

January 4, 2007

Reference No.: SASCO7001

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 Public Health Service Based Pricing for Reimbursement of Hemophilia Factor VIII Therapies (Amending 560-X-16-.06 (3))

Dear Mr. Butler:

On behalf of the Plasma Protein Therapeutics Association (PPTA), I am writing to request that you reconsider your decision to implement a new reimbursement rate for hemophilia factor concentrates based on Public Health Service (PHS) pricing. The decision articulated in the letter to providers dated November 28, 2006 could potentially adversely impact access to therapies for Medicaid beneficiaries with hemophilia in the state.

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.

PPTA and its member companies recognize the need for the state of Alabama's Medicaid agency to control its prescription drug expenditures. However, we urge 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 patient's healthcare needs. Implementing a reimbursement mechanism which will prevent providers who do not have access to PHS pricing from the 340B drug discount program from servicing Medicaid beneficiaries is not in the best interest of Alabama Medicaid beneficiaries and not consistent with the purpose and intent of the 340B program.

Section 602 of the Veterans Health Care Act of 1992 ("VHCA") enacted the 340B Drug Pricing Program. That statute requires drug manufacturers, as a condition for federal funds to be available to purchase their products under both Medicaid and Medicare Part B, to enter into an agreement with the Secretary of the Department of Health and

Human Services (HHS) to provide discounted prices on covered outpatient drugs to a list of “covered entities.”¹ In fact the 340B program was created to encourage pharmaceutical manufacturers to offer discounts to these covered entities that are outside the Medicaid program and thus not able to obtain Medicaid rebates under a Medicaid Rebate Agreement.

Under this 340B Drug Pricing Program, a manufacturer enters a Pharmaceutical Pricing Agreement with HRSA in which it agrees to charge covered entities no more than the “PHS ceiling price” for its products. The PHS ceiling price is equal to the average manufacturer price (AMP) minus the Medicaid unit rebate amount for the quarter that is two quarters prior to the quarter for which the PHS ceiling price is being calculated.² Prices made available to participating covered entities are excluded from the calculation of Medicaid Best Price.³ If the manufacturer plans to sell its product directly to end users, the PHS ceiling price is the maximum that can be charged the participating covered entities. If the manufacturer plans to distribute its product through commercial wholesalers, the PHS ceiling price is implemented through a wholesaler chargeback mechanism in the same way that other group purchasing contracts are implemented.

Maintaining continuity of care is essential for hemophilia patients in managing their condition. If a current patient is not receiving his hemophilia care from a 340B covered entity, he will not be defined as an “eligible” patient under applicable federal regulations. Alabama’s proposal could cause disruption for patients who currently see a hematologist or primary care physician not associated with an HTC (Hemophilia Treatment Center) in Alabama who may choose to discontinue providing hemophilia therapies.

It is crucial as a matter of sound public health policy that the beneficiaries receiving services from Alabama Medicaid are not denied timely access to the treatments they need to keep them alive and functioning. Utilizing PHS pricing could cause numerous providers of hemophilia therapies to decide to discontinue providing hemophilia therapies to their patients. Accordingly, the approach that the department contemplates in its proposal may result in a single source provider situation for many Alabama Medicaid beneficiaries under which Children’s Rehabilitative Services (CRS) becomes the lone option. PPTA believes that single source provider arrangements adversely affect access to the full range of therapies. Specifically, the single provider may choose to furnish a limited selection of therapies. According to the Medical and Scientific Advisory Committee of the National Hemophilia Foundation, access to the full range of licensed hemophilia therapies is essential for optimal treatment. Delayed access to the appropriate clotting factor for the patients’ unique condition can cause painful and crippling injury to a hemophilia patient’s joints and organs. Such complications also often lead to increased costs for medical assistance programs for hospital, skilled nursing and other specialty services.

¹ 42 U.S.C. § 1396r-8(a).

² Dear Manufacturer Letter Regarding the 340B Drug Pricing Program, HRSA (Aug. 17, 1993).

³ 42 U.S.C. § 1396r-8(c)(1)(C).

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. Different therapies may require different dosages and regimens, and may be appropriate only for specific populations. Further, the effectiveness of particular therapies may vary with different populations or with specific individuals. Failure to maintain open access to this full range of licensed therapies could result in the adverse health outcomes discussed above.

PPTA greatly appreciates the opportunity to comment on Alabama's proposed change to its reimbursement methodology for hemophilia therapies. 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,



Ryan M. Faden, JD, MPH
Manager, State Affairs

Cc: Glenn Mones, Vice President for Public Policy, National Hemophilia Foundation
Jan Hamilton, Advocacy Director, Hemophilia Federation of America