

REFERENCE NO: FASC10040

November 19, 2010

Ms. Dorcas Ann Taylor
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 Administrative Dispute Resolution Process

Dear Ms. Taylor:

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 340B Drug Pricing Program administrative dispute resolution (“ADR”) process. 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 is the creation of a formal ADR process, which is a key component of the program integrity section. Specifically, the new 340B(d)(3) of the Public Health Service Act (“PHSA”) calls for HRSA to establish through regulations a formal ADR process to address

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 Administrative Dispute Resolution Process, 75 Fed. Reg. 57233 (Sept. 20, 2010).

manufacturer “overcharges” of 340B covered entities, and product diversion and duplicate discounts by 340B covered entities.

Because the ADR process specifically addresses disputes involving these three issues, it would be appropriate for the agency to first promulgate regulations establishing the standards and methodology for calculating the 340B ceiling price and standards for manufacturer refunds, as well as finalize its proposed revisions to the definition of a patient, and revisit its duplicate discount guidance to address the significant Medicaid expansion in the PPACA, as amended by the HCERA. 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 the ADR process, PPTA respectfully urges the agency to resolve these essential issues.

PPTA looks forward to working with HRSA to adequately address our concerns about procedural fairness and due process to create a balanced and equitable ADR process, which is vital to achieving the goal of improved program integrity. We are particularly interested in resolving the issues that could create an imbalanced ADR process:

- A manufacturer audit is a prerequisite for a manufacturer to bring an ADR claim, while 340B covered entities have no similar barrier to participation.
- The right to discovery for 340B covered entities is enumerated, while a similar right for manufacturers is absent; and
- A third-party has the right to bring claims on behalf of individual or multiple 340B covered entities without having safeguards in place that ensure that covered entities comply with necessary confidentiality, discovery, and other administrative requirements of the ADR program.

The implementation of the ADR process will only be effective if the agency clarifies existing ambiguities through formal rulemaking. The agency will benefit also by having formal regulations established, which will ease management and enforcement of the 340B program. Unless there are clear, enforceable program rules, the benefits of an ADR process – a streamlined, cost-efficient alternative to litigation – will not be realized.³

³ See *Developments in the Law – The Paths of Civil Litigation: VI. ADR, the Judiciary, and Justice: Coming to Terms with the Alternatives*, 113 HARVARD L. REV. 1851, 1853 (2000) (suggesting that if there is a question of law, an alternative dispute resolution process is not an appropriate forum).

I. Administrative Procedures

Just as under the existing ADR process, prior to initiating the formal ADR process, the parties involved should be required to make a *bona fide* effort to resolve the dispute.⁴ If the dispute is not resolved after such an effort, a party may submit a written request to the agency to review the dispute. All matters related to the dispute should remain confidential throughout and after the conclusion of the dispute resolution process. Moreover, the agency should require all parties—including covered entities represented by a third party—to enter into written agreements clearly describing the confidentiality requirement.

PPTA also supports the current guidance that requires the submission to “set forth specific facts showing that there is a genuine and substantial issue of material fact in dispute that requires a review.”⁵ More specifically, PPTA believes the written submission initiating the process must set forth specific and concrete facts to support the allegations of manufacturer overcharge, product diversion, or duplicate discounts, including the date, product, and circumstances. Additionally, the manufacturer’s submission must include the manufacturer audit report, which is discussed in more detail in Part IX. HRSA should establish a formal process for the respondent to move to dismiss the allegations once the agency has provided notice of the dispute.

After the agency has received the submission, an ad hoc panel of three HRSA employees, including a chairperson from the Office of Pharmacy Affairs, shall be appointed to determine whether there is a question of fact that requires a resolution. Such a requirement would also be consistent with the existing ADR guidance.⁶ If the agency determines there is enough evidence to proceed, the parties should then have a choice of whether to use mediation or arbitration, since there are numerous methods of alternative dispute resolution.⁷ If the parties agree to mediation, the agency would provide a trained, neutral third party to help negotiate a resolution to the dispute through joint and private sessions with the parties. If, however, not all parties agree to mediation or if the mediation fails to resolve the dispute, the parties would begin the process of binding arbitration

II. Existing Models

Beyond some of the basic procedural components we identified in Part I, PPTA respectfully disagrees with HRSA’s comments in the ANPRM that the existing informal ADR serves as a good model from which to base the new formal ADR process. HRSA established the existing model through agency guidance because of its interest in

⁴ See Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406, 65412 (Dec. 12, 1996).

⁵ *Id.*

⁶ *Id.*

⁷ See, e.g., Matthew Parrott, *Note: Is Compulsory Court-Annexed Medical Malpractice Arbitration Constitutional? How the Debate Reflects a Trend Towards Compulsion in Alternative Dispute Resolution*, 75 *FORDHAM L. REV.* 2685, 2692 (2007) (discussing the history of alternative dispute resolution in the U.S.).

resolving “in an expeditious manner” any disputes that may arise between 340B covered entities and manufacturers, as it anticipated such disputes were very likely to occur.⁸ Although voluntary, the agency suggested that 340B participants should at least attempt the dispute resolution process before engaging in litigation,⁹ which is obviously the purpose of alternative dispute resolution.¹⁰ PPTA’s prime objection to using the existing ADR process as a model for the new process is its significant burden on the manufacturer and the uncertainty of its effectiveness in resolving disputes because it has not been used at all.

In the ANRPM, HRSA described the current ADR process as “underutilized,”¹¹ yet in doing so, significantly understated its actual use by program participants. For example, throughout the 340B Drug Pricing Program’s history, only one manufacturer has successfully brought a claim against a 340B covered entity for product diversion, yet HRSA technically did not issue its finding under the ADR process because the 340B covered entity, Aliquippa Community Hospital, failed to participate in the ADR process.¹² HRSA has suggested that the lack of use of dispute resolution is exclusively due to the voluntary nature of the current model.¹³ From a manufacturer’s perspective, the voluntary nature of the current ADR process is irrelevant. Rather, the lack of clear regulations governing the entire 340B program has prevented agency oversight and enforcement,¹⁴ which has created a situation where manufacturers must go through the financial and procedural burden of auditing a 340B covered entity to develop the requisite evidence to engage in dispute resolution.

Although manufacturers have “the option to proceed to the dispute resolution process...without an audit, if it believes it has sufficient evidence of a violation absent an audit,”¹⁵ it would seemingly take an egregious violation, such as those in the Aliquippa case, to successfully bring a claim without an audit. The audits are now a pre-requisite under the new model. The manufacturer audits are expensive, mostly because the guidelines require a manufacturer to retain an independent public accountant.¹⁶

III. Threshold Requirements

PPTA is very concerned with HRSA’s suggestion that a manufacturer refusal to sell a drug or biological to a 340B covered entity at or below the 340B ceiling price

⁸ See 61 Fed. Reg. at 65412.

⁹ *Id.* at 65411-65412.

¹⁰ See, e.g., Parrott, *supra* note 7, at 2685.

¹¹ See 75 Fed. Reg. at 57234.

¹² See Alice Valder Curran, et al., Hogan & Hartson, HRSA Issues First Monetary Award for Diversion Under 340B Program (2008), (explaining that HRSA used its independent authority to sanction a 340B covered entity under the statute).

¹³ See 75 Fed. Reg. at 57234.

¹⁴ 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 16-17 (2005) (describing the lack of legal authority HRSA has to enforce the 340B program).

¹⁵ See 61 Fed. Reg. at 65410.

¹⁶ *Id.* at 65409.

forcing the covered entity to purchase it outside of the 340B program is evidence of a manufacturer “overcharge.”¹⁷ 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 civil monetary penalties (“CMPs”) and the formal ADR process.¹⁸ Congress made a clear choice to limit the availability of this mandatory process, because of the risk that a broader mandate could invite covered entities—or their third party representatives—to use the ADR process to unduly burden manufacturers. PPTA does not believe that the agency has existing statutory authority to expand the mandate of the ADR process to include any issue other than alleged overcharging under the 340B program. Thus, a covered entity’s allegations about other 340B issues should not be a basis for using the ADR process.

To be clear, 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.¹⁹ After Congress spent more than a year evaluating these concerns, it determined that manufacturer refusals to sell fall under existing program guidance that 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.”²⁰ 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.²¹

According to Congress, the “must offer” provision will not create any new obligations for manufacturers beyond a re-execution of a pharmaceutical pricing agreement (“PPA”) to

¹⁷ See 75 Fed. Reg. at 57234.

¹⁸ See 42 U.S.C. § 256b(d)(1)(B)(vi)(III); 42 U.S.C. § 256b(d)(3)(A).

¹⁹ See, e.g., PUBLIC HOSPITAL PHARMACY COALITION, ACCESS TO IVIG BY SAFETY NET HOSPITALS PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM (2006).

²⁰ See 111 CONG. REC H4170 (May 28, 2010) (statement of Rep. Waxman).

²¹ Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

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.²² The statutory provision will finally afford the agency with the ability to enforce the non-discrimination guidance, just not through CMPs or ADR since a refusal to sell is not an overcharge. If Congress intended a “refusal to sell” to be subject to CMPs or ADR, 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.²³ Congress solidified their opposition to stockpiling in a 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 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.”²⁴ 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.²⁵ Waxman reaffirmed this proposition on the House Floor on May 28, 2010.²⁶

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

²² See DEFICIENCIES IN THE OVERSIGHT OF THE 340B DRUG PRICING PROGRAM, *supra* note 14.

²³ 61 Fed Reg. at 65406.

²⁴ 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).

²⁵ *Id.*

²⁶ See 111 CONG. REC H4170 (May 28, 2010) (statement of Rep. Waxman).

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.

IV. Hearings

PPTA agrees that the formal ADR process should include the opportunity for a hearing. Certainly, the type of hearing will differ depending on whether the parties are engaged in mediation or arbitration. Although requiring the Federal Rules of Civil Procedure and Federal Rules of Evidence to apply in this instance would defeat the purpose of engaging in alternative dispute resolution,²⁷ the regulations should establish basic procedural and evidentiary guidelines for the mediator or the chairperson of the arbitration panel to follow. Regardless of whether it is a mediation hearing or an arbitration hearing, rebuttal witness and evidence should be permitted, and the burden of proof should be a preponderance of the evidence, as is generally applicable in civil proceedings.

In establishing the regulations for hearings, is vitally important that manufacturers have access to third-party discovery because of the key contributions that wholesalers and contract pharmacies make in patient access to drugs and biologicals under the 340B program. For instance, HRSA guidance permits manufacturers to continue their business practice of selling through wholesalers when they are selling to 340B covered entities, but the manufacturer is still required to make its 340B ceiling price available through the wholesaler.²⁸ With regard to contract pharmacies, 340B covered entities are permitted to contract with multiple pharmacies as long as they comply with HRSA guidance to protect against product diversion and duplicate discounts.²⁹ Because the agency is not requiring 340B covered entities to audit the pharmacies with whom they have contracted³⁰ and also declined limit the number of arrangements or set any limits on the geographical locations of the pharmacies,³¹ manufacturers must have access to the contract pharmacy's pertinent records in instances of an ADR hearing.

V. Decision-making Official or Body

As discussed in Part I of this letter, the decision making official or body should vary with whether the parties are pursuing mediation or arbitration as the dispute resolution mechanism.

VI. Appropriate Appeals Procedure

PPTA believes the Appellate Division of the HHS Departmental Appeal Board may be an appropriate and independent venue to review the outcome of an ADR

²⁷ See *Developments in the Law*, *supra* note 3, at 1871.

²⁸ See 59 Fed. Reg. at 25113.

²⁹ See Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

³⁰ *Id.* at 10274.

³¹ *Id.* at 10276.

decision. Because the decision by the Appellate Division would likely be the final administrative division at HHS, parties to ADR must have judicial review of this decision. In cases of arbitration hearings, a judicial review for errors of fact or law may be an appropriate step after an appeal to the agency has been exhausted. A *de novo* trial in the United States District Court for the District of Columbia would be appropriate and urges the agency to specify this in its proposed regulations. Following an appeal to the agency, parties who reach a mediated settlement should have access to the judicial process only to enforce an agreed settlement.

VII. Deadlines

PPTA recommends a five year statute of limitations to bring a claim under the formal ADR process because of the record-keeping burden. The current ADR guidelines require HRSA to notify the party alleged to have committed a violation within 30 days of receiving a filing requesting the ADR process.³² Under the existing ADR model, the parties only have 37 days to respond to or rebut the allegations after receiving notification of the alleged instance from HRSA.³³ PPTA believes, however, that the respondent should typically be granted 60 days to respond to any filing, to balance the need for a timely response with the time necessary to investigate, research, and adequately respond to assertions and evidence submitted by the other side. Once the respondent has filed its response or rebuttal, the original ad hoc panel at the agency must, within 30 days, review the filings of both the complainant and respondent to determine if they have met their filing criteria and if there is enough evidence for a formal resolution under the ADR process. This deadline is similar to that under the current ADR model.³⁴ If a party is seeking a hearing as part of its ADR process, the mediator or the arbitration panel chairperson must not set a date any earlier than 60 days after notice of a hearing has been provided to both parties. Again, after the decision making body reaches a decision, the parties should be permitted to file an appeal with the Appellate Division of the HHS Departmental Appeal Board, as discussed in Part VI of the letter, within 60 days of that decision.

VIII. Discovery Procedures

The 340B statute permits 340B covered entities to assert a claim of an overcharge against a manufacturer in an ADR process.³⁵ While the agency now has the necessary tools to verify the accuracy of 340B ceiling prices,³⁶ 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 ADR 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.³⁷

³² See 61 Fed. Reg. at 65412.

³³ *Id.*

³⁴ *Id.*

³⁵ See 42 U.S.C. § 256b(d)(3)(A).

³⁶ See 42 U.S.C. § 256b(d)(1)(B)(i).

³⁷ 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

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.³⁸ 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.³⁹ 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.⁴⁰

As alluded to in the introduction, 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 ADR process. The statute requires HRSA to remove 340B covered entities from the program if their disproportionate share adjustment percentage falls below the 11.75% for the most recent reporting period,⁴¹ for violating the disproportionate share hospital ("DSH) group purchasing organization ("GPO") prohibition⁴² and for "systematic and egregious" product diversion that was "knowing and intentional."⁴³ 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."

The agency should also include subpoena authority in its regulations implementing the ADR process. Subpoena authority is critical to compelling third parties to the dispute to provide relevant materials during discovery. If a third party, such as a wholesaler or contract pharmacy refuses to participate in discovery, claims

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).

³⁸ See 42 U.S.C. § 256b(d)(1)(B)(vi)(I).

³⁹ 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."

⁴⁰ 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).

⁴¹ See 42 U.S.C. § 256b(a)(4)(L)(ii).

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

⁴³ See 42 U.S.C. § 256b(d)(2)(B)(v)(II).

involving transactions with that wholesaler or contract pharmacy should be excluded from the ADR process.

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.⁴⁴ PPTA would urge the agency to also promulgate this provision through notice and comment rulemaking prior to the promulgation of the ADR 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 340B 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.⁴⁵ Any 340B DSH attempting such arrangements with a GPO will no longer qualify as a covered entity under the statute.⁴⁶ “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.”⁴⁷

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

⁴⁴ See 42 U.S.C. § 256b(d)(2)(B)(iv).

⁴⁵ See 42 U.S.C. § 256b(4)(L)(iii).

⁴⁶ 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).

⁴⁷ *University Med. Ctr.*, 5 F. Supp. 2d at 6.

these hospitals from these organizations or arrangements,” hospitals with such arrangements are not eligible for 340B pricing.⁴⁸ 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%.⁴⁹ 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.⁵⁰

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.⁵¹ Congress and HRSA have previously resisted providing DSH hospitals with this collective bargaining advantage.⁵² 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.⁵³

Some DSH hospitals have admitted illegally purchasing IVIG through GPOs at the higher GPO price in order to satisfy alleged demand.⁵⁴ HRSA, however, has never brought an enforcement action against a 340B DSH hospital for using a GPO. Instead, the agency has merely opposed 340B DSH hospitals “disregarding the statutory GPO provisions” in these instances.⁵⁵ For more than 15 years, HRSA has “communicated its willingness to assist entities when there are problems with accessing [340B] pricing.”⁵⁶ 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.”⁵⁷

⁴⁸ See H.R. REP. NO. 102-384, PART 2 (1992).

⁴⁹ See *University Med. Ctr.*, 5 F. Supp. 2d at 6-8.

⁵⁰ See 42 U.S.C. § 256b(4)(L)(ii).

⁵¹ 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).

⁵² 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).

⁵³ See *University Med. Ctr. vs. Shalala*, 5 F. Supp. 2d 4, 8 (D.D.C. 1998).

⁵⁴ 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).

⁵⁵ 59 Fed. Reg. at 25111.

⁵⁶ *Id.*

⁵⁷ 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 d19jbnQ9MSwxJnBfcHJvZHM9JnBfY2F0cz00OSZwX3B2PSZwX2N2PTEuNDkmcF9zZWYy2hfdHlwZT

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 ADR, so that manufacturers are not forced to engage in ADR for an overcharge with 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.⁵⁸

IX. Manufacturer Audits

Manufacturer audits, which are now a pre-requisite to initiating the formal ADR process,⁵⁹ are limited to the covered entity's compliance with the prohibitions against product diversion and duplicate discounts.⁶⁰ A significant overhaul of the process is necessary to preserve the integrity of the 340B program. Manufacturers must have access to the necessary data without facing the daunting impediment of incurring the considerable expense of hiring an independent audit firm, as discussed in Part II of this letter. The current manufacturer audit guidelines should be modified to permit a manufacturer's in-house personnel to audit 340B covered entities. Removing the requirement of using independent auditors would lessen the one-sided nature of having manufacturers satisfy a pre-requisite in order to initiate the ADR process, as 340B covered entities have no similar requirement. Moreover, a manufacturer's in-house personnel are likely to have significantly greater familiarity with a covered-entity's operational structure and could conduct the audit in a more effective and efficient manner, benefiting both parties.

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(last visited Nov. 12, 2010).

⁵⁸ 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).

⁵⁹ See 42 U.S.C. § 256b(d)(3)(B)(iv).

⁶⁰ See 61 Fed. Reg. at 65406.

The manufacturer audits prerequisite also necessitates that HRSA finalize an earlier proposal to limit who may qualify as a patient of the covered entity for the purpose of the 340B discount. A covered entity may only procure covered outpatient drugs at or below the 340B ceiling price for individuals that qualify as patients of the covered entity.⁶¹ If a covered entity “resell[s] or otherwise transfer[s]” a covered outpatient drug that it purchased at or below the 340B ceiling price “to a person who is not a patient of the entity,” such covered entity is engaging in “product diversion.”⁶² Without stricter guidelines, especially in terms of record keeping, it will be difficult for a manufacturer to obtain the appropriate documentation to establish “reasonable cause” of product diversion. The manufacturer must establish “reasonable cause” to audit the 340B covered entity.⁶³

With regard to duplicate discounts, PPTA urges HRSA to evaluate its current guidance to ensure it is appropriate to account for the new influx of Medicaid patients into the health care system. The new health care reform laws will provide health care coverage to 32 million previously uninsured Americans, of which, 16 million of them will be enrolled in Medicaid.⁶⁴ Regular agency certification of each covered entity’s “mechanisms to prevent duplicate discounts” may be a sufficient way to ensure program integrity and provide for a more efficient manufacturer audit process.

X. Consolidation of Claims

PPTA agrees that there should be a process for consolidating manufacturer and covered entity ADR claims. The standard should be the same for both categories of program participants. A consolidation determination should rest primarily on consideration of whether the claims present common questions of law or fact such that it is more efficient in terms of time and cost to consolidate them and whether consolidation presents any fairness concerns. Consolidation requests should occur at the initial stages of the ADR process so that all of the parties are established at the beginning.

XI. Claims by Organizations Representing Covered Entities

PPTA is very concerned that the statute is providing HRSA with discretion to allow associations representing 340B covered entities to initiate the ADR process on behalf of individual or multiple covered entities against a manufacturer.⁶⁵ As briefly mentioned in Part I of the letter with regard to confidentiality agreements, we urge the agency to only use this new discretion once it has adequate safeguards to ensure that the third party (and the covered entities that third party represents) follows

⁶¹ See 42 U.S.C. § 256b(a)(5)(B).

⁶² *Id.*

⁶³ See 61 Fed. Reg. at 65409 (stating that manufacturers must have documentation that would lead a reasonable person to conclude that the 340B covered entity engaged in product diversion or accepted a duplicate discount).

⁶⁴ See Letter from Douglas W. Elmendorf, Director, Congressional Budget Office to Nancy Pelosi, Speaker, U.S. House of Representatives, at 9 (March 20, 2010).

⁶⁵ See 42 U.S.C. § 256b(d)(3)(B)(vi).

confidentiality rules, discovery and information requests, and agrees to comply, subject to the appeals process, with the final decision.

XII. Integration of Dispute Resolution with Other 340B Provisions in the PPACA, as amended by the HCERA

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, 340B covered entities (or their third-party representative) will initiate an ADR process for an overcharge based on skewed data that will not accurately reflect whether an overcharge has occurred.⁶⁶ 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.⁶⁷ 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.⁶⁸

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).⁶⁹ The URA may not exceed the AMP.⁷⁰ 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 the formal ADR process.

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.⁷¹ 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.⁷² More specifically, under the refund

⁶⁶ See 42 U.S.C. § 256b(d)(1)(B)(i)(I),

⁶⁷ See 42 U.S.C. § 256b(a)(1); 42 U.S.C. § 256b(d)(1)(B)(i).

⁶⁸ See 42 U.S.C. § 256b(d)(1)(B)(i)(II), (IV).

⁶⁹ 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).

⁷⁰ See 42 U.S.C. § 1396r-8(c)(2)(D).

⁷¹ See 42 U.S.C. § 256b(d)(1)(B)(ii).

⁷² *Id.*

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”),⁷³ 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 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.⁷⁴

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.

XIII. Conclusion

The PPACA, as amended by the HCERA, made many significant changes to the 340B Drug Pricing Program. PPTA urges the agency to consider its comments, especially those with regard to taking action prior to promulgating the proposed rule implementing the formal ADR process. When the agency does issue its ADR proposed rule, PPTA urges it to do so in an equitable manner. Thank you for the opportunity to comment. Please contact Jay Greissing (jgreissing@pptaglobal.org) or Jon McKnight (jmcknight@pptaglobal.org) at 202-789-3100 if you would like to further discuss our comments.

Sincerely,



Julie Birkofer
Senior Vice President, PPTA North America

⁷³ See 42 C.F.R. § 447.510(b)(1).

⁷⁴ 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).