March 13, 2023

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

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Proposed Rule and Request for Information; Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Cystic Fibrosis Foundation thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to respond to the Advancing Interoperability and Improving Prior Authorization Proposed Rule and Request for Information (RFI). 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 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. 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 thorough, 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. However, this system of care and the improvements in length and quality of life for those with CF can only be realized if patients have access to adequate and affordable insurance that covers the specialized care and treatments they need.

Prior authorization is a time-consuming process that can burden providers, divert valuable resources away from direct patient care, and cause delays in patient access to needed treatment. This process is particularly burdensome on the CF community as people with CF must adhere to intensive, ongoing treatment plans in order to stay healthy. Prior authorization policies present a unique set of challenges

for people with CF and other lifelong, chronic diseases. For CF patients, their diagnosis will never change; they will take many of the same drugs throughout their lifetime and it is unnecessary to require providers to continuously request reauthorizations and provide duplicative information in order to demonstrate the medical necessity of these therapies.

In response to the Proposed Rule and the questions in the RFI, the CF Foundation provides the following comments.

Application Programing Interface (API)

Patient Access

The CF Foundation supports increased transparency for patients through a standardized system across different payer types and coverage programs. This transparency will allow patients to quickly access prior authorization decisions and has the potential to limit delays or gaps in accessing needed treatments for people with CF covered under these plans.

To ensure access to the API for individuals with disabilities and limited English proficiency, we ask for the use of plain language materials to ensure patients understand the information shared via the interface. We urge CMS to establish accessibility requirement consistent with the Department of Justice's recommended strategies for developing multilingual digital services. This platform should indicate when all important information, like disclaimers, are not translated online and direct people with LEP to where they can find that information. Any telephonic consumer assistance should offer non-English voicemail menus, and customer service representatives should have access to qualified interpreters.

Further, we encourage CMS to consider patients who have limited digital or broadband access that may not be able to use this digital platform to obtain this information electronically. It is imperative that there is equitable access to the necessary coverage information for all people covered under these plans.

Provider Access

Similar to the patient access API, we support the effort to rapidly share prior authorization decisions with providers to avoid any gaps in treatment access for patients. Increased transparency and access to patient information will provide real-time decision-making tools to providers. Administrative burdens, such as prior authorizations can create more work for providers and delay care for patients. Often, providers are not aware of a prior authorization decision until informed by a patient which can delay a potentially necessary appeals process and treatment access for patients.

In the proposed rule, cost-sharing information is excluded from the provider API. The CF Foundation urges CMS to reconsider and supports increased transparency for this information. Giving providers access to cost-sharing information provides them an important tool to allow for more holistic provider-patient discussions by incorporating cost into treatment decisions.

Further, we request CMS ensure this provider API is available to all provider types and not just physicians. People with CF rely on a multidisciplinary, specialized care team to ensure best possible outcomes the CF clinical care team includes physicians, nurses, dietitians, social workers, and respiratory

therapists – each of whom plays a unique role in managing CF care. Access to current patient data from payers and other providers will support each member of the CF care team in providing high-quality care for their patients.

Payer Data Exchange and Reporting

Under the proposed rule, payers would be required to use a specific payer-to-payer data exchange standard that would allow payers to exchange patient information including prior authorization decisions from a patient's prior health insurer. This could have a significant impact on people with CF by reducing the administrative burden when changing health plans. The CF Foundation strongly supports this provision.

In addition, CMS would require payers to report on all items and services that require percentage of prior authorizations approved and those denied; the percentage of expedited requests that were approved and those that were denied; the percentage of denied requests that were approved upon appeal; the percentage of prior authorization requests for which the timeframe for review was extended; the average and median time that elapsed between the submission of a request and a determination by the payer for standard and for expedited requests. We strongly support all these requirements and ask all data to be publicly reported for each issuer and market so stakeholders, including policymakers, patents, and providers, can assess plans based on the prior authorization metrics.

Furthermore, we support CMS' requirement to report aggregated demographic information such as sex, race, age, ethnicity, and geographical data to help identify disparities in patient access to health data. Data are crucial for identifying disparities and where policy interventions are needed to address inequities. Data should be consistent across all payers using this system and reflect the full range of demographic characteristics of populations that have been marginalized. Existing data demonstrates that there is a need for more and better data. In addition, while data collection is essential, it is not sufficient. These data reported by payers must be used to inform policy and efforts to eliminate disparities and promote equity.

Improving Prior Authorization Processes

We are encouraged that CMS is looking to streamline the prior authorization process so that patients with chronic conditions do not have gaps in care when managing a life-long disease. However, we would like to see additional clarity in the proposed rule when prior authorizations are denied. Currently the rule states that payers need to provide a reason for denial, such as "medical necessity." Presently, payers are frequently sharing this reason without any additional context. This leads to confusion on behalf of the patient and provider in understanding the true reason for denial and can slow down the appeals process, thus increasing the administrative burden on the provider and potentially resulting in a gap in treatment access for the patient. The CF Foundation urges CMS to require that payers provide a more detailed clinical justification when a prior authorization is denied. Details such as how and why the request did not meet the prior authorization requirements set by the payer – including but not limited to the specific clinical data or documentation that is missing and needed by the payer, or specific requirements of the FDA label that are not met – would provide insight as to how providers and patients can best move forward with appeals or exploring other options.

CMS also proposes impacted payers send prior authorization decisions within 72 hours for expedited requests and seven calendar days for standard requests. The CF Foundation recommends CMS shorten this timeline to mirror that of prescription drug prior authorization exceptions, 24 hours for expedited

review, and 72 hours for standard review. For people with CF, delays in obtaining services and treatments can result in significant clinical decline and the potential for negative health outcomes. According to preliminary evidence from the CF Foundation patient registry, a 7-day interruption in one patient's chronic CFTR modulator treatment resulted in a significant decrease in lung function, a worsening cough, and a hospitalization requiring intravenous antibiotics.[1] It is imperative that prior authorizations are not a cause of delayed treatment and that they are promptly reviewed with the decision shared in a transparent manner to both the provider and patient.

To further expedite the prior authorization process, we recommend CMS explore options such as "gold carding" or automatically approving prior authorizations for providers that have a demonstrated history of prior authorization approvals. As stated, cystic fibrosis has no cure and people with CF take their medications chronically. Further, these medications have clear indications about which patients should them and do not provide benefit for those who do not meet eligibility requirements. Having to regularly go through the reauthorization process for life-long treatments causes significant time and administrative burden on both patients and providers. The time care teams spend on treatment authorizations is unnecessary for diseases such as cystic fibrosis and would be better spent providing clinical care. We request that CMS continue to explore ways, such as gold carding, to eliminate this burden and ensure providers are spending their time providing the high-quality care that people with CF require.

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

Within the CF population, social risk factors can be pervasive across all levels of income due to the high cost of CF care.[2] It is important when considering standardization of social risk factor data collection that everyone, regardless of perceived risk status, should be screened for these factors on a frequent and formal basis. The CF Foundation is similarly working to support the CF clinician community in standardizing their screening approach. While we recognize that CMS does not require a specific social needs assessment tool be used, we encourage CMS to provide or recommend a reliable and validated tool for screening. This would allow for more uniform recommendations on how screenings should be administered and data is collected, as well as more consistency in understanding the needs of the plan population. It is imperative that there is standardized training around use of the recommended validated tool that CMS recommends to ensure the screening is done in a sensitive, non-judgmental, and collaborative manner.

It is important when collecting data on social risk factors that clinicians also have standard approach for gathering and sharing information on referrals for patients who screen positive for a social risk factor. Tracking data on referrals, and also whether the patient accesses the referred intervention, are essential in order to better understand and address the barriers to access. This data will also help ensure that the referrals placed are for sustainable interventions. We urge CMS to consider how referrals and access to interventions will be included in data collection efforts.

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[1] https://www.cff.org/media/27986/download?inline

[2] Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Risk indicators of food insecurity in the CF population" (2021). *Health Policy and Management Issue Briefs.* Paper 59. https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/59

The CF Foundation appreciates the opportunity to provide comments on the proposed rule. We look forward to working with CMS on these critical issues to ensure access and affordability for people with CF.

Sincerely,

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