



December 19, 2024

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director,
Center for Medicare & Medicaid Services
7500 Security Boulevard Baltimore, MD 21244

Re: Drug Price Negotiation Process under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10849) - (IRA)

Dear Secretary Becerra, and Administrator Seshamani:

The Cystic Fibrosis Foundation thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002. We appreciate the robust list of questions for clinical experts and those with experience taking a drug selected for negotiation by CMS. The extensive list of data elements demonstrates the intention of CMS to understand the range of experiences a person can have with a selected drug. We write to provide suggestions to improve upon this existing list of data elements.

About Cystic Fibrosis and the CF Foundation

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 rare, genetic disease that affects close to 40,000 children and adults in the United States. CF 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. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. This milestone reflects over 50 years of hard work to improve CF treatments, develop

evidence-based standards of care, and encourage adherence to a lifetime of chronic care. With recent advancements in treatment options, more people with CF are aging onto Medicare than ever before.¹

Patient- or Caregiver-Focused Input Context

We appreciate CMS' commitment to collecting in-depth data regarding patients' experiences and that the questionnaire aims to capture data on the totality of patients' treatment. However, we have concerns regarding how a patient may respond to some of these questions without further instructions and context. As currently written, the sections titled "*Information on the Current Medication to Treat Your Condition*" and "*Information on the Medication(s) Used in the Past to Treat Your Condition*" do not specify which treatment(s) are most important to include in patient or caregiver responses.

People with CF take numerous specialized treatments with varying purposes. Some treatments can help manage symptoms and/or address how the disease impacts multiple organ systems – such as the lungs, gastrointestinal tract, liver, and more – while other treatments target one specific organ or organ system. As currently written, people with CF may provide their experience with each treatment without focusing primarily on the selected drug of interest. While sharing the totality of treatment burden and life with CF is essential to support CMS' goal of understanding the full patient experience, we fear patients may not understand how to appropriately tailor their response to address a selected drug.

The CF Foundation asks CMS to add further instructions to explain how patients and caregivers should address a selected drug versus the totality of their patient and medication experience in their responses.

Clinical-Focused Data Collection

We thank CMS' breadth of questions to clinical experts, as they will allow for a comprehensive assessment of the clinical impact of selected drugs. In addition to the proposed questions, we recommend a question that will allow CMS to capture information regarding patients' differing reactions to drugs in the same therapeutic class.

We suggest the following:

- ***Are there are different clinical responses to medications in the same therapeutic class as the selected drug, and if so, how would they manifest?***

The CF Foundation thanks you for the opportunity to provide comments and we look forward to continuing to work with the agency as it implements these policies.

Sincerely,



Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation