October 27, 2015

Captain Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop: 08W05A
Rockville, MD 20857

Re: RIN 0906-AB08 340B Drug Pricing Program Proposed Omnibus Guidance

Dear Captain Pedley:

The Hemophilia Federation of America (HFA) is the only community-based, grassroots advocacy organization that assists and advocates for people with bleeding disorders. We appreciate the opportunity to comment on the *340B Drug Pricing Program Proposed Omnibus Guidance* and thank you in advance for your consideration.

Background

Hemophilia is a genetic bleeding disorder that impairs the body's ability to clot properly. Those with hemophilia administer prescription clotting factor medication to avoid painful or potentially life threatening bleeding episodes that can lead to advanced medical issues such as joint and muscle damage and even death. These medicines are extremely effective and allow affected individuals to lead healthy, productive lives. However, clotting factor medication is extremely expensive, costing anywhere from $250,000 to $1 million annually, depending on the severity of the disorder.

People with bleeding disorders need access to specialists at the appropriate site of care whether in the hospital, outpatient clinic, office of the physician, in the home setting or at a hemophilia treatment center (HTC). HTCs are federally recognized medical entities that offer comprehensive, multi-disciplinary services in a single setting and have been shown through research at the Centers for Disease Control (CDC) to improve quality and reduce morbidity and mortality of individuals living with bleeding disorders. Allowing access to comprehensive care centers such as these, ensures that a balance of care is provided to the patient by medical professionals.

HTCs comprise a medical team including a physician, nurse, social worker, and physical therapist. Hemophilia treatment centers emphasize prevention services to help reduce or eliminate complications. They receive federal funding through programs at the Centers for Disease Control, National Center on Birth Defects and Developmental Disabilities, Division of Blood Disorders and the Health Resources and Services Administration, Maternal and Child Health Bureau, and National Hemophilia Program. HTCs also are eligible to be 340B entities through the federal Office of Pharmacy Affairs. HFA supports a system of HTCs that provides the best quality of care in the most transparent way possible.

Comments

HFA is concerned that the following items from the proposed Guidance may interfere with patients' ability to receive care at their HTC.

Part A – 340 B Program Eligibility and Registration

HFA is concerned that under the proposed Guidance, the majority of HTCs will not qualify as covered entities. As written, the proposed Guidance designates only those non-hospital covered entities that receive federal grants and does not include entities that receive federal sub-grants. The majority of HTCs receive federal sub-grants. HFA respectfully requests that the language in the Guidance be either amended to include sub-grants, or that the definition of "federal grants" make clear that this category includes federal sub-grants.

Part C – Individuals Eligible to Receive 340B Drugs

HTCs provide a broad range of care through a number of different situations and may perform clinics in rural areas or treat populations in their home. HTCs also have arrangements with physicians who treat the multiple co-morbidities faced by the patient population, such as Hepatitis C and HIV. HFA strongly supports the inclusion of telemedicine practices in the proposed Guidance, however, we are concerned that some items in the proposed Guidance might limit the HTCs ability to effectively treat these populations.

Criteria 1: HFA is concerned that the proposed criteria does not include satellites, clinics, or other areas where HTCs conduct outreach and care for patients. We support the addition of language that includes sites approved under the scope of HTC's federal grants, sub-grants, or projects and that may not be pre-registered.

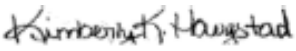
Criteria 2: Proposed criteria number two limits the definition of provider to those either employed by, or an independent contractor of, a covered entity so that the covered entity may bill for their services. HTCs often have arrangements with providers that do not qualify them as "employees" or "independent contractors" of that HTC in such a way as the HTC bills for their services. These providers may serve outreach clinics or rural areas, may bill separately and directly for their services, or provide their services to the HTC on a volunteer basis. HFA supports language that allows all providers who contract with HTCs to be included in this criteria.

Criteria 6: Many patients with hemophilia have multiple co-morbidities, including Hepatitis C and HIV. Providers outside of the HTC may be responsible for parts of their care and write prescriptions for drugs that are eligible for the 340b discount. The HTC may not be solely "responsible for the care" of the patient, but will have access to their records. HFA is concerned that criteria six is too limiting and supports language that allows for documented provider-to-patient relationship.

Conclusion

HFA appreciates the opportunity to comment on *340B Drug Pricing Program Proposed Omnibus Guidance* and provide HRSA with information on how changes to the proposed Guidance can maintain HTCs ability to adequately care for those with bleeding disorders. The 340B program is an integral part of how HTCs are able to financial support themselves and provide care to the patients they serve. If you have any questions on these comments, please contact Katie Verb at kverb@hemophiliafed.org.

Sincerely,



Kimberly Haugstad
Executive Director
Hemophilia Federation of America