



## NATIONAL HEMOPHILIA FOUNDATION

www.hemophilia.org

March 15, 2013

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

Submitted electronically to [ffecomments@cms.hhs.gov](mailto:ffecomments@cms.hhs.gov)

Re: Letter to Issuers on Federally-facilitated and State Partnership Exchanges

Dear Secretary Sebelius:

The National Hemophilia Foundation (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. We appreciate the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) our comments on the above referenced letter. Our comments focus on the need to ensure that the implementation of essential community provider, cost-sharing and prescription drug policies provide meaningful coverage for people with bleeding disorders.

Established in 1948, NHF is the largest and oldest patient advocacy organization representing individuals with bleeding and clotting disorders. 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 also very expensive. Drug costs for a person with severe hemophilia can be \$250,000 a year or more. Developing an inhibitor (an immune response to treatment), complications such as HIV/AIDS, hepatitis and joint diseases, or bleeding as a result of trauma or surgery can increase those costs to \$1 million.

Most individuals with hemophilia receive care at hemophilia treatment centers (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 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.

Chapter One, Section One: Network Adequacy and Inclusion of Essential Community Providers (ECPs)

*Section II – Essential Community Providers*

Thank you for providing more information about the number and types of ECPs that plans must include in their provider networks to satisfy network adequacy requirements. The Affordable Care Act (ACA) requires that entities specified under section 340B (a)(4) of the Public Health Service Act be defined as "essential community providers." Hemophilia treatment centers are covered entities in the 340B program. As a result, these details are particularly important to the bleeding disorders community since

the inclusion of HTC in plan networks is critically important to ensuring that people with bleeding disorders have access to the high-quality, specialized care necessary to keep them healthy.

We applaud CMS' decision to address the needs of the low-income, medically underserved individuals by requiring that ECPs be included in plan networks. According to recent data from the CDC's Universal Data Collection database on the bleeding disorders community, almost half of the hemophilia population is on Medicaid, covered by high-risk insurance pools or uninsured. As the ACA is implemented, HTCs are expected to see an increase in the number of publicly-insured and subsidized patients, who would otherwise face significant barriers to good health and appropriate medical care if denied access to HTCs.

CMS proposes two standards for plans to comply with the ECP policies, and we have concerns that neither will be sufficient for people with bleeding disorders.

#### Safe-Harbor Standard

CMS asserts that for 2014, plans can meet a safe harbor standard by including at least 20 percent of available ECPs in the service area, including "at least one ECP in each ECP category (see Table 2.1) in each county in the service area where an ECP in that category is available." We ask that HTCs not be included in the category of "other ECP providers" with STD Clinics, TB Clinics, Black Lung Clinics and "other entities" listed in Table 1.1. This grouping of providers which serve such distinct populations doesn't make sense. Our interpretation of the letter is that plans could satisfy the ECP requirement by including a TB clinic, instead of an HTC, even though this provider has no expertise or experience in treating people with bleeding disorders. Since hemophilia is so rare, is it extremely difficult to get quality care outside the HTC network. We respectfully request that plans be required to include one of each type of "other ECP providers" in their networks, not one from the entire category.

#### Minimum Standard

Alternatively, plans can demonstrate that they include 10 percent of the available ECPs in the service area and provide a "narrative justification describing how the issuer's provider network(s) . . . provide an adequate level of service." Please provide more details about what information must be included in this narrative justification, and/or what further standards CMS will use to ensure that there are sufficient ECPs in a plan's network. Again, we believe that a plan network cannot be adequate for people with bleeding disorders unless it includes an HTC. Please require plans to explain how they will meet the needs of those with bleeding disorders if they do not include an HTC in their plan network.

#### *Section III – Alternate ECP Standard for Integrated Issuers*

For integrated issuers, CMS requires plans to describe how their provider sites meet the needs of specific underserved populations, including people with HIV/AIDS, and American Indians/Alaska Natives, and women seeking health and reproductive health services. We support the inclusion of people with HIV/AIDS on this list, since as a result of tainted blood products in the 1980s, many men with hemophilia were co-infected with HIV and Hepatitis C.

In addition, we respectfully request that CMS amend the list of specific underserved populations for which plans must provide extra information to include people with hemophilia and other bleeding disorders since these people also have highly specialized needs. It is difficult to get high-quality care outside of the HTC, since many hematologists have limited or no experience in treating hemophilia and

other non-malignant bleeding disorders. All plans should be required to include HTC in their provider networks to ensure that patients can access providers with expertise in treating hemophilia.

#### Chapter One, Section Four: Benefit Design Review

##### *Section III – Annual Limitations on Cost-Sharing*

As providers recognized under Section 340B of the Public Health Service Act, HTCs are designated as ECPs by the ACA. Therefore, we anticipate that HTCs will be in-network providers for most health plans. For the reasons stated above, it is critically important that people with bleeding disorders can access these providers. However, if HTCs are excluded from plan networks, or if people need to access other providers not in the network (such as surgeons with experience in hemophilia), we are very concerned that spending on out-of-network services will not count towards the annual limit on out-of-pocket expenses. This policy would be detrimental for people with bleeding disorders who must be able to access the expertise at specialized centers across the country to effectively manage their disease. We request that this policy be amended so that out-of-network spending counts towards the annual limit on cost-sharing. Otherwise, this important protection will not meaningfully benefit patients.

Furthermore, it is unclear whether spending on a drug a patient uses not on the formulary will count as an EHB for purposes of the out-of-pocket maximum. Given the high-cost of clotting factor therapies, it is critical that any spending on drugs, whether on or off the formulary, covered under the medical or pharmacy benefit, count towards an enrollee's out-of-pocket maximum.

#### Appendix C: Additional Guidance on EHB Prescription Drug Coverage, AV, and Cost Sharing

##### *Section I – Drug Count Service*

We are concerned that CMS indicates that a “drug is considered covered regardless of tiers and cost-sharing.” Defining coverage this way ignores the barriers to access that specialty tiers provide. Clotting factor therapies are biologic products with no generic equivalents, so they frequently appear on specialty tiers where patients are asked to pay up to 33% of the total cost of the drug. Families simply cannot afford to pay 33% of \$300,000 annually. Moreover, individuals with bleeding disorders could reach the limit on out-of-pocket spending by filling their first prescription. We request that coverage be redefined so that specialty tiers, or any policy that requires exorbitant cost-sharing, are prohibited, thereby providing meaningful access.

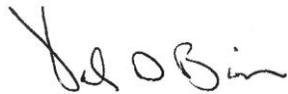
Also, we are concerned that the letter does not address physician-administered drugs, like clotting factor therapies, that are sometimes covered under the medical rather than pharmacy benefit. We respectfully request that CMS be explicit about any minimum coverage requirements for drugs covered under the medical benefit. Furthermore, the information released on the number of drugs covered by benchmark plans does not have sufficient details on how these drugs are covered under existing benchmark plans. There is information on whether classes of physician-administered drugs are covered, but not how many products in each class. Please provide additional information including how many drugs are covered under the medical benefit, as you have for the prescription drug formulary.

*Section II – Prescription Drug Exceptions Process*

Thank you for providing further details about the procedure plans must use to allow enrollees to request and access clinically appropriate drugs not covered by the plan. We were pleased that you require a timely exceptions process and encourage plans to allow enrollees to have the medication in dispute during the entire review process. We strongly support the proposal that if the exception request is granted, plans allow enrollees to access the non-covered drug in subsequent policy years –provided enrollment continues uninterrupted.

Thank you for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Val Bias". The signature is written in a cursive, flowing style.

Val Bias  
Chief Executive Officer