September 28, 2012

Theresa A. Eagleson, Administrator
Division of Medical Programs
Illinois Department of Health and Family Services
201 South Grand Avenue East
Springfield, Illinois 62763-0002

Subject: Proposed Rules Regarding Enrollment in the 340B Program (dated September 10, 2012)

Dear Ms. Eagleson:

The National Hemophilia Foundation (NHF) advocates on behalf of individuals with hemophilia and related bleeding disorders, leading the nationwide fight to ensure that all of our members have access to appropriate and affordable medical care and services. We are writing to express concerns with regard to proposed rules which changes Medicaid reimbursement for clotting factor products – the medications used to treat and control bleeding in persons with hemophilia and related bleeding disorders. The changes are scheduled to take effect on Monday, October 1, 2012, so it is imperative that the Department of Healthcare and Family Services (HFS) act immediately to prevent potentially devastating access to care challenges for Medicaid recipients with bleeding disorders.

Hemophilia and other bleeding disorders occur when a person is deficient in or lacks one of several proteins necessary for the blood to clot. Many individuals experience spontaneous internal bleeding, which can result in severely damaged joints or sometimes death. Treatment entails the infusion of clotting factor (derived either from human plasma or manufactured through recombinant technology) to compensate for missing or defective blood proteins. Therefore, access to the full range of approved clotting factor products is vital to the well-being of those with bleeding disorders.

While we understand that certain changes are necessary in ensuring the viability of the Medicaid program, some of the changes being implemented in accordance with Public Act 097-0689 would endanger access to care for our members. One rule we are very concerned about stipulates that HFS would only reimburse pharmacies that are eligible to participate in the 340B federal Drug Pricing Program as defined in Section 340B of the federal Public Health Services (PHS) Act for their “actual acquisition cost” (AAC) for drugs plus the “established dispensing fee of $2.40 for brand name drugs.” Although HFS included provisions allowing 340B entities that dispense clotting factor to be reimbursed for “shipping costs,” this is not nearly enough to cover the full scope of specialized services entities provide to their patients (see page 3).
Hemophilia treatment centers (HTCs) in particular rely on income from 340B programs to keep their centers afloat and continue providing comprehensive care to patients. If that income is no longer available, some centers will cut crucial services for Medicaid recipients. Such an outcome would be detrimental – even deadly – to those with bleeding disorders who rely on Medicaid for health benefits. Averting situations that could jeopardize patient care was a key reason why the U.S. Department of Health & Human Services (HHS) allowed 340B entities to be “excluded” from filling Medicaid prescriptions with 340B purchased drugs. The HHS was especially concerned about the low dispensing fees most state Medicaid programs paid pharmacies, which they argued was “often inadequate to cover the true cost of dispensing.” (HHS Medicaid exclusion guidance attached.)

We believe not increasing the dispensing fee at the same time when changes to the AAC go into effect is a huge mistake and a serious threat to patient access to care. Therefore, we highly encourage HFS to delay implementation of the proposed rule and in the interim work with hemophilia stakeholders to determine a rate that better accounts for the higher costs associated with dispensing clotting factor therapies.

Thank you for the opportunity to share our concerns. If you have any questions or require additional information, please do not hesitate to contact me at (212) 328-3730 or rnoel@hemophilia.org. You may also contact Michelle Rice, Director of Public Policy, at (317) 517-3032 or mrice@hemophilia.org.

Sincerely,

Ruthlyn Noel
Senior Manager of Public Policy

C: Ms. Julie Hamos, Director
Attachment 1

**Issues for consideration when assessing clotting factor dispensing costs**
*(Compiled for New York Medicaid Division, November 2011)*

A. Preparing and dispensing prescriptions

i. Medication profile set up and drug utilization review
ii. Monitoring for potential drug interactions
iii. Dispensing of variable assay sizes to reach target dosing
iv. Prescription dispensing materials (i.e., packages, labels)
v. Special packaging
   a. Packing materials
   b. Ice
   c. Temperature controlled boxes
vi. Special supplies
   a. Syringes
   b. Mixing supplies
   c. Gloves
   d. Port access supplies
   e. Catheters
   f. Dressing
   g. IV start kits
vii. Inventory maintenance/cost to carry inventory
    a. Blood clotting factor storage costs
    b. Maintain emergency supply
viii. Delivery costs
    a. Packaging
    b. Couriers
    c. Insurance
    d. Emergency deliveries
    e. Verification of delivery
ix. Pharmacy counseling
x. ePrescribing related costs

B. Patient Service

i. Pharmacist time in validating an individual’s coverage prior to every dispensing.
ii. Drug use review
iii. Preferred Drug List review activities
iv. Consumer/patient counseling
v. Consulting with prescribers
vi. Education and training
vii. Emergency telephone support
viii. Disease management
ix. Education materials/programs
x. Notification of product withdrawals/recalls
xi. Visiting Nurse Services
xii. Waste disposal services
xiii. Assay management
   a. Maintaining inventory
   b. Manufacturer communication
xiv. Patient communication and therapy monitoring
   a. Ensure stock rotation
   b. Determine if bleeds have occurred
   c. Validate in home inventory
xv. Outcomes monitoring
xvi. Patient counseling
xvii. On call (24/7 nurse and pharmacist) clinician, delivery and delivery support for patient emergencies
xviii. Interpretation/Translation for non-English speaking patients and family

C. Overhead Expenses

   i. Facility costs
   ii. Utilities
   iii. Information technology
   iv. Warehouse/inventory storage
   v. Employee costs
   vi. Business insurance
   vii. Compliance programs
      a. Accreditation
      b. Medicaid provider enrollment requirements