

On November 4, 2022, the Cystic Fibrosis Foundation submitted the following recommendations to the Centers for Medicare and Medicaid Services in response to the Request for Information: Make Your Voice Heard. CMS sought feedback on accessing healthcare and related challenges, understanding provider experiences, advancing health equity, and assessing the impact of waivers and flexibilities provided in response to the COVID-19 Public Health Emergency (PHE).

Topic 1: Accessing Healthcare and Related Challenges

CMS wants to empower all individuals to efficiently navigate the healthcare system and access comprehensive healthcare. We are interested in receiving public comment on personal perspectives and experiences, including narrative anecdotes, describing challenges individuals currently face in understanding, choosing, accessing, or utilizing healthcare services (including medication therapies) across CMS programs

Plan enrollment process

Choosing among plans can be difficult even for individuals who are well versed in plan type and enrollment. The CF Foundation has a team of Alliance of Information and Referral Systems (AIRS) accredited case managers who help with complex challenges, including and understanding insurance, troubleshooting insurance coverage issues, and provide side-by-side comparison of available plans for people with CF or their loved ones. Even with a wide breadth of knowledge and expertise, our case managers have a hard time accessing basic information across the Centers for Medicare and Medicaid Services (CMS) programs.

Details regarding availability of benefits, cost-sharing arrangements and premium costs, and network directories should be readily available to all potential enrollees and presented in a clear and understandable manner. For example, Medicare Part D previously had a side-by-side comparison tool that could be downloaded as a PDF and that allowed consumers to review drugs covered in each plan in a comprehensible manner. Recently that formatting was removed from the website making it more difficult for enrollees to compare coverage options. Additionally, comparing MA plan networks and available benefits still remains a challenge for beneficiaries due to the lack of readily available plan information. Beneficiaries need to be fully aware of any differences in coverage that could result in delays to appropriate care, such as prescription drug coverage and any potential prior authorizations that were unnecessary on their previous plan. MA Plans can also make significant changes to benefit options, cost-sharing arrangements, networks, and other details from year to year, making comparison even more difficult.

The CF Foundation asks for these tools to be updated across all platforms to be more consumer friendly and ensure enrollees are empowered to choose appropriate plans that meet their needs.

Updated Provider Directories

For individuals with CF, it is vital to ensure plans' provider networks are sufficient in size and composition to include the specialized care required, and that provider directories are accurate, informative, and clear. The current provider directories are important resources, but are fragmented, inefficient, and often contain inaccurate information.

CMS should model online provider directory requirements on that of the ACA Marketplaces. Federal law requires that marketplace health plans maintain an adequate network of providers, and up-to-date online provider directory. Having the same requirements across CMS program platforms would ensure that enrollees have timely, meaningful access to the care and services they need, as well as accurate information sufficient to enable them to understand plans' networks and identify the plans and providers most likely to meet their needs.

We are aware the Agency is exploring the option of a National Provider Directory as a centralized data hub across health plans and CMS programs. We look forward to responding to the open request for information and providing specific recommendations.

Prescription Drugs

Prior authorization and utilization tools

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. We ask CMS to alleviate this burden and exempt drugs and therapies used to treat chronic and long-term care conditions from repeat prior authorizations.

Prescription drug limits

Some state Medicaid programs limit the number of prescription drugs that beneficiaries can access every month, and some of these limits are as low as three or four drugs a month. Adults with CF take seven prescriptions daily, on average, but can take up to 20 medications per day. While most of these states allow for medical necessity overrides, such policies add administrative burden for providers and patients, and create potential delays in treatment. CMS should examine the impact of prescription drug limits and current override policies, and determine whether they are allowable under the requirement that Medicaid services be sufficient in amount, duration, and scope to reasonably achieve their purpose.

Coverage of inhaled hypertonic saline and vitamins A, D, E, and K

Many state Medicaid programs and Medicare do not cover inhaled hypertonic saline and vitamins A, D, E, and K—all of which are recommended by Cystic Fibrosis Foundation clinical consensus guidelines. CFF clinical consensus guidelines recommend use of inhaled hypertonic saline in individuals ages 6 and up for mucociliary clearance. Treatment with mucolytic products—including inhaled hypertonic saline solution—is shown to help clear mucus from the lungs, resulting in fewer lung infections, improved lung function, and better quality of life for people with CF. People with cystic fibrosis also often have trouble absorbing nutrients, including fat-soluble vitamins, because of the thick, sticky mucus that blocks pancreatic ducts. CFF nutritional guidelines therefore recommend the use of specially-designed supplements to ensure that people with CF receive adequate amounts of fat-soluble vitamins including

A, D, E and K. Because these products are not FDA-approved, Medicare and many state Medicaid programs do not cover them.

We believe states may cover medically necessary products and receive matching funds without collecting rebates if the product is not eligible to qualify as a “covered outpatient drug.” Because vitamins A, D, E and K and inhaled hypertonic saline solution are not FDA-approved and do not require prescriptions, they are not eligible to qualify as covered outpatient drugs under SSA §1927 and can be covered by Medicaid without an applicable rebate agreement and are eligible for federal match. CMS should provide a state medical letter clarifying that states are able to receive a federal match for coverage of these critical products. We also recommend CMS issue further guidance regarding Medicare coverage of products not FDA-approved that are medically necessary.

Topic 2: Understanding Provider Experiences

CMS wants to better understand the factors impacting provider well-being and learn more about the distribution of the healthcare workforce. We are particularly interested in understanding the greatest challenges for healthcare workers in meeting the needs of their patients, and the impact of CMS policies, operations, or communications on provider well-being and retention.

key factors that impact provider well-being

Across disciplines, chronic stress among providers has increased burnout in the workplace. A contributing factor is the current lack of staff and resources. Throughout the COVID-19 public health emergency, clinicians have seen increased demand for services but decreased staff and resources, leading to providers working both long hours and in areas for which they have not been trained – potentially delivering suboptimal care. This is particularly apparent for mental and behavioral health services. In recent years, the need for these types of services has increased, but there are not trained and certified clinicians inside the care center to accommodate patients or available for referral outside care centers.

Administrative burdens, such as prior authorizations and other utilization management tools, can create more work for providers and delay care for patients. Providers expressed frustration with the amount of time spent trying to get medications and testing covered through insurance. Providers are spending valuable time speaking with insurance plans about coverage of medications and the cost of these medications, rather than treating and caring for patients.

While digital health care can improve the effectiveness, efficiency, equity, and continuity of care, there are mixed responses from clinicians on whether these systems have a positive impact on overall well-being. Electronic health records (EHRs) have created an expectation that providers are always available. Physicians now have access to patient data when they are not at care centers, and some EHRs are able to track and report how quickly the provider views results and responds to patient and other provider request. This adds pressure on providers to constantly check the EHR or other digital messaging system. Furthermore, many EHRs are still not compatible across manufacturers, which makes coordination of care and communication with external providers difficult. This can lead to duplicative review of prior data and can lead to costly repetition of tests.

For many of our CF clinicians, insurance contracting is handled at an institutional level, so providers are not deciding which populations they serve based on insurance type. However, a number of our providers have expressed how burdensome many of the processes are under Medicare when prescribing medications, supplies, and referrals. Moreover, providers have expressed concerns with adequate networks within Medicare and Medicaid. Finding and referring patients to behavioral health providers for patients with Medicare and/or Medicaid can be particularly difficult. Community-based therapists do not always accept these insurance options, which leads to patients seeking mental health support in community health centers with long wait lists and high turnover.

Topic 3: Advancing Health Equity

CMS wants to further advance health equity across our programs by identifying and promoting policies, programs, and practices that may help eliminate health disparities. We want to better understand individual and community-level burdens, health-related social needs (such as food insecurity and inadequate or unstable housing), and recommended strategies to address health inequities, including opportunities to address social determinants of health and burdens impairing access to comprehensive quality care.

We share and support CMS's efforts to address social determinants and recognize the critical role social factors play in improving health outcomes. People with CF experience a significant financial burden regardless of age, income, and insurance type. In turn, that financial burden exacerbates social risk factors. A recent study conducted by the CF Foundation and George Washington University found that 33% of people with CF in the US experienced food insecurity, triple the national average. Moreover, 10% of people with CF delay care due to trouble with transportation. We are encouraged CMS has identified social factors as key elements impacting access to services that are essential to CF care, treatment, and management.

Coverage should be easy to understand and not pose a barrier to care. Yet, minority populations are frequently disadvantaged by accessibility of language in healthcare. Healthcare adequacy includes the ability to access and understand materials and processes. Social workers at CF care centers stressed lack of accessibility as they spoke about indecipherable Medicaid and CHIP applications and redetermination packages, reiterating even professionals familiar with these programs still struggle to understand the requirements. Results in marketplace issuer data also show that enrollees appeal less than 1 percent of all denied in-network claims, which is problematic due to the lack of time, resources, and an understanding of insurance terms that few consumers have, particularly those of lower socioeconomic status, who have limited English proficiency, or for whom the information and process is otherwise inaccessible.

This issue persists regarding data collection, as current OMB categories for race and ethnicity are not homogenous and do not cover all demographics. Similarly, when data is taken from minority groups, trauma and stigma regarding data collection can be inflicted from the lack of transparency regarding the purpose of the data.

To aid minority populations in language and accessibility assistance, we ask for the use of plain language materials including taglines to inform beneficiaries of their right to free language assistance and auxiliary aids to ensure patients understand requirements and application deadlines of medical services, especially when considering redetermination of coverage. We also ask the Agency to address the gaps in data regarding Medicaid, as only about half of states require Medicaid MCOs to screen for social needs and make referrals based on screening results. Similarly, Medicare Advantage has limited data reporting mechanisms available to provide CMS with information about plan-level coverage denials, appeals, and delays in care resulting from plan administrative processes. CMS should establish standardized reporting metrics and that data should be made publicly available and be stratified by the insurer. We ask that it should be made clear why data are being collected and how the data will be used. To aid in this, detailed race and ethnicity data should be made available along with the continuation of evidence-based health equity work.

Topic 4: Impact of the COVID-19 Public Health Emergency (PHE) Waivers and Flexibilities

CMS wants to understand the impact of waivers and flexibilities issued during the COVID-19 PHE, such as eligibility and enrollment flexibilities, to identify what was helpful as well as any areas for improvement, including opportunities to further decrease burden and address any health disparities that may have been exacerbated by the PHE.

During the COVID-19 public health emergency (PHE), individuals with CF were particularly conscientious about potential exposure to the virus, and therefore relied heavily on access to telehealth services, when in-person visits were not safe or feasible. We support CMS' goal to research the expanded use and availability of telehealth as well as the Agency's continuous efforts to collect data on the uses and outcomes of telehealth, including data to measure access and outcomes across different demographic groups.

As part of the pandemic response, CMS established a temporary coverage policy for audio-only telephone visits, ensuring patients without access to the internet or video platform are still able to receive needed care. This flexibility is particularly important for rural and low-income populations who are more likely to have limited or no access to the internet or insufficient broadband to support video conferencing.

In a survey of patients and families, the majority reported that telehealth services were of equal or higher quality than in-person services and nearly half of respondents relayed that they want telehealth to remain part of their care in the future. Additionally, a survey of over 400 CF patients and families conducted in fall of 2020 found nearly one in ten respondents participated in an audio-only visit and one in five of these opted for audio-only because of challenges with video technology or lack of reliable internet. While audio-only visits are not suitable for all health care services and are not a substitute for in-person care, there are a number of aspects of a regular CF visit that can be conducted through the phone. For instance, clinicians can review medical history, current medications, and symptoms, and adjust a patient's care plan. CF patients and care teams can also review data from home spirometers to track trends in lung function. For CF providers, listening to a patient's cough can also provide actionable information about potential exacerbations.

States are already taking steps to make some telehealth flexibilities permanent. In Wisconsin, the state's Department of Health Services (DHS) made covering audio-only telehealth visits permanent to supplement to in-person care, ensuring access for patients who do not have sufficient broadband to support video conferencing or do not have any internet access at all. Furthermore, Wisconsin's DHS proposed to remove originating site requirements to ensure that patients can receive needed care from their home. The use of telehealth should be determined by the preferences of the patient and clinical judgement of the provider; and we urge CMS to make audio-only visits a permanent benefit.

We urge CMS to evaluate and expand the types of clinicians who can provide online assessment and management. As previously mentioned, people with CF rely on a multidisciplinary, specialized care team to ensure best possible outcomes and patients would benefit from the option of having virtual check-ins with all members of the care team. 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. For example, individuals with CF require a specialized diet and nutritional plan that is high in calories, proteins, vitamins, and minerals. CF dietitians are trained to assess daily food intake and overall nutritional status, which helps the individual with CF work towards optimal body weight and the calories

and nutrients needed to fight off lung infections and maintain lung function. Brief virtual check-ins with dietitians would allow patients to address issues with feeding tubes, formula concentrations, diet, or vitamins and supplements in between their regularly quarterly visits with the full care team. Such access to all members of the care team could help patients better maintain and manage their care, leading to more consistent and better outcomes.

In addition, we ask CMS to continue working with Congress to remove barriers to accessing telehealth. Originating site and geographic restrictions should be permanently eliminated to ensure that patients are not required to travel to specific locations to access telehealth services unless special equipment is necessary for an examination by a remote provider.

Similarly, allowing providers to practice across state lines through telehealth services will increase access to care and improve care coordination for patients. For those who rely on out-of-state care centers to help manage their CF, clinician licensure reciprocity is an important tool to make remote care accessible. Enabling licensing reciprocity for all licensed and certified practitioners for all types of services would allow individuals with CF maintain continuous care with their established care team. We advise CMS to work with Congress to pass legislation that would ease patient access to telehealth services through clinician licensure reciprocity.