

May 30, 2014

CDR Krista M. Pedley, PharmD, MS, USPHS  
Director  
Office of Pharmacy Affairs  
Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane  
Parklawn Building, Room 10C-03  
Rockville, MD 20857

Dear Commander Pedley:

Thank you for taking the time to meet with the Plasma Protein Therapeutics Association (PPTA) on May 15, 2014. We greatly appreciate the Health Resources Services Administration (HRSA), Office of Pharmacy Affairs (OPA) consideration of PPTA's positions and policy proposals for the 340B drug discount program. PPTA is committed to ensuring that patients living with chronic and rare diseases who rely on plasma protein therapies for their lifesaving treatment have appropriate and timely access to the therapy and care that best suits their health status. Accordingly, PPTA firmly supports the implementation of regulations that advance patient access, reflect the vital importance of continuity of care for plasma protein patients, and ensure that the benefits of 340B discounts flow through to the most needy and vulnerable patient populations.

As we discussed during our meeting, based on the unique nature of plasma protein therapies, the distinct collection and manufacturing processes required to produce these lifesaving treatments, and the rare disease patients who rely on plasma protein therapies for the duration of their lives, the plasma protein industry respectfully proposes the following:

- Recognizing that federal grantees and HRSA's regulation of federal grantees, in particular hemophilia treatment centers (HTCs), offer a paradigm for program integrity, transparency, and care coordination that improves patient outcomes, HRSA should apply the federal grantee regulatory regime to 340B hospital entities (i.e. non-federal grantees).
- Improve existing policies to ensure that 340B benefits flow through to in-need patients, and that in cases where federal grantees are housed in covered entity hospitals that the federal grantees are given access to all of the 340B revenues that arise from the grantees' participation in the 340B program.
- Given the unique needs of chronic, rare disease patients who rely on lifelong treatment with physician-administered therapies for their lifesaving care, HRSA should safeguard continuity of care for 340B patients through an improved definition of a 340B patient that includes following tenets:
  - Individuals receiving care from a health care professional contracted with a 340B entity will be considered 340B patients when the care provided is pursuant to the provider's contract with the entity;
  - Individuals receiving care through a covered entity that is eligible based on its contract with a government entity will only be considered 340B patients if the

care provided is consistent with the scope of services established in the contract between the entity and government.

- Considering the significant impact that 340B-MCO “double dipping” has on the plasma protein therapeutics industry, HRSA should engage in the following efforts to prevent further downward economic pressure from being placed on 340B participants:
  - Issue guidance to states requiring: (1) the adoption of Medicaid MCO billing guidelines that, among other things, require that Medicaid MCOs add a 340B indicator to claims submitted to the state; (2) the adoption of a policy to cross-check utilization data against lists of 340B covered entities, including those which “carve-in”; and (3) the creation of a website to assist in identification of Medicaid MCO enrollees.
  - Address any unimplemented recommendations from the OIG’s 2011 report.
  - Work with HRSA and other stakeholders to identify best practices for states to avoid duplicate discount risk.
  - Issue guidance to states on these best practices, including an applicable State Plan Amendment (SPA) template.
  - Finalize proposed 42 C.F.R. § 447.518(a), with some additional detail on reimbursement mechanisms for 340B drugs.
  - Add data elements to proposed 42 C.F.R. § 447.511 to enable identification of duplicate discount risk.
  - Create a process and timeline for retrospective and prospective implementation of corrective action.
- Amend hospital and off-site facility eligibility to ensure program benefits flow through to 340B patients by requiring 340B hospitals to adhere to reporting requirements mirroring those applied to HTC’s, and where a 340B hospital’s participation is based on a contract with a government entity, limit the hospital’s program participation to the scope of the contract.

Thank you for your time and consideration of the plasma protein industry’s policy proposals. We greatly appreciate the agency’s willingness to engage PPTA in a productive and solutions-focused discussion, and we look forward to continuing to work with HRSA to ensure 340B patients have access to the best possible therapies. If you have any questions or require any additional information, please don’t hesitate to contact the association.

Best regards,



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