Plasma Protein Therapeutics Association

**February 24, 2012**

**VIA E-MAIL**

Ms. Stacey Johnston
Policy Analyst, Medicaid/CHIP Division
Texas Health and Human Services Commission

**RE: Comments on Proposed Rule Concerning Specialty Drugs**

**Dear Ms. Johnston:**

The Plasma Protein Therapeutics Association appreciates the opportunity to comment on proposed rule 1 TAC 15.354.F.354.1853 concerning Specialty Drugs. We would like to take this moment to thank Texas Health and Human Services Commission (HHSC) for not subjecting blood clotting factor, a plasma protein therapy, to prior authorization in your pharmacy program, and for ensuring that the Medicaid managed care plans HHSC contracts with will adhere to this principle.

The Plasma Protein Therapeutics Association (PPTA) represents the world's leading manufacturers of plasma-derived and recombinant biological therapies, collectively known as plasma protein therapies, and the collectors of source plasma. These critical therapies are infused or injected by more than 1 million people worldwide to treat a variety of rare, life threatening diseases and serious medical disorders. PPTA members produce in excess of 80 percent of the plasma protein therapies used in the United States today and more than 60 percent worldwide.

Plasma protein therapies treat rare, life-threatening diseases and disorders. Lifesaving therapies produced by PPTA members include clotting factor therapies for individuals with bleeding disorders, immunoglobulins (IG) to treat complex diseases in persons with compromised immune systems and neurological disorders, and therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset chronic obstructive pulmonary disease and substantially limits life expectancy.

PPTA supports patient access to all medically appropriate, lifesaving plasma protein therapies, which because of important clinical and manufacturing differences, an individual patient may tolerate or respond to one therapy better than another in the same class. Because such therapies are not therapeutically equivalent, pharmaceutically equivalent, or bioequivalent, they are not interchangeable. And since they are not interchangeable, PPTA believes an individual with a rare, chronic condition should have access to the full range of FDA licensed plasma protein therapies.

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This position is supported by the National Hemophilia Foundation (NHF) Medical and Scientific Advisory Council's (MASAC) Recommendation #159 which states,

> "Clotting factor therapies are neither pharmacologically nor therapeutically equivalent and vary based upon purity, half-life, recovery, method of manufacture, viral removal and 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 disorders community has access to a diverse range of therapies and that prescriptions for specific clotting factor concentrates are respected and reimbursed."[1]

In fact, the U.S. Food and Drug Administration (FDA) has approved the various clotting factor therapies [Factor VII, VIII, IX, X and XIII, and von Willebrand Disease] for distinct clinical indications. The therapies are neither clinically nor therapeutically interchangeable. In addition, some therapies are derived from human plasma, while others are made utilizing recombinant DNA technology, created from genetically modified cell lines.

The therapies in other plasma protein therapy categories are also not pharmaceutically or therapeutically equivalent. Each IG therapy has been approved by the FDA for distinct clinical indications and each has distinct contraindications. For example each has a significantly different shelf life, and each is prepared and administered in a distinct manner. Storage requirements vary. Sugar content varies.

Plasma protein therapies are delivered to consumers, including Medicaid and CHIP recipients, through specialty pharmacies. These specialty pharmacies are a vital component of health care delivery for individuals with rare, chronic diseases who rely on plasma protein therapies.

Because of this vital role, it is our hope that HHSC will allow recipients access to all qualified specialty pharmacy providers. Not every specialty pharmacy provider has the training and experience necessary to provide quality care to individuals that rely on plasma protein therapies. This is shown by the need for NHF's MASAC Recommendation 188[2]. We would urge HHSC to consider Recommendation 188 when deciding on specialty pharmacy services for Medicaid recipients with bleeding disorders.

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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] MASASC Recommendation #188 available at http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=1107

Once again, we would like to thank HHSC for exempting blood clotting –factor from prior authorization in the Texas Medicaid pharmacy program. This policy allows individuals with bleeding disorders, including hemophilia, timely access to their medically appropriate therapy. PPTA would ask HHSC, as it defines Specialty Drugs in compliance to the SB 7 enacted in Texas' 2011 special session, to reiterate its previous intent to not limit open access to specialty drugs such as blood clotting factor.

We appreciate your consideration of our concerns and would welcome the opportunity to discuss them with you further. Should you have any questions or require additional information please do not hesitate to contact me at: bspeir@pptaglobal.org or (443) 433-1110.

Best Regards,

Bill Speir
Director of State Affairs