Plasma Protein Therapeutics Association

September 2, 2008 **Via Fax and Mail**
Reference No.: SASC08066

Ms. Jill Brown
Office of Legal Services
275 East Main Street 5W-B
Frankfort, Kentucky 40601

Re: Department for Medicaid Services' Proposed Administrative Regulation Hemophilia Treatment Reimbursement and Coverage Via the 340B Drug Pricing Program 907 K.A.R. 3:205

Dear Ms. Brown:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to respond to the Department of Medicaid Services' (the "Department") proposed administrative regulation 907 K.A.R. 3:205 (the "proposed rule") governing hemophilia treatment reimbursement and coverage via the 340B Drug Pricing Program as codified under applicable federal law.

PPTA represents the world's leading manufacturers of plasma protein therapies and their recombinant analogs, known collectively as plasma protein therapies. These therapies, including clotting factor concentrates that treat individuals with hemophilia and other bleeding disorders, are used by more than a million people worldwide to treat a variety of diseases and serious medical conditions. PPTA member companies provide more than 80% of the plasma protein therapies used in the United States today. PPTA member companies distributing therapies in the U.S. include Baxter BioScience, Biotest, CSL Behring, Grifols, Octapharma, and Talecris Biotherapeutics.

In reviewing the proposed rule, the accompanying regulatory impact analysis, and the tiering statement, PPTA believes that it is unclear whether the 37 individuals specifically mentioned would be legally required to use the comprehensive hemophilia diagnostic treatment center (HTC) as the provider of factor product. In discussions with various interested parties concerning the proposed rule, PPTA has learned that the Department is not attempting to mandate the provider of factor product for the enrollee. As currently drafted, however, the plain language of the proposed rule in fact mandates use of the HTC as the provider. Therefore, PPTA respectfully requests that the Department consider adding provisions to the proposed rule clarifying that Medicaid enrollees are not required to use the HTC as the sole provider of their factor product.

PPTA generally advocates that Medicaid enrollees should not have their choice of therapies or providers restricted simply because they are enrolled in Medicaid, or because they suffer from a chronic illness. Decisions about which therapy a patient

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receives, and which provider he or she receives their treatment from, should be made by the prescriber in close consultation with the patient and should not violate the sanctity of the physician-patient relationship. An individual with hemophilia should have access to the full range of FDA licensed clotting factor concentrates from the medically appropriate provider. Specifically, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF)—a leading patient organization for persons with bleeding disorders in the United States--has stated that "Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal & inactivation processes, potential immunogenicity, and other attributes. The characteristics of each product and the resultant product choice for an individual patient require a complex decision making process with the ultimate product being agreed upon by the patient and their respective healthcare provider. It is critical that the bleeding disorder community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[1]

It should be noted that PPTA believes that HTCs constitute an essential part of any provider network for treating patients with bleeding disorders. The HTC model has been recognized as a center of excellence that demonstrably decreases potential morbidity and mortality associated with bleeding disorders through regular patient visits.[2] Our concern lies where HTCs are mandated as the sole option for care for patients with bleeding disorders which has the potential to impact access to care, particularly in cases where the HTC is not located within a reasonable distance from consumers who would be required to seek care there.

We appreciate the opportunity to respond to this proposed regulation and would welcome the opportunity to discuss it with you further. Should you have any questions or require additional information please do not hesitate to contact me at rfaden@pptaglobal.org or (202) 789-3100 ext. 2102 or my colleague Bill Speir at bspeir@pptaglobal.org or (202) 789-3100 ext. 2110.

Sincerely,

Ryan M. Faden, JD, MPH
Assistant Director, State Affairs

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1 MASASC Recommendation #159 (last visited August 14, 2008), available at http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=179

2 *See generally,* Baker, et al, "**A Model for a Regional System of Care to Promote the Health and Well-Being of People with Rare Chronic Genetic Disorders", AMERICAN JOURNAL OF PUBLIC HEALTH,** November 2005, Vol. 95, No. 11, 1910-16.