

Congress of the United States

Washington, DC 20515

[[DATE]]

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

We write today to express our concern over the impact that narrow prescription drug formularies that exclude coverage for all disease states have on patients. We believe many health plans across the US are not following current essential health benefit (EHB) standards and that the Department of Health and Human Services (HHS) is not enforcing these regulations, which were put in place to protect patient access to needed medications.

Narrow formularies occur when health plans significantly limit the medications they cover. This can be detrimental to any number of individuals who need access to medication to manage acute or chronic illnesses. For example, for people living with bleeding disorders, such as hemophilia, narrow formularies may offer as few as one treatment option across *all* bleeding disorders. There are currently 27 products used to manage nine different bleeding and clotting disorders and there are many differences among these products (not only disorder treated, but also mechanism of action, half-life, administration route, and more). Extremely narrow formularies can prevent access to the medication that a person's physician believes is best for them or even the one that can treat their condition.

Existing EHB regulations say formularies should:

1. Cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that **treat all disease states**, and . . . **not discourage enrollment by any group of enrollees**; and
2. Provide appropriate access to drugs that are included in **broadly accepted treatment guidelines** and that are indicative of general best practices at the time.¹

Unfortunately, these regulations are not being enforced and individuals across the country are being denied access to treatment. We are aware of formularies that exclude many and, in some cases, all available treatments for a given bleeding disorder. People without access to treatment face painful and potentially life-threatening bleeding episodes that are not only harmful to their health, but also cause complications that raise healthcare costs overall. We are hearing from an increasing number of patients across the country who are worried about facing similar issues.

These formulary designs jeopardize efforts for all to have access to high-quality insurance, regardless of their health status. While we are highlighting issues related to narrow formularies for people with bleeding disorders, we recognize that other patient communities face similar challenges. We urge HHS to enforce existing EHB regulations and ensure access to care.

¹ 45 C.F.R. § 156.122(a)(3)(iii)(H)

We believe that the language in subsection [45 C.F.R. § 156.122(a)(3)(iii)(H)], particularly when read in conjunction with § 156.125 (prohibition on discrimination), suggests that HHS already has tools to address this issue. We thank you for your attention to this matter and respectfully request that HHS use and enforce its existing authority to protect comprehensive coverage for individuals with pre-existing conditions.

[[CLOSING]]

[[SIGNATURES]]