

January 2, 2008  
Reference No.: FASC08001

Kerry Weems  
Acting Administrator, Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: CMS–2238—FC (Final Rule: Medicaid Program; Prescription Drugs)**

Dear Acting Administrator Weems:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to comment on the final rule pertaining to prescription drugs under the Medicaid Program, published in the *Federal Register* on July 17, 2007 (“Final Rule”).<sup>1</sup> As an association deeply committed to the health and safety of the patients it serves, these comments on the Final Rule are intended to ensure that Medicaid beneficiaries have full access to the complete range of life-saving, Food and Drug Administration (FDA) approved, plasma-based and their recombinant analog therapies (“plasma protein therapies”).

PPTA is the association that represents the manufacturers of plasma protein therapies. Physicians administer these critical therapies, which include albumin, blood clotting factors (both plasma-derived and recombinant), alpha-1 antitrypsin, and immune globulin, in their treatment of patients suffering from debilitating diseases or chronic medical conditions. Several very small patient populations require regular infusions or injections of plasma protein therapies in order to sustain life. PPTA members produce more than 80 percent of the plasma protein therapies for the U.S. market and more than 60 percent of such therapies for global consumption.

Patient access to plasma protein therapies is dependent on adequate and accurate reimbursement for the healthcare providers that administer these lifesaving therapies. Because of its use in multiple entitlement programs, an accurate, uniform calculation of the average manufacturer price (AMP) is critical. PPTA appreciates the efforts of the Centers for Medicare and Medicaid Services (CMS) in promulgating the Final Rule implementing these relevant sections of the Deficit Reduction Act of 2005.<sup>2</sup>

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<sup>1</sup> Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39142 (July 17, 2007).

<sup>2</sup> Deficit Reduction Act of 2005, Pub. L. 109-171, 120 Stat. 4, §§ 6001-6004 (2006).

While the Final Rule will generally provide more clarity to manufacturers in their AMP calculations, additional guidance is necessary in some instances. For example, PPTA urges CMS to consider providing additional guidance on whether or not the definition of “bundled sale”<sup>3</sup> requires the reallocation of discounts to products that are not part of a bundled arrangement but that may be in the same contract as the bundled agreement. The Final Rule seems to indicate that manufactures must reallocate these discounts to such products. PPTA believes such a broad interpretation could actually distort AMP calculations, rather than bring more clarity and accuracy to the process.

## **I. DISCUSSION**

### **A. BACKGROUND**

Outpatient prescription drug coverage by Medicaid is critical for the thousands of Medicaid beneficiaries that rely upon regular infusions or injections of plasma protein therapies for the duration of their lives. Since the implementation of the Medicare Part D Program in 2006, many of Medicaid’s elderly and disabled beneficiaries began receiving their drug coverage under Medicare as coverage of most traditional pharmaceutical and biologicals products provided to those beneficiaries dually eligible for the Medicare program shifted to Medicare Part D. Plasma protein therapies, however, are most generally administered incident to a physician office visit, rather than being fulfilled in retail pharmacies, and thus, are normally covered under Medicare Part B. By definition, if eligible for coverage by Medicare Part B, the drug may not be covered by Medicare Part D.<sup>4</sup> Plasma protein therapies will continue to be responsible for an increasingly significant portion of annual Medicaid drug expenditures.

Although States are not required to use AMP information to set Medicaid payment amounts, CMS contends that Congress intended that States have “drug pricing data based on actual prices” to facilitate this result.<sup>5</sup> PPTA agrees with CMS’ assessment and appreciates the agency’s efforts in providing clear guidance on the AMP calculation because of the use of this methodology not only in the Medicaid

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<sup>3</sup> A “bundled sale” is “an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.” 72 Fed. Reg. at 39240, codifying 42 C.F.R. § 447.502 (2007).

<sup>4</sup> See MEDICARE PART B VERSUS PART D COVERAGE ISSUES, at [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc\\_07.27.05.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf) (last visited on January 2, 2008).

<sup>5</sup> See 72 Fed. Reg. at 39146.

Outpatient Drug Rebate Program, but also in the 340B Drug Pricing Program and in determining reimbursement for drugs under Medicare Part B.

Pursuant to section 1927(a) of the Social Security Act (SSA), a manufacturer seeking federal reimbursement for its 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>6</sup> The rebate program, which has been in effect since January 1, 1991, requires manufacturers to provide to each state Medicaid program a rebate on the manufacturer's covered outpatient drugs that the state has reimbursed.<sup>7</sup> Such rebates are computed and paid by manufacturers each calendar quarter based on utilization information supplied by state Medicaid programs.<sup>8</sup> CMS calculates the rebate amount for "single source drugs," which, as defined by section 1927(k) of the SSA, includes all plasma protein therapies, and "innovator multiple source drugs" as the greater of the minimum rebate percentage of the AMP or the difference between the AMP and the best price (BP), which is the lowest price offered by the manufacturer in the same period to any wholesaler, retailer, nonprofit, or public entity.<sup>9</sup> Since 1995, the minimum rebate percentage for these brand name drugs has been 15.1%.<sup>10</sup>

Because the vast majority of plasma protein products are sold under long-term contracts with distributors, most plasma protein therapies are not subject, at present, to Medicaid rebates based on BP discounts. As such, PPTA's comments will primarily focus on the AMP. Section 1927(k) of the SSA defines the AMP as the average price, excluding the customary prompt pay discount, paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.<sup>11</sup> In the Final Rule, CMS establishes a more comprehensive definition of the AMP and also defines "retail pharmacy class of trade" and "customary prompt pay discount."<sup>12</sup>

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<sup>6</sup> Social Security Act § 1927(a) (2007).

<sup>7</sup> See SSA § 1927(b)(1)(a).

<sup>8</sup> See SSA § 1927(b).

<sup>9</sup> See SSA § 1927(c)(1). In addition to this basic rebate amount, CMS applies an extra "penalty" rebate to brand name drugs when the AMP for a product increases faster than a specified inflation factor. See SSA § 1927(c)(2). This added rebate unfairly subjects plasma protein therapies to a *much higher rebate amount* than all other drugs or biologicals in the marketplace. Prices increases for plasma protein therapies generally outpace inflation because of significant increases in manufacturing expenditures – including the costs of human plasma and emerging technologies – that are unique to producing these therapies.

<sup>10</sup> See SSA § 1927(c)(1)(B)(i)(V).

<sup>11</sup> SSA § 1927(k)(1).

<sup>12</sup> See 72 Fed. Reg. at 39241 codified at 42 C.F.R. § 447.504. The "retail pharmacy class of trade" is "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides these drugs to the general public." *Id.* The "customary prompt pay discount" is any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of

The Final Rule specifies that the “AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by the statute or regulation or is provided to an entity specifically excluded by state or regulation.”<sup>13</sup> In addition to the quarterly AMP reporting to CMS, manufacturers must provide CMS with AMP information on a monthly basis so that each month, CMS provide such information to state Medicaid agencies.<sup>14</sup> Furthermore, the agency must post this information on its Web site each quarter.<sup>15</sup>

Because of the statutory link between the 340B Drug Pricing Program and the Medicaid Outpatient Drug Rebate Program, the AMP methodology is used in determining the 340B ceiling price. The 340B Program requires a “manufacturer” to enter into an agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) to provide discounted prices on its “covered outpatient drugs” to a list of “covered entities.”<sup>16</sup> Specifically, such manufacturers must contract with the Health Resources and Services Administration in a Pharmaceutical Pricing Agreement in which they agree to sell their drugs to covered entities at or below the 340B ceiling price.<sup>17</sup> In order to determine the 340B ceiling price for the covered outpatient drug, manufacturers of these drugs shall calculate the AMP of such drugs for the preceding quarter and reduce it by the Medicaid unit rebate amount for that same quarter.<sup>18</sup>

In some instances, the AMP may also be used to reimburse Medicare Part B drugs. Under section 1847A(d)(2) of the SSA, the Office of Inspector General (OIG) of the HHS must compare the manufacturer’s average sales price (ASP) for a drug with such drug’s widely available market price (WAMP) and AMP.<sup>19</sup> If the OIG finds that the ASP for a product exceeds the AMP or the WAMP by a specified percentage threshold, the OIG informs CMS and the agency, in the next quarter, shall replace the ASP amount with the lesser of the WAMP or 103 percent of the AMP.<sup>20</sup> The current

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purchased drugs within a specified timeframe consistent with customary business practices for payment.”

*Id.*

<sup>13</sup> *Id.*

<sup>14</sup> See 72 Fed. Reg. at 39143. CMS provides guidance on monthly AMP calculations in the Final Rule.

See 42 C.F.R. § 447.510(d) (2007).

<sup>15</sup> *Id.*

<sup>16</sup> 42 U.S.C. § 256b(a) (2007). Section 340B of the Public Health Service Act, however, can be interpreted to *not require* manufacturers to sell their products to covered entities, but rather only to mandate that manufacturers who do choose to sell to covered entities do so at a deep discount.

<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, 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 PHS ceiling price).

<sup>18</sup> See 42 U.S.C. § 256b(a)(1).

<sup>19</sup> SSA § 1847A(d)(2) (2007).

<sup>20</sup> See SSA § 1847A(d)(3).

threshold of 5% has been extended by CMS into 2008.<sup>21</sup> Since the implementation of the ASP, the OIG has not determined that the ASPs of any plasma protein therapies have exceeded their WAMPs or AMPs.

The broad statutory application of the AMP methodology notwithstanding, this methodology serves two chief purposes for manufacturers of pharmaceuticals and biologicals: (1) determining the Medicaid outpatient drug rebate liability for a manufacturer; and (2) in the case of multiple source drugs, determining the federal upper payment limit (FUL). All plasma protein therapies are, however, “single source drugs,” as defined by section 1927(k) of the SSA, so there will be no discussion in PPTA’s comments of the impact of the Final Rule on the FUL.

With regard to the rebate, because approximately 35% of the 18,000 hemophilia patients in the United States are Medicaid beneficiaries, PPTA members have significant Medicaid drug rebate liability. Accurate AMP reporting by manufacturers is critically important for the proper operation of both the drug rebate program and the 340B Program. By providing strict guidance on the types of sales, rebates, discounts, and other price concessions to be included and excluded from the calculation of the AMP, manufacturers will be able to provide CMS the most accurate drug pricing information, which is essential to achieve this efficiency.

## **B. PPTA APPRECIATES THE PROMPT REMOVAL BY CMS OF FACTOR VIII RECOMBINANT AND FACTOR VIII FROM THEIR INADVERTENT INCLUSION IN THE MEDICAID TOP 20 MULTIPLE SOURCE PHYSICIAN ADMINISTERED DRUGS LIST**

PPTA would like to express its gratitude to CMS for its prompt removal of Factor viii recombinant (J7192) and Factor viii (J7190) from the CMS list of the 20 physician-administered multiple source drugs that have the highest dollar volume of drugs dispensed to Medicaid beneficiaries. Pursuant to section 1927(a)(7)(B) of the SSA, the agency is to identify and publish a list of such drugs. In its initial list, the CMS inadvertently included both types of blood clotting factors.<sup>22</sup> As you have recognized in the Final Rule, including Factor viii recombinant and Factor viii in this list was an error.<sup>23</sup>

In a February 8, 2007 letter to Dennis Smith, Director, Center for Medicaid and State Operations, and in our comment letter on the Medicaid Prescription Drug Proposed Rule, PPTA alerted CMS to its oversight. As you know, plasma protein

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<sup>21</sup> See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 66222, 66259 (Nov. 27, 2007).

<sup>22</sup> See MEDICAID TOP 20 PHYSICIAN-ADMINISTERED MULTIPLE SOURCE DRUGS, CENTER FOR MEDICAID AND STATE OPERATIONS, U.S. DEP’T OF HEALTH AND HUMAN SERVS., at <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf> (last visited January 2, 2008).

<sup>23</sup> See 72 Fed. Reg. at 39221.

therapies, including both plasma-derived and recombinant blood clotting factors, do not meet the definition of a “multiple source drug” for the purpose of the Medicaid statute.<sup>24</sup> These therapies do, however, meet the definition of a “single source drug” under the Medicaid statute as they are all produced or distributed under an original new drug application approved by the FDA.<sup>25</sup>

Again, PPTA is grateful for CMS’ response in a June 8, 2007 letter to PPTA as well as the publication in the Final Rule of the agency’s decision to remove J7192 and J7190 from the list.

### **C. PPTA RESPECTFULLY DISAGREES WITH THE CMS DECISION TO EXCLUDE THE FURNISHING FEE FOR BLOOD CLOTting FACTORS FROM THE CALCULATION OF THE AMP.**

As you know, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) [Pub. L. No. 108-173, 117 Stat. 2066 et. seq. (2003)] established a “furnishing fee” for blood clotting factors,<sup>26</sup> which is currently \$0.152.<sup>27</sup> This amount will increase to \$0.158 for CY 2008.<sup>28</sup> This furnishing fee is a separate payment for the administration of these factors. We believe this furnishing fee has been instrumental in preserving patient access to blood clotting factor in the physician office since the ASP plus six percent went into effect in 2005.

In our comments on the Proposed Rule, PPTA had argued that this furnishing fee be included in the calculation of the AMP. PPTA contends that such inclusion will provide a more accurate calculation of the AMP. In dismissing PPTA’s request, CMS relies on the “sufficient latitude” of the States in setting prices for blood clotting factors allows the States to ensure patient access with appropriate reimbursement, including the use of a “dispensing fee” or “other service categories.”<sup>29</sup> PPTA respectfully disagrees that this flexibility by the States will consistently result in adequate reimbursement levels for blood clotting factors. We respectfully urge CMS to reconsider its position on this issue and require that manufacturers include this furnishing fee amount in the AMP calculation because not accounting for this fee in a uniform manner

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<sup>24</sup> See SSA § 1927(k)(7)(A)(i) (demonstrating that only products that have a therapeutic equivalent, according to the FDA’s Orange Book, and that can be deemed as pharmaceutically equivalent and bioequivalent meet the criteria for a “multiple source drug”).

<sup>25</sup> See SSA § 1927(K)(7)(A)(iv). The Final Rule also includes a covered outpatient drug approved under a biological license application, a product license approval, establishment license approval, or antibiotic drug approval. See 72 Fed. Reg. at 39240-39241.

<sup>26</sup> See SSA § 1842(o)(5).

<sup>27</sup> See Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B, 71 Fed. Reg. 69623, 69680 (Dec. 1, 2006).

<sup>28</sup> See, e.g., 72 Fed. Reg. at 66258.

<sup>29</sup> See 72 Fed. Reg. at 39223.

could potentially create a situation where reimbursement for these therapies is inadequate to sustain patient access.

## **II. CONCLUSION**

PPTA appreciates the opportunity to comment on the Final Rule. Again, we are especially grateful for your decision to remove Factor viii recombinant and Factor viii from the Medicaid Top 20 Physician-Administered Multiple Source Drugs list. We urge CMS to consider carefully these comments, especially with regard to the furnishing fee for blood clotting factors in the calculation of the AMP. Please contact me at 202-789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie Birkofer  
Vice President, North America