May 10, 2023

The Honorable Bernie Sanders
Chairman
Senate Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
100 Constitution Avenue, NE
Washington, DC 20510

The Honorable Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health, Education, Labor & Pensions
455 Dirksen Senate Office Building
100 Constitution Avenue, NE
Washington, DC 20510

Dear Chairman Sanders, Ranking Member Cassidy:

The undersigned patient groups, representing over millions of patients across the United States living with cancer, cystic fibrosis, epilepsy, hemophilia, and multiple sclerosis, hear consistently from people with these conditions about the many challenges they face accessing life-changing or life-saving medications across the drug supply chain. Reforms are needed in many areas to help patients access the medications they need in a more timely and more affordable manner—including the practices of pharmacy benefit managers (PBMs).

We therefore thank you for your focus on passing bipartisan legislation through the Senate Committee and Health, Education, Labor & Pensions (HELP Committee) to reform the practices of PBMs and urge you to pass meaningful PBM reform that prioritizes the needs of patients and ensures transparency and accountability of PBMs and their practices. **Prioritizing patients within PBM reform means ensuring transparency, prohibiting unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments, banning PBMs from using discriminatory formularies, requiring pass-through pricing models, and advancing proposals that will address utilization management practices that present barriers for patients accessing medically necessary medications.**

We appreciate that many of these proposals are included in the Pharmacy Benefit Manager Reform Act; however, we believe other provisions could be added to meet the needs of and make the healthcare system work better for people living with chronic diseases and conditions. PBMs pay an increasingly central- but often hidden- role in the U.S. healthcare system, and their practices have significant impacts on the access that patients have to the medications they need and the cost of those medications. PBMs also play an outsized role in determining the cost of prescription drugs for payors, determining how much pharmacies are paid for these medications and which pharmacies patients can use to get their medications.

Establish Transparency

We appreciate that the Pharmacy Benefit Manager Reform Act includes language to improve transparency of information and allows researchers to utilize this information in their studies. There is increased pressure on patients to make informed choices about the cost of their care and prescription drug medications. Yet, there is very little transparency to guide patients as they discuss their care with their health care providers. Ensuring transparency and requiring reporting of relevant data is necessary to level the playing field and give all stakeholders access to information necessary to guide their decision-making.

Recommendation: We urge the Committee to advance proposals that improve transparency so that all stakeholders including patients are working with the same level of information to inform healthcare decision-making.

Ensure Accountability

The opaqueness of the healthcare system has made it hard to hold stakeholders accountable for actions that drive up costs for patients. We are pleased that the Committee is examining policies that establish an entity that has responsibility for monitoring PBM behavior. Improved transparency and reporting requirements will allow entities to hold PBMs that act in violation of the law accountable and respond when policies are not operating in the best interest of the patient.

Recommendation: Include provision that establishes an entity that has jurisdiction to examine PBM behavior and authority to impose effective accountability measures.

Prohibit discriminatory formularies and unfair and deceptive pricing models

PBMs are not compelled to act in the best interest of the patient. Instead, they often act in ways that are more profitable for their business model. The vertical integration that has occurred throughout the healthcare system has served to further remove the patient's interest from the center of decision-making.

For example, PBMs may negotiate formulary placement for a health plan that places all drugs for a certain condition, including generics, on the highest tier, thereby forcing patients who need those medications to pay high out-of-pocket costs. This action can also discourage enrollment of patients who live with that condition. These actions do not benefit the patient and are business practices to protect the payor's profitability.

While PBMs often cite part of their role as helping to lower health care and prescription drug costs, our organizations believe that it is important that patients see the benefit of a PBM's negotiated savings. While we appreciate the Pharmacy Benefit Manager Reform Act draft language includes provisions to pass 100% of rebates through to the plan, we believe patients should be able to see how that savings impacts their costs and premiums.

Recommendation: Align incentives within the system to ensure that PBMs have a responsibility to act on what is best for the patient. Advance proposals that prohibit unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments, ban PBMs from using discriminatory formularies and require all savings to be passed through to patients.

Address Utilization Management Practices

PBMs play a powerful role in determining what access patients have to their medications. Their unique role allows them to determine what medications are covered by payors, what tier those medications are on, and what pharmacies people can use to get their medications. As costs and utilization of medications have increased, health plans and PBMs have utilized strict utilization management practices – such as prior authorization and step therapy – to minimize the use and cost liability for medications.

Utilization management practices present significant hurdles for patients and prescribers and cause real delays and barriers for people with chronic diseases in accessing the treatments they need. Unnecessary use of these requirements often results in increased nonadherence and dangerous delays that can put

patients at risk. Twenty-four percent of physicians report that prior authorization requirements have led to a serious adverse event for patients in their care, and 16% of physicians say that these practices have led to a patient's hospitalization[i]. Some step therapy practices can require between three to five medications to fail a person with a chronic disease before access to the provider and individual's medication of choice is approved.

Additionally, copay accumulator programs (which are a feature within insurance plans whereby a manufacturer's assistance does not count towards a patient's deductible and out-of-pocket maximum), do very little to benefit their beneficiaries. These programs jeopardize health outcomes due to a lack of transparency as to how they are implemented and have a greater impact on patients who rely on specialty drugs, many of which do not have generic options, for which manufacturers often provide copay assistance. With these programs in place, a manufacturer's assistance no longer applies toward a patient's copay or out-of-pocket maximum. This results in patients experiencing increased costs and taking longer to reach required deductibles. Patients with costly specialty medications too often struggle to afford and eventually forgo treatment due to high copay costs.

We urge the Committee to include common-sense legislative proposals that minimize the impact of utilization management on patients and ensure they have affordable access to their treatments.

Recommendation: PBM reform must include provisions that ensure patients have affordable and prompt access to the treatments they need. Please include the Safe Step Act (S.652) and the HELP Copays Act (S. 1375) in the final version of the Pharmacy Benefit Manager Reform Act.

Emerging Issues for Consideration

Alternative Funding Vendors

PBMs and PBM-affiliated entities are also often responsible for a deceptive practice that goes by the name of "alternative funding." Alternative funding vendors (AFVs) promise to lower employer drug spending, via schemes that drop or limit plan coverage for one or more drugs or drug classes. The AFV then tries to steer impacted employees into manufacturer charitable free product programs – programs that are intended to bridge short-term needs and are not designed to be long-term solutions for patient access to medication. As reimbursement for its services, the AFV charges the employer a large monetary amount (often a percentage of the savings). A recent survey reveals that up to forty percent of commercial plans use or are considering using abusive AFV practices[ii].

Alternative funding practices, as implemented by PBM-affiliated entities like ShaRx, Payer Matrix, and Payd Health, are distorting health insurance and undermining the hard-won patient protections guaranteed by the Affordable Care Act. Steering employees to manufacturer patient assistance programs violates nondiscrimination requirements while shifting costs within the health care system. Patients subjected to AFVs experience gaps and delays in care that can harm their health. They must contend with confusion and anxiety over their insurance and even employment status. Some may be forced to switch therapies, for non-medical reasons, and may even be coerced into sourcing their medications from overseas. We also know that not all patients affected by these harmful schemes are able to qualify for manufacturer patient assistance programs, since they are above the income eligibility criteria and (despite AFV-cultivated appearances) they have insurance.

Recommendation: PBM reform should rein in "alternative funding" abuses.

Conclusion

Millions of people who live with chronic diseases and conditions need Congress to act now to pass common sense legislation to reform the practices of PBMs to improve access to and affordability of the medications they need to live their lives. We urge you to consider the human faces behind each of the proposals under discussion, and to ensure inclusion of the bipartisan proposals outlined above as you advance legislation through Committee. We encourage you to utilize our groups as a resource and are ready to work with you. If we can be of assistance, please reach out to Leslie Ritter, AVP of Federal Government Relations, at Leslie.Ritter@nmss.org. Thank you for your consideration of our recommendations, and we look forward to working with you.

Sincerely,
The National Multiple Sclerosis Society
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Muscular Dystrophy Association
National Hemophilia Foundation
National Organization for Rare Disorders
Susan G. Komen®

cc: House of Representatives Committee on Energy and Commerce, Senate Committee on Finance, Senate Committee on Commerce, Science, & Transportation, Senate Committee on the Judiciary

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[i] American Medical Association. 2019 AMA prior authorization (PA) physician survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[ii] Adam Fein. The Shady business of Specialty Carve-Outs, a.k.a. Alternative Funding Programs. Drug Channels (Aug. 2, 2022), https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html.