

October 27, 2015  
Reference No.: PEDL15001

Via E-mail

Captain Krista M. Pedley, PharmD, MS, USPHS  
Director  
Office of Pharmacy Affairs, Healthcare Systems Bureau  
Health Resources and Services Administration  
5600 Fishers Lane, Mail Stop 08W05A  
Rockville, MD 20857

***By Electronic Submission***

**Re: Regulatory Information Number (RIN) 0906-AB08 (Notice, 340B Drug Pricing Program Omnibus Guidance)**

Dear Captain Pedley:

The Plasma Protein Therapeutics Association (“PPTA”) is pleased to have this opportunity to comment on the proposed omnibus guidance (“Proposed Guidance”) that the Health Resources and Services Administration (“HRSA”) published in the Federal Register on August 28, 2015 regarding the 340B Drug Pricing Program (“340B Program”).<sup>1</sup>

PPTA represents human plasma collection centers and leading manufacturers of plasma protein therapies, including Baxalta, Biotest, CSL Behring, Grifols Inc., and Kedrion SpA. PPTA is committed to ensuring that patients living with chronic and rare diseases who rely on plasma protein therapies for their lifesaving treatment have appropriate and timely access to the therapy and care that best suits their health status.

PPTA firmly supports the implementation of guidelines that advance patient access, reflect the vital importance of continuity of care for plasma protein patients, and ensure that the benefits of 340B discounts accrue to the intended beneficiaries of the 340B program—the most needy and vulnerable patient populations. PPTA members frequently sell their products to hemophilia treatment centers and other entities participating in the 340B Program as covered entities, and PPTA therefore has significant interest in the program and how it is administered. In particular, PPTA asks that HRSA:

1. Address the status of sub-recipients of federal grants in the 340B program;
2. Clarify in any final guidance the relationship that is required between a provider and a 340B covered entity under the patient definition;

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<sup>1</sup> 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300 (Aug. 28, 2015).

3. Develop a workable method to prevent duplicate discounts with respect to utilization by Medicaid Managed Care Organizations (“MCOs”);
4. Refrain from treating the “must offer” provision as a binding requirement until it is implemented through the Pharmaceutical Pricing Agreement; and
5. Acknowledge in any final guidance that the submission of limited distribution plans by manufacturers is not mandatory.

In addition, PPTA urges HRSA to provide stakeholders with sufficient notice and time before any final guidance becomes effective.

## **I. Background Regarding PPTA**

Most of the rare conditions that require treatment with plasma protein therapies are genetic, chronic, and life-threatening, including alpha-1 proteinase inhibitor deficiency, hemophilia, von willebrand disease, and primary immune deficiency diseases (“PIDDs”).<sup>2</sup> Plasma protein therapies includes albumin, alpha<sub>1</sub>-proteinase inhibitor, antithrombin III, plasma-derived and recombinant blood clotting factors,<sup>3</sup> C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, prothrombin complex concentrate and protein C concentrate.<sup>4</sup>

Due to their unique nature, plasma protein therapies face distinct challenges and regulatory treatment, and some of these unique aspects may be impacted by their treatment under the 340B Program. First, the vast majority of plasma proteins treat rare diseases, and in some cases, prevalence may be fewer than 100 patients. In light of these circumstances, patients can struggle to access providers that have sufficient expertise to treat their conditions, and patients may experience challenges in accessing treatment at their preferred site of care.

The non-interchangeable nature of plasma protein therapies is also a unique aspect of these therapies that highlights the importance of reimbursement mechanisms that

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<sup>2</sup> Diseases treated with plasma protein therapies also include chronic B-cell lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, hereditary angioedema, hereditary antithrombin III deficiency, protein C deficiency, PIDDs, such as common variable immunodeficiency, X-linked agammaglobulinemia (Bruton’s disease), DiGeorge syndrome, Wiskott-Aldrich syndrome, Nezelof’s syndrome, severe combined immunodeficiency, graft-versus-host diseases, and bleeding disorders, such as hemophilia A, hemophilia B, congenital fibrinogen deficiency, and factor XIII deficiency. Cytomegalovirus disease associated with transplant patients, hepatitis B reinfection in liver transplant patients, idiopathic thrombocytopenic purpura, infant botulism, and Kawasaki’s disease. Rabies, rhesus incompatible pregnancies, and tetanus are examples of acute rare conditions that are treated with plasma protein therapies.

<sup>3</sup> Recombinant blood clotting factor therapies are those created using recombinant DNA technologies, which entail the integration of genes coding for the production of human blood clotting factor proteins into laboratory cell cultures. The cell cultures produce the blood clotting factor proteins, which are subsequently collective, purified, and further refined into safe and effective biologic medicines.

<sup>4</sup> Human plasma is the clear liquid portion of blood that remains after the red cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. See Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, in 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209 (2005, 2006).

ensure uninterrupted access to all brands of plasma protein therapies. Distinct fractionation processes are used to generate each brand within a plasma protein therapeutic class. The result is plasma protein therapies that are non-interchangeable, sole source biologics that produce different therapeutic outcomes depending on the patient.

A third unique characteristic of plasma protein is that its manufacturers depend upon human donated plasma as the raw material for therapeutic production. The process for collecting human donated plasma is highly regulated, resource-intensive, and time-consuming, with a production process spanning seven to nine months.

## **II. 340B Program Background**

The 340B Program was created by the enactment of section 602 of the Veterans Health Care Act of 1992 (Public Law No. 102-585), which added Section 340B of the Public Health Service Act.<sup>5</sup> Most recently, the Patient Protection and Affordable Care Act (“ACA”) amended Section 340B in 2010.<sup>6</sup>

As a condition of coverage for its covered outpatient drugs under Medicaid and Medicare Part B, a manufacturer must participate in both the Medicaid Drug Rebate Program (“MDRP”) and the 340B Program.<sup>7</sup> In order to participate in the 340B program, the 340B statute requires manufacturers to enter into a Pharmaceutical Pricing Agreement (“PPA”) with the Department of Health and Human Services (“HHS”). Pursuant to the PPA, the manufacturer agrees to charge statutorily defined “covered entities” no more than a discounted ceiling price<sup>8</sup> for its covered outpatient drugs.<sup>9</sup> The 340B statute provides a formula for the ceiling price that is based on price points reported by the manufacturer to the MDRP.<sup>10</sup>

The 340B statute grants HRSA the authority to make rules regarding the 340B program in only a limited number of areas.<sup>11</sup> It is therefore appropriate that the Proposed Guidance has been issued in the form of guidance instead of regulation, given HRSA’s limited rulemaking authority. HRSA has yet to issue final rules in areas where it does have rulemaking authority.<sup>12</sup> HRSA to date has instead issued program guidance in the

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<sup>5</sup> Section 340B of the PHSA is codified at 42 U.S.C. § 256b.

<sup>6</sup> ACA, § 7102, Pub. L. No. 111-148 (2010).

<sup>7</sup> 42 U.S.C. § 1396r-8(a)(5).

<sup>8</sup> *Id.* at § 256b(a).

<sup>9</sup> The defined term “covered outpatient drug” includes, among other things, biological products other than vaccines. Plasma protein therapies are therefore included in the 340B program. *See* 42 U.S.C. § 1396r-8(k)(2)(B).

<sup>10</sup> 42 U.S.C. § 256b(a)(1)

<sup>11</sup> *See Pharm. Research & Mfrs. v. Dep’t of Health & Human Servs.*, No. 1:14-cv-01685-RC (D.D.C. Oct. 14, 2015).

<sup>12</sup> The only regulation that HRSA has released in final form, which addressed the treatment of orphan-designated drugs under the 340B program, was invalidated in 2014 following a legal challenge. *See Pharm. Research & Mfrs. v. Dep’t of Health & Human Servs.*, 43 F.Supp. 3d 28 (D.D.C. Oct. 14, 2015). HRSA has issued a notice of proposed rulemaking addressing the ceiling price and manufacturer civil monetary penalties but has not yet issued a final regulation. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties, 80 Fed. Reg. 34,583 (June 17, 2015).

form of Federal Register notices, often after notice and opportunity for comment; through releases posted on HRSA's website; or through frequently-asked-question lists or other bulletins, also published on HRSA's website.

### **III. The Status of Sub-Recipients of Federal Grants Under the 340B Program Should Be Clarified**

Safety net providers may participate in the 340B program either because they are federal grantees or because they are hospitals that meet specific eligibility criteria. PPTA is concerned that the Proposed Guidance reflects a one-size-fits-all approach to covered entity compliance across both grantees and hospital covered entities. Federal grantees participate in the 340B program only by virtue of their federal grants, and these grants themselves include detailed eligibility criteria that the entity must satisfy on an ongoing basis, in addition to complying with 340B program requirements. Hospital covered entities, by contract, are not subject to analogous requirements or oversight. PPTA encourages HRSA to consider these disparate compliance frameworks in any final guidance, particularly when imposing additional requirements on federal grantee covered entities.

One area of differentiation between grantee type covered entities and hospitals is the eligibility of child sites. PPTA members frequently sell their products to hemophilia treatment centers, some of which do not themselves receive federal grants but instead are sub-recipients of federal grants. PPTA urges HRSA to address the status of sub-recipients of federal grants with respect to the 340B program. The Proposed Guidance addresses this topic in the "Summary of the Proposed Guidance" section and states that "HHS will list sites that are sub-recipients of Federal grants, but seeking their own 340B identification numbers separate from a parent entity" if the sub-recipient demonstrates the receipt of eligible federal funds and provides the related grant number.<sup>13</sup> However, in the "Proposed Guidance" section, there is no discussion of sub-recipients.<sup>14</sup> PPTA believes that HRSA should clarify in any final guidance whether sub-recipients of federal grants, such as hemophilia treatment centers, are permitted to independently participate in the 340B program if they meet the other program eligibility requirements, even if the parent entity itself is not participating in the 340B program. A sub-recipient of a federal grant that independently participates in the 340B program, rather than as a child site of a federal grantee, should be listed in the 340B database and would be responsible for compliance with all 340B program requirements.

### **IV. The Proposed Patient Definition Should Provide Additional Clarity Regarding the Relationship Required Between a Provider and a 340B Covered Entity**

The 340B statute prohibits covered entities from diverting covered outpatient drugs purchased at the 340B ceiling price to individuals who do not qualify as "patients" of the

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<sup>13</sup>80 Fed. Reg. at 52,301.

<sup>14</sup>See *id.* at 52,316.

covered entity.<sup>15</sup> The pivotal term “patient,” however, is not defined in the 340B statute. HRSA issued a patient definition through Federal Register guidance in 1996.<sup>16</sup> That 1996 definition is not only out-of-date, but ineffectual as well, failing to successfully prevent diversion of discounted drugs to non-340B patients.<sup>17</sup> PPTA therefore appreciates HRSA’s release in the Proposed Guidance of a more clear and precise definition of patient, but believes that definition requires further clarification before it can be issued in any final guidance.

Plasma protein therapies are predominantly physician-administered biological therapies that require patients to receive infusions on a regular basis for the duration of their lives. It is imperative that the definition of a 340B patient support continuity of care for the chronic and rare disease patients who rely on these therapies for their lifesaving treatment. To achieve this goal, the definition of a 340B patient must clearly define the relationship between a 340B covered entity and the providers delivering care to 340B patients. PPTA believes that some of the six criteria that make up the patient definition in the Proposed Guidance should be clarified in that regard.

The second prong of the proposed patient definition requires that the individual “receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.”<sup>18</sup> The nexus between the provider and the covered entity is that the covered entity may bill for the services on behalf of the provider. PPTA suggests that in addition, the definition should make clear that the care the individual receives from the covered entity provider must be consistent with the services established in the provider’s contract with the 340B covered entity.

The proposed patient definition’s second prong also states that an individual returning to receive medical care at a covered entity will be considered eligible for 340B drugs if the individual receives “ongoing medical care” from the covered entity.<sup>19</sup> In addition, the sixth prong of the patient definition requires that the individual have “an established relationship” with the covered entity, such that the “covered entity has a provider-to-patient relationship for the health care service” that results in the prescription.<sup>20</sup> PPTA suggests that HRSA define more clearly what constitutes an “ongoing” relationship. HRSA should consider imposing additional compliance and oversight requirements where the duration between the date of a prescription and the date on which it was initially filled or subsequently refilled is significant, as that may indicate that the provider-to-patient relationship no longer should sustain access to 340B medications.

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<sup>15</sup> 42 U.S.C. § 256b(a)(5)(B).

<sup>16</sup> See 62 Fed. Reg. 55,156 (Oct. 24, 1996).

<sup>17</sup> See, e.g., Gov’t Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 23, 2011).

<sup>18</sup> 80 Fed. Reg. at 52,306, 52,319.

<sup>19</sup> *Id.* at 52,307.

<sup>20</sup> *Id.*

The third prong of the proposed patient definition requires that the prescription to the individual be the result of the service by the covered entity provider, as described in the second prong of the definition. PPTA supports this approach, and welcomes HRSA's clarification that an individual does not qualify as a patient if the only relationship to the covered entity is "the dispensing or infusion of a drug."<sup>21</sup> Importantly, the definition states that if the other criteria of the patient definition are met, and the covered entity infuses a drug, the individual may still qualify as a patient. PPTA supports this statement, as it ensures that individuals can receive plasma protein therapies through covered entities, but suggests that HRSA make clear that where a drug is infused at the covered entity location, the infused drug must be both prescribed and administered by a covered entity healthcare provider for the drug to be eligible for the ceiling price.

The fourth prong of the proposed patient definition applies only to covered entities that are grantees and requires that the individual's healthcare be consistent with the scope of the covered entity's grant.<sup>22</sup> PPTA believes this criterion also should apply to covered entity hospitals that participate in the 340B program as a result of a contract with a state or local government to provide health care services to low income individuals who are not entitled to Medicaid or Medicare beneficiaries. Individuals receiving care at these hospitals should qualify as patients for 340B purposes only when the healthcare is consistent with the hospital's contract.

In the second prong of the patient definition, HRSA states that "[f]aculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships" meet the requirement that the healthcare provider is employed or under contract with the covered entity. PPTA urges HRSA to clarify that services provided to individuals by healthcare providers who are contractors and not employees of the covered entity also must be consistent with the scope of the covered entity's grant or, in case of a hospital described in the prior paragraph, consistent with the hospital's contract with a state or local government.

Clarifying the relationship not only between the covered entity and the individual, but also between the covered entity and the covered entity's healthcare provider in the 340B patient eligibility criteria will support continuity of care for patients who rely on access to regular physician-administered treatments as part of their lifesaving regimens.

#### **V. HRSA's Proposed Approach to Implement the Prohibition on Duplicate Discounts with Respect to Medicaid MCO Utilization Is Unworkable**

Under the MDRP, participating manufacturers must pay state Medicaid programs a rebate on each unit of their covered outpatient drugs reimbursed by the state Medicaid program. Because both the 340B Program and the MDRP apply to "covered outpatient drugs," there exists the possibility that a manufacturer could sell a unit of a drug to a covered entity at the discounted 340B ceiling price and then subsequently receive an

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<sup>21</sup> Id. at 52,307.

<sup>22</sup> Id. at 52,307, 52,319.

invoice from a state Medicaid program for a Medicaid rebate on that same unit. The 340B statute seeks to avoid such “duplicate discounts” by prohibiting covered entities from billing Medicaid for a unit of a drug purchased at the 340B price.<sup>23</sup> In 2010, the ACA expanded manufacturer rebate liability from fee-for-service (“FFS”) Medicaid utilization to include the utilization of Medicaid MCOs as well. The 340B duplicate discount prohibition was expanded at the same time and therefore applies equally to both FFS and MCO utilization. However, until the release of the Proposed Guidance, HRSA has not taken any steps to implement the duplicate discount prohibition with respect to Medicaid MCO utilization. PPTA welcomes HRSA’s attempt at addressing the duplicate discount prohibition, but believes the approach set forth in the Proposed Guidance is unworkable.

The 340B statute makes clear that compliance by covered entities with the duplicate discount prohibition is a condition of participation in the 340B program, such that a covered entity is not eligible to participate if it does not have the ability to prevent duplicate discounts. This is especially important to PPTA because, between 2003 and 2010, total outpatient hospital payments for intravenous immunoglobulin (“IVIG”) treatment increased by 531 percent, while physician office payments increased by only 36 percent, representing a 495 percent shift in IVIG utilization over that seven-year period.<sup>24</sup> The shift in site of care for IVIG utilization to the hospital setting, compounded by the exponential growth in the 340B program over the same period, has resulted in a rapid increase in the proportion of total plasma protein therapies that are subject to the 340B ceiling price. Plasma protein therapeutic manufacturers are therefore acutely affected by any duplicate discounts in connection with Medicaid MCO utilization.

The approach to implementing the duplicate discount prohibition set forth in the Proposed Guidance appears to be focused less on the statutory requirement to avoid duplicate discounts, and more on a desire to provide the greatest measure of flexibility to covered entities. The resulting approach is overly complex and unworkable, as PPTA explains below.

**A. HRSA’s Proposed Approach to Implement the Duplicate Discount Prohibition with Respect to Medicaid MCO Utilization Is Overly Complex and Unlikely to Increase Compliance**

HRSA has, to date, implemented the duplicate discount prohibition only with respect to Medicaid FFS utilization, disregarding the statutory requirement added to the 340B statute by the ACA—in effect since 2010—that covered entities must comply with the duplicate discount prohibition in the Medicaid MCO context as well. PPTA supports HRSA’s efforts to address this requirement at long last and generally supports HRSA’s longstanding mechanism for duplicate discount avoidance in the FFS context, the “Medicaid Exclusion File.” Under the FFS methodology, HRSA requires that covered entities either (1) “carve-out” by using only non-340B-priced drugs for Medicaid patients, or (2) “carve-in” and use 340B-priced product for Medicaid patients. An entity that

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<sup>23</sup> 42 U.S.C. § 256b(a)(5)(A).

<sup>24</sup> “340B Drug Discount Program PPTA Engagement Strategy, April 7, 2014”.

“carves in” must ensure that its provider number is listed on the Medicaid Exclusion File, which state Medicaid programs then use to identify and exclude the covered entity’s Medicaid utilization from rebate invoices submitted to manufacturers, thereby avoiding the duplicate discount.

The Proposed Guidance would expand the use of the Medicaid Exclusion File to address Medicaid MCO utilization as well.<sup>25</sup> In the FFS context, each covered entity’s “carve in/out” election applies to *all* of its Medicaid FFS utilization. The Proposed Guidance, on the other hand, would allow covered entities to make a different “carve-in/out” elections with respect to Medicaid MCO utilization not only for each of the covered entity’s sites, but then also on an MCO-by-MCO basis. HRSA also would allow a covered entity’s “carve-in/ out” election with respect to Medicaid MCO utilization to differ from the election it makes in the FFS context.<sup>26</sup>

HRSA’s own audit results demonstrate that the “carve-in/ out” approach in the FFS context, which is simple in comparison to the proposed MCO approach, nevertheless resulted in audit findings of duplicate discounts in more than 20 percent of audited covered entities.<sup>27</sup> Inaccuracies within the file and inappropriate or ineffective use by covered entities have been described in a recent report by the HHS Office of the Inspector General, arising even when the “carve-in/out” approach is applied in a straightforward, binary way.<sup>28</sup> HRSA’s proposal with respect to Medicaid MCO utilization would dramatically increasing the risk of such errors.

The approach suggested in the Proposed Guidance appears to be concerned primarily with allowing covered entities the greatest possible level of flexibility in their MCO arrangements, rather than implementing the actual prevention of duplicate discounts—which is what the 340B statute requires. PPTA believes HRSA should focus on the statutory purpose of protecting manufacturers from duplicate discounts. The Proposed Guidance fails to explain how the Medicaid Exclusion File, if expanded to address Medicaid MCO utilization, would operate in a way that makes it feasible for covered entities to select between “carve-in” and “carve-out” status for MCO utilization on an MCO-by-MCO and site-by-site basis.

PPTA is concerned that the absence of any details regarding the workability of the HRSA proposal, combined with the complexity of the proposed approach in general, unreasonably burdens manufacturer interests. PPTA understands that implementation of the duplicate discount prohibition in the Medicaid MCO context will require cooperation among 340B program stakeholders, including HRSA, Medicaid MCOs, covered entities and manufacturers, which is challenging in and of itself. But such cooperation and coordination is especially important because HRSA has explained neither how it would track and communicate the myriad covered entity “carve-in/out”

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<sup>25</sup> 80 Fed. Reg. at 52,320.

<sup>26</sup> *Id.*

<sup>27</sup> See generally HRSA’s Audit Results, *available at*:

<http://www.hrsa.gov/opa/programintegrity/auditresults/fy15auditresults.html>.

<sup>28</sup> See, e.g., OIG, Deficiencies in the 340B Drug Discount Program’s Database, OEI-05-02-00071 (May 13, 2010).

elections that are possible under its suggested approach, nor whether state Medicaid programs would even be able to accommodate the proposal to track which utilization relates to 340B purchases. HRSA's own audit results make clear that the approach to preventing duplicate discounts in the MCO context would be wholly impractical.

PPTA urges HRSA to rethink its approach to implementing the statutory duplicate discount prohibition in the Medicaid MCO context, and to develop a different proposal that focuses first and foremost on implementing the statutory requirement. HRSA's implementation framework must be one that reasonably can enable compliance with the statutory requirement that covered entities be able to prevent duplicate discounts if they are to participate in the 340B program. In that regard, HRSA should extend the current FFS approach to Medicaid MCO utilization as well, such that a covered entity's "carve-in/out" election in the MCO context applies to each covered entity as a whole.

### **B. The Risk of Duplicate Discounts Is Especially Significant Where Contract Pharmacies Are Involved**

The risk of duplicate discounts is particularly significant in the contract pharmacy context. These additional risks of violation of the duplicate discount prohibition by covered entities are in part due to limitations of the Medicaid Exclusion File, which is ill-suited to identify the "carve-in/out" status of contract pharmacies.<sup>29</sup> Contract pharmacies dispense both 340B and commercial drugs and generally bill for all utilization under the same provider number. As a result, listing the provider number of a contract pharmacy on the Medicaid Exclusion File is not sufficient to enable state Medicaid programs to identify and remove the contract pharmacy's 340B utilization from the Medicaid rebate invoices sent to manufacturers.

HRSA's current policy regarding prevention of duplicate discounts in the contract pharmacy context provides that the covered entity may not dispense 340B drugs to Medicaid patients, "unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts," with the arrangement reported to HRSA.<sup>30</sup> PPTA generally supports that current policy. The Proposed Guidance clarifies that the presumption that a contract pharmacy does not dispense 340B drugs to Medicaid patients applies in the Medicaid MCO context as well, and reiterates that if a covered entity intends to have its contract pharmacy dispense 340B drugs to Medicaid patients, it "will provide HHS a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts."<sup>31</sup> In the interest of transparency, PPTA urges HRSA to make the existence of such an agreement known through the 340B database, where applicable, on a contract pharmacy and covered entity specific basis. PPTA also urges HRSA to make a copy of the agreement available to manufacturers upon request to

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<sup>29</sup> OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 4, 2014) ("We also found that contract pharmacy arrangements create complications in preventing duplicate discounts.").

<sup>30</sup> 75 Fed. Reg. 10,272, 10,278 (Mar. 5, 2010).

<sup>31</sup> 80 Fed. Reg. at 52,309.

enable manufacturers to ensure the data they receive from State Medicaid programs are consistent with such arrangements.

For contract pharmacies that use only non-340B-priced drugs for Medicaid patients, HRSA also should clarify how it will monitor covered entity compliance. As noted above, the limited number of audits that HRSA has conducted have revealed a significant level of non-compliance with the duplicate discount prohibition by covered entities, and PPTA therefore is concerned that HRSA should focus its attention on covered entities with a large number of contract pharmacies. PPTA also urges HRSA to establish mechanisms to ensure that each covered entity correctly lists the “carve-in/out” status of all of its contract pharmacies in the 340B database, as the database is the only avenue available to manufacturers to determine contract pharmacy status. The foregoing transparency measures are essential in order for manufacturers to monitor Medicaid utilization by covered entities and to identify possible violations of the duplicate discount prohibition.

## **VI. The 340B Statute’s “Must Offer” Provision is Not Currently Binding**

The ACA amended the 340B statute to provide that the PPA “shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price,” often referred to as the “must offer” provision.<sup>32</sup> HRSA has repeatedly asserted that this provision is binding on manufacturers, most recently in the Proposed Guidance,<sup>33</sup> despite the fact that HRSA has not implemented the provision by amending the PPAs in place with manufacturers or releasing a new form PPA.<sup>34</sup> The current form PPA expressly states that it “will not be altered except by an amendment in writing signed by both parties,” and its terms therefore may not be unilaterally revised.<sup>35</sup> Further, unlike the CMS form agreement pursuant to which manufacturers participate in the MDRP, the PPA in its current form also does not contain any provision to the effect that the contract terms will automatically conform to future statutory changes. The CMS form agreement, on the other hand, does require manufacturers to comply with changes to the Medicaid statute.<sup>36</sup>

HRSA has now issued a notice in the Federal Register proposing to implement the must offer provision in the PPA through an addendum.<sup>37</sup> Nevertheless, the current form PPA, and the PPAs that are currently in place with manufacturers, do not include the must offer provision. Unless and until manufacturers have entered into a PPA that contains such a requirement, the must offer provision continues to be not binding on

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<sup>32</sup> 42 U.S.C. §256b(a)(1).

<sup>33</sup> 80 Fed. Reg. at 52,311.

<sup>34</sup> HRSA’s current form PPA is available at:

<http://www.hrsa.gov/opa/manufacturers/pharmaceuticalpricingagreement.pdf> (last visited Oct. 5, 2015).

<sup>35</sup> PPA § VII(h).

<sup>36</sup> CMS’s form Medicaid Drug Rebate Program Agreement, at § II(c), *available at*:

<http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/samplerbateagreement.pdf> (last visited Oct. 5, 2015).

<sup>37</sup> 80 Fed. Reg. 63,560 (Oct. 20, 2015).

manufacturers—which HRSA now has implicitly acknowledged by suggesting in its Federal Register notice that an addendum to the PPA is necessary to implement the provision.

## **VII. Manufacturer Submission of Limited Distribution Plans is Not Mandatory**

PPTA is concerned that the Proposed Guidance seemingly would obligate manufacturers to provide written notification of a “limited distribution plan” to HRSA before manufacturers are permitted to implement it. The Proposed Guidance also implies that such plans would be subject to HRSA’s comment and approval, erroneously suggesting that HRSA has the authority to reject any plan that HRSA does not agree with.<sup>38</sup>

HRSA appears to recognize that the prior submission of limited distribution plans is not mandatory, as it states in the Proposed Guidance that a manufacturer is “expected,” rather than required, to submit the plan to HRSA.<sup>39</sup> PPTA urges HRSA to explicitly state that the submission of limited distribution plans to HRSA is in fact voluntary. The statute in no way supports such a mandate, and even if the “must offer” provision could provide a basis for doing so, that provision currently is not binding.<sup>40</sup> In light of the lack of a statutory basis for HRSA to require manufacturers to provide advance notification of any limited distribution arrangements, or for HRSA to review and/or make changes to such plans before they may be implemented, PPTA does not believe HRSA can or should impede a manufacturer’s determination of how to bring its products to market.

PPTA’s concerns are magnified by the absence of a definition of the term “limited distribution plan.” Without a clear definition of that term, the Proposed Guidance is overly broad and would apply to ordinary distribution mechanisms that in fact are not limited. PPTA therefore specifically requests that HRSA define what constitutes a “limited distribution plan” that triggers the disclosure expectation. PPTA objects to the idea that any specialty pharmacy or limited supply distribution arrangement would do so, as the Proposed Guidance currently suggests.<sup>41</sup> The scope of this proposal should be precisely defined and narrowly tailored to HRSA’s specific goals.

PPTA supports HRSA’s efforts to encourage collaboration between covered entities and manufacturers with respect to issues that arise in connection with limited distribution arrangements. This is a particularly valid concern for PPTA members, given that they depend upon human donated plasma as the raw material for the therapeutic production of many of their products, which inherently limits the available supply of the drugs. But nevertheless these are policy objectives, not statutorily supported mandates, and HRSA may not compel manufacturer disclosure in furtherance of these goals.

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<sup>38</sup> 80 Fed. Reg. at 52,312.

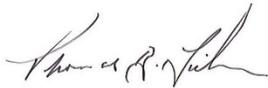
<sup>39</sup> *Id.* at 52,321 (emphasis added).

<sup>40</sup> *See id.* at 52,312 (“Pursuant to section 340B(a)(1) of the PHSA . . . the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers.”).

<sup>41</sup> 80 Fed. Reg. at 52,312.

PPTA appreciates HRSA's efforts to offer detailed guidance regarding the 340B program and welcomes the opportunity to comment on the specific proposals. Please feel free to contact Thomas B. Lilburn, Director of Government Relations, at (443) 458-4682 or [tlilburn@pptaglobal.org](mailto:tlilburn@pptaglobal.org) if you have any questions or would like to discuss these comments further.

Sincerely,



Thomas B. Lilburn  
Director, Government Relations