



April 12, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
239 Dirksen Senate Office Building
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Statement for the Record

“Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers”

On behalf of the nearly 40,000 children and adults with cystic fibrosis in the United States, we write to share additional perspectives on the topics discussed at the recent hearing on pharmacy benefit managers (PBMs), including concerns about the opaque influence of PBMs and the confusing, labyrinthian system they have created for patients.

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies, advocate for access to care for people with CF, and fund and accredit a network of specialized CF care centers. Cystic fibrosis is a life-threatening genetic disease that causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. If left untreated, infections and exacerbations caused by CF can result in irreversible lung damage, and the associated symptoms of CF lead to early death, usually by respiratory failure. Transformative therapies—such as CFTR modulators—have been paramount in changing what it means to live with CF. However, PBM cost containment strategies have created a convoluted system that patients struggle to navigate and often results in significant barriers to care.

PBMs manage prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, large employers, and other payers. By negotiating with drug manufacturers and pharmacies to determine drug coverage and reimbursement, PBMs can exert significant control over total drug costs for insurers, patients’ access to medications, and how much pharmacies are paid.¹ PBMs often focus cost mitigation strategies on specialty drugs because of their high cost but low utilization within the overall population. PBM practices and the opacity of the system are extremely problematic and burdensome for chronic conditions like CF that primarily use specialty drugs.

¹ https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178-1660136543567.pdf

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CF Community's Experience with PBMs

Overall, PBMs cause significant barriers to care for people with CF in navigating insurance. This is largely due to the lack of understanding of the role of PBMs in coverage decisions and evolving strategies that PBMs put in place to mitigate their own costs and those of their clients, which add out-of-pocket costs or administrative burden for patients.

Transparency

There is a lack of transparency on the role of PBMs, insurers, and subcontracted third-party entities in coverage and cost-sharing decisions, especially in the self-funded insurance market. This causes confusion on the appropriate point of contact for coverage decisions, increasing administrative burden on both patients and their care teams, and causing gaps in access to important therapies. PBMs and insurance companies both regularly claim that the other entity makes the final determinations on coverage for a therapy, resulting in an avoidance of responsibility from both parties and delays and confusion for the patients they cover. Patients and care teams frequently report being “passed back-and-forth” between the two entities when seeking to understand coverage decisions. The result is that people with CF do not know who is ultimately responsible for decisions about their drug coverage, or where to appeal in order to access their essential treatments.

Third-party entities such as maximizers—many of which are owned by PBMs—and alternative funding programs add complexity to an already opaque system. Maximizers often outsource a patient's drug coverage to a third-party entity that sets the patients' cost-sharing at a level to maximize use of manufacturer copay assistance. Alternative funding programs also rely on third-party entities that seek to enroll patients in manufacturer patient assistance programs that provide free drugs, which are usually intended for people without insurance. Without transparency on the decision-maker (PBM vs. payer vs. third-party), patients often face unnecessary, confusing, and time-consuming administrative barriers and unacceptable and inappropriate treatment gaps. New coverage tactics emerge frequently, requiring patients and care teams to consistently learn and adapt to new, opaque, and confusing policies. PBMs are often at the center of these challenges.

Increased Out-of-Pocket Costs

In addition to maximizers and alternative funding programs, PBMs and insurers are increasingly implementing accumulator programs—which prevent third-party payments from counting towards deductibles and out-of-pocket limits and therefore increasing out-of-pocket costs for patients. Many people with CF rely on third-party financial assistance to cover some of the costs associated with their care, as CF is an expensive disease. The CF Foundation recognizes that copay that copay assistance programs mask bigger cost and affordability issues; however, cost containment strategies like accumulator programs that further burden patients are unacceptable.

Recommendations

The CF Foundation appreciates the committee's attention to this issue. We urge Congress to ensure that the legislative proposals seek to improve the experience for patients, in addition to regulating the business and financial structure of PBMs. We provide the following recommendations:

HELP Copays Act: The CF Foundation recommends including the Help Ensure Lower Patient Copays Act (HELP Copays Act; HR 830) in to any PMB reform legislation. This bill reduces patient administrative and financial barriers imposed by PBMs and payers by 1) requiring payers to apply third party assistance to out-of-pocket maximums and other patient cost-sharing

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requirements; and 2) ensuring any item or service covered by a health plan is considered part of their essential health benefits (EHB) package. Together, these policies would prohibit accumulators, maximizers, and alternative funding programs in federally-regulated insurance plans, eliminating some of the most problematic PBM practices for patients.

Transparency: CF Foundation recommends Congress direct the FTC and HHS to expand transparency measures for PBMs and insurers to ensure patients receive better information about coverage policies for specialty drugs, including relationships with third-party entities. Specifically, Congress should direct the FTC and HHS to require PBMs and payers to provide enrollees with notices and disclosures on which entity is responsible for coverage determinations and provide clear contact information.

Oversight & Enforcement: The CF Foundation supports efforts by Congress to require the FTC to determine whether there is more information about PBMs that should be available to consumers and whether there are any legal or regulatory obstacles the FTC currently faces in enforcing the antitrust and consumer protection laws in the PBM marketplace.

Thank you for your leadership on this important issue. The CF Foundation stands ready to work with you to ensure patients' health and financial wellbeing are not sacrificed in the ongoing systemic debate among payers, PBMs, and drug manufacturers.

Sincerely,



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