



July 23, 2021

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

Re: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs, File Code CMS-9905-NC

Dear Secretary Becerra,

The Hemophilia Federation of America, National Hemophilia Foundation and Hemophilia Alliance are pleased to submit this response to your Request for Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs. We are hopeful that well-crafted reporting requirements will support the Department in establishing policies for health plan design that promote access and affordability.

The National Hemophilia Foundation (NHF) and Hemophilia Federation of America (HFA) are national non-profit organizations that represent individuals with bleeding disorders across the United States. Our missions are to ensure that individuals affected by hemophilia and other inherited bleeding disorders have timely access to quality medical care, therapies, and services, regardless of financial circumstances or place of residence. 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.

About Bleeding Disorders and Current Patient Challenges in Accessing Treatments

Hemophilia is a rare, genetic bleeding disorder affecting about 20,000 Americans that impairs the ability of blood to clot properly. Without treatment, people with hemophilia bleed internally, sometimes as a result of trauma, but sometimes simply as a result of everyday activities. This bleeding can lead to severe joint damage and permanent disability, or even – with respect to bleeds in the head, throat, or abdomen – death. Additional related bleeding disorders include von Willebrand disease (VWD), another inherited bleeding disorder, which is estimated to affect more than three million Americans.

Patients with bleeding disorders have complex, lifelong medical needs. They depend on ongoing use of prescription medications (clotting factor or other novel treatments) to treat or avoid painful bleeding episodes that can lead to advanced medical issues. These medications are biological products, derived from human blood plasma or created by recombinant technology: the treatments are very effective, but very expensive. Because there are no cheaper treatments – no generics – available to treat hemophilia and related disorders, affected individuals have no choice but to use hundreds of thousands of dollars' worth of medication each year, for life, in order to prevent or treat bleeding episodes and preserve their

health. As a result, people with bleeding disorders depend, to an almost unparalleled degree, on access to quality health coverage, comprehensive pharmacy benefits, and meaningful affordability protections.

These needs are imperiled by current trends in health spending and insurance benefit design. High deductible health plans have proliferated in recent years, now accounting for up to half of all enrollees in employer-sponsored insurance (as well as many with ACA Marketplace coverage).¹ Millions of other Americans (even if not enrolled in plans that qualify under IRS rules as HDHPs) face ever-rising deductibles which leave them functionally underinsured.² These general trends are exacerbated for individuals with chronic or life-threatening diseases such as bleeding disorders by payer strategies that target specialty and high-cost medications via tiering and coinsurance. Such pharmacy benefit designs increasingly shift costs to the “sickest” enrollees – exposing them to onerous year-after-year cost-sharing, impeding their access to treatment, and undermining the protections against financial toxicity that insurance should confer.³

How should plans account for manufacturer copay assistance programs and copay accumulators

In the current landscape, manufacturer copay assistance programs provide bleeding disorders patients with critical support in accessing their life-saving medications. As CMS,⁴ the Massachusetts Health Policy Commission,⁵ and many others have recognized, manufacturer-sponsored patient assistance programs can play an important role in safeguarding access to therapy for many individuals with chronic health conditions.

Yet people with bleeding disorders are increasingly experiencing access barriers and financial hardship arising from copay accumulator adjusters. This proliferating insurer/PBM strategy redirects the value of manufacturer copay assistance away from patients and into payer coffers: health plans accept copay assistance but then disregard those amounts when calculating the subscriber’s annual deductible or OOP maximum. When the copay assistance dollars are fully depleted, the consumers find themselves on the hook for cost-sharing associated with their prescription refills and other care, potentially up to their full OOP maximum; in this manner, health plans end up collecting twice (or more) on subscriber deductibles. Payers understand⁶ that copay accumulators harm patient access to appropriate therapy,⁷

¹ SHADAC staff report, State-level Trends in Employer-sponsored Health Insurance, 2015-2019 (Sept. 2020), <https://www.shadac.org/ESIReport2020>; NHF Press Release: National Patient & Caregiver Survey Shows that COVID-19 Has Exacerbated Treatment Affordability Challenges & Health Inequities for Vulnerable Americans (May 19, 2021), <https://www.hemophilia.org/news/covid-19-exacerbates-treatment-affordability-challenges-health-inequities>.

² Sara R. Collins, Munira Z. Gunja, Gabriella N. Aboulafia, U.S. Health Insurance Coverage in 2020: A Looming Crisis in Affordability (Aug. 19, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/looming-crisis-health-coverage-2020-biennial>.

³ Stacie Dusetzina, Juliette Cubanski, Diane Rowland, Scott Ramsey. Improving the Affordability of Specialty Drugs by Addressing Patients’ Out-of-Pocket Spending. Health Affairs (March 15, 2018), https://www.healthaffairs.org/doi/10.1377/hpb20180116.800715/listitem/HPP_2018_CMWF_01_W.pdf.

⁴ CMS proposed rule on Medicaid VBP (June 19, 2020), 85 Fed. Reg. 37289.

⁵ See Peter Pitts and Jason Zemcik, Best Price Rule on Drug Costs Comes at Worst Time for Americans. Real Clear Health (April 2, 2021), https://www.realclearhealth.com/articles/2021/04/02/ best price rule on drug costs comes at worst time for americans_111185.html

⁶ Kevin Patterson et al. Copay Accumulators: Sifting Cost of Care from Plan Sponsors to Patients? (Jan. 27, 2021), <https://mmeadvisors.com/news-and-analysis/copay-accumulators-shifting-cost-of-care-from-plan-sponsors-to-patients/>.

⁷ Six in 10 respondents to a recent national survey reported that they would have extreme difficulty affording their medication if copay assistance is not counted toward their out-of-pocket costs. NHF national survey, supra note 1; Kollet Koulianos and Keri

yet they continue to push forward with this strategy, building accumulators into plans that now account for 80% or more of commercial coverage.⁸

Our organizations together with other stakeholders continue to urge CMS, state insurance commissioners, and other lawmakers to prohibit this harmful practice. With respect to the present RFI, we respectfully ask the Departments, at a minimum, to require plans to account for sums they collect pursuant to their copay accumulator and copay maximizer programs. The collection of this data would help to redress the lack of transparency around plan implementation of copay accumulators.⁹ It would also inform and support policymakers' efforts to ensure that patient assistance programs fully benefit patients, as intended, rather than being absorbed by payers or PBMs.¹⁰

A troubling new approach to pharmacy benefit design: the “alternative funding model”

We also ask the Departments to require reporting on a dangerous new strategy now cropping up in some self-funded employer health plans: the so-called “alternative funding model.” Under this model, marketed by various brokers as a purported solution to the problem of high specialty drug costs, the health plan drops coverage for certain products (sometimes all specialty drugs, sometimes just bleeding disorders products or some other class of medications). The broker promises to protect the interests of employees who rely on such products. The mechanism for doing so? Enroll the employee in a drug manufacturer's patient assistance program to get access to their treatments for free.

The problem is that manufacturer patient assistance programs (PAPs) are not optimal for managing bleeding disorders treatments. Historically, PAPs have been used to support patients with short-term gaps in health insurance; and are not designed to be long-term solutions for patient access to medication. Many PAPs are only offered to patients for a specified period of time or under specific circumstances, making it unclear if patients will have access to their therapies all year. Additionally, with PAPs, patients have more difficulty in managing inventory for optimal care at home. Patients may receive more vials per dose and they do not typically receive ancillary products like syringes, making it harder to administer the treatment and maintain compliance. This poor management can potentially cause patients to miss infusions or to have to go to the emergency room to receive treatment.

The alternative funding model delays care, drives up costs and produces poor patient outcomes. This practice is also bad for other payers and patients – if manufacturers end up giving product for free to patients with large group coverage, they will increase costs elsewhere – including for Medicare, Medicaid and on the ACA marketplaces. This will raise costs for taxpayers, too.

We are aware of people with bleeding disorders being affected by these models in several states, including: Indiana, Illinois, Michigan, Minnesota, Missouri, Nevada, Texas, Utah, Washington, DC, and Wisconsin. We fear that they will only grow without policy intervention. We respectfully request the Departments collect information on the use of “alternative funding models” as a first step in addressing this discriminatory and abusive twist on pharmacy benefit design. As you collect information about

Norris, Copay assistance should count as part of patients' cost sharing for medications, STATNews (June 30, 2021), <https://rb.gy/da9fmz>.

⁸ Joyce Wang, Kathryn Kirk, Chance Scott. Providers and Patient Push Back, Payers Push Forward – Co-Pay Mitigation Programs. Am. J. Managed Care (Feb. 7, 2021), <https://www.aimc.com/view/contributor-providers-and-patients-push-back-payers-push-forward-co-pay-mitigation-programs>.

⁹ Pitts and Zemcik, supra note 5.

¹⁰ Medicaid VBP rule, 85 Fed. Reg. 87000 (Dec. 31, 2020).

costly prescription drugs and relationships between issuers, PBMs and manufacturers, one option could be to ask a question about whether the issuer excludes coverage of any entire categories or classes of drugs or if it or a PBM has shifted any patients to get their drugs through manufacturer assistance programs.

Transparency for Rebates

We support that you will seek information about a variety of rebates and other financial relationships between issuers, PBMs and manufacturers. We believe that many of these opaque arrangements only serve to increase drug costs, including patient out-of-pocket costs, and reduce patient access to the treatment prescribed by their physician. Accordingly, we support that you intend to ask questions about how these rebates benefit – or harm – patients as part of your information collection. We believe that quantifying this impact and publicly releasing information about it will be very useful for policymakers and other stakeholders seeking to lower costs and increase access.

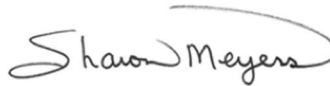
Conclusion

We appreciate the opportunity to provide these comments on this effort to promote greater price transparency in health care. We are deeply invested in ensuring that all people with bleeding disorders have access to affordable, quality health insurance, and are hopeful that well-crafted reporting requirements will provide you with the data necessary to safeguard such access. Please contact Sonji Wilkes, HFA Vice President for Policy and Advocacy, s.wilkes@hemophiliafed.org, Nathan Schaefer, NHF Vice President for Public Policy, nschaefer@hemophilia.org, and Joe Pugliese, President and CEO of the Hemophilia Alliance, joe@hemoalliance.org, with any questions.

Sincerely,



Dr. Leonard Valentino
President and CEO
National Hemophilia Foundation



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