



June 6, 2019

The Honorable Richard Neal  
Chairman  
Ways and Means Committee  
US House of Representatives  
Washington, DC 20515

The Honorable Frank Pallone  
Chairman  
Energy and Commerce Committee  
US House of Representatives  
Washington, DC 20515

The Honorable Kevin Brady  
Ranking Member  
Ways and Means Committee  
US House of Representatives  
Washington, DC 20515

The Honorable Greg Walden  
Ranking Member  
Energy and Commerce Committee  
US House of Representatives  
Washington, DC 20515

Dear Chairmen Neal and Pallone and Ranking Members Brady and Walden,

On behalf of more than 30,000 people with cystic fibrosis (CF) living in the United States, the Cystic Fibrosis Foundation is pleased to submit comments on your draft legislation aimed at improving Medicare Part D. We applaud your effort to protect people with Medicare Part D coverage from excessive out-of-pocket (OOP) drug costs and restructure the program to encourage long-term sustainability.

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 serious infections. Typically, people with CF who rely on Medicare are under age 65 and have qualified for coverage through receipt of Social Security Disability Insurance. As a complex, multi-system condition, CF requires targeted, specialized treatment, and multiple medications. For individuals with CF covered by Medicare, OOP drug spending is a real pain point because it can be difficult to predict and financially burdensome.

### **Eliminating Beneficiary Out-of-Pocket Costs**

We applaud your effort to protect beneficiaries from excessive OOP drug costs. Living with CF is expensive. Families must bear the cost of premiums, deductibles and copays for medication, medical equipment, visits to the clinic, and hospitalizations. Capping Part D costs would make this important program more affordable for individuals with complex medical needs like CF and enable patients to better predict their own health care spending.

Because many CF therapies are expensive specialty therapies, people with CF often enter catastrophic coverage and pay the 5% coinsurance until the end of the year. Furthermore, for a subset of people with CF who rely on new, highly effective, high cost drugs, OOP spending can quickly mount to tens of thousands of dollars, leaving individuals with the difficult choice to forgo medication unless the person is able to find a way to afford them.

## **Reducing Reinsurance Subsidies**

We understand the intent behind the provision of the bill that decreases the government's share of catastrophic coverage from 80 percent to 20 percent over four years and shifts the costs of catastrophic coverage to Part D plans. However, if you pursue this change, it is critical that you ensure that it does not have the unintended consequence of limiting patients' access to necessary drugs, including drugs for rare diseases, or simply shifting patients' spending to other areas.

We appreciate the goal of encouraging plans to manage catastrophic costs. However, we are concerned about the possible negative impact on patients if the changes in financing of catastrophic coverage are not accompanied by other Part D financing changes. As described above, CF is a complex disease requiring multiple therapies taken daily. Should a significant portion of catastrophic coverage costs be shifted to health plans, as proposed, we fear that health plans will implement aggressive utilization management techniques aimed at managing spending and reducing their financial responsibility for catastrophic coverage.

Depending on how utilization management tools are employed, the impact on patients could be serious if they encounter limits on access to critical drugs. We anticipate that the effects will be especially significant for drugs for rare diseases like cystic fibrosis, where drugs are expensive, and options are extremely limited. Strict drug coverage criteria to qualify for a drug results in delays or sometimes simply going without needed medication. We are also concerned that insurers may respond to this change by shifting costs to patients in the form of higher premiums or increased cost sharing in other ways, leaving patients no better off and potentially in a worse financial position. We understand the challenge of managing the rising cost of drugs, but we urge careful consideration of policy changes to ensure they won't harm patients.

## **Additional Considerations**

In response to the additional question outlined by the Chairmen and Ranking Members, we believe that streamlining Part D into an initial coverage phase and a catastrophic coverage phase, thereby eliminating the coverage gap ("donut hole") could result in better understanding of cost sharing requirements among beneficiaries. Streamlining plan design to make health care coverage more easily understood to those who need it would be a major improvement for Medicare beneficiaries.

Regarding low-to-moderate income Part D beneficiaries, we urge the Committees to focus particularly on alleviating the financial burden for moderate income beneficiaries. Within the CF community, those who qualify for low-income subsidies are often able to afford the care they need. We believe individuals with moderate incomes may be more vulnerable to altering their care-seeking behavior because they cannot afford the treatments they need. Moderate income individuals have neither the access to LIS nor the income needed to afford their care. We urge the Committees to keep this reality in mind when considering changes to Part D for these individuals.

Finally, we appreciate the Committee's approach to tackling patient affordability issues and spending in the Part D program. However, it must be noted that this legislation does not address systematic issues facing our health care system related to drug affordability and system sustainability. People with CF and other serious diseases are caught in a battle between

manufacturers and payers and this legislation does not address this harsh reality. In fact, it may serve to exacerbate the problem by shifting costs to plans and therefore access challenges to patients.

Thank you for your leadership on this critical issue. We look forward to continuing discussions with you as you develop your legislation further.

Sincerely,

**Mary B. Dwight**

A handwritten signature in black ink, appearing to read "Mary B. Dwight". The signature is fluid and cursive, with a large initial "M" and "D".

Senior Vice President of Policy & Advocacy  
Cystic Fibrosis Foundation