

February 20, 2007

Reference No.: SASCO7007a

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: CMS-2238-P (Medicaid Program; Prescription Drugs, Proposed Rule Implementing Provisions of the Deficit Reduction Act of 2005)

Dear Administrator Norwalk:

The Plasma Protein Therapeutics Association (“PPTA”) appreciates this opportunity to comment on the proposed rule implementing provisions of the Deficit Reduction Act of 2005 that was published in the Federal Register on December 22, 2006. (“the Proposed Rule”). As an Association deeply committed to the health and safety of the patient community it serves, these comments on the Proposed Rule are intended to ensure that Medicaid beneficiaries have access to the full array of life-saving, Food and Drug Administration (“FDA”) approved plasma-derived therapies and their recombinant analogs (“plasma protein therapies”).

PPTA represents commercial producers of plasma protein therapies. PPTA member companies produce over 80% of the plasma protein therapies used in the United States. These therapies are used to treat a variety of life threatening diseases and serious medical conditions. Plasma protein therapies include blood clotting factors for the treatment of people with hemophilia and other bleeding disorders, immune globulin used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitor used to treat people with alpha-1 antitrypsin deficiency, also known as genetic emphysema.

I. Providing Average Manufacturer Price Information to States

Section 6001 (a) of the Deficit Reduction Act of 2005 (“DRA”) amends Section 1927(b)(3) of the Social Security Act (“SSA”) to create a requirement that manufacturers report certain prices to the Secretary of Health and Human Services on a monthly basis. It also requires the Secretary to provide Average Manufacturer Prices (“AMP”) to States on a monthly basis and post on a web site on quarterly basis. PPTA believes that the posting of AMPs will help to ensure patient access to therapies. We would, however, raise concerns about the method by which AMPs are disclosed. Specifically, we ask

that CMS ensure that its disclosure of AMP data accurately reflects the reimbursement methodologies for certain therapies. Under SSA § 1842(o)(5), as added by the Medicare Modernization Act of 2003, reimbursement for hemophilia factor concentrates includes a furnishing fee that is adjusted each year based upon the consumer price index and an administratively defined methodology. This furnishing fee takes into account the reconstitution (if appropriate) and delivery of factors to an individual including special inventory management and storage requirements, and ancillary supplies and patient training necessary for the self administration of such factors. Congress viewed the payment of a furnishing fee as important to ensuring that health care providers are reimbursed sufficiently when providing hemophilia factor therapies to their patients.

PPTA believes that if the AMPs as reported by the manufacturers are reported to the States as required under the DRA without reference to this additional furnishing fee for blood clotting factors, it could potentially create inadequate reimbursement if States rely solely on the AMPs in setting their reimbursement levels in their State health programs and do not take into account the furnishing fee payment that Congress recognized as critical. **We believe that this problem could be rectified by including an asterisk in the AMP information for hemophilia factor concentrates. That asterisk would reference the furnishing fee, thus helping to assure that AMP based prices for hemophilia factor concentrates will not be set at levels below acquisition costs.**

II. Listing of the Top-20 Multiple Source Drugs

Section 6002 of the DRA added a new paragraph (7) to SSA § 1927(a) to require collection and submission of utilization data by States for certain physician administered drugs. Section 1927(a)(7)(A) requires data to be collected and submitted for physician administered single source drugs beginning January 1, 2006 for States to receive Federal matching payments for drugs, unless they receive a hardship waiver. Section 1927(a)(7)(B) establishes a similar requirement for multiple source drugs beginning January 1, 2008, except that the requirement extends only to multiple source drugs that appear on a top 20 multiple source drug list (with the statute requiring the first publication of such a list by January 1, 2007).

Section 6002 of the DRA and new SSA § 1927(a)(7) do not define “single source drug” or “multiple source drug.” Such definitions, however, were not necessary because of the preexisting definitions of “single source drug” and “multiple source drug” in SSA § 1927(k)(7), which apply to all aspects of SSA § 1927, including section 1927(a)(7). According to SSA § 1927(k)(7)(A)(i), a “multiple source drug” is a product for which there is at least one other product that is:

1. rated as therapeutically equivalent to another product under the Food and Drug Administration's (FDA's) most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (i.e., the Orange Book);
2. pharmaceutically equivalent and bioequivalent as determined by the FDA; and
3. sold or marketed in the State during the period.

The definition of a “single source drug” is contained in SSA § 1927(k)(7)(A)(iv). The Proposed Rule utilizes these statutory definitions of “single source drug” and “multiple source drug” for purposes of implementing DRA § 6002, 71 Fed. Reg. at 77177, and PPTA views that as the correct, if not also the statutorily mandated, approach. However, we believe that the agency’s implementation of section 6002 has not followed these statutory definitions and is not consistent with the direction of the Proposed Rule.

CMS implemented the statutory requirement to establish a top 20 multiple source drug list by releasing a list in December of 2006. The codes for Factor VIII recombinant and Factor VIII plasma-derived (J7192 and J7190, respectively) were included on this list, with the different brand name products identified in the listing. Significantly, none of the products listed for either of the two codes appear in the FDA’s Orange Book, nor have they been determined by the FDA to be pharmaceutically equivalent or bioequivalent.

Under the statute, the top 20 multiple source drug list is supposed to include only those products that fit within the statutory definition of multiple source drug contained in SSA § 1927(k)(7)(A)(i), and Factor VIII recombinant and Factor VIII plasma-derived do not fit within that definition. As noted above, the pertinent statutory definition of “multiple source drug” requires that there be at least one other product rated as therapeutically equivalent in the Orange Book and that there be at least one other product determined by the FDA to be pharmaceutically equivalent or bioequivalent. Neither Factor VIII recombinant nor Factor VIII plasma-derived appears in the Orange Book, which means that they are not multiple source drugs for purposes of SSA § 1927(a)(7). Similarly, the FDA has not determined either product to be pharmaceutically equivalent or bioequivalent. As a result, under the pertinent Medicaid statute, these products are not “multiple source drugs” and thus should not appear in the top 20 multiple source drug list. **PPTA respectfully asks that CMS reissue the top 20 multiple source drug list and state explicitly that Factor VIII recombinant and Factor VIII plasma-derived were removed from list because they are not multiple source drugs based on the applicable statutory definitions, and that these definitions be utilized in the final rule, as CMS proposes.**

PPTA greatly appreciates the opportunity to comment on the proposed rule implementing provisions of the Deficit Reduction Act of 2005. Should you have any questions, or if you require additional information, please do not hesitate to contact me at (202) 789-3100 or by email at jbirkofer@pptaglobal.org

Very truly yours,



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