August 13, 2018

Pharmacy and Therapeutics Committee
Mississippi Division of Medicaid
c/o Terri Kirby, PharmD, RPH
Office of Pharmacy Walter L. Sillers Building
550 High Street, Suite 100
Jackson, Mississippi 39201

RE: Testimony for Mississippi Pharmacy and Therapeutics Committee regarding addition of Factor Deficiency Products to Medicaid Preferred Drug List

Dear Dr. Kirby:

Hemophilia Federation of America (HFA) has learned that the Mississippi Medicaid Pharmacy Program (the Program) is planning to review the class of hemophilia therapies at its upcoming meeting on August 14th. We appreciate the opportunity to provide materials and comments.

HFA is the leading patient-led advocacy group representing those with hemophilia and other bleeding disorders. We are writing to urge the Pharmacy & Therapeutic (P&T) Committee members to adhere to the longstanding practice (widely followed across state Medicaid programs) of carving out hemophilia therapies from the standard drug utilization review/preferred drug list (PDL) process. Limiting product options for individuals with bleeding disorders via PDLs or otherwise would put patient health at risk and could actually result in higher overall medical costs with respect to this patient population. We are concerned about the implementation of *any* prior authorization protocols for bleeding disorders treatment and ask the committee to review and re-consider this requirement..

Since August of 2015 HFA has been collecting data to determine how access issues impact patient health outcomes. Through an HFA initiative named Project CALLS, patients can report insurance issues affecting their access to care such as prior authorization, preferred drug lists/formularies, or step therapy. Data from Project CALLS shows that over 50%f patients who experience an insurance issue of this type delay their care by either not treating when they are supposed to, or delaying a visit to their provider. When people with hemophilia delay care, they experience excess bleeds that can cause long term joint damage or other serious, more expensive health issues. Data from Project CALLS suggests that insurance issues that impede access lead to more expensive, negative health outcomes. We would expect the same results when state Medicaid programs implement PDLs, and place strict prior authorization or step therapy procedures in the way of access to factor. For more information on Project CALLS, and for the most recent CALLS data, please click here.

HFA understands that the Program is necessarily concerned with containing costs. However, while hemophilia treatment is undeniably expensive, limiting product options for patients with bleeding disorders is neither an effective nor a therapeutically appropriate way to manage this class of patients. Bleeding disorders products vary in a number of important respects, including

half-life and immunogenicity, and as such are not therapeutically equivalent or interchangeable. **No generic bleeding disorders products exist.** Patient bleeding patterns and responses to different medications vary widely.

Recognizing this diversity of bleeding disorders products, the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) has stated that product selection for bleeding disorder patients "require[s] a complex decision making process" between a patient and his or her physician: "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] Because the selection of the medically-optimal product for each patient is so individualized and so important, MASAC urges third-party payers to cover whichever factor product is prescribed by the patient's treating physician rather than resorting to a PDL or formulary approach.[2]

HFA advocates that all individuals with hemophilia should have access to all federally approved drugs on the market and that patients, following the recommendations from their doctors, have the access to whichever product fits their medical needs. A one-size-fits-all approach (for example, requiring patients, for non-medical reasons, to switch from a prescribed product to a different, PDL-listed product) can undermine adherence to therapy, weaken the doctor-patient relationship, and worsen patient outcomes in both the short and long term – while also raising payer costs due to additional doctors' visits, hospitalization, and/or extra required factor usage. Closing off access to certain factor products for Medicaid patients could thus end up costing more for state programs **and** impairing patient care.

Additionally, prior authorization protocols that are longer than a 48-72 hour time limit to determine whether a patient can have access to a factor deficiency product on the non-preferred list are unacceptable. For patients living with rare or chronic conditions, like hemophilia and other bleeding disorders, timely access to treatment is a necessity. The potential consequences of a major bleed, or of cumulative damage from repeated bleeding episodes, are just too severe. As a result, prior authorization potentially subjects people with bleeding disorders to unnecessary harm while waiting for approval for a non-preferred drug already prescribed by their doctor.

We respectfully request that in lieu of bringing hemophilia therapies within its PDL framework, Mississippi considers other utilization tools currently under consideration and study in other states.

In 2015, Washington State funded $600k in the 2015-2016 Washington State Budget to support the Bleeding Disorders Collaborative of Care (a consortium of doctors, patients and

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[1] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #159. Accessed August 13, 2018. MASAC Document #159

[2] National Hemophilia Foundation, Medical and Scientific Advisory Council. *MASAC Recommendation Regarding Factor Concentrate Prescriptions and Formulary Development and Restrictions,* Document #153. Accessed August 13, 2018. MASAC Document #153

representatives from the Washington State Health Care Authority) to examine utilization practices in factor consumption among state Medicaid patients. Instead of limiting choice, Washington State chose to examine other means of saving the system needed funds. Currently, the state is reviewing whether patients should be dosed on the basis of ideal rather than actual body weight. (Because factor dosing is based on patient weight, overweight patients receive higher doses of factor compared to non-overweight patients; however, since fatty tissues contain less blood volume than muscle, dosing patients with reference to their ideal rather than actual body weights may reduce the amount of factor used without increasing the risk of bleeding or other adverse events.) While this study is still under way, it is possible that its results could eventually impact how patients consume factor, and implementation of these evidence-based policies may prove more effective at cost-saving than instituting a PDL. In addition, the state has looked at a number of questions facing hemophilia care using the Center of Evidence-Based Policy Medicaid Evidence-Based Decisions Project (MED) at Oregon Health & Science University. The website and all current data can be located at http://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/bleeding-disorder-collaborative-care.

In order to best serve the medical needs of Mississippi's small but vulnerable population of bleeding disorder patients, HFA respectfully requests that the Program exclude bleeding disorders products from the scope of its upcoming drug review this summer . HFA recommends that Mississippi instead look into other, potentially more therapeutically appropriate and most cost-effective, methods to manage this class of Medicaid beneficiaries, as for example suggested by the study under way in Washington State. If you have any questions, please do not hesitate to call Kim Isenberg at 612-669-2175 or email k.isenberg@hemophiliafed.org

Sincerely,

Kim Isenberg
Vice President, Policy Advocacy & Government Education
Hemophilia Federation of America