

REFERENCE NO: FASC10041

November 19, 2010

Bradford R. Lang
Public Health Analyst
Office of Pharmacy Affairs (OPA)
Heath Systems Bureau (HSB)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Room 10C-03
Rockville, MD 20857

BY ELECTRONIC DELIVERY

Re: Comments on the Civil Monetary Penalties

Dear Mr. Lang:

The Plasma Protein Therapeutics Association¹ (“PPTA”) appreciates this opportunity to respond to the advance notice of proposed rulemaking (“ANPRM”) and request for comments on the establishment of civil monetary penalties (“CMPs”) in the 340B Drug Pricing Program. The Health Resources and Services Administration (“HRSA”) published the ANPRM in the *Federal Register* on September 20, 2010.²

Subtitle B of title VII of the Patient Protection and Affordable Care Act (“PPACA”), Pub. L. No. 111-148, as amended by section 2302 of the Health Care and Education Reconciliation Act (“HCERA”) of 2010, Pub. L. No. 111-152, made significant changes to the 340B Drug Pricing Program. As the agency begins to implement these new provisions, PPTA appreciates the opportunity to work with the agency to help ensure the numerous regulations called for by the new law treat all program participants equally.

One of the most important changes to the program is the program integrity provisions added by section 7102(a) of the PPACA. At issue in the ANPRM are CMPs, which are a key component of the program integrity section. Specifically, the new 340B(d)(1)(B)(vi) of the Public Health Service Act (“PHSA”) calls for HRSA to establish through regulations a standard for assessing CMPs to a drug manufacturer that has a

¹ PPTA is the association that represents human plasma collection centers and the manufacturers of lifesaving, medicinal therapies, including albumin, alpha₁-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.” The manufacturer membership of PPTA in the United States includes Baxter, Biotest, Cangene, CSL Behring, Grifols, and Talecris.

² See 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57230 (Sept. 20, 2010).

signed pharmaceutical pricing agreement (“PPA”) for each “instance” such manufacturer “knowingly and intentionally” charges a 340B covered entity a price in excess of the 340B ceiling price for a particular covered outpatient drug. There is not a similar CMP provision in place for product diversion and duplicate discounts by the 340B covered entity. This inequity notwithstanding, PPTA hopes our comments today will lead to HRSA promulgating balanced CMP regulations.

Because the authority to assess CMPs hinges on whether there was a knowing and intentional manufacturer overcharge, it is counterintuitive for the agency to implement this provision without first clearly establishing regulations for the calculation and reporting of 340B ceiling prices and for manufacturer refunds in the event of an overcharge. As a matter of due process, it is equally necessary for manufacturers to have the capability to identify whether a covered entity was enrolled in the 340B program at the time of the alleged overcharge, so HRSA must provide manufacturers with the right to discover. Discovery will be most useful in this scenario if the agency also establishes a “single, universal, and standardized identification system by which each covered entity site can be identified” and implements processes for increased enforcement of covered entity requirements. Thus, prior to HRSA’s promulgation of a proposed rule on manufacturer CMPs, PPTA respectfully urges the agency to resolve these vital issues.

Although the U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) has suggested the adoption of CMPs is critical to deter manufacturer malfeasance,³ determining an instance of a manufacturer overcharge is complicated and first requires the agency to remove much of the program’s existing ambiguity through notice and comment rulemaking. Unless there are clear, enforceable program rules, the benefits of CMPs as an effective deterrent will not be realized.

Part I of this letter will demonstrate why it is imperative that the agency implement standards for ceiling price calculation, reporting, and refunds and for program oversight through federal regulations prior to implementing the regulations establishing CMPs. Part II of this letter will focus directly on issues related to CMPs, including existing models, procedures, and definitions.

I. HRSA Must Address Several Key Issues Prior to Promulgating a Proposed Rule Establishing Civil Monetary Penalties

A. Calculating and Reporting the 340B Ceiling Price

PPTA is concerned that unless HRSA, as required under the statute, expressly establishes “precisely defined standards and methodology” for manufacturers in their calculation and reporting of 340B ceiling prices the agency will inappropriately assess CMPs based on skewed data that will not accurately reflect whether an overcharge has

³ See OFFICE OF INSPECTOR GEN. (“OIG”), U.S. DEP’T OF HEALTH AND HUMAN SERVS. (“HHS”), DEFICIENCIES IN THE OVERSIGHT OF THE 340B DRUG PRICING PROGRAM 16 (2005).

occurred.⁴ As a result of the PPACA, manufacturers will have to re-execute their PPAs to agree to furnish HRSA with their quarterly 340B ceiling price calculations so that the agency may “verify the accuracy” of those calculations.⁵ This information will allow HRSA to compare its calculation of the 340B ceiling price for a covered outpatient drugs with the manufacturer’s calculation of such price for such drug and make inquiries if there are discrepancies.⁶

The 340B ceiling price for a covered outpatient drug is determined by subtracting the Medicaid unit rebate amount (“URA”) from the average manufacturer’s price (“AMP”) for the quarter that is two quarters prior to the quarter for which the ceiling price is being calculated (i.e., the Q1 AMP and URA will determine the Q3 340B ceiling price).⁷ The URA may not exceed the AMP.⁸

With the agency’s new statutory authority to develop a system to verify the 340B ceiling prices for covered outpatient drugs comes the responsibility to establish detailed procedures to ensure manufacturers have clear guidance on how to calculate the 340B ceiling price. The precise standards and methodology for accounting for variables, including late arriving pricing data, must be implemented prior to the establishment of standards for CMPs.

1. Routine Price Adjustments and the Manufacturer Refund

Section 7102(a) of the PPACA created a new provision calling for HRSA to establish a procedure for manufacturers to issue refunds to a 340B covered entity in the event that such manufacturer inadvertently sells to such covered entity a product in excess of the 340B ceiling price.⁹ The statute even expressly requires manufacturers to issue refunds to 340B covered entities in instances of routine pricing data adjustments lowering the 340B ceiling price.¹⁰ More specifically, under the refund proposal, if a manufacturer makes a routine adjustment for late arriving data for its AMP and best price (“BP”) calculations for a covered outpatient drug within the three-year period permitted by the Centers for Medicare & Medicaid Services (“CMS”),¹¹ but after such manufacturer has submitted the original information for that covered outpatient drug to CMS for the purpose of establishing its Medicaid outpatient drug rebate and 340B ceiling price, the manufacturer would be required to revise the original 340B ceiling

⁴ See 42 U.S.C. § 256b(d)(1)(B)(i)(I),

⁵ See 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 256b(d)(1)(B)(i).

⁶ See 42 U.S.C. § 256b(d)(1)(B)(i)(II), (IV).

⁷ See 42 U.S.C. § 256b(a)(1). The total URA equals the “Basic URA” plus the “Additional URA.” The “Basic URA” equals the greater of the AMP multiplied by the minimum Medicaid outpatient drug rebate percentage or the AMP minus BP. The “Additional URA” equals the quarterly AMP minus the quarterly CPI-U multiplied by the total of the baseline AMP (the AMP for the first quarter after the drug’s market data) divided by the baseline CPI-U (the CPI-U for the month prior to the first quarter after the drug’s market data).

⁸ See 42 U.S.C. § 1396r-8(c)(2)(D).

⁹ See 42 U.S.C. § 256b(d)(1)(B)(ii).

¹⁰ *Id.*

¹¹ See 42 C.F.R. § 447.510(b)(1).

price to reflect the revised AMP and BP figures, and issue a refund, no matter how small, where the ceiling price decreased. Manufacturers have not previously had a restatement obligation under the 340B program.¹²

The regulations implementing the standards for 340B ceiling price refunds must also include a *de minimis* threshold for routine price adjustments for late arriving AMP and BP data. Requiring manufacturers to issue nominal refunds to as many as 15,582 covered entity sites is an unnecessary administrative burden on all parties involved in the transaction, including the agency. PPTA believes manufacturers should not be obligated to issue a refund where the restatement of AMP or BP for the quarter results in a decrease that is less than two percent of the original ceiling price paid by the 340B covered entity. Such a threshold is reasonable when compared with similar thresholds used by the federal government.

2. Establishing Standards for a Manufacturer Overcharge: A Refusal to Sell Does Not Constitute an Overcharge

The regulations establishing the precise standards and methodology for 340B ceiling price calculations must establish standards for a manufacturer overcharge. In the ANPRM, HRSA expressed its desire to subject a manufacturer to CMPs in instances where it has refused to sell product to 340B covered entities at or below the 340B ceiling price.¹³ The agency went further in the ANPRM for the administrative dispute resolution process by suggesting that a manufacturer refusal to sell to a 340B covered entity at or below the 340B ceiling price forcing the covered entity to purchase it outside of the 340B program is evidence of a manufacturer overcharge.¹⁴ A manufacturer refusal to sell is, however, not an “overcharge,” so according to the plain language of the statute, such action is ineligible for both CMPs and the formal administrative dispute resolution process.¹⁵ Congress does not view a refusal to sell as an overcharge, but instead as discrimination against the 340B covered entity.

During the health care reform debate, Congress considered how to address instances of a manufacturer refusal to sell to 340B covered entity at or below the 340B ceiling price. Many public hospitals enrolled in 340B have complained about difficulties purchasing large quantities of certain drugs, including immune globulin, at the 340B discounted price, claiming manufacturers are refusing to make enough product available.¹⁶ After Congress spent more than a year evaluating these concerns, it determined that manufacturer refusals to sell fall under existing program guidance that

¹² See Letter from William L. Hickman, Director, Office of Medicaid Policy, Dep’t of Health & Human Servs., to Joel Bobula, Manager, Public Studies, Pharmaceutical Manufacturers Association (Feb. 25, 1993) (illustrating that a manufacturer under the 340B Program is only obligated to calculate the 340B ceiling price for a particular quarter by using available data at the time of the calculation – no further adjustments or recalculations are required).

¹³ See 75 Fed. Reg. at 57232

¹⁴ *Id.* at 57234.

¹⁵ See 42 U.S.C. § 256b(d)(1)(B)(vi)(III); 42 U.S.C. § 256b(d)(3)(A).

¹⁶ See, e.g., PUBLIC HOSPITAL PHARMACY COALITION, ACCESS TO IVIG BY SAFETY NET HOSPITALS PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM (2006).

prohibits manufacturer discrimination against 340B covered entities and codified this guidance by including the “must offer” provision in the PPACA.

Specifically, House Committee on Energy and Commerce Chairman Henry Waxman stated that the “must offer” provision is merely a codification of HRSA’s “current approach” of prohibiting manufacturers from “discriminat[ing] against or refus[ing] to sell to 340B [covered] entities.”¹⁷ Chairman Waxman is referring to agency guidance that is referred to as HRSA’s “non-discrimination” guidance:

Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective. Manufacturers must not place limitations on transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount drug program.¹⁸

According to Congress, the “must offer” provision will not create any new obligations for manufacturers beyond a re-execution of a PPA to expressly include this as a term of the agreement. The U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) had previously criticized HRSA for its approach to program enforcement, blaming many of its shortcomings on the agency’s lack of enforcement authority.¹⁹ The statutory provision will finally afford the agency with the ability to enforce the non-discrimination guidance, just not through CMPs or administrative dispute resolution since a refusal to sell is not an overcharge. If Congress intended a “refusal to sell” to be subject to CMPs or administrative dispute resolution, it would have expressly stated that to be the case in this recent overhaul of the 340B Drug Pricing Program or its accompanying legislative history, but Congress did not.

HRSA must issue guidance regarding appropriate and permissible approaches to those situations where drug manufacturers are unable to fill a 340B covered entity’s order in its entirety because the order is excessive, the product ordered has supply issues, or both. Such a scenario should be evaluated by the agency on a case by case, or therapeutic class by therapeutic class basis, but it certainly should never be considered a manufacturer overcharge, and most often, it is unlikely to be construed as a manufacturer refusal to sell.

With regard to excessive orders, current manufacturer audit guidelines clearly state that “[s]ignificant changes in quantities of specific drugs ordered by a covered entity...may be a basis for establishing reasonable cause” for a manufacture to bring a dispute resolution action.²⁰ Congress solidified their opposition to stockpiling in a

¹⁷ See 111 CONG. REC H4170 (May 28, 2010) (statement of Rep. Waxman).

¹⁸ Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

¹⁹ See DEFICIENCIES IN THE OVERSIGHT OF THE 340B DRUG PRICING PROGRAM, *supra* note 3.

²⁰ Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed Reg. 65406 (Dec. 12, 1997).

colloquy during the final House Committee on Energy and Commerce mark up of the health care reform legislation, which included the “must offer” provision. Chairman Waxman and Representative Joe Barton (R-TX), who was the committee’s ranking member, agreed that they intend the 340B program to “limit the purchase of [drugs with supply issues] to the actual need of the hospital to dispense those drugs.”²¹ These same lawmakers also agreed that they do not intend the “must offer” provision to result in putting “340B covered entities automatically...at the front of the line,” to purchase drugs with supply issues but do intend for equal treatment.²² Waxman reaffirmed this proposition on the House Floor on May 28, 2010.²³

PPTA strongly agrees with Congress’ handling of 340B covered entity concerns regarding perceived manufacturer refusal to sell product. Because there are so many issues involved with product allocation and non-discrimination, the reinforcement of existing program non-discrimination guidance to better allow the agency to evaluate each case on its merits was the most balanced approach to address these concerns. We urge the agency to do this carefully so as not to interfere with the ability of a manufacturer to contract with its customers on a non-discriminatory basis. It is in the best interests of patients to allow manufacturers to remain able to freely allocate product in a non-discriminatory manner, consistent with agency guidance.

The issues surrounding 340B ceiling price restatements, the need for a materiality standard, and the suggestion by HRSA that a “refusal to sell” should constitute a manufacturer “overcharge” has made it necessary for HRSA to expressly define “overcharge” as follows:

A manufacturer ‘overcharge’ occurs when the price paid for a covered outpatient drug by a 340B covered entity exceeds the 340B ceiling price for that drug. If the overcharge was a direct result of lagged average manufacturer price and best price data, the price paid must have exceeded the 340B ceiling price by an amount greater than two percent.

The certainty provided by this definition of overcharge will further the goal of improved program integrity by allowing the agency to appropriately punish true malefactors through CMPs.

²¹ See *Supplemental Markup: Amendments to H.R. 3200, the America’s Affordable Health Choices Act of 2009 Before the House Comm. on Energy and Commerce*, 111th Cong (Sept. 23, 2009) (colloquy between Rep. Waxman and Rep. Barton), available at <http://energycommerce.edgeboss.net/wmedia/energycommerce/2009.09.23.fc.1.wvx> (last visited Nov. 12, 2010).

²² *Id.*

²³ See 111 CONG. REC H4170 (May 28, 2010) (statement of Rep. Waxman).

B. Manufacturer Discovery Rights Are Critical

The 340B statute clearly authorizes HRSA to seek CMPs against a drug manufacturer for “knowingly and intentionally [overcharging] a covered entity”²⁴ and permits 340B covered entities to assert a claim of an overcharge against a manufacturer in an administrative dispute resolution process.²⁵ While the agency now has the necessary tools to verify the accuracy of 340B ceiling prices,²⁶ many instances of overcharges that result in the assessment of CMPs will be a direct result of a 340B covered entity initiating the claim by notifying HRSA or through the administrative dispute resolution process. Manufacturers must have the ability to offer an affirmative defense, such as lack of standing, which can often be established through the discovery process.²⁷

Although not expressly stated in the new law, HRSA has the authority to provide for manufacturer-initiated discovery because the statute does not prohibit that discovery and, consequently, the issue was left to HRSA’s regulatory authority in implementing the statute.²⁸ Allowing discovery by manufacturers would further the interests of the 340B Drug Pricing Program because it would ensure that the facts are fully developed (e.g., that the entity seeking to raise an issue is a 340B covered entity, that the applicable covered entities have met their obligations under the program, etc.). HRSA should make the discovery permitted bi-lateral, because unilateral discovery would raise disturbing and avoidable due process issues.²⁹ If the manufacturer can prove the covered entity is not eligible for the 340B Drug Pricing Program, the courts have held that the 340B covered entity does not have standing to bring a claim asserting a manufacturer overcharge.³⁰

Many important cornerstones of the 340B Drug Pricing Program must be addressed through notice and comment rulemaking prior to HRSA’s promulgation of proposed rules implementing CMPs. Under the statute, HRSA must remove 340B covered entities from the program if their disproportionate share adjustment percentage

²⁴ 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

²⁵ See 42 U.S.C. § 256b(d)(3)(A).

²⁶ See 42 U.S.C. § 256b(d)(1)(B)(i).

²⁷ While it is true that manufacturers are permitted to audit the 340B covered entities, this right to audit is at great expense to the manufacturer, primarily because of the requirement that the manufacturer retain an independent third party accountant to conduct the audit. See 61 Fed. Reg. at 65409. Moreover, this right to audit is limited to examine the 340B covered entity’s compliance with the prohibitions against product diversion and duplicate discounts. See 42 U.S.C. § 256b(a)(5)(C).

²⁸ See 42 U.S.C. § 256b(d)(1)(B)(vi)(I).

²⁹ See U.S. CONST. amend, V; see, e.g., *Bolling vs. Sharpe*, 347 U.S. 497, 500 (1954) (suggesting that if HRSA does not provide for manufacturer-initiated discovery but does provide for covered entity-initiated discovery and this distinction “is not reasonably related any proper governmental objective,” the Court may find such actions to be “an arbitrary deprivation of [a manufacturer’s] liberty in violation of the Due Process Clause.”

³⁰ See *University Med. Ctr. vs. Shalala*, 5 F. Supp. 2d 4 (D.D.C. 1998), *aff’d* 173 F.3d 438 (D.C. Cir. 1999).

falls below the 11.75% for the most recent reporting period,³¹ for violating the DSH GPO prohibition³² and for “systematic and egregious” product diversion that was “knowing and intentional.”³³ In order for the discovery to be useful for a manufacturer to raise an affirmative defense, HRSA must establish a “single, universal, standardized identification system” for 340B covered entities, establish protocols through notice and comment rulemaking for bringing enforcement actions against DSH hospitals that are enrolled in 340B and have falsely certified they do not participate in a GPO, and re-issue through notice and comment rulemaking the agency’s proposed revised definition of a “patient.”

1. Single, Universal, Standardized Identification System for 340B Covered Entities

The HRSA website has a database of 340B covered entities and 340B contract pharmacies. According to the database, there are 15,582 covered entity sites, with 50 additional hospital sites enrolling in the program January 1, 2011. There are also 7,227 contract pharmacy sites. Section 7102(a) of the PPACA provided the agency with the authority to establish a “single, universal, and standardized identification system by which each covered entity site can be identified by” the agency, program participants, and authorized distributors.³⁴ PPTA would urge the agency to also promulgate this provision through notice and comment rulemaking prior to the promulgation of the CMP proposed rule. In doing so, PPTA would further urge a formal overhaul of this database to better validate 340B covered entity eligibility.

HRSA must establish a process to remove from the database those entities that no longer meet the statutory definition of a covered entity. PPTA believes the plain language of the 340B statute is very clear – the agency must remove from the program a DSH hospital whose disproportionate share adjustment fails to meet the 11.75 threshold, a DSH hospital who use GPOs to purchase drugs at or below the 340B ceiling price, and any 340B covered entity that engaged in “systematic and egregious” product diversion that was “knowing and intentional.” The standardized identification system will not only allow manufacturers to track entities that are not eligible for the 340B discounts, but also ensure 340B covered entities who are entitled to 340B discounts are receiving them.

2. Enforcement of the DSH GPO Prohibition

PPTA strongly supports the existing statutory prohibition against DSH hospitals that qualify as 340B covered entities from obtaining covered outpatient drugs through a group purchasing organization.³⁵ Any 340B DSH attempting such arrangements with a

³¹ See 42 U.S.C. § 256b(a)(4)(L)(ii).

³² See 42 U.S.C. § 256b(a)(4)(L)(iii).

³³ See 42 U.S.C. § 256b(d)(2)(B)(v)(II).

³⁴ See 42 U.S.C. § 256b(d)(2)(B)(iv).

³⁵ See 42 U.S.C. § 256b(4)(L)(iii).

GPO will no longer qualify as a covered entity under the statute.³⁶ “In other words, a [DSH hospital can] not participate in two drug price-reducing arrangements at the same time, but [must instead] choose between the price negotiated under the 340B program and prices it could obtain as part of a group purchasing arrangement.”³⁷

In making the decision to prohibit 340B DSH hospitals from using GPOs to purchase covered outpatient drugs, Congress unequivocally indicated that although it did not “intend to disturb [such existing] arrangements or to require the withdrawal of these hospitals from these organizations or arrangements,” hospitals with such arrangements are not eligible for 340B pricing.³⁸ For example, a federal court affirmed HRSA’s decision to deny a request to retroactively enroll (and thus make it eligible for retroactive 340B discounts) a DSH hospital that argued it had been effectively forced into continuing a GPO arrangement because it mistakenly believed its disproportionate share adjustment for the period in question was less than 11.75%.³⁹ Again, the disproportionate share adjustment percentage for a DSH hospital must exceed 11.75% in order for it to be eligible to enroll in the 340B Drug Pricing Program.⁴⁰

The DSH GPO prohibition serves an important policy objective. HRSA has suggested that the intent behind the DSH GPO prohibition is to limit one-sided negotiations that would likely result in 340B DSH hospitals receiving discounts much deeper than the 340B ceiling price.⁴¹ Congress and HRSA have previously resisted providing DSH hospitals with this collective bargaining advantage.⁴² Additionally, one court even claimed a DSH hospital obtaining both 340B pricing and GPO pricing was “double dipping” because it viewed a scenario in which the DSH hospital simultaneously benefitted from “two drug price-reducing mechanisms” as identical to a 340B covered entity receiving a duplicate discount for a covered outpatient drug.⁴³

Some DSH hospitals have admitted illegally purchasing IVIG through GPOs at the higher GPO price in order to satisfy alleged demand.⁴⁴ HRSA, however, has never brought an enforcement action against a 340B DSH hospital for using a GPO. Instead,

³⁶ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994); see, e.g., *University Med. Ctr. vs. Shalala*, 5 F. Supp. 2d 4 (D.D.C. 1998).

³⁷ *University Med. Ctr.*, 5 F. Supp. 2d at 6.

³⁸ See H.R. REP. NO. 102-384, PART 2 (1992).

³⁹ See *University Med. Ctr.*, 5 F. Supp. 2d at 6-8.

⁴⁰ See 42 U.S.C. § 256b(4)(L)(ii).

⁴¹ See 59 Fed. Reg. at 25113 (distinguishing purchasing agents from GPOs for the purpose of the DSH GPO prohibition, which suggests the intent behind the prohibition is to prevent 340B DSH hospitals from using an additional advantage of collective bargaining power to obtain drugs at sub-340B prices, instead of negotiating their own 340B pricing).

⁴² See, e.g., 59 Fed. Reg. at 25111 (describing HRSA’s clear opinion that agency enforcement against manufacturer non-compliance is more appropriate than relaxing the existing prohibition against 340B hospitals using GPOs for the purchase of covered outpatient drugs).

⁴³ See *University Med. Ctr. vs. Shalala*, 5 F. Supp. 2d 4, 8 (D.D.C. 1998).

⁴⁴ See *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 109th Cong. 62-63 (2005) (testimony of William von Oehsen).

the agency has merely opposed 340B DSH hospitals “disregarding the statutory GPO provisions” in these instances.⁴⁵ For more than 15 years, HRSA has “communicated its willingness to assist entities when there are problems with accessing [340B] pricing.”⁴⁶ The most recent demonstration of this willingness to address such concerns is evidenced by the agency’s recent publishing of a question and answer document, “IVIG 340B Pricing and GPO.”⁴⁷

Whether a 340B covered entity is actually eligible to participate in the program is a fundamental issue affecting program obligations for all parties, including the ability for a 340B covered entity to assert standing in a claim of manufacturer overcharge. Therefore, PPTA urges HRSA to demonstrate that it will enforce the law and remove from the master list of covered entities those DSH hospitals that are illegally purchasing products through GPOs. Such a demonstration must occur prior to the agency’s promulgation of a proposed rule for CMPs, so that the agency is not attempting to assess CMP claims against a manufacturer for overcharging an entity that is not eligible to participate in the 340B program.

3. Definition of a Patient

Now that HRSA has express authority to remove from the 340B program those 340B covered entities that have engaged in “systematic and egregious” product diversion that was “knowing and intentional,” PPTA urges HRSA to finalize an earlier proposal that further clarified who may qualify as a patient of the covered entity for the purpose of the 340B discount.⁴⁸

II. PPTA Comments on the ANPRN

A. Existing Models

HRSA described several models it is reviewing, including the OIG’s recommendation that “HRSA consider as a model CMS’s statutory authority to enforce the Medicaid rebate program, pursuant to § 1927(b)(3)(C)(i) of the Social Security Act,

⁴⁵ 59 Fed. Reg. at 25111.

⁴⁶ *Id.*

⁴⁷ See HEALTH RESOURCES & SERVICES ADMIN, U.S. DEP’T OF HEALTH & HUMAN SERVS., IVIG 340B PRICING AND GPO, http://answers.hrsa.gov/cgi-bin/hrsa.cfg/php/enduser/std_adp.php?p_faqid=1766&p_created=1251746327&p_sid=8Lzal2lj&p_accessibility=0&p_redirect=&p_lva=101&p_sp=cF9zcmNoPTEmcF9zb3J0X2J5PSZwX2dyaWRzb3J0PSZwX3Jv d19jbnQ9MSwxJnBfcHJvZHM9JnBfY2F0cz00OSZwX3B2PSZwX2N2PTEuNDkmcF9zZWYyY2hfdHlwZT1hbnN3ZXJzLnNIYXJjaF9ubCZwX3BhZ2U9MSZwX3NIYXJjaF90ZXh0PUIWSUcl&p_li=&p_topview=1 (last visited Nov. 12, 2010).

⁴⁸ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Definition of “Patient”, 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007). HRSA first promulgated this definition nearly four years after President George Bush signed into law the legislation creating the 340B Program. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156, 55156-55157 (Oct. 24, 1996) (describing its rationale for a definition flexible enough not to exclude eligible patients).

and seek similar authorities with respect to enforcement of the 340B Program.”⁴⁹ After reviewing the Medicaid statute and reviewing the ANPRN, it is unclear what standards HRSA would be able to use in assessing its CMPs. More specifically, because the penalties under the Medicaid statute are assessed based on manufacturer failure to file its pricing data with CMS in a timely manner, rather than failing to provide a state Medicaid agency its rebate on covered outpatient drugs, PPTA believes the Medicaid statute is not the best model for HRSA. Under the plain language of the 340B statute, it would be inappropriate for HRSA to seek authority to increase penalties in a punitive manner as CMS does for noncompliance.⁵⁰ Additionally, HRSA already has the authority to remove program participants – covered entities and manufacturers – from the 340B Drug Pricing Program.⁵¹

The regulations affording the HHS OIG to assess CMPs is a more useful model.⁵² While, again, HRSA has no authority to expand the basis for CMPs, increase the maximum fine, or assess punitive damages against the drug manufacturers, it could develop a threshold where CMPs may be an appropriate remedy, establish a standard for mitigating circumstances that would allow the agency to limit or waive the CMPs, implement a procedure for removing malefactors from the 340B Drug Pricing Program, and set forth a statute of limitations for assessing CMPs.

B. Threshold Requirements

PPTA agrees with HRSA that a decision to initiate a CMP process with a manufacturer should be determined by “the frequency of the overcharge, the compliance history of the manufacturer in question, and the number of covered entities affected.” We also agree that the amount of the overcharge should be considered, but only as a percent of the total charge. Manufacturers of expensive products would be unfairly penalized, otherwise.

Before notifying the manufacturer that it is initiating a process to seek CMPs, however, the agency must first determine whether the overcharge meets the threshold of “knowingly and intentionally.” PPTA would dispute that a manufacturer’s “refusal to sell” to a covered entity at or below the 340B ceiling price is evidence of a manufacturer “knowingly and intentionally” overcharging the 340B covered entity. As discussed above, we believe a “refusal to sell” allegation is actually an allegation that the manufacturer’s distribution system is discriminatory and violates program guidance. There is no statutory basis for imposing CMPs to resolve such claims.

⁴⁹ See DEFICIENCIES IN THE OVERSIGHT OF THE 340B DRUG PRICING PROGRAM, *supra* note 3, at 22.

⁵⁰ See 42 U.S.C. § 1396r-8(b)(3)(C)(i).

⁵¹ See 42 U.S.C. § 256b(d)(2)(B)(v)(II) (stating that HRSA can remove from the program covered entities that have engaged in “systematic and egregious” product diversion that was “knowing and intentional.”); 61 Fed. Reg. at 65412 (describing its authority to terminate a manufacturer’s PPA to expel it from the program).

⁵² See 42 C.F.R. § 1003 (2009).

Additionally, just as PPTA believes it is important for HRSA to develop standards to evaluate when CMPs are an appropriate remedy, we also would suggest that it is critical to establish a standard for mitigating circumstances that would allow the agency to limit or waive the CMPs. For instance, HRSA must also consider whether: (1) an overcharge is *de minimis*; (2) the manufacturer took timely corrective action; (3) when considered in proportion to the manufacturer's sales of all covered drugs to all covered entities, the occurrence rate for an overcharge is small; and (4) the legal basis for asserting that an overcharge occurred had previously been established by statute, regulation, or published agency guidance. As discussed in Part I of this letter, there are several areas in which HRSA must issue regulations before HRSA or a 340B covered entity could attempt to assert an overcharge.

C. Administrative Procedures

The regulations should require HRSA to issue a Notice of Assessment of Civil Monetary Penalties alleging the instance or instances of a manufacturer overcharge of the 340B covered entities. The preferred venue for a 340B covered entity to assert such a claim is through the formal administrative dispute resolution process, which was also created under the PPACA. Prior to the agency issuing such a notice, the fact finder, which could potentially be the agency in a binding arbitration process, must first determine if the 340B covered entity is lawfully enrolled in the 340B program to give the covered entity the appropriate standing to allege such a claim. If the covered entity does have standing, HRSA must then determine if an actual overcharge occurred. As suggested by PPTA in Part I.A of this letter, for the purpose of the 340B program:

A manufacturer 'overcharge' occurs when the price paid for a covered outpatient drug by a 340B covered entity exceeds the 340B ceiling price for that drug. If the overcharge was a direct result of lagged average manufacturer price and best price data, the price paid must have exceeded the 340B ceiling price by an amount greater than two percent.

If an overcharge did occur and was done "knowingly and intentionally," the agency may then evaluate any aggravating and mitigating circumstances to determine if CMPs are an appropriate remedy in each instance of an alleged overcharge, and if the full amount of \$5000 authorized by the statute is appropriate in each instance.

The agency should establish procedural standards for the timely notification of the manufacturer by the agency. A Notice of Assessment of Civil Monetary Penalty shall include: (1) a description of the facts and conduct demonstrating that there was an overcharge of a 340B covered entity and that overcharge meets the knowing and intentional threshold; (2) an explanation as to why the stated violation justifies the CMP; (3) the amount of the proposed CMP; (4) a description of all factors that HRSA considered when determining the amount of the proposed penalty; and (5) instructions for the manufacturer's response to the notice, including the right to a hearing, deadline for response, and consequences for failing to respond in a timely manner. The notice

should be served in a manner consistent with Rule 4 of the Federal Rules of Civil Procedure.

In demonstrating an overcharge occurred, the notice must specify the ceiling price that the agency has identified as the correct 340B ceiling price for that covered outpatient drug and detail the steps it took to arrive at that calculation, including the calculation of the URA. The agency should state the mathematic equations it used and other the relevant information. The notice must also identify the 340B covered entity subject to any alleged overcharge and certify that such entity is indeed eligible for the 340B discount for the specified covered outpatient drug. Confirmation of whether the drug is subject to the 340B ceiling price is appropriate because of the new orphan drug exclusion for certain covered entities.⁵³

The established procedure must give the manufacturer adequate opportunity to review and respond to the notice, review the evidence of an overcharge, including any documents and records, and begin efforts to resolve the issue. The rule should expressly describe the manufacturer's right to a hearing, an appeals process, and judicial review.

D. Hearings

The rule should provide a fair, impartial hearing as a matter of manufacturer right. Civil penalty hearings, across agencies, typically take place before an administrative law judge ("ALJ") or presiding officer. If HRSA instead opts to propose a decision making body comprised of multiple individuals, PPTA requests that any representation for covered entities be equally balanced with representation for manufacturers. An ALJ, or any other individual involved as part of a decision-making body, must be trained in the 340B program's requirements and demonstrate a strong understanding of the statute, regulations, and program guidance.

As stated in Part I.B of this letter, a manufacturer's right to discover is critical to their ability to offer an affirmative defense. The rule must expressly provide for third-party discovery prior to a hearing, since only HRSA and the manufacturer will be parties to the hearing. In addition to the right to discover from 340B covered entities, they must have the right to compel discovery from wholesalers and contract pharmacies, both of which play integral roles in the success of the 340B program.

E. Appeals Process

A number of CMP mechanisms provide for interlocutory appeals in certain circumstances. The FDA regulations provide for an interlocutory appeal if the officer presiding over a hearing "certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or

⁵³ See 42 U.S.C. § 256b(e).

substantial harm to the public interest.”⁵⁴ FDA also authorizes the filing of a brief on the interlocutory appeal issues.⁵⁵

Permitting interlocutory appeals in situations presenting a controlling question of law or policy as to which substantial grounds exist for a difference of opinion encourages efficiency and helps to ensure fairness in hearings. Neither the agency nor parties should bear the costs of a full-fledged hearing where the ALJ agrees that the legal basis for the CMP itself or a particular ruling underlying the hearing is a novel question of law lacking a clear answer.

F. Definitions

The purpose of the CMP provision is not to assess a manufacturer with punitive damages, but to provide a deterrent to incorrect 340B ceiling price reporting and to encourage corrective actions. Additionally, because of the threshold of “knowingly and intentionally,” the term “instance” should only include actions that can be directly attributed to a drug manufacturer. If “instance” is broadly defined as “per unit of a drug and/or per commercial transaction,” the penalties will be punitive at \$5,000 per instance. In order to ensure that CMPs are not excessive in relation to the remedial purpose of the provision, the term “instance” should be defined as follows:

An ‘instance’ of a manufacturer overcharge occurs (1) when furnishing the agency with its quarterly 340B ceiling price report, a manufacturer reports for a covered outpatient drug an incorrect 340B ceiling price that results in an ‘overcharge’ and (2) a manufacturer fails to take corrective action within a certain period, generally one year after the manufacturer has demonstrated knowledge of an overcharge for the covered outpatient drug. If the overcharge was a direct result of lagged average manufacturer price and best price data, a manufacturer must take corrective action within a four year period following the date of the originally reported 340B ceiling price for the covered outpatient drug.

Again, PPTA proposes the following definition for an overcharge:

A manufacturer ‘overcharge’ occurs when the price paid for a covered outpatient drug by a 340B covered entity exceeds the 340B ceiling price for that drug by an amount greater than two percent. If the overcharge was a direct result of lagged average manufacturer price and best price data, the price paid must have exceeded the 340B ceiling price by an amount greater than two percent.

⁵⁴ 21 C.F.R. § 17.18(b).

⁵⁵ *Id.* § 17.18(c).

These two definitions – “overcharge” and “instance” of an overcharge – will work together to accomplish Congress’ goal and satisfy the HHS OIG’s recommendation of broadening HRSA’s enforcement power. In establishing the definition of “instance,” it is especially critical that HRSA make a distinction between overcharges caused by routine price adjustments for late arriving pricing data and data that were incorrectly reported because of an error. On its face, an overcharge resulting from lagged data will not create CMP liability because it would fail to meet the requisite “knowingly and intentionally” threshold.⁵⁶ If, however, after restating its 340B ceiling price, a manufacturer failed to issue a refund if a refund is necessary, the lack of corrective action would meet this threshold. Again, because existing regulations governing routine adjustment for late arriving AMP and BP data for a covered outpatient drug allow three years for an adjustment,⁵⁷ providing the manufacturer one additional year to make any corrective actions, such as the issuance of a refund or a credit to the 340B covered entity is appropriate. If a manufacturer fails to take corrective action within this time frame, it would be a *per se* knowing and intentional overcharge of the 340B covered entity.

PPTA is concerned, however, that HRSA is attempting to re-define the threshold of “knowingly and intentionally” beyond the intended meaning. HRSA has stated that “knowledge of [individual] employees or agents of the manufacturer may be attributed to the company as a whole.”⁵⁸ The agency has taken this premise to suggest that a fact finder could infer that even if no single individual employee or agent had knowledge of all the necessary elements to demonstrate an “overcharge,” the manufacturer is guilty of “knowingly and intentionally” overcharging the covered entity if an overcharge occurs.⁵⁹ The agency suggests a similar inference could be made merely based on a repeated miscalculation by the manufacturer of the 340B ceiling price for a particular covered outpatient drug.⁶⁰ While PPTA understands manufacturers must be held accountable in instances where an overcharge could have been avoided, negligence does not meet the “knowingly and intentionally” threshold. Additionally, PPTA does not believe the knowledge and intent of an authorized distributor should have bearing on whether a manufacturer should be liable for CMPs. For the purpose of this provision, the standard for “knowingly and intentionally” should only be used to describe a specific intent to overcharge a customer that the manufacturer knows is a 340B covered entity.

G. Computation of Penalties

PPTA provides its views on penalty computation in Part II.C of the letter.

⁵⁶ See 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

⁵⁷ See 42 C.F.R. § 447.510(b)(1).

⁵⁸ See 75 Fed. Reg at 57232

⁵⁹ *Id.*

⁶⁰ *Id.*

H. Payment of Penalties

PPTA agrees that HRSA should establish methods for transferring any penalty assessed to the government. We also support the ability of HRSA to bring a civil action if the manufacturer has failed to pay the CMP in a timely manner, which should be defined as a minimum of 60 days following the final adjudication of a CMP claim. PPTA is concerned that HRSA is suggesting interest should be paid on CMPs. If the agency is referring to interest paid on the refund owed to the 340B covered entity, such interest is probably appropriate, but, in the case of an overcharge that was a direct result of lagged AMP and BP data, the interest should not begin accruing until the date the manufacturer provided its final 340B restatement for the covered outpatient drug for the quarter during which the overcharge was alleged to have occurred. Again, this beginning point for the interest accrual is appropriate because existing regulations governing routine adjustment for late arriving AMP and BP data for a covered outpatient drug allow three years for an adjustment.⁶¹

IV. Conclusion

The PPACA, as amended by the HCERA, made many significant changes to the 340B Drug Pricing Program. Before HRSA promulgates regulations implementing the CMPs and the formal administrative dispute resolution process, it must first address many issues involving the 340B ceiling price, including a precise determination of an “overcharge,” as well as 340B covered entity eligibility. Thank you for the opportunity to comment. Please contact Jay Greissing or Jon McKnight if you would like to further discuss our comments.

Sincerely,



Julie Birkofer
Senior Vice President, PPTA North America

⁶¹ See 42 C.F.R. § 447.510(b)(1).