Fed. Reg. 22,692 (May 16, 2018).

147 Old Solomons Island Road · Suite 100 · Annapolis, MD 21401 USA
tel: 202.789.3100 · 410.263.8296 · fax: 410.263.2298 · e-mail: ppta@pptaglobal.org · www.pptaglobal.org
PPTA Offices in Washington · Annapolis · Brussels · Tokyo

- HHS should exclude plasma protein therapies if it adopts a competitive acquisition program (CAP).
- HHS should facilitate the adoption of value-based payment (VBP) arrangements by adopting waivers and clarifications of government price reporting and other laws.
- HHS should adopt guidelines to preserve patient access to plasma protein therapies as part of any Medicaid demonstration project that it implements.
- HHS should adopt appropriate clarifications and reforms to 340B Program guidance.
- HHS should ensure that there is parity in facility fees to promote patient access to sites of service for plasma protein therapy administration.
- HHS should not adopt any caps or inflation limits on Medicare Part B pricing for plasma protein therapies.

Further explanation of these suggestions is provided in the subsequent comments.

BACKGROUND

Plasma protein therapies are made from human plasma[2] donated by healthy donors, or by using recombinant technology[3]. These therapies include immunoglobulins to treat individuals with primary immunodeficiency diseases and chronic inflammatory demyelinating polyneuropathy; C1 esterase inhibitor to treat hereditary angioedema; Alpha-1 proteinase inhibitor to treat Alpha-1 antitrypsin deficiency, and blood clotting factors to treat individuals with bleeding disorders, such as hemophilia.[4]

Plasma protein therapies treat a variety of rare and debilitating diseases, some with a prevalence of fewer than 100 patients. Many patients struggle to access providers who have sufficient expertise to treat their conditions, and patients may experience challenges in accessing treatment both geographically and at the appropriate site of care.

Individuals treated with plasma protein therapies require uninterrupted access to all branded products. Manufacturers of plasma-derived therapies depend upon donated plasma as the raw material for therapeutic production. The process for collecting donated plasma is highly regulated, resource-intensive, and time-consuming, with a production process spanning seven to ten months. Individual proteins within plasma are isolated for therapeutic use through distinct fractionation processes. The result is plasma protein

[2] Plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed.
[3] Recombinant therapies are only available for clotting factors and C1 esterase inhibitors; plasma-derived therapies are the only lifesaving treatment for most plasma protein deficiencies.
[4] Plasma protein therapies also treat acute conditions such as rabies, tetanus, and when pregnant women's blood types are incompatible with their babies' (rhesus incompatible pregnancies).

therapies that are non-interchangeable, sole source biologicals that produce different therapeutic outcomes depending on the patient. Each plasma protein therapy is approved by the Food and Drug Administration (FDA) for distinct clinical indications. There are no generic or follow-on versions of plasma-derived or recombinant therapies.

Because of the particularly vulnerable populations treated by plasma protein therapies, it is critical that any proposed reforms do not affect what PPTA, its members, and its stakeholders consider to be the essential patient protections: prohibiting lifetime and annual caps, discrimination around preexisting conditions, limiting out-of-pocket costs and allowing children to stay on their parents' health plans until age 26.

DISCUSSION

PPTA Urges HHS Not to Move Plasma Protein Therapies Currently Available Under Medicare Part B to Medicare Part D As Doing So Would Threaten Patient Access

I. Utilization management tools such as drug formularies, fail first policies, and step therapy requirements impose significant access barriers for patients who rely on plasma protein therapies.

Tools used by Medicare Part D plans to leverage their negotiating authority with manufacturers could diminish access to the particular plasma protein therapy an individual has been using. For example, Part D plans are only obligated to include two drugs per therapeutic class on their formularies where the drugs are not therapeutically or bioequivalent.[5] Under the RFI, the two drug per class requirement could be eliminated which would exclude a significant number of plasma protein therapies and effectively block individuals from accessing their medically appropriate therapy. Other utilization management tools used by Part D plans are similarly inappropriate for coverage of plasma protein therapies. These include:

- Tiering, under which different therapies may be covered at different cost-sharing amounts on different tiers;[6]
- Prior authorization, under which a therapy is not covered at all without the permission of the plan; and
- Step therapy, under which a therapy is only covered after treatment with another product has failed.[7]

[5] 42 C.F.R. § 423.120(b)(2)(i), (ii).
[6] *Id*. at § 423.104(d)(2)(ii).
[7] *Id*. at § 423.120(b)(1)(x).

These tools were designed for interchangeable drugs so a plan could substitute its preference for the judgment of the patient's physician in prescribing a particular drug therapy without understanding the particular health condition of the patient. However, individuals who rely on plasma protein therapies need full and efficient access to all brands so that physicians with expertise in these rare conditions can select the most medically appropriate therapy.

PPTA would like to remind HHS that plasma protein therapies are not interchangeable. This position is supported by numerous studies and the clinical guidelines/recommendations of medical experts.[8] To be interchangeable, a biologic product must be "expected to produce the same clinical result as the reference product in any given patient"[9] and "the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alteration or switch."[10] For this unique class, small differences in manufacturing can result in significant changes in plasma protein therapies. The interactions of such changes with potentially relevant patient characteristics are numerous and highly variable and can produce different therapeutic outcomes. Patients can experience intolerance or inefficacy with a particular therapy but can be medically stable on another therapy that best fits their health status. As for risk, while plasma protein therapies have favorable adverse-event profiles, rare but serious adverse events can occur (e.g. formation of inhibitors caused by immunogenicity in clotting factor patients, thrombosis in intravenous immune globulin patients). Such adverse events often result from interactions between product characteristics (e.g. pH, IgA) and patient characteristics; small differences in manufacturing can also result in different adverse-event profiles in patients.

II. Beneficiaries may experience higher out-of-pocket costs

Moving plasma protein therapies from Medicare Part B to Medicare Part D could increase cost-sharing for individuals, creating barriers to access if out-of-pocket costs are unaffordable for some beneficiaries. For many individuals, the tiered

[8] Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis (Miami). 2016; 3(3): 668-682.; Goldstein, S., MD, FAAAAI, & Orange, J., MD, PhD, FAAAAI. (2011, December). Eight guiding principles for safe, effective and appropriate use of IVIG (Publication). Retrieved from American Academy of Allergy Asthma & Immunology website: http://www.aaaai.org/practice-resources/practice-tools/ivig-toolkit; Patwa, H. S., Chaudhry, V., Katzberg, H., Rae-Grant, A. D., & So, Y. T. (2012). Evidence-based guideline: Intravenous immunoglobulin in the treatment of neuromuscular disorders: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology, 78(13), 1009-1015.; Zuraw BL, Banerji A, Bernstein JA, Busse PJ, Christiansen SC, Davis-Lorton M, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. J Allergy Clin Immunol: In Practice 2013; 1:458-67.: (PPT Clinical Guidelines)

[9] Section 351(k)(4)(A) of the PHS Act

[10] Section 351(k)(4)(B) of the PHS Act

cost-sharing under Medicare Part D, including 25% up to the initial coverage limit and 35% while in the coverage gap, is higher than the 20% cost-sharing under Medicare Part B.[11] Furthermore, individuals can purchase secondary insurance to help cover the 20% cost-sharing under Medicare Part B, but that insurance cannot be used to defray out-of-pocket costs under Medicare Part D.[12] These differences mean beneficiaries could have higher cost-sharing if plasma protein therapies were to be moved to Medicare Part D, which would not achieve the HHS goal of lowering out-of-pocket costs.

III. Drugs covered under Part D are subject to a different distribution system under which drug administration services are not covered

Drugs covered by Medicare Part B are typically administered in a physician setting, whereas drugs covered by Medicare Part D are distributed through retail pharmacies. Moving plasma protein therapies from Part B to Part D coverage would threaten access due to differing coverage of drug administration services. Medicare Part B provides a drug administration service reimbursement for drugs covered under its coverage[13], but these same services are not covered under Medicare Part D.[14] A comparison of the limited number of plasma protein therapies paid through both Medicare Part B and Medicare Part D available in the CMS Drug Spending Dashboards shows a higher average annual spending per beneficiary in Medicare Part D.[15] This difference may be due to efficiencies achieved when administration services are covered. HHS should not move plasma protein therapies currently covered under Medicare Part B to Medicare Part D because doing so would divorce these unique but essential therapies from coverage of the services necessary to administer them, resulting in substantial and perhaps insurmountable access problems for patients.

Moving plasma protein therapies from Medicare Part B to Medicare Part D would not be appropriate given the challenges patients and providers would experience with utilization management tools, increased out-of-pocket costs, reimbursement for administration services, and demonstrated historic higher spending.

PPTA Urges HHS to Exclude Plasma Protein Therapies from the CAP

The RFI asks for comments on reforming the CAP, a program previously implemented in 2007-2008 in which HHS contracted with vendors to negotiate pricing with manufacturers

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[11] Social Security Act (SSA) § 1860D-2(b); 42 C.F.R.§ 423.104(d); CMS, CY 2018 Call Letter at 48, 54 (Apr. 3, 2017), *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.
[12] *Id* SSA § 1882(v)(1).
[13] SSA §§ 1832(a)(2)(B), 1861(s)(2)(A).
[14] *Id*. at § 1860D-2 (discussing coverage of drugs but not discussing coverage of drug administration services).
[15] Analysis of CMS Medicare Part B Drug Spending Dashboard and CMS Medicare Part D Drug Spending Dashboard.

on behalf of physicians who would then purchase their in-office administered drugs through those vendors.[16] CMS has the authority to exclude certain categories of drugs if it is unlikely to generate savings or if there would be an adverse effect on patient access[17]. As such, several plasma protein therapies were not included in the CAP at the time the program was originally implemented.[18] PPTA requests that HHS follow this precedent and exclude all plasma protein therapies from any CAP.

PPTA is extremely concerned that a CAP would complicate the distribution system[19], thereby delaying patient access to necessary therapies. PPTA is also concerned that the CAP would make it difficult for physicians to provide plasma protein therapy services, thereby reducing patient access to these drugs entirely.

Should CAP vendors take possession of drugs before they are purchased by physicians, HHS would need to be sure that physicians would be able to access these drugs as quickly as possible so that there are no delays in patient care.

PPTA also urges HHS to ensure that the CAP remains truly voluntary for physicians. The program should not adopt extreme incentives to induce physician participation, such as reducing the percentage above ASP (*i.e.*, plus 6 percent) for the existing reimbursement system. An analysis of access issues by the HHS Office of the Assistant Secretary for Planning & Evaluation[20] found that previous reductions in Medicare reimbursement resulted in access challenges, treatment delays, and shifts in site of service for individuals who use plasma protein therapies. [21]

Individuals who require plasma protein therapies already suffer from reduced access because not all physicians have the expertise to provide plasma protein therapies. Lack of available specialists (e.g. hematologists, immunologists, pulmonologists, etc.) could delay access to treatment as patients struggle to find a provider who covers their therapy. These barriers to access are particularly problematic for Medicare beneficiaries managing

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[16] 83 Fed. Reg. at 22,697.
[17] SSA § 1847B(a)(1)(D)
[18] 70 Fed. Reg. 39,021, 39029-32
[19] The CAP previously implemented in 2007 - 2008 was problematic for a number of reasons, including that it was difficult to recruit vendors and physicians to participate. For example, HHS was only able to contract with one vendor to implement this program. In addition, vendors were to take possession of the drugs whose prices they negotiated and participating physicians purchased the drugs from the vendor, which added an additional layer of complexity to the existing drug distribution system.
[20] HHS, Office of the Assistant Secretary for Planning and Evaluation, Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV), p. 4-31 (February 2007). (ASPE)
[21] Tomas Philipson & Anupam B. Jena*, The Impact of Medicare Modernization Act Reimbursement Changes on the Utilization of Intravenous Immune Globulin*, The University of Chicago; The Irving B. Harris Graduate School of Public Policy Studies. This study found that after a reduction in Medicare reimbursement rate for IVIG at the start of 2005, the average number of IVIG claims among Medicare eligible individuals grew more slowly than in the non-Medicare eligible population, despite growing at the same rate in the previous three years. There was a significant reduction in the share of IVIG claims for Medicare beneficiaries originating in the physician office with no accompanying change in the non-Medicare population. Changes in the Medicare reimbursement of IVIG negatively impacted access to IVIG.

chronic conditions. It is also important to note that the Medicare Part B plus 6 percent increment is already subject to a reduction through sequestration[22] as well as prompt pay discounts given to wholesalers by manufacturers which are not typically passed on to providers.

Alternatively, some physicians who can no longer afford to cover all brands of plasma protein therapies may feel pressure to prescribe only the least expensive version or to turn away Medicare patients. This incentive threatens patient health if they are no longer able to access the plasma protein therapy that in their physician's judgment works best for them. Plasma protein therapies are not interchangeable, and therefore patients need access to their medically appropriate therapy.

PPTA recommends excluding these therapies from the CAP completely. To do so would be consistent with past legislative and regulatory intent, in addition to recognition by CMS that modifications in its policies were made to protect access to plasma protein therapies.

For example:

- In 2005, CMS adopted site-neutral payments with respect to furnishing fees for blood clotting factor across the physician office and hospital settings.[23]
- CMS also created a temporary add-on payment for IVIG preadministration services following concerns that there was inadequate access to IVIG products.[24]
- CMS has historically excluded some plasma protein therapies from the previous version of the CAP.[25]

PPTA asks HHS to extend the exclusion to all plasma protein therapies[26] for the updated CAP consistent with its statutory authority to do so.[27]

PPTA Urges HHS to Facilitate the Adoption of VBP Arrangements As Much As Possible By Adopting Waivers and Clarifications As Warranted of Government Price Reporting and Other Laws

The RFI asks "what benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price-guarantees included in value-based arrangements."[28] It also asks how

[22] Part B drugs are reimbursed at ASP plus 4.3 percent.
[23] 70 Fed. Reg. 68,516, 68,661 (Nov. 10, 2005).
[24] *Id*. at 68,649.
[25] 70 Fed. Reg. 39,002, 39028-29 (Jul. 6, 2005) (excluding blood clotting factors, IVIG, and alpha-1 proteinase inhibitors).
[26] The plasma protein therapies which should be excluded from the Competitive Acquisition Program include: blood clotting factors, immune globulins (both intravenous and subcutaneous), Rho(D) immune globulins, Alpha-1 proteinase inhibitors, C1 esterase inhibitors, prothrombin complex concentrates, and hyperimmune globulins.
[27] SSA § 1847B(a)(1)(D).
[28] 83 Fed. Reg. at 22,697.h

this exclusion would impact the Medicaid Drug Rebate Program (MDRP), ASP, and the 340B Program.[29]

PPTA is supportive of HHS's efforts to facilitate the adoption of VBP arrangements as an essential step to promoting innovation in reimbursement arrangements and supporting patient access to life-changing medical therapies through innovative payment arrangements. However, steps are needed to truly facilitate such arrangements. For example, it is important to exclude value-based arrangements from government price calculations, including the determination of best price (BP). Without doing so, there will always be a limit to how effective these VBP arrangements can be as manufacturers will always need to structure them to avoid dramatically increasing their MDRP rebate and 340B drug discount liability. MDRP rebates and related 340B discounts for single source or innovator multiple source drugs are the greater of the Average Manufacturer Price less best price or the applicable statutorily defined rebate percentage.[30] So long as this pricing methodology applies, VBP arrangements could effectively set a floor for the price of the drug and inadvertently set a new BP, thereby increasing the rebate or 340B discount.

HHS should facilitate VBP arrangements by adopting waivers of best price and other applicable government price reporting requirements. In addition, HHS should clarify or adopt waivers of other federal laws as necessary, such as the anti-kickback statute, to facilitate the adoption of VBP arrangements.

PPTA Urges HHS to Adopt Appropriate Guidelines to Preserve Patient Access to Plasma Protein Therapies as Part of Any State Medicaid Demonstration Project

If HHS were to establish a new Medicaid demonstration authority that allows states to test private sector practices such as closed formularies[31], it is important to ensure that guardrails exist to prevent individual states from taking steps that inadvertently harm patients by reducing access to needed therapies. Restrictive drug utilization management policies such as closed formularies are implemented in pursuit of cost savings and are wholly unrelated to patient health.[32] These policies could require individuals to either switch products or go through an appeals process to access their medically appropriate therapy.

It is established that individuals who use plasma protein therapies should not switch from a product on which they are currently stable in order to avoid serious adverse events.[33] However, this population also requires urgent access to the appropriate therapy in order to manage their complex conditions. For example, the National Hemophilia Foundation Medical & Scientific Advisory Committee recommends patients have access to their

[29] *Id*.
[30] SSA § 1927(c).
[31] 83 Fed. Reg. at 22,693 (emphasis added).
[32] Hemophilia Federation of America. (2016). Non-medical switching and step therapy (Issue brief).
[33] PPT Clinical Guidelines, *supra* n. 10.

physician's recommended therapy within three to twelve hours in order to manage spontaneous bleeds.[34] Yet a recent survey of physicians revealed that nearly a quarter of prior authorization decisions take between three to five business days.[35]

PPTA recommends that states should not be permitted to adopt closed formularies with respect to plasma protein therapies. All plasma protein therapies should be covered to ensure patient access to the most appropriate therapy for these rare diseases and to avoid severe adverse events. Further, access to appropriate therapies should not be hampered by an appeals process. Any Medicaid demonstration must protect patients already stable on a plasma protein therapy by grandfathering their current treatments. Alternatively, to truly preserve access for patients receiving plasma protein therapies, HHS could exclude them from any state Medicaid demonstration projects it adopts to ensure that there is no risk that they will not somehow be covered.

PPTA Urges HHS to Adopt Appropriate Clarifications and Reforms to 340B Program Guidance

The RFI asks a number of questions about the 340B Drug Discount Program, with a particular focus on program growth, program covered entity eligibility, and duplicate discounts.[36] The 340B program has expanded dramatically in recent years, including the growth of contract pharmacies that covered entities may list as eligible to dispense 340B-purchased drugs under the program[37] and a growing number of child sites listed in the 340B covered entity database. This growth has been particularly deleterious for plasma protein therapies because there has been a stark shift in the site of service for some of these therapies, namely intravenous immune globulin (IVIG).

Our comments with respect to the 340B Program are as follows:

- The Health Resources and Services Administration (HRSA) should clarify that sub-recipients of federal health care grantees eligible to participate in the 340B program are not eligible to participate in the 340B program unless they are independently eligible.
- HRSA should clarify the 340B patient definition to state that the predicate health care service to the dispensing of a 340B discounted drug should be consistent with the contract that a disproportionate share hospital has with the state that qualifies it to participate in the 340B program. Federal health care grantees are subject to a similar requirement.

[34] National Hemophilia Foundation Medical and Scientific Advisory Committee. (2008). MASAC Recommendations regarding standards of service for pharmacy providers of clotting factor concentrates for home use to patients with bleeding disorders. (Recommendation No. 188). National Hemophilia Foundation.
[35] 2017 AMA Prior Authorization Physician Survey
[36] 83 Fed. Reg. at 22,69899.
[37] 75 Fed. Reg. 10,272 (Mar. 5, 2010).

- HRSA should clarify that a patient will not qualify as a patient of a covered entity if the only relationship with the covered entity is the dispensing or infusion of a drug.
- HRSA should clarify that the predicate services that lead to the dispensing of a 340B purchased drug should be consistent with a provider's contract with the 340B covered entity.
- The Medicaid exclusion file should be expanded to apply to both Medicaid fee-for-service and Medicaid managed care, and covered entities should be permitted to make only one carve-in/carve-out decision across both Medicaid programs and across all Medicaid managed care contractors.
- HRSA should provide further clarification as to how contract pharmacies may comply with the duplicate discount prohibition, including that any contract pharmacies that do use 340B-purchased drugs for Medicaid patients must have an agreement with the state to do so and must make that agreement public. A contract pharmacy's carve-in/carve-out status should also be listed in the 340B Medicaid exclusion file.
- HRSA should limit the number of contract pharmacies that a covered entity may list as eligible to dispense 340B purchased drugs in the 340B covered entity database.

The RFI also notes that one of the steps taken in the past year to create incentives to lower list prices was "finalizing Medicare Outpatient Prospective Payment System (OPPS) rules to reduce beneficiary out-of-pocket spending for 340B drugs administered in certain hospitals by an estimated $320 million in 2018, which would equal $3.2 billion when multiplied over ten years."[38] This statement appears to be referring to the change in reimbursement for 340B drugs under Medicare Part B adopted in the 2018 OPPS Final Rule from ASP+6 percent to ASP less 22.5 percent. As noted in PPTA's comments on the proposed CY 2018 outpatient prospective payment system, HHS should not apply this policy to blood clotting factors because of the unique nature of these therapies and the additional cost of furnishing them. PPTA urges CMS to reconsider its policy of paying for 340B drugs at ASP less 22.5 percent for blood clotting factors.

PPTA Urges HHS to Ensure That There Is Parity in Facility Fees as Necessary to Allow Patient Access to Sites of Service for Plasma Protein Therapy Administration

The RFI asks for comments on the benefits of adopting site neutrality payments for both physician administered drugs and the outpatient setting and between the inpatient and outpatient settings.[39]

PPTA members that produce blood clotting factor for hemophilia patients have experienced firsthand the benefits of site neutrality payments for certain physician

[38] 83 Fed. Reg. at 22,698.
[39] *Id*. at 22,697.

administered drugs. Under the Medicare statute, blood clotting factor provided in physician offices is paid at ASP+6 percent plus a furnishing fee per unit of factor.[40] CMS has established parity between payments for clotting factor in the physician's office and the hospital outpatient setting so that the same furnishing fee is available for the latter on the grounds that the same resources are used to provide clotting factor in the outpatient setting.[41] This furnishing fee has been critical to maintaining access to blood clotting factor for patients. For other plasma protein therapies under the Medicare program, there has been parity in payments for the products in the physician and hospital outpatient settings, which should continue.

PPTA urges HHS to ensure that parity extends to facility fees to maximize patient access to drug administration services and increase patient choice of providers.

PPTA Urges HHS Not to Adopt Any Caps or Inflation Limits on Medicare Part B Pricing for Drugs

The RFI mentions that one of the steps that may be considered to provide better support for negotiation is "establishing an inflation limit for reimbursement of Medicare Part B drugs; . . . ."[42] PPTA urges HHS not to apply this concept to plasma protein therapies, as doing so could create patient access issues for these highly sensitive therapies. While the overall increase in the ASP for plasma protein therapies has been lower than the producer price index for pharmaceutical preparations in recent years,[43] any artificial cap on reimbursement could present patient access issues. This barrier to access occurred when Medicare reimbursement for Part B drugs was reduced under the Medicare Modernization Act of 2003. Beneficiaries receiving plasma protein therapies experienced access challenges as providers were forced to choose between treating patients who need these therapies and maintaining the financial stability of their practices.[44] PPTA and its members encourage the Administration to protect patient populations who rely on plasma protein therapies by maintaining sufficient reimbursement for providers who administer them.

Finally, the RFI asks for feedback on the inflationary penalty under the Medicaid drug rebate program. Specifically the concern that the cap on this penalty at 100 percent of Average Manufacturer Price allows for "excessive price increases to be taken without manufacturers facing the full effect of the price inflationary penalty established by Congress."[45] Expanding the price inflationary penalty is similar to imposing a price cap on drugs and could create the same concerns with respect to patient access and the ability of manufacturers to produce and market these drugs.

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[40] SSA § 1842(o)(5)(C).
[41] 70 Fed. Reg. at 68,661.
[42] 83 Fed. Reg. at 22,693.
[43] Bates White Report at 17-22.
[44] ASPE, *supra* n. 20.
[45] 83 Fed. Reg. at 22,698.

Plasma Protein Therapeutics Association

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PPTA thanks HHS for this opportunity to offer comments on the RFI. If you have any questions about these comments, please do not hesitate to contact Thomas B. Lilburn at TLilburn@pptaglobal.org.