

June 30, 2009

Reference No.: FASC09034

The Honorable Edward M. Kennedy  
Chairman, Committee on Health, Education, Labor & Pensions  
United States Senate  
Washington, DC 20510

The Honorable Michael B. Enzi  
Ranking, Committee on Health, Education, Labor & Pensions  
United States Senate  
Washington, DC 20510

**RE: Section 611 and Section 612 of the Affordable Health Choices Act (Revised)**

Dear Chairman Kennedy and Ranking Member Enzi:

On behalf of the Plasma Protein Therapeutics Association (“PPTA”),<sup>1</sup> I am writing today to underscore several concerns we have with the decision to circumvent regular order in the committee by including sections 611 and 612 in the Affordable Health Choices Act (“AHCA”), which would expand the 340B Drug Pricing Program well beyond its legislative intent. While many issues are being raised and considered during the health care reform debate, the Senate Committee on Health, Education, Labor and Pensions has not held any hearings on this proposal. Because of the complexity of the 340B program, changes of the magnitude proposed in the AHCA require an inclusive debate of the issue by the full committee and regular order to be followed.

Plasma protein therapies are used in the treatment of a number of rare diseases.<sup>2</sup> Most of these disorders are genetic, chronic, life threatening conditions that require, as part of the standard of care, patients to receive regular infusions or injections of plasma protein therapies for

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<sup>1</sup> PPTA is the association that represents human plasma collection centers and the manufacturers of medicinal therapies, including albumin, alpha<sub>1</sub>-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.”

<sup>2</sup> The National Institute of Health Office of Rare Diseases generally defines rare diseases as those having a “prevalence of fewer than 200,000 affected individuals in the United States.” See OFFICE OF RARE DISEASES, U.S. DEP’T OF HEALTH & HUMAN SERVS., RARE DISEASE AND RELATED TERMS, *at* <http://rarediseases.info.nih.gov/RareDiseaseList.aspx?PageID=1> (last visited May 12, 2009). Afibrinogenemia, alpha1-antitrypsin deficiency, B-cell chronic lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, Guillain-Barre syndrome, hemophilia A, hemophilia B, hyperimmunoglobulinemia E syndrome, hypofibrinogenemia, idiopathic thrombocytopenic purpura, Kawasaki syndrome, Lambert-Eaton myasthenic syndrome, multifocal motor neuropathy, multiple sclerosis, myasthenia gravis, primary immune deficiency disease, staphylococcal toxic shock syndrome, and von Willebrand disease are among the diseases that satisfy this definition.

the duration of their lives. Very often, plasma protein therapies are the only viable treatment option for these patients.

Nearly all plasma protein therapies<sup>3</sup> rely on the donation of human plasma for the source material. In 2007, more than 85% of human plasma collected for use in the U.S. was source plasma,<sup>4</sup> which cost about \$150 per liter in 2008.<sup>5</sup> The cost of nucleic acid amplification technology testing for HIV and hepatitis A and B is included in this price.<sup>6</sup> Threats of emerging pathogens will also increase the overall manufacturing costs of plasma protein therapies because manufacturers may have to develop new tests and viral inactivation and viral reduction procedures.

In order to recover these significant, unavoidable costs, manufacturers of plasma protein therapies must produce brands in multiple therapeutic classes from each liter of plasma that it fractionates. This economic necessity also provides incentives for plasma fractionators to invest in the research and development of therapies for treating diseases with extraordinarily low prevalence. For example, the Food and Drug Administration recently approved a biologics license application for a plasma-derived coagulation therapy used to treat Factor I protein deficiency, which afflicts only 300 people in the U.S.<sup>7</sup> The proposal to expand the 340B Drug Pricing Program, as outlined in the committee draft, will, however, provide disincentives for such innovation in the future.

Plasma protein therapies are a vital component of the 340B Drug Pricing Program. For example, approximately 80% of the approximately 20,000 hemophilia patients (those suffering from either hemophilia A or hemophilia B) in the United States receive care at the 147 federally funded comprehensive hemophilia treatment centers (“HTCs”) throughout the country. Ninety-four of these HTCs – approximately 64% – are currently enrolled in the 340B program.<sup>8</sup> Nearly 25% of all blood clotting factors sold in the U.S. is sold at or below the 340B ceiling price to HTCs or the hospital outpatient departments (“HOPD”) of disproportionate share hospitals (“DSH”), which is another type of 340B covered entity.<sup>9</sup> This sales volume is more than ten times the average of all other drugs sold under the 340B program.<sup>10</sup> Additionally, a significant

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<sup>3</sup> Of the six brands of recombinant blood clotting factors available for consumption in the U.S., four brands contain traces of human plasma or a derivative (albumin).

<sup>4</sup> See THE MARKETING RESEARCH BUREAU, INC., THE PLASMA FRACTIONS MARKET IN THE UNITED STATES 2007 14 (2008).

<sup>5</sup> *Id.* at 40.

<sup>6</sup> *Id.*

<sup>7</sup> See Press Release, CSL Behring, CSL Behring Receives FDA Approval of RiaSTAP(TM), First and Only Approved Treatment of Acute Bleeding Episodes in Patients with Congenital Fibrinogen Deficiency (Jan 16, 2009) available at <http://news.prnewswire.com/ViewContent.aspx?ACCT=109&STORY=/www/story/01-16-2009/0004956268&EDATE> (last visited May 26, 2009).

<sup>8</sup> See Office of Pharmacy Affairs, HHS, List of Covered Entities, <http://opanet.hrsa.gov/opa/CE/CEExtract.aspx> (last visited June 19, 2009) [hereinafter “OPA List”].

<sup>9</sup> See ROBERT N. FENILI, PHD AND CAROL B. STEHL, THE POTENTIAL IMPACT OF RAISING THE MEDICAID REBATE ON BLOOD CLOTTING FACTOR PRODUCTS 5 (2009) (on file with author).

<sup>10</sup> *Id.*

percentage of intravenous immune globulin (“IVIG”) sold in the HOPD is also sold to DSH hospitals.<sup>11</sup>

PPTA and its members strongly support the intent behind and the preservation of the 340B Drug Pricing Program. We are, however, greatly troubled that the number of 340B covered entity sites have increased by more than 1030% – from 1,223 to 13,872 – in the last eleven years,<sup>12</sup> while lacking any corresponding increase in the safeguards necessary to protect the integrity of the program. Sections 611 and 612 of the AHCA would expand the 340B program even further without appropriately addressing any of its existing deficiencies, of which there are many. According to Medicare cost report data, this expansion means more than 46% of all hospital drugs by cost sold in the U.S. will be eligible for 340B pricing.<sup>13</sup>

PPTA is committed to ensuring that patients who require regular infusions or injections of lifesaving plasma protein therapies as part of their treatment plan are able to obtain the therapy best suited for their individual needs without impediment. We recognize the importance of health care reform in achieving this goal and support many policies currently under consideration by the HELP Committee. Furthermore, we agree that improving the 340B Drug Pricing Program must be part of the debate on health care reform. We, however, respectfully request your consideration of the following proposals to improve sections 611 and 612 of the AHCA so that the 340B program is properly reformed before it is expanded:

- 1. Refrain from expanding the 340B Program beyond its legislative intent:** In establishing the 340B Program, it was not the intent of Congress to: (1) require manufacturers to sell product to 340B covered entities as they are required to under the VA program; or (2) include drugs sold for inpatient use. Before considering such expansion, Congress should direct the Government Accountability Office (“GAO”) to conduct a study to determine how well the patients of 340B covered entities are being served under the current program [**Appendix: § 1**];
- 2. Establish a strict statutory definition of a “patient”:** In order to limit the risk of product diversion, the covered entity must meet defined standards to demonstrate it is actually providing regular health care services to the “patient” to whom it is dispensing or administering 340B product, and not merely serving as a discount pharmacy. If manufacturers are going to be required to sell product to 340B covered entities, as proposed by this bill, the definition of a patient must be much more narrowly crafted [**Appendix: § 2**];
- 3. Preserve the existing GPO prohibition for DSH hospitals:** It is not only unjustifiable as a matter of policy, but also illogical for Congress to give DSH hospitals that are 340B covered entities the advantage of collective bargaining power through a GPO as a means

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<sup>11</sup> See Chris Hogan, Hospital Outpatient Prospective Payment System Drug Split by 340B Hospital (2008) (on file with the author).

<sup>12</sup> Compare OIG, HHS, Audit of the Utilization of the Public Health Service 340B Drug Pricing Program 3 (1998) with OPA List, *supra* note 8.

<sup>13</sup> See Chris Hogan, Hospital Drug Costs by Type of Hospital, Based on Most Recent Cost Report As Of 4/2008 (2009) (on file with the author).

to obtain product in shortages and manufacturer non-compliance, to facilitate generic substitution, or to reduce the administrative burden of managing drug inventories. [Appendix: § 3];

4. **Refrain from requiring manufacturers to calculate an additional AMP in certain instances to establish the 340B ceiling price:** The implementation of this additional AMP calculation would create not only an excessive administrative burden for manufacturers, but also incredible confusion [Appendix: § 4];
5. **Refrain from establishing new, burdensome quarterly reporting requirements for manufacturers, as proposed in section 612(b), unless 340B income reporting requirements for covered entities are also established:** HRSA is currently considering requiring HTCs to report use of 340B income, but PPTA believes all 340B covered entities must have a statutory obligation to report use of such income [Appendix: § 5];
6. **Provide for parity in ceiling price true-ups:** As a matter of equity, PPTA respectfully urges that you either: (1) modify this legislation to mandate that any true-up of ceiling prices result in corrective payments by both the manufacturer (if the ceiling price goes down) and the covered entities (if the ceiling price goes up), or (2) strike the provision from the bill, because the AMP and BP calculations, even when compliant, necessarily involve restatements, such that restatements typically do not represent any misconduct by the manufacturer [Appendix: § 6];
7. **Impose more equitable civil monetary penalties (“CMPs”):** 340B covered entities and manufacturers alike must be liable for CMPs in instances where they have “knowingly and intentionally” violated the 340B program – the proposed “interest penalty,” the maximum penalty assignable to covered entities, is not a sufficient deterrent for malfeasance by covered entities [Appendix: § 7]; **and**
8. **Impose more equitable dispute resolution processes:** Amending this legislative language to provide manufacturers with an equal right to discover and join claims, as well as waive the audit requirement that manufacturers must satisfy before asserting a claim would achieve this result [Appendix: § 8].

Thank you for your consideration. If you would like to discuss these recommendations further, please contact Jay Greissing ([jgreissing@pptaglobal.org](mailto:jgreissing@pptaglobal.org)) or Jon McKnight ([jmcknight@pptaglobal.org](mailto:jmcknight@pptaglobal.org)) in our office at 202-789-3100.

Sincerely,



Julie Birkofer  
Vice President, PPTA North America

Attachment

CC: Sens. Dodd, Bingaman

## APPENDIX

**1. PPTA urges Congress to refrain from expanding the 340B program beyond its legislative intent.** Manufacturers seeking federal reimbursement for their covered outpatient drugs from both Medicaid and Medicare Part B must participate in both the 340B Drug Pricing Program and the Medicaid Outpatient Drug Rebate Program.<sup>14</sup> In 1992, Congress created the 340B program in section 602 of the Veteran’s Health Care Act (“VHCA”) of 1992<sup>15</sup> to protect federally funded clinics and hospitals from the unintended consequence of excessive price increases for prescription drugs by manufacturers in the wake of the implementation of the Medicaid rebate program one year earlier.<sup>16</sup> Congress believed the “price controls”<sup>17</sup> established by the 340B program would “enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>18</sup>

In contrast to section 603 of the VHCA, which requires that a manufacturer of covered drugs makes its products available for procurement on a Department of Veterans Affairs (“VA”) Federal Supply Schedule (“FSS”) Contract (also a response to the excessive price increases resulting from the Medicaid drug rebate),<sup>19</sup> the 340B program only requires a manufacturer to enter into pharmaceutical pricing agreement (“PPA”) with the Secretary of the Department of Health and Human Services (“HHS”) in order to be in compliance with the 340B statute.<sup>20</sup> The PPA requires the contracting manufacturer to charge 340B covered entities no more than the 340B ceiling price if and when they sell their covered outpatient drugs to 340B covered entities.<sup>21</sup>

The Health Resources and Services Administration (“HRSA”), its Office of Pharmacy Affairs (“OPA”), and other interested parties have, however, consistently misconstrued and misapplied unambiguous HRSA guidance in arguing that manufactures are required to make product

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<sup>14</sup> See 42 U.S.C. § 1396r-8(a) (2008).

<sup>15</sup> Pub. L. 102-585, Title VI, § 602(a), 106 Stat. 4967 (1992).

<sup>16</sup> See H.R. REP. NO. 102-384, PART 2 (1992) (highlighting congressional hearing testimony describing canceled contracts and price increases to public hospitals following the implementation of the Medicaid Outpatient Drug Rebate Program). See also 102 CONG. REC. S17882-S17902 (Oct. 8, 1992) (statement by Sen. Cranston); see also 102 CONG. REC. S17724 (Oct. 8, 1992) (statement by Sen. Chafee) (illustrating that prior to the passage of the legislation creating the Medicaid Outpatient Drug Rebate Program in 1990, some Members of Congress expressed their concern regarding the impact of the program on the business practices of drug companies, and thus, federal purchasers).

<sup>17</sup> See Guidance Regarding Section 602 of the Veterans Health Care Act of 1992: Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289 (May 7, 1993) (describing the legislative intent of protecting safety net hospitals from excessive price increases by drug manufacturers).

<sup>18</sup> H.R. REP. NO. 102-384, PART 2 (1992).

<sup>19</sup> See 38 U.S.C. § 8126(a) (2008).

<sup>20</sup> See 42 U.S.C. § 256b(a)(1) (2008).

<sup>21</sup> See Guidance Regarding Section 602 of the Veterans Health Care Act of 1992: Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993) (providing guidance on the duties of a manufacturer required by a PPA); see also 42 U.S.C. § 256b(a)(10) (indicating it is permissible for a manufacturer to sell products below the 340B ceiling price).

available to 340B covered entities, similar to their obligation under VA FSS contracts.<sup>22</sup> This position is flawed. The plain language of the 340B statute does not require manufacturers to sell to covered entities and HRSA clearly lacks the administrative authority to go beyond the legislative language of the 340B statute to interpret it to require manufacturers to sell to 340B covered entities.<sup>23</sup>

Section 612(b)(1) of the Affordable Health Choices Act would address the concerns of HRSA and other interested parties by “requir[ing] that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” PPTA strongly opposes this language because it clearly goes well beyond the original legislative intent behind the establishment of this program. Seventeen years ago, Congress made a conscious decision to extend the price protection initially intended only for the VA to “federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”<sup>24</sup> In doing so, however, lawmakers also deliberately opted not to require manufacturers to make product available for purchase by 340B covered entities as they had expressly done for the FSS.<sup>25</sup> Amending the statute to do so now would be a very poor and unjustified policy decision.

Such a requirement would be especially troublesome for IVIG, which has had a history of supply challenges. In recent years, the DSH hospital community has blamed its IVIG access difficulties on both a shortage of IVIG as well as independent refusals by IVIG manufacturers to participate in the 340B Program.<sup>26</sup> Both assertions, however, lack merit.

IVIG supply is currently adequate. In 2008, immune globulin distribution in the U.S. rose by nearly 8% from the previous year to 36,788 kg. Additionally, former CMS Acting Deputy Administrator Herb Kuhn, the HHS Advisory Committee on Blood Safety and Availability (“ACBSA”), and the Food and Drug Administration’s Center for Biologics Evaluation and Research have all determined that IVIG supply is sufficient.<sup>27</sup> A 2007 report by the HHS Office

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<sup>22</sup> See *HHS Rejects Manufacturers’ Proposal to Cap 340B Drug Supply: HRSA Calls Plan “Contrary to the Intent” of 340B*, 2 FEDERAL DRUG DISCOUNT AND COMPLIANCE MONITOR 4 (April 2005).

<sup>23</sup> See, e.g., *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988) (describing “an administrative agency’s power to promulgate legislative regulations [as] limited to the authority delegated by Congress.”). See also *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986) (describing the lack of authority an administrative agency possesses without congressional mandate); *Killip v. Office of Personnel Management*, 991 F.2d 1564, 1569 (Fed. Cir. 1993) (concluding a federal agency may only act pursuant to the authority Congress expressly grants it).

<sup>24</sup> H.R. REP. NO. 102-384, PART 2 (1992).

<sup>25</sup> Compare 42 U.S.C. § 256b with 38 U.S.C. § 8126(a).

<sup>26</sup> See, e.g., PUBLIC HOSPITAL PHARMACY COALITION, ACCESS TO IVIG BY SAFETY NET HOSPITALS IN THE 340B DRUG DISCOUNT PROGRAM (2006).

<sup>27</sup> See *Medicare Reimbursement of Physician Administered Drugs: Hearing Before the Subcomm. On Health of the House Comm. on Ways and Means*, 109<sup>th</sup> Cong. (2006) (statement of Herb Kuhn, Director, Centers for Medicare and Medicaid Services); ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY, U.S. DEP’T OF HEALTH AND HUMAN SVCS., STATUS OF IMMUNE GLOBULIN INTRAVENOUS (IGIV) PRODUCTS, available at <http://www.hhs.gov/bloodsafety/igiv.html> (last visited April 30, 2009); CTR. FOR BIOLOGICAL RESEARCH & EVALUATION, U.S. DEP’T OF HEALTH & HUMAN SERV., BIOLOGICAL PRODUCT SHORTAGES, at <http://www.fda.gov/cber/shortage/shortage.htm> (last visited April 30, 2009).

of Inspector General on IVIG access issues also indicates that even most physicians believe IVIG supply is adequate.<sup>28</sup> Furthermore, in order to ensure patients are always able to access the appropriate IVIG therapy for their individual needs, manufacturers of IVIG maintain an inventory of this therapy to meet any emergency requests they may receive.<sup>29</sup>

All IVIG manufacturers in the U.S. have signed PPAs with HRSA and are participating in the 340B Program. Individual business practices notwithstanding, all IVIG manufacturers also allocate the majority of their supply pursuant to contractual arrangements with authorized distributors, group purchasing organizations (“GPOs”), hospital pharmacies, homecare companies, physicians, health maintenance organizations (“HMOs”), and the federal government. Manufacturers individually began to contract in this manner in response to Congressional and Administrative pressure to address an IVIG supply shortage more than a decade earlier.<sup>30</sup> Because IVIG therapies are not interchangeable, manufacturer allocation of IVIG therapies based on historical utilization provide a safeguard to ensure patients are able to access the therapy best suited for their individual needs. Although such allocation may contribute to short term access challenges for both 340B covered entities attempting to purchase IVIG and providers who treat Medicare or Medicaid beneficiaries with IVIG, this business method is critical to maintaining long term patient access to this lifesaving therapy.

Despite tight supply and having no statutory obligation to sell to 340B covered entities, about 1/3 of all IVIG sold under the Medicare Outpatient Prospective Payment System (“OPPS”) is sold to 340B hospitals – this is just under the average for overall pharmaceutical sales to these hospitals, according to 2007 OPPS claims data.<sup>31</sup> The DSH hospitals participating in 340B continue to push for more IVIG because of the particularly large profit margins they can obtain from the resale of this high value therapy to each patient.

The purpose of the 340B program is for the 340B covered entities to profit enough from the revenue obtained from purchasing outpatient drugs at or below the 340B ceiling price and reselling to patients at higher prices near the market value to remain in operation to benefit the uninsured and underinsured by affording them the opportunity to continue to utilize such covered entities for the receipt of both medical services and prescription drugs. It was not the intent of Congress for patients to directly benefit by paying lower prices for prescription drugs, nor was it the intent of Congress for 340B covered entities to make windfall profits on the backs of

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<sup>28</sup> See OFFICE OF INSPECTOR GENERAL, U.S. DEP’T OF HEALTH AND HUMAN SERVS., INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (2007).

<sup>29</sup> See OFFICE OF THE ASS’T SEC. FOR PLANNING & EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) 2-21 (2007).

<sup>30</sup> See *Public Health 2000: Immune Globulin Shortages – Causes and Cures: Hearing Before the Subcomm. on Human Resource of the House Comm. on Government Reform and Oversight*, 105<sup>th</sup> Cong. 2 (1998) (statement of Rep. Shays, Chairman, Subcomm. on Human Resources of the House Comm. on Government Reform and Oversight) (calling for manufacturers to adopt the ACBSA recommendations to allocate therapy based on historical utilization in order to address the 20% shortage of IVIG in 1997).

<sup>31</sup> See Memorandum from Chris Hogan, Direct Research, LLC to Interested Parties 2 (July 27, 2008) (on file with the author).

pharmaceutical manufacturers. Congress should not exceed the legislative intent of the program by making an arbitrary policy decision to amend the 340B statute to mandate product sales to covered entities.

Section 611(b) of the Affordable Health Choices Act would also exceed the 340B Drug Pricing Program's legislative intent by extending the 340B discount to inpatient drugs. The entire purpose of the 340B program was to protect against manufacturer price increases on outpatient drugs at public hospitals stemming from the implementation of the Medicaid Outpatient Drug Rebate Program.<sup>32</sup> While we do not dispute the fact, as Senator Jeff Bingaman (D-NM) has asserted, that "requiring participating hospitals to credit their Medicaid agencies a percentage of their savings on inpatient drugs" would generate savings for the Medicaid program,<sup>33</sup> PPTA does not believe this rationale is sufficient justification to expand the program in this manner. Again, the purpose of the 340B Program is to directly benefit safety net hospitals, not the Medicaid program.

When submitting claims for Medicaid reimbursement, providers must submit utilization data and coding information for each physician-administered covered outpatient drug used for that period.<sup>34</sup> In the case of reimbursing a 340B covered entity for drugs purchased at or below the 340B ceiling price, the State Medicaid agency will reimburse the drug's acquisition cost at the 340B discount. Moreover, because of the current safeguards that HRSA has implemented to protect against duplicate discounts, State Medicaid agencies are able to use information from HRSA to create a separate provider file for 340B covered entities in order to exclude products purchased at or below the 340B ceiling price from submission for a Medicaid outpatient drug rebate from manufacturers.<sup>35</sup>

State Medicaid agencies, therefore, will either benefit from the 340B discount, or the Medicaid drug rebate on outpatient drugs. Because only covered outpatient drugs are subject to Medicaid rebates and State Medicaid agencies do not provide separate reimbursement for drugs used in the inpatient setting, Senator Bingaman has correctly recognized this credit would be the mechanism to allow the States to benefit from the lower price hospitals will pay for covered drugs should inpatient drugs become eligible for the 340B discount. While PPTA opposes extending 340B pricing to inpatient drugs, if Congress is determined to enact such a provision, it must further amend the 340B statute to apply the duplicate discount prohibition to sales of drugs for inpatient use.

The 340B Drug Pricing Program has grown at an alarming rate in the last eleven years. Before expanding the 340B Program as discussed in this section, PPTA urges Congress to direct the GAO to conduct a study to determine how well the patients of 340B covered entities are

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<sup>32</sup> See H.R. REP. NO. 102-384, PART 2 (1992) (describing results from a study conducted by New York University on the most widely used outpatient drugs at five public hospitals).

<sup>33</sup> See 153 Cong. Rec. S. 6057 (daily ed. May 14, 2007) (statement of Sen. Bingaman).

<sup>34</sup> See 42 U.S.C. § 1396r-8(a)(7).

<sup>35</sup> See Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27293 (May 7, 1993).



currently being served. Such study should also examine the prevalence of product diversion resulting from the breadth of the current definition of “patient” in HRSA guidance, as well as how effective the current safeguards are in protecting against duplicate discounts.

- **On page 598, strike line 1 and all that follows through page 599, line 2.**
- **On page 601, strike line 5 and all that follows through line 13.**
- **On page 602, strike line 3 and all that follows through line 23.**
- **On page 615, line 1, strike “, and” and all that follows through line 5, and replace with “.”.**
- **On page 615, insert after line 9 the following:**

*“SEC. 613. GAO REPORT ON THE 340B DRUG PRICING PROGRAM.*

*Not later than 18 months after enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that examines whether “patients” of 340B covered entities are receiving optimal health care services. Such a report shall include determinations whether 340B income is being used by 340B covered entities to further program objectives and whether such covered entities are complying with the applicable law regarding product diversion and duplicate discounts.”*

**2. The integrity of the 340B Program would benefit greatly if Congress would enact a strict statutory definition of a “patient” for the purpose of the program.** The 340B statute does not place any restrictions on the price a covered entity may charge a patient for its discounted drugs, but it does restrict to whom a covered entity may dispense or administer such products. Specifically, 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.<sup>36</sup> 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.<sup>37</sup> Congress created this prohibition against product diversion in order to prevent covered entities from profiting through the artificial expansion of their patient population at the expense of manufacturers, yet Congress never defined the term “patient” in the 340B statute and HRSA only finalized guidance for a definition nearly four years after the statute went into effect.<sup>38</sup>

With that original guidance, HRSA promulgated a “definition flexible enough to describe accurately each covered entity’s patients while at the same time not excluding eligible patients.”<sup>39</sup> The agency, however, has recently recognized that the breadth at which 340B

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<sup>36</sup> See 42 U.S.C. § 256b(a)(5)(B).

<sup>37</sup> *Id.*

<sup>38</sup> 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 (Oct. 24, 1996).

<sup>39</sup> See 61 Fed. Reg. at 55156-55157

covered entities have interpreted the current definition has increased the threat for the diversion of product to ineligible patients.<sup>40</sup>

In response to criticisms of the “ambiguity” of the existing definition of a “patient,” HRSA proposed a stricter definition in the January 12, 2007 *Federal Register*.<sup>41</sup> Among the changes to the existing definition, HRSA’s proposal would now require: (1) covered entities to satisfy more rigorous requirements for maintaining the healthcare records of the patient, (2) the health care services to be provided by a health care provider employed or under contract to the covered entity, (3) the drug product to be prescribed by that provider as part of the treatment or diagnosis of the patient, and (4) DSH hospitals or a location that qualifies “as a provider-based facility within a DSH” hospital to be included in the existing scope of service requirement found in the current definition.<sup>42</sup> HRSA also provided much needed guidance on the role of case management arrangements, loose affiliation networks, DSH expansion, and employees of covered entities.<sup>43</sup>

Although statute requires a covered entity to reimburse a manufacturer if the products sold at the 340B discount price by the manufacturer to the covered entity are sold to ineligible patients by the covered entity,<sup>44</sup> and HRSA guidance requires covered entities to “develop and institute adequate safeguards,” including separate purchasing accounts and dispensing records, in order to prevent individuals who are not eligible patients from obtaining these discounted drugs,<sup>45</sup> the threat of product diversion remains problematic. While PPTA supports HRSA’s efforts at establishing a more rigid definition of a patient, PPTA believes it should not only be even stricter, but also be placed in statute. PPTA recommends the following amendment to the Affordable Health Choices Act:

- **On page 598, strike line 15 and all that follows through page 599, line 2, and replace with the following:**

*“(2) PATIENT.—In this section, the term ‘patient’ means an individual who receives at a covered entity site outpatient health care services that result in the use of, or prescription for, covered outpatient drugs purchased by such covered entity at or below the ceiling price described in this section as part of such individual’s diagnosis or treatment by a health care provider.*

*(A) Relationship with covered entity. The health care provider treating the individual must be employed by, or under a contract to, the covered entity.*

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<sup>40</sup> See 72 Fed. Reg. at 1544.

<sup>41</sup> See 72 Fed. Reg. at 1543.

<sup>42</sup> See 72 Fed. Reg. at 1544.

<sup>43</sup> See 72 Fed. Reg. at 1545-1546.

<sup>44</sup> See 42 U.S.C. § 256b(a)(5)(D).

<sup>45</sup> See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25112 (May 13, 1994). These safeguards are also required for larger institutions that contain covered entities within their structure. *Id.* at 25113.

*(B) Requirements for health records. The covered entity must maintain ownership, control, maintenance, and possession of the individual's health records, which*

*(i) may be an electronic health record shared by the individual and the covered entity; and*

*(ii) must include appropriate documentation when such services result in the use of, or prescription for, covered outpatient drugs purchased by the covered entity at or below the ceiling price.*

*(C) Scope. The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, covered outpatient drugs purchased by the covered entity at or below the ceiling price must be:*

*(i) part of a health care service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided to the covered entity; or*

*(ii) provided by a disproportionate share hospital described in subsection (a)(4)(L) of this section or by a provider-based facility within such a hospital as reflected in that hospital's Medicare Cost Report.*

*(D) Limitation. An individual may not qualify as a patient of the covered entity if:*

*(i) the only outpatient health care services provided to the individual at the covered entity are the dispensing of a covered outpatient drug for subsequent self-administration or administration in the home setting;*

*(ii) the outpatient health care services that result in the use of, or prescription for, covered outpatient drugs purchased by the covered entity at or below the ceiling price are provided to the individual at an entity outside the covered entity through a case management arrangement, a loose affiliation network, a referral arrangement, or other arrangements that the Secretary determines do not demonstrate the provision of health care services described in this paragraph;*

*(iii) the individual is an employee of the covered entity but does not satisfy other requirements of this paragraph; or*

*(iv) in the case of Indian Tribes and tribal organizations, the Indian Health Service has not given prior formal approval to treat non-Indian Health Service beneficiaries.*

*(E) Exception. An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act shall be considered a patient of a covered entity.*

**3. Congress must not create exceptions to the GPO prohibition for drug “shortages” or “manufacturer non-compliance.”** Covered entities may use third parties, such as the 340B prime vendor, GPOs, and purchasing agents, to facilitate the purchase of prescription drugs at prices below the 340B ceiling price. The 340B program, however, prohibits DSH hospitals that qualify as covered entities from obtaining covered outpatient drugs through a GPO.<sup>46</sup> Any DSH attempting such arrangements with a GPO will no longer qualify as a covered entity under the

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<sup>46</sup> See 42 U.S.C. § 256b(4)(L)(iii).

statute.<sup>47</sup> Covered entities, including DSH hospitals, may, however, use purchasing agents if certain conditions are met by the agent.<sup>48</sup>

With regard to this GPO prohibition for DSH hospitals, section 611(c) of the Affordable Health Choices Act would direct HRSA to develop exceptions in certain instances, including for covered outpatient drugs unavailable because of a shortage, or manufacturer non-compliance. The legislation would leave to the agency's discretion the identification of those situations that would qualify either as a product "shortage" or as "manufacturer non-compliance," as well as who would evaluate the facts of a case to make such a determination.

PPTA strongly believes this provision unfairly targets the IVIG industry. As detailed in Section 1 of the Appendix, there is no need for such intervention because the manufacturers of IVIG are complying with the 340B statute and there is no IVIG shortage. Moreover, providing groups of DSH hospitals with collective bargaining power in the broad instances described in section 612(c) of the bill goes against the very purpose for establishing this exemption in the first place. Congress put the GPO prohibition for DSH hospitals in place to protect manufacturers from being forced into one-sided negotiations that would result in the provision of discounts much deeper than the 340B ceiling price.<sup>49</sup> Price negotiations must remain between a manufacturer and each individual DSH hospital to which it sells.<sup>50</sup> It is not only unjustifiable as a matter of policy, but also illogical for Congress to give DSH hospitals that are 340B covered entities the disproportionate advantage of collective bargaining power through a GPO as a means to obtain product in shortages and manufacturer non-compliance, to facilitate generic substitution, or to reduce the administrative burden of managing drug inventories.

Additionally, if Congress successfully expands the 340B program to cover inpatient drugs, it must also expand the 340B program's GPO prohibition to covered drugs purchased by DSH hospitals at the 340B discount for inpatient use. As drafted, section 611(c) of the Affordable Health Choices Act would extend the statutory prohibition against DSH hospitals purchasing covered outpatient drugs from GPOs to the new covered entity types added by section 611(a): DSH children's hospitals, DSH critical access hospitals, rural referral centers, and DSH sole community hospitals. These new covered entities and DSH hospitals would, however, be expressly permitted to purchase drugs for inpatient use through GPOs.

Because section 611(b) of the Affordable Health Choices Act would expand the 340B Program to include drugs purchased for inpatient use, which accounts for the majority of drug use in the healthcare system, PPTA urges you to extend the GPO prohibition to cover both outpatient drugs and inpatient drugs. If such protection is not extended to cover drugs purchased for inpatient use, this legislation will greatly exceed the intended scope of the 340B Program because GPO negotiation will provide for inflated volumes of drugs to be purchased below the 340B ceiling price by a proliferation of covered entities. PPTA would recommend the following amendment:

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<sup>47</sup> See 59 Fed. Reg. at 25113.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

- **Beginning on page 599, strike line 3 and all that follows through page 601, line 4.**

**4. Congress must not require a separate average manufacturer's price ("AMP") calculation to determine the 340B ceiling price in certain instances.** The Medicaid Outpatient Drug Rebate Program, which has been in effect since January 1, 1991, requires manufacturers to provide to each State Medicaid agency a rebate on the manufacturer's covered outpatient drugs that the State has reimbursed.<sup>51</sup> Because of the statutory link existing between the 340B Drug Pricing Program and the Medicaid Outpatient Drug Rebate Program,<sup>52</sup> policies affecting the calculation of the Medicaid outpatient drug rebate percentage, such as the recent proposal by the Senate Committee on Finance to increase it by 53%, significantly shape both programs. For example, manufacturers calculate the 340B ceiling price for a covered outpatient drug by subtracting the Medicaid unit rebate amount ("URA") from the 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).<sup>53</sup>

The AMP is "the average price paid to the manufacturer for the [covered outpatient] drug [for a rebate period] in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."<sup>54</sup> Although not expressly stated in the definition, CMS has interpreted it "to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer."<sup>55</sup> Manufacturers are not, however, permitted to include the customary prompt pay discounts extended to wholesalers.<sup>56</sup>

The AMP methodology serves two chief purposes for manufacturers: (1) it determines the Medicaid drug rebate liability for a manufacturer; and (2) in the case of multiple source drugs, it determines the federal upper payment limit.<sup>57</sup> Although States are not required to use AMP

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<sup>51</sup> See 42 U.S.C. § 1396r-8(b)(1).

<sup>52</sup> The late Chairman of the Senate Committee on Finance, Lloyd Bentsen (D-TX), stated his concern regarding this linkage during debate of the VHCA in 1992. See 102 CONG. REC. S17903 (Oct. 8, 1992) (statement of Sen. Bentsen). In addition, because of this statutory link between the Medicaid Outpatient Drug Rebate Program and the 340B Drug Pricing Program, the fraud and abuse with regard to the Medicaid drug rebate that manufacturers submit adversely affects the 340B program. See *Allegations of Waste, Fraud, and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Comm. on Oversight and Gov't Reform*, 110<sup>th</sup> Cong. (2007) (statement of Lewis Morris, Chief Counsel to the Inspector General, U.S. Dep't of Health & Human Servs).

<sup>53</sup> See 42 U.S.C. § 256b(a)(1)

<sup>54</sup> 42 U.S.C. § 1396r-8(k)(1)(A).

<sup>55</sup> See Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39147 (July 17, 2007).

<sup>56</sup> See 42 U.S.C. § 1396r-8(k)(1)(B). Both existing statute and the national rebate agreement fail to define "customary prompt pay discounts." CMS, however, finalized this definition customary prompt pay discounts under a new 42 C.F.R. § 447.504(c) as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment." 72 Fed. Reg. 39241.

<sup>57</sup> 42 U.S.C. § 1396r-8(e); 42 C.F.R. § 447.514. As of May 2009, implementation of this statutory requirement has been stayed pursuant to ongoing litigation. See *Order, Nat'l Ass'n of Chain Drug Stores v. Leavitt*, Civil Action No. 1:07cv02017 (D.D.C. Dec. 19, 2007).

information to set payment amounts, CMS contends that Congress intended that States have “drug pricing data based on actual prices” to facilitate this result.<sup>58</sup>

With regard to Medicaid drug rebate liability, the URA for generic drugs is 11% of a product’s AMP.<sup>59</sup> The calculation of the URA for branded pharmaceuticals and biologicals is, however, a bit more complicated. For these drugs, CMS calculates the basic URA as the greater of the 15.1% minimum rebate percentage of AMP, or the difference between the AMP and the best price (“BP”).<sup>60</sup> Because most plasma protein therapies are sold under long term contracts with distributors, they will usually be subject to the minimum rebate percentage rather than rebates based on BP discounts; thus, the basic URA for these therapies would likely then be 15.1% of their AMP.<sup>61</sup> Brand name drugs may also be liable for an “additional rebate” if the AMP for a product outpaces a specified inflation factor.<sup>62</sup> The basic URA and additional URA are then added to determine the total URA for the purposes of both the Medicaid drug rebate and the 340B ceiling price.

In 2007, upon the effect date of the amendments to the definition of AMP and corresponding regulations provided by the Deficit Reduction Act (“DRA”) of 2005,<sup>63</sup> HRSA’s OPA began its quest to alter the AMP reported by manufacturers for the purpose of calculating the 340B ceiling price. Specifically, a January 30, 2007 “Dear Manufacturers Letter” from OPA directed manufacturers that have signed PPAs to “continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts,” which, as stated earlier, was no longer permitted under the DRA.<sup>64</sup> On May 9, 2007, OPA retracted its position after manufacturers alerted the agency that it lacked the statutory authority to unilaterally promulgate such a policy shift.<sup>65</sup>

PPTA is concerned with a provision found in section 611(f) of the Affordable Health Choice Act that would expand upon OPA’s previous efforts by defining AMP for drugs not distributed to the retail pharmacy class of trade under the 340B program to mean “the average price paid to the manufacturer for the [covered] drug in the United States [in a rebate period] by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts.” CMS has defined the retail pharmacy class of trade for the purpose of the AMP to specifically mean “any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity

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<sup>58</sup> *Id.*

<sup>59</sup> See 42 U.S.C. § 1396r-8(c)(3).

<sup>60</sup> See 42 U.S.C. § 1396r-8(c)(1)(A).

<sup>61</sup> See 42 U.S.C. § 1396r-8(c)(1)(B)(i).

<sup>62</sup> See 42 U.S.C. § 1396r-8(c)(2). This “penalty” rebate can create a situation where a drug’s URA becomes greater than its manufacturer reported AMP, which can result in a negative 340B ceiling price. In such instances, manufacturers are directed to charge a 340B ceiling price of one penny per unit, rather than the previous quarter’s ceiling price. See OIG, HHS, REVIEW OF 340B PRICES 3, 14 (2006).

<sup>63</sup> Pub. L. 109-171, 120 Stat. 4 (2006)

<sup>64</sup> See Letter from Jimmy R. Mitchell, OPA, to Pharmaceutical Manufacturers (Jan. 30, 2007).

<sup>65</sup> See Letter from Jimmy R. Mitchell, OPA, to Pharmaceutical Manufacturers (May 9, 2007).

and subsequently sells or provides the drugs to the general public.”<sup>66</sup> The agency has further clarified that retail entities for the purposes of the retail pharmacy class of trade include specialty and home infusion pharmacies,<sup>67</sup> physician offices,<sup>68</sup> pharmacy benefits management-operated mail order pharmacies,<sup>69</sup> surgical and ambulatory care centers, mental health outpatient facilities, non-hospital based dialysis clinics, and HOPDs where sales can be separately quantified;<sup>70</sup> thus, this proposed provision found in the Affordable Health Choice Act would apply to drugs used exclusively in the in-patient hospital setting.

This provision is necessary to provide a baseline for the 340B ceiling price for covered drugs sold exclusively for use in the inpatient setting, if the 340B program is expanded. Notwithstanding its limited application, this second AMP calculation differs greatly from the current AMP submitted to CMS for the Medicaid Outpatient Drug Rebate Program, as neither prompt pay discounts nor the acute care class of trade is an element of the current definition of AMP. The implementation of this additional AMP calculation would create not only an excessive administrative burden for manufacturers, but also incredible confusion.

Implementation would require a precise definition of the acute care class of trade, as well as instructions regarding whether the URA to be used when calculating the ceiling price in these cases should be separately calculated by reference to the new AMP or the AMP reported to CMS. If the “acute” AMP is to be used in the URA calculation for ceiling price purposes, then in the case of innovator products, additional guidance also would be needed as to whether a distinct “acute” base AMP also would need to be calculated so as to ensure that the additional rebate calculation compares two AMPs that have been calculated using the same approach. For older products, the availability of data for such “acute” base AMP calculations could be limited, at best. For all of these reasons, the complexity and burden of implementing this approach cannot be overstated. PPTA would recommend the following amendments:

- **On page 602, line 23, strike “; and” and replace with “.”**
- **On page 602, strike line 24 and all that follows through page 603, line 20.**

**5. Congress must require all 340B covered entities to report their use of income generated by their participation in the 340B Program.** As discussed previously in sections 1 and 2 of the Appendix, because the 340B statute does not place a limitation on the price at which 340B covered entities can sell covered outpatient drugs to their patients, such entities have the ability to earn substantial profits from purchasing pharmaceutical and biological products at or below the 340B ceiling price and reselling to their patients at a higher price. While this is consistent with the legislative intent expressed by Congress when it created the program, the ability to profit creates the potential for fraud and abuse by the covered entity.

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<sup>66</sup> 42 C.F.R. § 447.504(e).

<sup>67</sup> 42 C.F.R. § 447.504(g)(10)-(12).

<sup>68</sup> 42 C.F.R. § 447.504(g)(13).

<sup>69</sup> 42 C.F.R. § 447.504(g)(6).

<sup>70</sup> 42 C.F.R. § 447.504(g)(8).

All grants from HHS are subject to regulation under the “Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.”<sup>71</sup> Under these rules, program income is “gross income earned by the [grantee] that is directly generated by a supported activity or earned as a result of the award.”<sup>72</sup> For 340B covered entities receiving federal grants, program income is this net income realized from selling drugs purchased at or below the 340B ceiling price at a mark-up.

The agency within HHS awarding the grant and HRSA are responsible for providing guidance on the use of such income within the scope of the federal regulations and agency policy. For example, the Maternal and Child Health Bureau (“MCHB”) and HRSA require HTC grantees and their affiliate institutions to use the program income to “further eligible project and program objectives.”<sup>73</sup> HTCs use income gained from the 340B discount to maintain or expand supporting services as well as provide factor replacement products (“FRP”) to uninsured patients.<sup>74</sup>

HRSA recently proposed to require that MCHB HTC grantees and their affiliate HTC FRP programs report on patient FRP program participation, FRP program revenue, FRP program costs, FRP program net income, and use of such income.<sup>75</sup> PPTA supports this increased transparency as it will afford greater agency oversight of the 340B program. Such oversight is necessary because of the ongoing threat that these entities may attempt to manipulate the program for their financial benefit by broadly interpreting the existing definition of patient to artificially expand their patient population.

HRSA’s proposal evidences its concern for the potential for fraud and abuse by HTCs in use of the profits made in dispensing blood clotting factors. Specifically, these profits may be inappropriately filtered back to a parent hospital, which is not considered a covered entity for the purpose of the 340B program.<sup>76</sup> As a matter of policy, patients should benefit from this program either directly from covered entities passing the savings of the covered outpatient drugs to the patient or indirectly by covered entities using the revenue from the program to enhance the capabilities of the covered entity to serve its patients. Furthermore, increased transparency through income reporting of HTCs will ultimately benefit the hemophilia community if HRSA uses this data to enforce the requirements of the 340B program.

During the designated comment period, PPTA submitted a letter of support to HRSA for this proposal. In the interest of program transparency and patient access, PPTA respectfully requests

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<sup>71</sup> 45 C.F.R. § 74.1.

<sup>72</sup> 45 C.F.R. § 74.2.

<sup>73</sup> See Letter from MCHB and HRSA to HTC Grantees (May 23, 2003).

<sup>74</sup> See Health Resources & Serv. Admin., U.S. Dep’t of Health & Human Serv., Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 15 (July 2006).

<sup>75</sup> See Proposed Project Reporting Form for the MCHB National Hemophilia Program Grantees and Hemophilia Treatment Center Affiliates Having Factor Replacement Product Programs, 72 Fed. Reg. 5444 (Feb. 6, 2007).

<sup>76</sup> 42 U.S.C. § 256b(a)(6).



that you amend section 612 of the Affordable Health Choices Act to require all covered entities under the 340B program to annually provide HRSA with details regarding the income generated from their participation in the program, including the use of such income. As a matter of equity, manufacturers must not be required to provide 340B ceiling price data to the Secretary, as proposed in section 612(b) of the Act, unless covered entities are providing 340B income data to the Secretary. PPTA recommends the following amendment:

- **On page 614, after line 15, re-designate paragraph (b) as paragraph (c) and add the following new paragraph (b):**

*“(b) COVERED ENTITY REPORTING REQUIREMENT.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. § 256b(a)(5)) is amended by adding at the end the following:*

*“(F) Reporting. A covered entity shall furnish the Secretary with annual reports detailing the following information from the preceding calendar year concerning covered outpatient drugs subject to an agreement under this subsection:*

- (i) the number of patients it treated with such drugs;*
- (ii) the revenue from resale of such drugs;*
- (iii) the administrative costs associated with purchasing and dispensing such drugs;*
- (iv) the net income from the resale such drugs; and*
- (v) the use of income from the resale of such drugs.*

## **6. Congress must amend the 340B Program to properly account for manufacturer refunds.**

Section 612(a) of the Affordable Health Choices Act would direct HRSA to establish procedures for the issuance of a refund by a manufacturer to a covered entity in the event that such manufacturer inadvertently sells to such covered entity a product in excess of the 340B ceiling price. As a means of improving HRSA oversight of the 340B Drug Pricing Program, the refund provision would also require the manufacturer issuing a refund to provide HRSA with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued. This provision would further require HRSA to ensure that the refunds are issued accurately and within a reasonable period of time.

While well intended, this proposed policy is flawed. Medicaid is fundamentally a retroactive pricing system, while the 340B program is a prospective pricing system. When Congress created another prospective pricing system, it specifically required only errors to trigger recalculations.<sup>77</sup> Under the proposal in section 612(a), if a manufacturer makes a routine adjustment for late-arriving data for its AMP and BP calculations within the three-year period permitted by CMS,<sup>78</sup> but after such manufacturer has submitted the original information to CMS for the purpose of the

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<sup>77</sup> See 42 C.F.R. § 414.806 (suggesting that while there is no clear threshold for reporting errors, in the interest of avoiding strict CMPs, manufacturers will restate ASP data, even when the change from the originally reported ASP is immaterial, or where the error was discovered many quarters after the quarter CMS used the ASP information for reimbursement – lagged ASP data is not treated in the same manner).

<sup>78</sup> See 72 Fed. Reg. at 39143.

Medicaid drug rebate amount 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. Existing HRSA guidance suggests that no such manufacturer restatement obligation currently exists under the 340B program.<sup>79</sup> Section 612(a) must be amended to make a distinction between 340B price restatements resulting from manufacturer pricing calculations that were incorrect when filed, as opposed to pricing changes that result from lagged data. Additionally, because the language in section 612(a) would create a conflict with the PPA, such obligation to restate prices could not begin until PPAs are reissued and executed, as a matter of basic contract law.<sup>80</sup>

It is critical to note that this provision in section 612(a) also mistakenly assumes that corrections to AMP and BP data work only to lower ceiling prices, when in fact such revisions are equally capable of resulting in increases to those ceiling prices. Any obligation to “true-up” ceiling prices to reflect changes to the underlying AMP and BP figures, based on an underlying obligation to charge the correct price based on the correct AMP and BP figures, must address price adjustments that can go both up and down. Imposing an obligation on a manufacturer to issue refunds, where revised ceiling prices go down, with no right to charge additional amounts where revised ceiling prices go up acts effectively as a requirement that manufacturers charge “sub-ceiling” prices in the latter case. That has never been a requirement of the 340B statute and should not now be added to the legislation, de facto, through a true-up process that is one-sided only.

As a matter of equity, PPTA respectfully urges that you either: (1) modify this legislation to mandate that the ceiling price “true-up” or reconciliation process address both price increases and decreases, or (2) delete this provision from the bill in recognition of the fact that the AMP and BP calculation and reporting process necessarily results in revisions to AMP and BP data and that those revisions are part of compliant methodologies and not necessarily because of any manufacturer misconduct.<sup>81</sup>

**7. Congress must impose CMPs against both manufactures and covered entities for violating the requirements of the 340B program.** In order to deter unlawful behavior by program participants and preserve program integrity, section 612(a) of the Affordable Health Choices Act would impose sanctions against covered entities and manufacturers for failing to

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<sup>79</sup> 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).

<sup>80</sup> See Section 340B Pharmaceutical Pricing Agreement (2006), at 8 [hereinafter “PPA”]; see also *County of Santa Clara v. Astra USA, Inc.*, 2006 WL 1344572 at 6 (N.D. Cal. 2006) (demonstrating that a PPA is an enforceable contract between a manufacturer and the Secretary of HHS, the interpretation of which is governed by federal common law, according to § VII(g) of the PPA).

<sup>81</sup> See 72 Fed. Reg. at 39242-43 (codifying 42 C.F.R. § 447.504(i)(2) (quarterly AMP is a weighted average of the three monthly AMP figures) and § 447.510(d) (directing use of 12-month rolling average to estimate lagged price concessions in the calculation of monthly AMP and to limit restatements of AMP to addressing issues other than late-arriving data)).

comply with program requirements. Specifically, this legislation would direct HRSA to impose a fine up to \$5,000 per instance on a manufacturer that it determines “knowingly and intentionally” charged a covered entity a price in excess of the 340B ceiling price despite having signed a PPA. CMPs, however, would not be available against a covered entity for program violations.

Instead, section 612(a) of the Affordable Health Choices Act would only require a covered entity that “knowingly and intentionally” sells 340B discounted drugs to individuals who are not “patients” of such covered entity to pay interest<sup>82</sup> on the restitution it must pay under current statute.<sup>83</sup> If HRSA determines that a violation of this prohibition by a covered entity was “systematic and egregious as well as knowing and intentional,” it may remove the covered entity from the 340B program and disqualify it from reentry into the program for a reasonable period of time to be determined by the agency.

PPTA generally supports these penalties, but, in the interest of equity, we urge you to strengthen this legislation to provide for a true civil penalty against a covered entity for the described violation. With the understanding that covered entities do not have the resources for significant fine liability, the threshold of “knowingly and intentionally” is high enough to preclude inadvertent sales to non-patients from the scope of the statute. A reasonable monetary penalty in this instance will be a stronger deterrent against true malfeasance than merely paying interest on the restitution. In addition, while such sanctions are an important first step in improving the program, until the definition of a patient is tightened, product diversion will continue to harm the integrity of the 340B program.

**8. The dispute resolution language in section 612(a)(3) must be amended to treat covered entities and manufacturers equally.** In its current guidance, HRSA established an informal, voluntary process for resolving certain disputes between manufacturers and covered entities. The specific requirements for this process are found in the December 12, 1996 edition of the *Federal Register*.<sup>84</sup> Although parties in dispute are not required to engage in this process, if they do, they must in good faith attempt to resolve their issue prior to requesting HRSA to mediate.<sup>85</sup> Section 612(a) of the Affordable Health Choices Act would, however, formalize this dispute resolution process.

Specifically, the Affordable Health Choices Act would designate or establish a decision-making official or decision-making body within HHS to be responsible for reviewing and finally resolving claims that (1) a manufacturer has charged a covered entity a price for covered drugs in excess of the 340B ceiling price and (2) a covered entity is engaging in product diversion and duplicate discounts to the detriment of a manufacturer. PPTA generally supports this provision

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<sup>82</sup> According to section 612(a) of the Affordable Health Choices Act, such interest is to be compounded monthly and equal to the current short-term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

<sup>83</sup> 42 U.S.C. § 256b(a)(5)(D).

<sup>84</sup> Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996).

<sup>85</sup> *See id.*

but objects to several advantages to which covered entities would be entitled under this legislative language. While covered entities would have the right to discover and join claims, manufacturers would not be afforded a similar right under this section of the bill. Moreover, even before asserting a claim under this provision, the Affordable Health Choices Act would require a manufacturer to perform an audit. PPTA asks that you please consider amending this language to provide manufacturers with an equal right to discover and join claims, as well as waive the audit requirement that manufacturers must satisfy before asserting a claim.