



NATIONAL HEMOPHILIA FOUNDATION

for all bleeding and clotting disorders

June 13, 2011

Secretary Janie Miller
Cabinet for Health and Family Services (CHFS)
275 E. Main Street
Frankfort, KY 40621

RE: Comments Regarding the Cabinet's Medicaid Managed Care RFP

Dear Secretary Miller:

The National Hemophilia Foundation (NHF) is the nation's largest advocacy organization working to ensure that individuals affected by hemophilia and related bleeding disorders has access to high quality medical care and support services. The Kentucky Hemophilia Foundation (KHF), a chapter of the NHF, assists persons with hemophilia or related bleeding disorders living in the State of Kentucky by providing education, advocacy, support services, and promoting research toward a cure. **We recently became aware of the Cabinet's Request for Proposal (RFP, 758 110000276) which would essentially move pharmacy benefits for most Medicaid and KChip enrollees to managed care.** We realize that the RFP has since closed and the Department for Medicaid Services is currently reviewing submissions from various managed care organizations (MCOs). However, we wanted to convey our concerns about MCOs handling pharmacy benefits for individuals with bleeding disorders and other State initiatives allowing these entities to limit access to prescription drugs through prior authorization, preferred drug lists and specialty pharmacy distribution channels.

As you probably already know, hemophilia and related bleeding disorders are rare conditions. These conditions are often genetic in origin and result in prolonged and abnormal bleeding into joints and muscles. There is no cure for any these conditions. Instead, individuals will require lifelong infusion of clotting factor products to replace missing or defective blood proteins. Adding to the complexity of managing bleeding disorders is the fact that patients can have very diverse needs depending on age, severity of the condition, experience level of caregivers, and the existence of complications such as inhibitors, joint diseases, and hepatitis and HIV/AIDS (which some patients acquired due to the contaminated blood catastrophe in the 1980s). **It is therefore crucial that affected individuals, including those on state-run health care programs, have timely access to care and treatment to maintain optimal health and avoid potentially debilitating and costly complications that can result from less than optimal care.**

Our organizations understand and support most efforts to reform the State's Medicaid program. However, we are especially concerned about the State expanding the role of MCOs to handle pharmacy benefits for individuals with bleeding disorders. Our consumers require access to health care specialists and service providers who are knowledgeable about treating and managing their conditions. This not only include highly specialized clinicians affiliated with federally-recognized hemophilia treatments centers (HTCs), but also specialty pharmacies whose employees are knowledgeable about handling clotting factor products. **MCOs have**

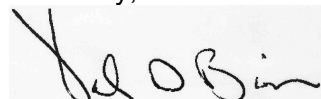
shown that they are unable to ensure adequate care for individuals with complex health care needs. For example, there have been instances in other states where MCOs have denied access to necessary specialty care at HTC for people with bleeding disorders, contracted with medical and pharmacy providers who have little or no experience managing people with bleeding disorders, and imposed restrictions that made it difficult for individuals to access necessary care and treatment. The risk of having the same thing happen in Kentucky is significant and has the potential for dire consequences. **We are thus requesting that the Cabinet delay implementation of moving individuals with bleeding disorders to managed care until these entities can guarantee individuals will continue to have timely access to the full range of FDA-approved clotting factor therapies and access to specialists (both HTC and pharmacy providers) who are knowledgeable about bleeding disorders.**

Further, we are requesting that **prescribing protections be maintained for individuals with hemophilia and other bleeding disorders**, ensuring that a doctor's decision regarding a specific course of treatment be honored. This is especially important because each clotting factor product has unique characteristics that often result in varying effectiveness and tolerability from individual to individual.¹ The implementation of prior authorizations and preferred drug lists will limit prescribing authority. Moreover, it subjects individuals to risky step therapy, requiring they "fail first" on so called preferred drugs before getting approval for products their treating physician has determined will work best for their particular situation. This can be problematic for individuals with bleeding disorders whose long-term health and well-being is negated by them having timely access to clotting factor products. Simply put, not having timely access to care can result in unnecessary hospitalizations, immune responses and other complications – all of which will increase overall healthcare costs.

People with hemophilia have had to deal with many challenges in their struggle to get access to adequate treatment, ranging from not having any effective treatment at all, to having tainted products in the 1980s that led to illness and many deaths. We therefore urge the Cabinet to not place further obstacles between them and the care they so greatly need. Instead, we urge the Cabinet to work with us to explore other viable options that can lower state Medicaid expenses while ensuring that low-income individuals with bleeding disorders have access to appropriate care and treatment.

Thank you for allowing us to convey our concerns and for giving them your careful consideration. If you have questions or concerns, please contact Ursela Lacer, Executive Director of KHF, at (502) 456-3233 or ursela@kyhemo.org, or Ruthlyn Noel, Manager of Public Policy at NHF, at (212) 328-3730 or rnoel@hemophilia.org.

Sincerely,



Val Bias
Chief Executive Officer
National Hemophilia Foundation

President of the Board
Kentucky Hemophilia Foundation

C: Neville Wise, Acting Commissioner, Department for Medicaid Services
Representative Jimmie Lee, Co-Chair, Medicaid Oversight and Advisory Committee

¹ Please see Attachment 1, MASAC Document #159. MASAC is the Medical and Scientific Advisory Council of the NHF. They are a world renowned group of medical experts which establishes quality of care guidelines for the treatment of hemophilia and other bleeding disorders in the United States.

Senator Katie Kratz Stine, Co-Chair, Medicaid Oversight and Advisory Committee
Representative Tom Burch, Co-Chair, Interim Joint Committee on Health and Welfare
Senator Julie Denton, Co-Chair, Interim Joint Committee on Health and Welfare
Ms. Mary Lassiter, Secretary of the Cabinet, Office of the Governor

ATTACHMENT 1

MASAC Document #159: MASAC RECOMMENDATION REGARDING FACTOR CONCENTRATE PRESCRIPTIONS AND FORMULARY DEVELOPMENT AND RESTRICTIONS

The following recommendations were approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation on February 12, 2005, and adopted by the NHF Board of Directors on March 12, 2005.

Persons with bleeding disorders require treatment with clotting factor concentrates for prevention and treatment of bleeding.

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.

MASAC supports continued availability and reimbursement of the full range of all prescribed replacement therapies for treatment of bleeding disorders. Prescriptions for clotting factor therapies should be written as non-generic to assure that the product prescribed is appropriately dispensed and reimbursed. Reimbursement for clotting factor replacement therapies should continue to be based upon methodologies appropriate to each specific product. The benefit of limiting products to one within a class, such as one recombinant factor VIII concentrate, solely for the purpose of cost containment is not supported by present clinical practice or by published data.

Additional MASAC recommendations and guidance pertaining to care for individuals with bleeding disorders can be found on the National Hemophilia Foundation's website: www.hemophilia.org.