

August 14, 2008

Department of Health
Office of the General Counsel
825 North Capital Street, N.E.
Fourth Floor
Washington, DC 20002

Re: Department of Health's Proposed Rule creating Chapter 17, Pharmaceutical Education Program, of Title 22, Public Health and Medicine, of the District of Columbia Municipal Regulations (DCMR).

Dear Sir/Madam:

The Plasma Protein Therapeutics Association (PPTA) appreciates this opportunity to respond to the Department of Health's proposed rule creating the Pharmaceutical Education Program in Chapter 17 of Title 22 of the DCMR (the "Proposed Rule").

PPTA represents the world's leading manufacturers of plasma protein therapies and their recombinant analogs, known collectively as plasma protein therapies. These therapies 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 Pharmaceuticals, CSL Behring, Grifols, Octapharma, and Talecris Biotherapeutics.

PPTA would like the Department to consider two points when finalizing the Proposed Rule. First we would propose the adoption of the Food and Drug Administration's (FDA) Orange Book as the source for therapeutic-equivalence. Second, we would ask that educators have experience in treating rare, chronic diseases before they educate providers on the proper therapies for such individuals.

Section 1702.1.b states in part that the Program shall, "Inform prescribers about pharmaceutical marketing practices that are intended to circumvent competition from generic, other **therapeutically-equivalent** alternatives..."

We believe that therapeutically-equivalent is a subjective term as currently stated in the Proposed Rule. We would request that the term be clarified by using the FDA Orange Book for guidance. This may be done by adding the phrase "listed in the FDA Orange Book" after alternatives in Section 1702.1.b, or by adding the following definition to Section 1799.1.

Therapeutically-equivalent alternatives mean therapies that are rated as therapeutically equivalent under the Food and Drug Administration's Orange Book.

Adoption of either suggestion would remove the inherent subjectivity of the educator from the equation, and, moreover, would protect patients and their physicians from the possibility that the educator is misinformed about which alternatives are therapeutically-equivalent.

Plasma protein therapies treat individuals with rare, chronic conditions such as hemophilia, primary immunodeficiency disorders, and alpha-1 antitrypsin deficiency. Plasma protein therapies are not interchangeable, and there are no generic substitutes. In fact, the FDA classifies all biologics, including plasma protein therapies as sole source rather than multi-source or generic. Individual therapies are approved by the FDA for specific clinical indications. The needs of each patient are unique, and patients respond to the same treatment differently based upon their own individual medical circumstances. The ability to tolerate a specific treatment over time may also change requiring careful monitoring of any treatments.

The typical use of Intravenous Immune Globulin (IVIG) provides a clear illustration of this important consideration. Effective, July 1, 2007 the federal Centers for Medicare & Medicaid Services (CMS) implemented brand specific reimbursement for all brands of IVIG entering the market after October 1, 2003 through revision of the relevant HCPCS codes.¹ This development represents a clear acknowledgment by CMS that all brands of IVIG are unique and that patients must have access to all FDA licensed brands as part of their treatment protocols.

Specifically, IVIG therapies are unique not only because of the unique production processes, but also because of the “substantial variation in manufacturing, fractionation, and bottling process times that may also influence the biological activity of the final product,” as well as formulation, volume load, sodium content, sugar content, osmolality, immunoglobulin A (“IgA”) content, and pH.² For example, physicians may prefer prescribing IVIG therapies: (1) without sugar for diabetics; (2) with low osmolality and low volume for those patients with congestive heart failure or compromised renal function; (3) with less IgA for those patients with IgA deficiencies; (4) with lower pH for those patients with small peripheral vascular access or a tendency toward phlebitis. In addition, therapies with sucrose may create a higher risk of renal failure in some patients. Because IVIG is not an interchangeable, “one-size-fits-all” therapy, patient outcomes may be adversely affected if physicians fail to administer the IVIG therapy best suited for the individual needs of a patient.³ The Immune Deficiency Foundation—a leading patient organization highlights the importance of access to all therapies in its public presentations and on its website.⁴

¹ See Social Security Act, Tit. XVIII, § 1847A(c)(6)(C)

² See OFFICE OF THE ASS'T SEC. FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH AND HUMAN SERV., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) (2007)

³ *Id.* (Describing the recommendations of the Clinical Immunology Society of the appropriate IVIG therapy for certain patient risk factors.)

⁴ See www.primaryimmune.org, visited August 14, 2008. See also, S. 2990, the Medicare IVIG Access Act of 2008 introduced in the U.S. Senate by Sen. John Kerry finding that, “ The Food and Drug Administration recognizes each IVIG brand as a unique biologic. The differences in basic fractionation and the addition of various modifications for further purification, stabilization, and virus inactivation/removal yield clearly different biological products. As a result IVIG therapies are not interchangeable, with patient tolerance differing from one brand to another. “

A similar argument may be made for therapies used to treat hemophilia and other bleeding disorders. 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.”⁵

For the reasons stated above, PPTA respectfully asks that the Department add language to proposed section 1702.5 of the Proposed Rule that would require the educators have experience, either actual or educational, in the medically appropriate treatment for the conditions the prescriber is treating.

We appreciate your consideration of our comments and would welcome an opportunity to discuss them with you further. Should you wish to discuss our comments or if you have further questions, please do not hesitate to contact me at 202 789-3100, ext. 2110 or by email at bspeir@pptaglobal.org

Respectfully submitted,

Bill Speir
Manager, State Affairs

⁵ MASASC Recommendation #159, available at <http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&contentid=179>, visited August 14, 2008.