CYSTIC FIBROSIS FOUNDATION®

April 22, 2026

Statement on Behalf of the Cystic Fibrosis Foundation
House Education and Workforce Committee Hearing
"Profits Over Patients: The PBM Business Model Under Scrutiny"

On behalf of the Cystic Fibrosis Foundation, we submit the following statement for the record in response to the "Profits over Patients: The PBM Business Model Under Scrutiny" hearing. We support the committee's focus on employer-sponsored health coverage and the entities that increasingly control access to prescription medications within these plans.

Pharmacy benefit manager (PBM) opacity directly harms people with cystic fibrosis (CF) through delayed access, high out-of-pocket spending, restrictive formularies, and shifting responsibility between PBMs and insurers. PBMs and insurers frequently claim the other is the decision-maker on coverage for a therapy, leaving patients confused and "passed back and forth" without understanding who is responsible for their treatment coverage determination. This confusing and opaque system creates significant administrative burden for people with CF and often results in gaps in care. Since 2023, among CF community members who contacted our 1:1 case management program about PBM-related issues, 1 in 4 experienced a known gap in care. Increased transparency is essential to addressing these issues and improving continuity of care.

The Foundation commends the committee's ongoing efforts to regulate the norms and practices of PBMs that put patients at risk and looks forward to working with the committee on additional reforms that can better address the needs of people living with CF and other chronic health conditions.

Background on Cystic Fibrosis and Employer-Sponsored Insurance
The CF Foundation has seen an erosion of the once gold standard employer plan regulated by the Employee Retirement Income Security Act (ERISA) and with each plan year, employers offer less and less generous options. Employers have sought to combat the rising cost of health care prices by shifting the financial burden to employees through a combination of higher cost-sharing, benefit restrictions, and limited provider networks. According to the Kaiser Family Foundation, about a third of working adults covered through employer-sponsored insurance face an annual deductible of about $2,000 or more, and employee premium contributions have risen by about 300% since 1999. In 2022, fewer than half of employers offering health benefits believe their provider network in the plan had a sufficient number of behavioral health providers to ensure timely access to services for their workers, and one-third reported that they did not know. For people with CF that are trying to manage a complex, chronic condition, this shift is extremely problematic.

Over the last 20 years, plan issuers, pharmaceutical manufacturers, and PBMs have been ratcheting up subversive tactics, with patients caught in the middle. As a result, patients have turned to manufacturer

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copay assistance to help meet their increasingly high deductible and lower their out-of-pocket spending. In response, employers are now implementing programs that limit the effect of copay assistance, while drug manufacturers are restricting the amount of copay assistance available for patients, increasing the risk that patients will run out of financial assistance and be unable to afford medications. Self-insured plans are at the forefront of the programmatic changes because of the flexibilities of benefit design offered under ERISA. This systemic debate between payers, PBMs, and pharmaceutical manufacturers about drug pricing puts patients' health and financial wellbeing at risk and forces patients to consistently need to adapt and navigate a confusing, opaque, ever-changing landscape.

Barriers for People with CF

PBM practices create real, measurable barriers to care for people with CF, particularly around access to essential, high-cost specialty therapies.

Copay accumulators, maximizers, and alternative funding programs

PBMs are increasingly using tactics that make it more difficult for patients to access the specialized treatments they need. One of the most common of these tactics is the use of copay accumulator programs, which prevent third-party assistance from counting toward a patient's deductible or out-of-pocket maximum. As a result, patients face significantly higher out-of-pocket costs and are more likely to delay, disrupt, or forgo necessary treatment. While the vast majority (93%) of people with CF have health insurance for the entire year, having insurance does not protect many people with CF from experiencing significant cost burden. Seventy-four percent of people with CF use at least one additional form of financial assistance — including nonprofit grants and manufacturer assistance programs – to afford their care. The CF Foundation recognizes that copay assistance programs mask bigger cost and affordability issues; however, cost containment strategies like accumulator programs that further burden people with CF are unacceptable.

As mentioned above, PBMs are continuing to contract with affiliated entities, such as maximizer programs and AFPs administer, which carve out, or otherwise assume responsibility for part or all of the specialty drug benefit. These entities exist to lower costs for health plans but also add complexity to an already unclear system for patients. Maximizers often subcontract 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. AFPs seek to source high-cost drugs by enrolling patients in manufacturer patient assistance programs that provide free drugs, which are usually intended for people without insurance. AFPs can cause consumers to experience financial losses and lose access to critical medications while they navigate these programs. When a patient is forced to enroll in a third-party program, any financial assistance the patient receives will not count towards meeting their deductible or out-of-pocket limit, increasing the cost burden for the patient. Many people with CF are struggling with these constantly evolving cost containment strategies. Here are just some examples:

- A family of a child with cystic fibrosis was denied access to nebulizer treatment for five months after their employer partnered with an AFP that required enrollment for coverage. When the family declined to grant the AFP access to medical records and provider communications, coverage was denied and they were directed to seek the medication for free from the manufacturer, despite having insurance. Manufacturer assistance was denied, yet coverage continued to be withheld. During this period, the child's health declined, including a new bacterial infection. Access was only restored after the family ultimately enrolled in the AFP, following months of appeals and administrative barriers. The employer has since changed AFPs which now mandates international importation of the therapy.

- A person with cystic fibrosis experienced a six-month gap in access to their CFTR modulator treatment, which treats the underlying cause of CF, after losing coverage under their employer-sponsored health plan with an AFP. Despite repeated appeals, coverage was denied and no temporary assistance was provided. During this lapse, the individual's health deteriorated, resulting in hospitalization. Access to medication was only restored after leaving their employer plan and enrolling in a marketplace plan.

- A person with cystic fibrosis was informed that accessing their CFTR modulator treatment through their employer-sponsored plan with an AFP would require a $18,000 copay. After appealing to the plan and employer and applying for manufacturer assistance, an employer override temporarily allowed coverage with standard cost sharing. However, coverage was limited to one month at a time, requiring repeated reapplications for assistance. This administrative burden resulted in a two-week gap in access to the medication.

New coverage tactics emerge frequently, requiring people with CF, their families, and their care teams to constantly learn and adapt to new, opaque, and confusing policies. These examples illustrate the current coverage landscape for patients taking high-cost therapies and challenges that may worsen as more costly treatments come to the market

Vertical integration and patient steering

PBMs are constantly evolving and often not independent entities, as insurers, PBMs, and specialty pharmacies are continuing to consolidate under only a few companies. Furthermore, PBMs are increasingly restructuring their operations through group purchasing organizations, rebate aggregators, and related entities (such as maximizers and alternative funding programs (AFPs)),[1] fragmenting responsibility for coverage and cost decisions. Functions that directly affect access for people with CF—such as formulary development, utilization management, network design, and claims processing—are increasingly distributed across multiple entities. This evolution complicates legislative and regulatory oversight and leaves patients uncertain about who is accountable for drug coverage determinations. For people with CF, coverage decisions for specialty therapies are increasingly made outside the traditional PBM entity itself, further obscuring accountability and creating barriers to obtaining timely, medically necessary treatments

For example, pharmacy access is the result of decisions made by PBMs and insurance plans, and is increasingly dependent on corporate relationships. For people with CF with numerous daily treatments, some therapies can only be filled at select pharmacies. When PBMs restrict access to their preferred specialty pharmacy, it requires people with CF to go to the limited distribution pharmacies for specific medications and then the preferred pharmacy for other treatments. Having multiple pharmacies for chronic medications requires significant coordination to the person with CF or caregiver, increasing administrative and time burden. While this issue is not solely the result of PBM practices, increased disclosure requirements on ties between PBMs and pharmacies will allow for more informed decision making among consumers and may potentially alleviate some of this burden.

Congressional and Regulatory Oversight

[1] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, Interim Staff Report. July 2024. Available at: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies

The CF Foundation has consistently supported congressional and regulatory efforts to improve transparency and accountability for PBMs.[2] Through the 2026 Consolidated Appropriations Act, Congress made clear that service provider transparency is essential to ensuring that ERISA fiduciaries can effectively carry out their duties of prudence and loyalty with respect to health plan administration — particularly where complex third-party arrangements affect costs and access for plan participants. We believe the Department of Labor's (DOL) proposed "Transparency into Pharmacy Benefit Manager Fee Disclosure Proposed Rule" aligns with Congress's clear expectation that transparency should serve the interests of plan participants and beneficiaries. While the proposed rule itself does not regulate PBM conduct or benefit design, it provides an essential infrastructure for these reforms by ensuring fiduciaries and regulators have reliable, actionable information. In doing so, it supports Congress's broader objective of restoring accountability in the prescription drug supply chain and protecting individuals with complex medical needs from convoluted practices that restrict access to care. We were also pleased to see the announcement earlier this year of a settlement between the Federal Trade Commission and Express Scripts, that includes sweeping reforms to help lower patient costs, adjust formulary preference of high-cost drugs, and provider greater transparency into the relationships between all involved stakeholders.

For people with CF, the alignment between federal agencies and Congress is especially critical. ERISA fiduciaries cannot safeguard beneficiary access or affordability without full visibility into PBM incentives that shape coverage decisions. We strongly support this coordinated effort to strengthen transparency and oversight in employer-sponsored health benefits.

CF Foundation Recommendations: Increase Accountability and Patient Impact

We are encouraged by recent congressional scrutiny of PBM practices, yet we continue to recommend that Congress work toward a more comprehensive reform package that brings cost relief for people enrolled in all plan types, including employer-sponsored insurance. While the CF Foundation strongly supports enhanced transparency, disclosures alone are not sufficient to prevent practices that can undermine access to care for people with CF. As evidenced by today's hearing, there is still a great deal of work to be done to shine light on the opaque business practices pf PBMs and bring down costs for patients, especially for those enrolled in employer-sponsored coverage.

Therefore, it is critical that transparency requirements are structured and implemented in a way that leads to actionable fiduciary decision making.[3] Disclosures should not function merely as informational, but as tools to enable fiduciaries to actively assess conflicts of interest, evaluate coverage and utilization management policies, and intervene where PBM practices are inconsistent with the best interest of plan participants and beneficiaries. Without this connection between transparency and oversight, disclosure risks becoming a procedural exercise rather than a mechanism for protecting beneficiaries. With this in mind, **we support the PBM Kickback Prohibition Act (H.R. 7895)** that would prohibit PBMs from providing direct or indirect referral fees to brokers, consultants, or similar intermediaries in exchange for steering employer-sponsored plans to a PBM. However, we urge this committee to consider stronger enforcement language that outlines civil penalties under ERISA, better defines referrals to avoid noncompliance from PBMs that recharacterize these fees as something else (such as "consulting

[2] Coalition Outlines PBM Reform Priorities for the 119th Congress | Cystic Fibrosis Foundation

[3] ERISA section 404 requires fiduciaries to prudently review and monitor service provider arrangements, while section 406 and 408(b)(2) condition the prohibited transaction exemption on reasonable compensation and adequate disclosure. Where disclosures reveal conflicts or unreasonable arrangement that fiduciaries fail to assess or address, the Department may pursue corrective action or prohibit transaction under existing law.

services"), and/or provide explicit oversight authority to the Department of Labor, Department of Justice and the Federal Trade Commission.

Additionally, we are delighted to see DOL and Congress exploring expanding fiduciary responsibility to PBMs, which would improve patient access by realigning incentives and decision making in concrete ways. At its core, a fiduciary standard would require PBMs to act in the best interest of patients and plan sponsors, instead of prioritizing their own revenue streams. We therefore **strongly support the bipartisan, bicameral PBM Fiduciary Accountability, Integrity and Reform (FAIR) Act (S.3549/H.R. 6837).** Together with the DOL's proposed rule, this legislation would provide greater visibility and accountability to help protect patients from PBM practices that restrict access to care.

Finally, while not in the committee's jurisdiction, **we urge Congress to swiftly pass the bipartisan, bicameral Help Ensure Lower Patients Copays Act (HELP Copays Act; S.864/H.R. 6423**). This bill reduces patient administrative and financial barriers imposed by PBMs and plans by 1) requiring plans to apply third party assistance to out-of-pocket maximums and other patient cost-sharing requirements; and 2) ensuring any item or service covered by a health plan is considered part of their essential health benefits package. Together, these policies would prohibit accumulators and maximizers and significantly limit AFPs in federally-regulated insurance plans, including ERISA regulated employer-sponsored health benefit plans.

To date, PBM reforms have largely focused on financial transparency and reasonableness. However, this approach does not fully capture the patient-level consequences of PBM practices, such as how compensation incentives may affect patient access, continuity of care for individuals with serious, chronic conditions like cystic fibrosis, or the downstream impacts on affordability, medication adherence, and long-term health outcomes. Transparency should serve as the foundation for further policy development and oversight where market practices undermine access to care. We are encouraged the committee views recent PBM reforms as an iterative process and continues to consider additional guardrails that will lead to improved market behavior and ultimately reduce the administrative burden and out-of-pocket costs for patients.

Conclusion

The Cystic Fibrosis Foundation thanks the committee for the ongoing commitment to PBM reforms that put patients first. We look forward to ongoing engagement with the committee as it works to ensure that transparency in the pharmacy benefit market translates into meaningful protection for plan participants with serious, chronic conditions like CF.

Sincerely,

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