NATIONAL HEMOPHILIA FOUNDATION
for all bleeding disorders

August 1, 2012

Health Insurance Exchange Advisory Task Force
Minnesota Department of Commerce
Insurance Division
85 7th Place East, Suite 500
St. Paul, MN 55101

RE: Public Comments on Certification Statutes and Rules Reference Document

The National Hemophilia Foundation (NHF) is the nation's leading advocacy organization working to ensure that individuals with hemophilia and related bleeding disorders have timely access to high quality medical care and services, regardless of financial circumstances or place of residence. We appreciate the opportunity to provide comments on the certification statues and rules reference document concerning the unique health care needs of those with bleeding disorders.

Hemophilia and related bleeding disorders are rare, complex genetic conditions for which there are no known cures. Individuals often experience spontaneous and prolonged internal bleeding in the joints and tissues. To effectively manage these disorders, patients often require life-long infusions of clotting factor therapies that replace the missing or deficient blood proteins, thus preventing debilitating and life threatening internal bleeding. While therapies are safer and more effective than ever, they are also more costly than other types of medication. For example, cost of treatment for a person with severe hemophilia can be $250,000 a year or more. Developing an inhibitor (i.e., an immune response to treatment), complications such as HIV/AIDS, hepatitis and joint diseases, or bleeding as a result of trauma or surgery can increase those costs to over $1 million.

The specialized care and services required by those with bleeding disorders, and other rare disorders for that matter, was not addressed in the state's "reference document," which identified federal standards or state statutes. However, it is imperative that state decision-makers ensure that plans offered through the Exchange can provide the necessary services and have the appropriate networks those with bleeding disorders need to lead, healthy productive lives. Specifically, we highly encourage the Task Force to ensure the following:

1. Access to specialists at federally recognized hemophilia treatment centers (HTCs)

Since 1974, Congress has authorized and funded a national network of HTCs to provide comprehensive, specialized care for individuals with hemophilia and other bleeding disorders. These centers are staffed with healthcare professionals across multiple disciplines including hematologists, physical therapists, nurses, dentists and social workers that work as a team to provide coordinated care for this complex patient population. In addition to disease and case management, HTCs monitor blood safety and offer many educational programs for individuals and their families.

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Numerous U.S. Centers for Disease Control and Prevention (CDC) studies show that individuals receiving comprehensive care at HTCs have a 40 percent reduction in morbidity and mortality, despite the fact that more severe patients are seen at an HTC. Moreover, studies show that patients who use HTCs experience fewer long-term complications and hospitalizations, increasing quality of life and reducing total healthcare care costs over a patient's lifetime.[1,2]

The ACA specifies that entities covered under section 340B(a)(4) of the Public Health Service Act (which includes federally recognized HTCs) be designated as essential community providers. This designation helps ensure that HTCs are included in qualified health plans and that individuals have access to these specialized healthcare providers (i.e., physical therapist, hematologist). We encourage the Task Force to require plans to permit access to state-based and/or regional HTCs.

2. Access to the full range of FDA approved clotting factor products

Clotting factor therapies are biological products (derived from human blood plasma or using recombinant technology). There are no generic equivalents. Moreover, because of the nature of bleeding disorders, an individual's response and tolerability for a specific product is unique. For these reasons, NHF's Medical and Scientific Advisory Council (MASAC) recommends that individuals have access to the full range of FDA approved clotting factor products.[3] Limiting access through the use of restrictive drug formularies, such as requiring prior authorization and preferred drug lists, will negatively impact patient care. Therefore, drug benefit designs employing these methods should be avoided and which product an individual uses should be a decision between patient and physician.[4]

3. Access to a range of specialty pharmacy providers

Unlike other types of medication typically bought at a retail pharmacy, clotting factor therapies require special handling, shipping and refrigeration. Additionally, patients often require other products (i.e., syringes, saline), nursing services, and intensive education to manage their complex health condition. These requirements are beyond the ability of a traditional retail pharmacy and are only available through specialty pharmacy providers. These providers are specially trained to handle the unique needs of the bleeding disorder community and are expected to adhere to the standards outlined by MASAC.[5]

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[1] Soucie JM et al. Mortality among males with hemophilia: relations with source of medical care. Blood 2000; 96:437-442.
[2] Soucie JM et al. Home-based factor infusion therapy and hospitalization for bleeding complications among males with hemophilia. Haemophilia 2001; 7:198-206.
[3] MASAC Document #132. (2002). Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders. www.hemophilia.org.
[4] MASAC Document #159. (2005). Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions. www.hemophilia.org.
[5] MASAC Document #188. (2008). Recommendation Regarding Standards of Service for Pharmacy Providers of Clotting Factor Concentrates for Home Use to Patients with Bleeding Disorders. www.hemophilia.org.

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Considering the variability of patient needs and provider services, patients need access to a network of pharmacy providers to properly manage their conditions and live longer, healthier lives. We would also encourage that the agency incorporate provider standards for pharmacies that dispense clotting products.

We thank you for taking the time to review our comments and for giving them your careful consideration. If you have questions, please contact Michelle Rice, Director of Public Policy, at (317) 517-3032 or mrice@hemophilia.org; or Marla Feinstein, Medical Information and Public Policy Coordinator, at (212) 328-3750 or mfeinstein@hemophilia.org.

Sincerely,

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