

November 1, 2007

Reference No.: SASCO7064

VIA FACSIMILE & FIRST CLASS MAIL

Mr. William O. Butler, III
Administrative Secretary, Alabama Medicaid Agency
501 Dexter Avenue
Post Office Box 5624
Montgomery, Alabama 36103-5624

RE: Medicaid Program Decision to Implement Changes for Reimbursement of Hemophilia Factor Therapies (Amending 560-X-16-.06 (3)) and Creating a Standard of Care for Individuals with Bleeding Disorders

Dear Mr. Butler:

On behalf of the Plasma Protein Therapeutics Association (PPTA), I am writing to commend you on your decision to responsibly change the reimbursement methodology for hemophilia factor concentrates as well as the implementation of standards of care for providers. The regulatory proposal represents a substantial improvement for patients as compared to the decision articulated in the letter to providers dated November 28, 2006. We greatly appreciate the Alabama Medicaid Agency's ("Alabama Medicaid") responsiveness in addressing the concerns raised by PPTA as well as the affected consumer and provider groups.

PPTA is the primary advocate for the world's leading producers of plasma-derived and recombinant analog therapies, including blood clotting factor therapies. These therapies are used by more than a million people worldwide to treat a variety of diseases and serious medical conditions, including hemophilia and other bleeding disorders.

Reimbursement Methodology

In early 2007, PPTA and its member companies recognized the need for Alabama Medicaid to control its prescription drug expenditures. However, we urged the agency to seek a fair and reasonable reimbursement modality that ensures all distribution providers servicing the hemophilia community are able to continue doing so without any disruption to their patients' healthcare needs. We believe that the proposed regulations create such a modality. We would, however, like to make comments on the reimbursement approach outlined in 560-X-16-.06(3)(c). That section contemplates that reimbursement would be based upon "Medicare Part B drug pricing plus a reasonable

dispensing fee.” We request that the reasonable dispensing fee amount be specifically defined in the regulation. Such a fee should address the costs associated with dispensing medications taking into account factors such as labor costs, overhead and other verifiable expenses.

With respect to the Medicare Part B pricing approach, we would also argue that such reimbursement should be specific to reported data for each individual blood clotting factor therapy. Since blood clotting factor concentrates are not interchangeable, we would suggest a reimbursement methodology based on each specific product, at the individual NDC level. There has been success in California’s Medi-Cal program, which uses an ASP per NDC reimbursement for all factor products. Most recently, Illinois State Medicaid adopted a new reimbursement methodology based on each manufacturer’s ASP plus an additional “furnishing fee”, which was agreed upon by all providers servicing Medicaid beneficiaries within the state. We believe that this type of methodology will help ensure access to all therapies by reducing the possibility that reimbursement would be lower than acquisition costs in any given transaction. Finally, we reiterate the point raised in our earlier comments that the reimbursement methodology should also include the statutorily defined furnishing fee for hemophilia factor concentrates. This fee, created by the Medicare Modernization Act of 2003, is adjusted each year based upon a formula established by regulation. The current level for 2007 is \$.152 per unit. This fee should apply to the individual brand based reimbursement and should be specified in regulation.

Hemophilia Management Standards of Care

In general we would like to applaud Alabama Medicaid for its decision to implement Hemophilia Management Standards of Care. We know that this proposed rule is the result of several months of discussions with the patient community, distributors, providers and manufacturers. There are, however, a couple of points on which we offer suggestions for improvement. First, rule 560-X-16-.31 contains the following statement: “In order to be paid for providing blood clotting factor to Alabama Medicaid recipients, the provider must agree to provide, at the minimum, the following clinically appropriate items and services to their hemophilia patients.” We propose that rather than using “hemophilia patients” that the regulation instead use the term “patients with hemophilia and related blood clotting factor related diseases as defined in X-16-.31 (5). This would remove any ambiguity in ascertaining that the management standards apply to all patients with bleeding disorders.

In section (9) of the proposed regulation, section c states that, “In the event of a product recall or withdrawal... c) The prescribing physician shall be notified of a medication recall. A prescription for an equivalent product shall be obtained if necessary.” PPTA respectfully objects to the use of the word “equivalent” in this instance. Patients, in close consultation with their physicians, make informed decisions regarding the particular therapy they will utilize. Hemophilia therapies are not interchangeable and open access to all products should remain unimpeded. Each therapy has been approved by the federal Food and Drug Administration (FDA) for specific clinical

indications. These are branded therapies, with no generic substitutes. Accordingly, we suggest the following language, “a prescription for another licensed blood clotting factor concentrate shall be obtained after consulting with the patient’s treating physician or, if he or she is not available, an individual with expertise in treating hemophilia and related blood clotting factor diseases.”

PPTA greatly appreciates the opportunity to comment on Alabama Medicaid’s proposed rules changing its reimbursement methodology for blood clotting factor concentrates and implementing a standard of care for individuals with hemophilia and related blood clotting factor related diseases. 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 rfaden@pptaglobal.org.

Very truly yours,



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cc: Glenn Mones, Vice President for Public Policy
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