April 6, 2007
Reference No.: FASC07022a

Susan G. Queen, Ph.D.
Reports Clearance Officer
Health Resources and Services Administration
5600 Fishers Lane; Parklawn Building; Room 10-33
Rockville, MD 20857

Re: Proposed Project: Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center (HTC) Affiliates Having Factor Replacement Product (FRP) Programs

Dear Dr. Queen:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the Health Resources and Services Administration's ("HRSA") notice that was published in the *Federal Register* on February 6, 2007 regarding the proposed implementation of a reporting form for the Maternal and Children Health Bureau ("MCHB") of HRSA's National Hemophilia Program grantees and hemophilia treatment center ("HTC") affiliates having factor replacement product ("FRP") programs.' As an association deeply committed to the health and safety of the patients it serves, these comments on the proposed HTC reporting requirements are intended to ensure patients have full access to the complete range of life-saving, Food and Drug Administration approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") under the mandated drug discount program under Section 340B of the Public Health Service Act ("340B Program").[2]

PPTA is the association that represents the manufacturers of plasma protein therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80 percent of the plasma protein therapies for the United States market and more than 60 percent worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha- l-antitrypsin deficiency, also known as genetic emphysema.

[1]72 Fed. Reg. 5444 (Feb. 6, 2007).
[2]242 U.S.C. §256b (2007)

PPTA commends HRSA for proposing regulations that require MCHB HTC grantees and their affiliate HTCs having FRP programs to report on patient FRP program participation, FRP program revenue, FRP program costs, FRP program net income, and use of such income. This information will provide much needed transparency to the 340B Program. While much of the existing scrutiny of this program focuses on whether covered entities are actually receiving products at or below the mandated 340B discount price, HRSA must also examine the business practices of these covered entities, including HTCs. PPTA encourages HRSA to use the data obtained through this proposed reporting requirement for HTCs to increase its oversight of these covered entities in order to eliminate malefactors from profiting through product diversion, restricted patient access, and coercion.

MCHB Response:

MCHB acknowledges that PPTA is in favor of the proposed data collection. The purpose of the proposed data collection is to increase HRSA/MCHB oversight of the Hemophilia 340B covered entities including an assessment of the appropriateness of the Factor Replacement Product (FRP) Sales Program operations.

I. Background

Section 602 of the Veteran's Health Care Act of 1992 enacted the 340B Program, also known as the Public Health Service Drug Pricing Program. Under this statute, drug manufacturers must enter into an agreement with the Secretary of the Department of Health and Human Services to provide discounted prices on "covered outpatient drugs" to a list of "covered entities" in order for payment to be available under Medicaid or Medicare Part B for such outpatient drugs.[4] Such covered entities include any "comprehensive hemophilia diagnostic treatment centers" receiving a maternal and child health services block grant under Section 501(a) (2) of the Social Security Act.[5] According to the HRSA Web site, 85 of approximately 145 HTCs receiving MCHB grants are currently participating in the 340B Program.[6]

Although participation in the 340B Program is voluntary for entities that fall within the definition of a "covered entity", such participation is mandatory for all PPTA members that provide therapies to both Medicaid and Medicare Part B beneficiaries. Under the 340B Program, a manufacturer enters into a pharmaceutical pricing agreement with

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[3]72 Fed. Reg at 5444.
[4]42 U.S.C. § 1396r-8(a) (2007).
[5]42 U.S.C. § 256b(a)(4)(G). In the interest of improving the health of mothers and children, Section 501 (a)(2) of the SSA provides federal funding for grants, including funding for HTCs, relating to hemophilia without regard to age. 42 U.S.C. § 701(a)(2) (2007).
[6]See OFFICE OF PHARMACY AFFAIRS, U.S. DEP'T OF HEALTH & HUMAN SERV., LIST OF COVERED ENTITIES at http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last visited April 3, 2007).

HRSA in which it agrees to charge covered entities no more than the average manufacturer's price of the drug for the preceding quarter reduced by the Medicaid unit rebate amount for that same quarter.[7] This discount is also known as the 340B ceiling price.

According to statute, a covered entity may only obtain covered outpatient drugs at these discounted prices for those who qualify as patients of such covered entity.[8] Specifically, the 340B Program prohibits covered outpatient drugs purchased at the mandated drug discount price by a covered entity from being resold or otherwise transferred "to a person who is not a patient of the entity.[9] This "diversion" of products purchased at this 340B ceiling price occurs when covered entities attempt to artificially expand their patient population.

Although PPTA advocates for eligible patients to receive the intended cost savings of the 340B Program, in most instances, the covered entities fail to pass those savings to these eligible patients - a practice that seems to contradict at least part of the intent of the 340B Program. Because existing statute does not place a limitation on the price at which covered entities can sell covered drugs to their patients, such entities have the ability to earn substantial profits from purchasing pharmaceutical and biological products at the mandated drug discount price and reselling to their patients at a higher price. The expansion of the patient population of covered entities through product diversion significantly increases the opportunity for these entities to manipulate the program for their financial benefit. The hemophilia community and manufacturers of blood clotting factor share concerns regarding the use of this revenue by HTCs as well as the failure of HTCs to pass the savings of these discounted prices to their patients.

MCHB Response:

The proposed data collection is designed to provide information regarding how revenue is used.

As acknowledged by PPTA, the existing statute does not place a limitation on the price at which covered entities can sell covered drugs to their patients.

II. Utilization of Collected Data to Increase HRSA's Oversight of the 340B Drug Pricing Program

Both the Office of Inspector General ("OIG") at the Department of Health and Human Services ("HHS") and the Government Accountability Office ("GAO") have recently expressed concern that the 340B Program lacks transparency, which increases opportunities for potential fraud and abuse. Although the focus of this concern has been whether manufacturers are providing covered entities with pharmaceuticals and

[7] 42 U.S.C. §256b(a)(1). The current rebate amount for plasma protein therapies is 15.1 percent. See 42 U.S.C. § 1396r-8(c)(1)(B)
[8] 42 U.S.C. §256b(a)(5)(B).
[9] Id.

biologicals at the mandated drug discount price both the OIG and GAO recommended HRSA increase its oversight capabilities of the program.[10]PPTA is deeply troubled by the potential for fraud and abuse by covered entities and believes that requiring HTCs to report income information is an important first step in improving program oversight.

MCHB Response:

The proposed data collection does require HTCs to report program income generated by FRP Sales Programs .

Although existing statute and HRSA guidance prohibit parent hospitals of a covered entity from benefiting from the 340B Program, PPTA is concerned that the profits created by the dispensing of 340B discounted drugs by covered entities, such as HTCs, are often filtered back to a parent hospital which are not considered a covered entity for the purposes of this program.[11] PPTA strongly believes the patients should benefit from this program either directly from covered entities passing the savings of the covered drugs to the patient or by using the revenue to enhance the capabilities of the covered entity to serve patients. Increased transparency through income reporting of HTCs will ultimately benefit the hemophilia community if HRSA uses this data to enforce the requirements of the program.

MCHB Response:

HRSA/MCHB is in agreement that patients should benefit from FRP Sales Programs by savings being passed on to them or by using the income from the program to enhance the capabilities of the covered entity to serve patients, or both.

HRSA/MCHB plans to use the data from the proposed data collection to enforce the requirements of the program whenever the need for this is indicated by the data.

In addition, blood clotting factor are unique biological therapies that may not be used interchangeably by healthcare providers. PPTA is concerned that some HTCs may be putting profit ahead of patient safety. Increased oversight of the 340B Program by HRSA will ensure that patients have access to every blood clotting factor therapy in the market and that physicians are prescribing based on the safety and efficacy of the therapy for each individual patient. Without the transparency provided by the proposed reporting requirement, HTCs may have the ability limit patient access to certain therapies in the interest of profitability.

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[10]See OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERV., REVIEW OF 340B PRICES (July 2006); *Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Comm. On Oversight and Government Reform*, 110th Cong. (Feb. 9, 2007) (statement of John E. Dicken, Director, Health Care, Government Accountability Office).
11 42U.S.C. §256b(a)(6).

MCHB Response:

HRSA/MCHB acknowledges the PPTA concerns for patient safety. The data collection has not been designed to attempt to analyze any possible limitation being placed on patient use of any of the various blood clotting therapies. The HRSA/MCHB Hemophilia Grant Guidance requires each HTC to have a Patient Freedom of Choice Policy making it clear to patients that they may choose any blood clotting therapy appropriate for their particular bleeding disorder.

The proposed data collection does not include items regarding specific therapies. HRSA/MCHB does not have any information to support the concern that HTCs may be prescribing therapies that are not in the interest of patient safety.

III. Public Availability of Collected Data

In order to allow those in the hemophilia community to make informed decisions on which HTCs will best serve their individual needs, PPTA strongly believes the data collected by HRSA should be made available to the public. Because HTCs receive federal funding, it is inappropriate to allow HTCs to continue to operate in the shadows. By further enhancing the transparency of the program by making this data publicly available, HTC will no longer be insulated from public scrutiny.

***MCHB Response*:**

HRSA/MCHB acknowledges the PPTA recommendation that data from this proposed data collection be made available to the public, but public release of this information is subject to Freedom of Information Act determination. HRSA/MCHB will not release information to the public regarding individual grantees including individual HTCs in the absence of such determination. Any request for this data will be forwarded to the HRSA Freedom of Information Officer. MCHB will cooperate with the HRSA Freedom of Information Officer in providing any needed program information. A description of the Freedom of Information Act (FOIA) including HRSA and MCHB contacts can be found at: http://intranet.hrsa.gov/Communications/FOIA.asp

IV. Conclusion

PPTA is very encouraged by HRSA's proposal to require HTCs to provide quantitative information regarding participation, costs, revenue, and use of the income provided by the discounts obtained for blood clotting factor under the 340B Program. PPTA believes that such reporting by HTCs should be a condition to maintain federal funding from MCHB, and thus, participate in this program. The data obtained through this collection process can be used as an effective oversight tool. PPTA urges HRSA to formally adopt this reporting requirement and provide a thorough analysis of this data in order to use it as a basis for enforcement of program requirements. Moreover, it is also in the interest of patients that such data should be disclosed to the public.

MCHB Response:

The reporting of the information called for by the proposed data collection is required by the HRSA/MCHB Hemophilia Grant Guidance for continued HRSA funding and thereby for continued eligibility to participate in the 340B Program.

PPTA appreciates the opportunity to comment on this notice and looks forward to working with HRSA to ensure continued access to plasma protein therapies under the 340B Program. 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, PPTA North America