NATIONAL HEMOPHILIA FOUNDATION

for all bleeding disorders

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

Submitted via regulations.gov.

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

Dear Captain Pedley:

The National Hemophilia Foundation (NHF) appreciates the opportunity to provide comments on the 340B Drug Pricing Program Proposed Omnibus Guidance. NHF is the nation's leading advocacy organization working to ensure that individuals affected by hemophilia and related bleeding disorders have timely access to high quality medical care and services, regardless of financial circumstances or place of residence.

NHF fully supports the participation of the national network of hemophilia treatment centers (HTCs) in the 340B drug discount program and as a result, has comments on provisions of the Guidance that we are concerned could jeopardize HTC participation in the program. NHF seeks to preserve the HTCs' ability to participate in 340B since the provision of pharmacy services furthers the comprehensive care mission of HTCs and benefits all patients at HTCs.

Background on Bleeding Disorders and HTC Participation in 340B

Hemophilia is a rare, chronic bleeding disorder affecting approximately 20,000 people in the US, who infuse high-cost clotting factor therapies to replace missing or deficient blood proteins. These therapies are safer and more effective than ever, but are also very expensive. Drug costs for a person with severe hemophilia can be $250,000 a year. Developing an inhibitor (an immune response to treatment) can increase these costs to $1 million or more. In addition, complications such as HIV/AIDS, hepatitis and joint diseases, or bleeding as a result of trauma or surgery have the potential to impact clotting factor utilization and costs. Due to the high costs of treatment and volatile nature of hemophilia, and its associated complications and comorbidities, the hemophilia community is extremely medically vulnerable. There are also similar bleeding disorders, like von Willebrand Disease, that affect up to 1 million Americans.

Most individuals with bleeding disorders receive care at HTCs, which provide comprehensive, multi-disciplinary, patient-centered care for bleeding disorders and their long-term complications, including inhibitors, liver disease and HIV/AIDS. Studies from the Centers for Disease Control and Prevention (CDC) have shown that mortality and hospitalization rates are 40% lower for people who use HTCs than in those who do not, despite the fact that more severely affected patients are more likely to be seen in HTCs.

The Veterans Health Care Act of 1992 designated federally-funded Hemophilia Diagnostic and Treatment Centers as covered entities eligible to participate in the 340B Drug Pricing Program. HTCs were included as covered entities to stretch their federal grant funding to provide comprehensive services to all patients served by the center. The availability of the 340B drug discounts for clotting factor can also reduce the comprehensive life-long health care costs for patients seen at HTCs.

Today, approximately 100 of the 140 HTCs have elected to participate in the 340B program. HTCs treat a mix of patients with private and public insurance, as well as the uninsured. As a condition of their federal grant, HTCs must invest all revenues from the 340B program back into patient services, care coordination, research and other programs that directly benefit patients. In order to dispense 340B drugs to a patient, the individual must receive clinical services at the center.

Comments on the Guidance

Part A – Eligibility and Registration of Covered Entities

NHF is concerned that HRSA has drafted the Guidance such that only recipients of Federal grants, contracts, designation or projects can be considered eligible non-hospital covered entities. This is a problem for HTCs, since most HTCs are sub-recipients of Federal grants or sub-grantees; in fact, there are only eight grantees in the HTC network and the remaining 100 HTCs in the 340B program are sub-grantees. Since the Guidance does not reference sub-grantees, NHF is concerned that the eligibility language jeopardizes participation for nearly every HTC that participates in the 340B program.

To ensure that HTCs can continue to participate in the program, we respectfully request that the Final Guidance states clearly that sub-grantees are eligible to be covered entities and are independently responsible for compliance with all 340B program requirements. We believe that the simplest way to do this would be to be to add the term "Federal sub-grant" to the list of eligible non-hospital covered entities and include the term Federal sub-grant throughout the guidance wherever the term "Federal grant" is used. As an alternative, we would suggest making it clear in the guidance that sub-recipients of Federal grants as defined in section 340B (a) (4) (G) (the statutory reference to HTC participation in the 340B program) are eligible non-hospital covered entities.

Part C – Individuals Eligible to Receive 340B Drugs

NHF has several concerns with the provisions in this section of the Guidance, which sets a six-criterion test to define the patients to whom 340B drugs can be dispensed.

First, for our community, it doesn't make sense for patient eligibility for 340B drugs to be defined on a prescription-by-prescription/order-by-order basis. Bleeding disorders are lifelong, chronic conditions, and individuals receive healthcare services from HTCs throughout their lives. An HTC patient's eligibility will remain fairly constant throughout his lifespan. When patients switch HTCs (due to a move or transition from pediatric to adult centers), this change in patient care responsibility is well-documented, making eligibility clear. NHF asks that HRSA not require that the patient definition test be implemented for HTCs on a per prescription or order basis.

Second, we are concerned about a number of the criteria required for patients to be eligible to receive 340B drugs. As currently drafted, the criteria would jeopardize successful HTC activities that directly benefit patients, such as telemedicine and care coordination with specialists that treat hemophilia co-morbidities. In addition, since HTCs have many different structures, the six criteria combined could

prevent some HTCs from serving any patients with 340B drugs. Recognizing the broad scope of services provided by HTCs, NHF endorses the specific recommendations on the patient definition made by the Hemophilia Alliance to ensure that existing HTC programs and patient services can continue:

Criterion 1: The individual receives a health care **or clinical** service at a facility or clinic site **or a site that is approved under the scope of the grant, sub-grant, or project of** the non-hospital covered entity **and is** provided by a covered entity which is registered for the 340B Program and listed on the public 340B database.

The addition of "or clinical" is required to reflect the broad array of health care services and the inter-disciplinary team of providers at HTCs, including nurses, physician assistants, pharmacists, and clinical social workers, who are an integral part of the comprehensive care team. These professionals train patients to self-infuse, assure patients are complying with medication adherence, and provide appropriate psychosocial support.

The second change is necessary because HTCs provide significant outreach services at multiple locations, which may change on a monthly or weekly basis. In fact, outreach is an important element of the HTCs' grant requirements and is included in the scope of the Federal grants and sub-grants. To date, HTCs have not been asked to identify any of their "outreach" locations to MCHB or OPA. Some off-site clinics are regularly scheduled, but others are just single events or only occasionally offered. In addition, HTCs serve patient populations, such as the Amish in Ohio, Michigan and Indiana, in their own communities since they are not able to come to the main HTC facilities. We are concerned that outreach locations sometimes change at the last minute and based on the registration process outlined in the Guidance 340B drugs could not be provided to many of these patients.

Criterion 2: The individual receives a health care service from a health care provider who is employed by the covered entity or who is an independent contractor for the covered entity~~, such that the covered entity may bill for services on behalf of the provider~~ **or a provider who performs the services pursuant to a written agreement with the 340B covered entity. Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered entity-provider relationships that would meet this standard.**

We seek this change since there are many different ways that HTCs engage with the providers that serve their patients. In the academic setting (a frequent model for HTCs), the HTC may be owned and operated by a university or a hospital, but the hematologists and other physicians prescribing medications will be part of the larger physician group practice plan that serves the hospital's patients. Other arrangements exist between HTCs and physicians in rural areas serving in outreach clinics and for the treatment of comorbidities of hemophilia such as HIV and Hepatitis C. While the HTCs can have written agreements with these providers, they are typically not "employed by" the HTC and are not necessarily defined as "independent contractors," which denotes that the HTC pays them for their services. Some clinicians provide their services at no charge to the HTC and others bill directly for their services.

Criterion 3: An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). **The service delivery may include the use of telemedicine, telepharmacy, remote, or other health care arrangements.** An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion or dispensing of a drug.

This change is to codify the language included in the preamble that the delivery of health care services by "telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) involving the issuance of a prescription by a covered entity is permitted." This is important since patients often live far away from their HTC and there are frequently situations where the most appropriate consultation with the provider is by telephone. This is an essential component to the comprehensive care of people with bleeding disorders.

Criterion 6: The individual has a relationship with the covered entity such that the covered entity maintains access to ~~auditable~~ health care records which demonstrate that the covered entity has a provider-to-patient relationship~~, that the responsibility for care is with the covered entity~~ and that each element of this patient definition in this section is met. ~~for each 340B drug~~.

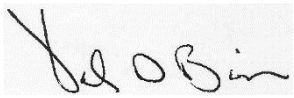
The requirement that the health care records be "auditable" is problematic since HRSA does not define the term. As a result, it is not clear what kind of records a covered entity must maintain.

We also seek to delete the requirement that "the responsibility for care is with the covered entity." This is because people with bleeding disorders experience co-morbidities such as HIV and Hepatitis C, among more common problems that are treated collaboratively by HTC personnel and other specialists. Other physicians may see the HTC patients, but HTCs closely coordinate the overall care. The HTC doctor or the collaborating physician may write the prescription for drugs used to treat both diseases, which would be eligible for 340B discount. The HTC will have access to all patient records establishing its "provider to patient relationship," but the "responsibility for the care" of the patient could be shared and is not solely the responsibility of the covered entity.

Conclusion

Our comments seek to preserve HTCs' ability to participate in 340B since this has provided a critical means of financial support for HTC to maintain comprehensive care for all patients seen at the center. If you have any questions or would like to discuss these comments further, please contact Johanna Gray at jgray@dc-crd.com.

Sincerely yours,



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