PPTA
Plasma Protein Therapeutics Association

September 23, 2009
Reference No.: FASC09051

Jimmy R. Mitchell, R.Ph, MPH, MS
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health & Human Services
5600 Fishers Lane,
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: The Disproportionate Share Hospital Prohibition for Purchasing from Group Purchasing Organizations

Dear Mr. Mitchell:

On behalf of the Plasma Protein Therapeutics Association ("PPTA"),[1] I am writing today to underscore our opposition to a recent legislative proposal that would relax the current statutory prohibition against disproportionate share hospitals ("DSH") purchasing covered outpatient drugs from group purchasing organizations ("GPOs"). This proposal would give DSH hospitals that are 340B covered entities the advantage of collective bargaining power through a GPO in instances of product shortages and manufacturer non-compliance, to facilitate generic substitution, and to reduce the purported administrative burden of managing drug inventories.[2] For the reasons detailed below, PPTA strongly opposes this provision, which is currently in two health care reform bills that have been ordered to be reported by the respective committees in both the House of Representatives and the Senate with jurisdiction over the 340B Drug Pricing Program. Moreover, PPTA has opposed this language not only throughout the health care reform debate in the 111th Congress,[3] but also since it first appeared in legislation introduced during the 110th Congress.[4]

[1] PPTA is the association that represents human plasma collection centers and the manufacturers of medicinal therapies, including albumin, alpha$_1$-proteinase inhibitor, blood clotting factors, and immune globulin from this human plasma. 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."
[2] *See, e.g.*, H.R. 3200, § 2501(b) (as ordered to be reported by the H. Comm. on Energy & Commerce on July 31, 2009).
[3] *See, e.g.*, Letter from Julie A. Birkofer, Vice President, PPTA North America to Edward M. Kennedy, Chairman, Senate Committee on Health, Education, Labor, and Pensions, et al. (revised June 30, 2009) (on file with the author).
[4] *See, e.g.*, Letter from Julie A. Birkofer, Vice President, PPTA North America to Senator Jeff Bingaman, et al. (Sept. 7, 2007) (on file with the author).

Any suggestions that may have been made that PPTA supports this provision are simply incorrect and are a misrepresentation of our position.

As you are well aware, under current law, 340B covered entities may generally use third parties, such as the 340B prime vendor, GPOs, and purchasing agents, to facilitate the purchase of prescription drugs at prices below the 340B ceiling price. The statute does, however, prohibit DSH hospitals that qualify as covered entities from obtaining covered outpatient drugs through a GPO.[5] Any DSH attempting such arrangements with a GPO will no longer qualify as a covered entity under the statute.[6]

Section 611(c) of the Affordable Health Choices Act, as ordered to be reported by the Senate Committee on Health, Education, Labor, and Pensions, and section 2501(b) of H.R. 3200, the America's Affordable Health Choices Act of 2009 (Waxman Substitute), as ordered to be reported by the House Committee on Energy and Commerce, would direct the Health Resources and Services Administration to develop exceptions to the existing DSH GPO prohibition in broad circumstances, where, for instance, the application of the exception would allegedly ease administrative burdens. PPTA respectfully objects to the exceptions.

PPTA is further concerned that these exceptions unfairly and unnecessarily target the intravenous immune globulin ("IVIG") sector of the plasma protein therapeutics industry. In recent years, the DSH hospital community has claimed that it has experienced difficulties in accessing IVIG because of alleged independent refusals by IVIG manufacturers to comply with 340B Drug Pricing Program requirements.[7] This assertion, however, lacks merit. Manufacturers of IVIG are complying and have complied with the 340B statute.

All IVIG manufacturers in the U.S. have signed pharmaceutical pricing agreements with HRSA and are participating in the 340B Program. Individual business practices notwithstanding, all IVIG manufacturers also allocate the majority of their supply pursuant to contractual arrangements with authorized distributors, GPOs, hospital pharmacies, homecare companies, physicians, health maintenance organizations, and the federal government. Manufacturers individually began to contract in this manner in response to Congressional and Administrative pressure to address an IVIG supply shortage more than a decade earlier.[8] Because IVIG therapies are not interchangeable, manufacturer allocation of IVIG therapies based on historical utilization provide a safeguard to ensure patients are able to access the therapy best suited for

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[5] *See* 42 U.S.C. § 256b(4)(L)(iii).

[6] *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

[7] *See, e.g.*, PUBLIC HOSPITAL PHARMACY COALITION, ACCESS TO IVIG BY SAFETY NET HOSPITALS IN THE 340B DRUG DISCOUNT PROGRAM (2006).

[8] *See Public Health 2000: Immune Globulin Shortages – Causes and Cures: Hearing Before the Subcomm. On Human Resource of the House Comm. on Government Reform and Oversight*, 105th Cong. 2 (1998) (statement of Rep. Shays, Chairman, Subcomm. on Human Resources of the House Comm. on Government Reform and Oversight) (calling for manufacturers to adopt the ACBSA recommendations to allocate therapy based on historical utilization in order to address the 20% shortage of IVIG in 1997).

their individual needs. This business method is critical to maintaining long term patient access to this lifesaving therapy.

The plasma protein therapeutics industry, which accounts for approximately 2% of the entire U.S. drug market with $6.37 billion in sales in 2008,[9] is distinguished by a unique economic structure that requires manufacturers to recover large, unavoidable costs by producing brands in multiple therapeutic classes from each liter of plasma that it fractionates. The capital intensity of the facilities, equipment, and source material,[10] the direct and indirect costs of compliance with stringent Food and Drug Administration regulations[11] and rigorous voluntary industry standards[12] by both the plasma collectors and fractionators, the small patient populations in each therapeutic class,[13] and the limited pricing flexibility due to the brand-to-brand competition in most therapeutic classes (e.g., there are currently eight different immune globulin therapies available for U.S. consumption) are critical factors that a manufacturer must consider prior to not only entering the marketplace, but also determining which therapies it will produce from the liter of plasma. For example, such considerations play an especially critical role in the

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[9] *Compare* THE MARKETING RESEARCH BUREAU, INC., THE PLASMA FRACTIONS MARKET IN THE UNITED STATES 2008 1 (2009) [hereinafter "MRB REPORT"] (providing U.S. sales data for 2008) *with* IMS Health Inc., Channel Distribution by U.S. Sales, http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=85f4a56216a10210VgnVCM100000ed152ca2RCRD&cpsextcurrchannel=1 (last visited Sept. 2, 2009).

[10] *See* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, BLOOD POLICY AND TECHNOLOGY 66 (Jan. 1985) (discussing the capital intensive nature of the facilities necessary to fractionate plasma proteins); *see* MRB REPORT, *supra* note 9, at 41 (demonstrating the capital intensity of the source material required to produce plasma-derived therapies).

[11] *See* 21 C.F.R. §§ 210 and 211 (2009) (describing current good manufacturing processes); *see* 21 C.F.R. §§ 640.60– 640.76 (detailing requirements for plasma donor suitability; plasma donor identification; medical supervision at the plasma collection facility; the plasmapheresis process; the collection and storage of plasma in a sterile setting; the pooling, storage, and transportation of collected source plasma at appropriate temperatures; labeling; laboratory screening tests; and recordkeeping); *see, e.g.*, 21 C.F.R. §§ 640.100–640.104 (providing federal regulations for the production of IVIG).

[12] *See* PLASMA PROTEIN THERAPEUTICS ASSOC., INTERNATIONAL QUALITY PLASMA PROGRAM ("IQPP"), http://www.pptaglobal.org/UserFiles/File/QSEAL/Program%20Description_v2.0_January%202009.pdf (last visited Aug. 27, 2009) (providing standards for the certification of plasmapheresis centers); *see* PLASMA PROTEIN THERAPEUTICS ASSOC., QUALITY STANDARDS OF EXCELLENCE, ASSURANCE, AND LEADERSHIP, http://www.pptaglobal.org/program/QSEAL_CERTIFICATION_PROGRAM_DESCRIPTION%20V1.5.pdf (last visited Aug, 27, 2009) (providing standards for the certification of plasma fractionators).

[13] Plasma protein therapies are used in the treatment of rare diseases. The National Institute of Health Office of Rare Diseases Research generally defines rare diseases as those having a "prevalence of fewer than 200,000 affected individuals in the United States." According to the agency's database, those diseases that meet this threshold and are treated by plasma protein therapies include afibrinogenemia (Factor I deficiency), alpha1-antitrypsin deficiency, B-cell chronic lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, congenital antithrombin deficiency, Guillain-Barre syndrome, Factor II deficiency, Factor V deficiency, Factor VII deficiency, Factor X deficiency, Factor XII deficiency, Factor XIII deficiency, hemophilia A (Factor VIII deficiency), hemophilia B (Factor IX deficiency), hemophilia C (Factor XI deficiency), hyperimmunoglobulinemia E syndrome, hypofibrinogenemia (Factor I deficiency), idiopathic thrombocytopenic purpura, Kawasaki syndrome, Lambert-Eaton myasthenic syndrome, multifocal motor neuropathy, multiple sclerosis, myasthenia gravis, primary immune deficiency diseases, staphylococcal toxic shock syndrome, and von Willebrand disease *See* OFFICE OF RARE DISEASES RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., RARE DISEASE AND RELATED TERMS, http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1 (last visited Sept. 8, 2009).

ability of a manufacturer to invest in the research and development of therapies for treating diseases with extraordinarily low prevalence.[14]

Nearly 88 percent of human plasma collected for use in the U.S. was source plasma,[15] which cost approximately $150 per liter.[16] This price includes the costs of its nucleic acid amplification technology testing for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus.[17] Threats of emerging pathogens, such as variant Creutzfeldt-Jakob disease, will continue to increase the overall manufacturing costs of plasma protein therapies because manufacturers may have to develop new laboratory screening tests, as well as new procedures for viral inactivation and viral reduction.

In addition to these concerns with the proposed exceptions to the DSH GPO prohibition, PPTA also has strong objections to the basic concept of giving DSH hospitals with collective bargaining power in such broad instances because it runs counter to the very purpose of establishing this exemption in the first place. One of the reasons that Congress put the GPO prohibition for DSH hospitals in place to protect manufacturers from being forced into one-sided negotiations that would result in the provision of discounts much deeper than the 340B ceiling price.[18] Relaxing the existing prohibition would co-mingle the very different purchasing activities of 340B covered entities and GPOs in a way that would make product diversion and duplicate discounts inevitable.

It is also critical to note that providing exceptions to the GPO prohibition for DSH hospitals would greatly undermine the 340B Prime Vendor Program. If DSH hospitals are able to purchase drugs at 340B prices through GPOs, the nearly 3,800 community health centers enrolled in the 340B program[19] would likely be put at a competitive disadvantage. It is not only unjustifiable as a matter of policy, but also illogical to give DSH hospitals that are 340B covered entities the disproportionate advantage of collective bargaining power through a GPO when that power is not used to benefit the entire 340B community.

Additionally, PPTA has urged Congress, if it successfully expands the 340B program to cover inpatient drugs, to also expand the 340B Drug Pricing Program's GPO prohibition to covered drugs purchased by DSH hospitals at the 340B discount for inpatient use. As drafted,

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[14] *See, e.g.*, Press Release, CSL Behring, CSL Behring Receives FDA Approval of RiaSTAP(TM), First and Only Approved Treatment of Acute Bleeding Episodes in Patients with Congenital Fibrinogen Deficiency (Jan 16, 2009), http://news.prnewswire.com/ViewContent.aspx?ACCT=109&STORY=/www/story/01-16-2009/0004956268&EDATE (last visited May 26, 2009) (illustrating that despite the expectation to treat only 300 patients in the U.S. with a new plasma-derived Factor I therapy that recently received FDA approval, the manufacturer is filling a critical patient need by making the business decision to treat a patient population that, until now, had been untreated).

[15] *See* MRB REPORT, *supra* note 9, at 15.

[16] *Id.* at 41.

[17] *Id.*

[18] *See* 59 Fed. Reg. at 25113.

[19] *See* OFFICE OF PHARMACY AFFAIRS, HHS, LIST OF COVERED ENTITIES, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last visited Sept. 22, 2009).

the legislative language in these two bills would extend the statutory prohibition against DSH hospitals purchasing covered outpatient drugs from GPOs to the new covered entity types added by section 611(a) of the Senate bill and section 2501(a) of the House bill. These new covered entities and DSH hospitals would, however, be expressly permitted to purchase drugs for inpatient use through GPOs.

Because these bills would expand the 340B Program to include drugs purchased for inpatient use, which accounts for the majority of drug use in the healthcare system, PPTA has requested that Congress extend the GPO prohibition to cover both outpatient drugs and inpatient drugs. If such protection is not extended to cover drugs purchased for inpatient use, this legislation will greatly exceed the intended scope of the 340B Program because GPO negotiation will provide for inflated volumes of drugs to be purchased below the 340B ceiling price by a proliferation of covered entities.

In the alternative, PPTA has also proposed that Congress, at minimum, clarify that DSH hospitals may purchase covered drugs for inpatient use through a GPO purchasing agreement according to the terms of the applicable GPO agreement. Such clarification is necessary in order to preserve both the existing law and the integrity of the applicable GPO agreement.

PPTA and its members strongly support the intent behind and the preservation of the 340B Drug Pricing Program. Moreover, this industry is committed to ensuring that patients who require regular infusions or injections of lifesaving plasma protein therapies as part of their treatment regimen are able to obtain the therapy best suited for their individual needs without impediment. We recognize that improving the 340B Drug Pricing Program is an integral part health care reform, but we do have some objections to several existing proposals, including the relaxation of the DSH GPO prohibition in certain instances.

Thank you for your consideration. If you would like to discuss our views on this further, please contact Jay Greissing (jgreissing@pptaglobal.org) or Jon McKnight (jmcknight@pptaglobal.org) in our office at 202-789-3100.

Sincerely,

Julie Birkofer
Vice President, PPTA North America

Attachments