



July 12, 2017

The Honorable Thomas E. Price, M.D.  
Secretary  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

*Re: Request for Information: Reducing Regulatory Burden Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients*

Dear Secretary Price,

I am writing on behalf of the Hemophilia Alliance to comment on the Request for Information: Reducing Regulatory Burden Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients (the RFI). Our comments focus on ways that your Department can make changes to the ACA that will empower patients to access specialized care provided by hemophilia treatment centers and enhance the affordability of this coverage.

The Hemophilia Alliance is a non-profit organization comprised of hemophilia treatment centers (HTCs) across the United States that provide patients with hemophilia and other bleeding disorders with comprehensive specialized diagnostic and treatment services and clotting factor delivery programs by participating in the 340B Drug Pricing Program. Hemophilia is a rare, chronic bleeding disorder affecting about 20,000 people in the US, who require life-long infusions of high-cost clotting factor therapies to replace missing or deficient blood proteins.

#### About Hemophilia Treatment Centers

The national network of 135 federally-funded HTCs was authorized under Title V of the Social Security Act (Maternal and Child Health Services (MCH)) in 1976. HTCs receive grant funding from the MCH Special Programs of National Significance (SPRANS) and the Centers for Disease Control and Prevention (CDC). The majority of HTCs also participate in the 340B drug discount program, which generates program income to support comprehensive care for all patients seen at the center.

More than 40,000 individuals with bleeding disorders receive specialized care at HTCs, and many receive their clotting factor through HTCs' 340B drug delivery programs. The HTC network HTCs are comprised of a multi-disciplinary team of providers – hematologists, nurses, physical therapists, social workers, and pharmacists – that provide highly specialized care to assess and provide treatment for bleeding disorders and their complications, including inhibitors, liver disease and HIV/AIDS. An analysis of the HTC network performed in 2014 by the National Hemophilia Program Coordinating Center (NHPCC), which is funded by the Health Resources and Services Administration (HRSA), found that 340B program income supported 569 full-time equivalents (FTEs) at 83 HTCs and an average of more than 5,500 telephone triage, care coordination and case management patient encounters per center.

The HTC comprehensive care model is patient-centered and trains individuals with bleeding disorders to recognize and quickly treat life-threatening internal bleeding episodes to prevent complications. Studies

have shown that mortality and hospitalization rates are 40% lower for people who use HTC than in those who do not, despite the fact that more severely affected patients are more likely to be seen in HTCs.

### Comments on the RFI

While the ACA's private insurance reforms have unquestionably benefited the bleeding disorders community, many individuals continue to struggle to afford expensive insurance premiums and high out-of-pocket costs for needed treatments. We support efforts to further improve affordability and access to health insurance and to stabilize health insurance markets, but ask that these changes enhance and not impede access to care for people with bleeding disorders. As you consider changes to existing regulations or guidance related to the Affordable Care Act (ACA), we respectfully offer specific comments by question in the RFI:

#### 1. Empowering Patients and Promoting Consumer Choice

We appreciate that you seek to implement policies to empower patients to choose the insurance plan, health care providers, and financing that are most appropriate for them. We share this goal and support policies that facilitate access to HTCs by all members of the bleeding disorders community who wish to use them for clinical and/or pharmacy services.

Current CMS policy related to essential community providers (ECPs) complicates access to HTCs today. The ACA designates HTCs as ECPs and requires Qualified Health Plans (QHPs) offered on the ACA Marketplaces to offer a "sufficient" number of ECPs in their plan networks. On a regulatory level, CMS has defined sufficiency to mean that plans must include a threshold number of ECPs in their service areas, as well as one per category. Despite their statutory designation as ECPs, CMS permits plans to exclude HTCs from their networks since they are lumped in the "Other ECP Providers" category with STD Clinics, TB Clinics, Black Lung Clinics and other entities.

We are disappointed that plans can satisfy ECP requirements even if they do not contract with HTCs. QHPs in multiple states have declined to contract with HTCs and there are some localities where no QHPs contract with the local HTC. Individuals with bleeding disorders are medically vulnerable and must have access to the expert care provided by HTCs to effectively manage their complex, expensive, life-threatening condition. In these areas, patients do not have access to HTCs or are required to pay significant out-of-pocket costs to access out-of-network care.

In prior comment letters, we have requested that CMS make HTCs a separate category like Ryan White providers and FQHCs as it indicated it was considering in the 2016 Notice of Benefit and Payment Parameters Final Rule. In keeping with the goals of the RFI to empower patients, we encourage you to revise ECP policies to separate HTCs into their own category of ECPs. This is the only way to ensure that QHP networks are adequate for people with bleeding disorders.

In addition, please maintain current essential health benefits (EHBs), network adequacy and non-discrimination standards. These policies are critical to providing access to coverage and are necessary for the bleeding disorders community. Some have argued that these standards should be relaxed to provide insurers with more flexibility; this would jeopardize access to care for our vulnerable patient population.

### 3. Enhancing Affordability

We support policies that would enhance affordability and reduce out-of-pocket costs for individuals. The breadth of the definition of EHBs determines the extent to which other ACA protections help with affordability, including the ban on lifetime and annual limits, ban on discriminatory benefit design, and the out-of-pocket maximum. These policies are critical for the bleeding disorders community, who face very high out-of-pocket costs and regularly hit lifetime and annual limits before they were prohibited. Again, we ask that you maintain current EHB policies to ensure that these protections enhance affordability.

Moreover, in seeking to enhance affordability for both payers and individuals, we encourage you to consider policies that will promote public and private payers to contract with 340B pharmacy providers, like HTC. Access to 340B discounts enables HTCs to create shared savings models that pass along discounts to payers, while generating program income to enable HTCs stretch scarce federal resources to care for their patient population. Moreover, by combining clinical and pharmacy services, HTCs are able to more closely manage pharmacy services, which is the most significant healthcare cost for this population. Contracting with HTCs is the best way to manage this expensive and complex patient population.

#### Conclusion

The Hemophilia Alliance appreciates the opportunity to comment on the RFI as we hope to ensure that individuals with bleeding disorders have full access to the treatments and specialists they need to lead healthy, productive lives. If you have any questions or would like any additional information, please contact me at [joe@hemoalliance.org](mailto:joe@hemoalliance.org).

Sincerely,



Joseph Pugliese  
President  
Hemophilia Alliance