February 27, 2024

Health and Government Operations Committee
Maryland House of Delegates
House Office Building
6 Bladen Street
Annapolis, MD 21411

Dear Honorable Members of the Health and Government Operations Committee:

On behalf of the people living with cystic fibrosis (CF) in Maryland, we write to express our support for HB 879, which would require insurers to apply third-party assistance to out-of-pocket maximums and other patient cost-sharing requirements and prohibit some alternative funding programs (AFP). We recognize that copay assistance is problematic; it allows pharmaceutical companies to charge payers high prices, while shielding many individual patients from the costs. It is reasonable that payers would push back against this tactic, as drug costs continue to increase. Nevertheless, patients with chronic diseases like CF often struggle to afford their care and rely on copay assistance to access vital medications. HB 879 would help ensure patients' health and financial wellbeing are not sacrificed in the ongoing, systemic debate between payers and pharmaceutical companies about prescription drug pricing.

About Cystic Fibrosis
Cystic fibrosis is a progressive, genetic disease that affects the lungs, pancreas, and other organs. There are close to 40,000 children and adults living with cystic fibrosis in the United States, including approximatley 570 living in Maryland, and CF can affect people of every racial and ethnic group. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. Cystic fibrosis is both serious and progressive; lung damage caused by infection is irreversible and can have a lasting impact on length and quality of life. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. While advances in CF care are helping people live longer, healthier lives, we also know that the cost of care is a barrier to care for many people with the disease.

Accumulator Programs Jeopardize Access to Care
Accumulator programs prevent third-party payments from counting towards deductibles and out-of-pocket limits and therefore increase out-of-pocket costs for patients—which can cause people with CF to forgo needed care and lead to adverse health outcomes. According to a survey conducted by George Washington University of over 1,800 people living with CF and their families, nearly half reported skipping medication doses, taking less medicine than prescribed, delaying filling a prescription, or skipping a treatment altogether due to cost concerns.[i] Because CF is a progressive disease, patients who delay or forgo treatment—even for as little as a few days—face increased risk of lung exacerbations, costly hospitalizations and potentially irreversible lung damage.[ii]

Accumulator programs also place additional financial strain on people with CF who are already struggling to afford their care. More than 70 percent of survey respondents indicated that paying for health care has caused financial problems such as being contacted by a collection agency, filing for bankruptcy, experiencing difficulty paying for basic living expenses like rent and utilities, or taking a second job to make ends meet. And while three quarters of people received some form of financial assistance in 2019 to pay for their health care, nearly half still reported problems paying for at least one CF medication or service in that same year.

We understand the challenge insurers face in managing the rising cost of drugs, and that copay assistance programs mask bigger cost and affordability issues in the health care system. However, cost containment strategies that further burden patients are unacceptable. Accumulators are especially challenging for a disease like CF, which has no generic options for many of the condition's vital therapies. The situation has become even more

dire as a company that manufactures CF therapies recently reduced the amount of copay assistance available for people enrolled in accumulator programs.

Alternative Funding Programs Cause Confusion and Delays in Accessing Care
Pharmacy benefit managers (PBMs) and health plans have recently developed new tactics to capitalize on pharmaceutical companies' financial assistance programs by contracting with third-party vendors to manage their specialty medication benefits through AFPs. The PBM or health plan denies coverage of the specialty medication—either by eliminating the drug from its formulary or denying the prior authorization request—and therefore forces the consumer to enroll in the AFP to get his or her drugs. AFPs then work to get the consumer enrolled in a manufacturer assistance program in order to shift drug costs from the payer to the pharmaceutical company.

The lack of transparency and coercive nature of these programs leave people with CF facing unnecessary, confusing, and time-consuming administrative barriers, financial harms, and treatment gaps. Often, people with CF are not aware that these third-party programs are a part of their benefit design, so they are confused about this entity and their role in their health benefits. When they are contacted by the AFP at the start of the benefit plan year, people with CF are told that their essential medications are not covered by their plan and their option is to either pay the full or very significant proportion of the therapy's cost or work with the AFP, which will then assist with obtaining their medication at no- or low-cost. The AFPs then follow-up repeatedly if patients choose not to enroll. This creates a significant amount of stress and confusion for people with CF and in the meantime, there are often delays in getting needed care. For instance, in 2023, 48 percent of the CF Foundation's case management cases related to AFPs have resulted in a therapy gap.

As more plans have begun using AFPs, we appreciate that HB 879 would prohibit use of AFPs by some plans. A recent survey reveals that up to forty percent of commercial plans use or are considering using AFP practices.[iii] This legislation would take an important step in protecting access to care for people with CF by banning some of these practices.

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The Cystic Fibrosis Foundation, along with the undersigned directors of CF care programs in Maryland, urge you to support HB 879 and help ensure continued access to quality, specialty care for people with CF. We appreciate your attention to this important issue for the CF community in Maryland.

Sincerely,

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[i] https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1056&context=sphhs_policy_briefs
[ii] Trimble AT, Donaldson SH. Ivacaftor withdrawal syndrome in cystic fibrosis patients with the G551D mutation. J Cyst Fibros. 2018 Mar;17(2): e13-e16. doi: 10.1016/j.jcf.2017.09.006. Epub 2017 Oct 24. PMID: 29079142.
[iii] 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