



November 7, 2021

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

Attn: Strategic Plan Comments

Dear Secretary Becerra:

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 more than 35,000 children and adults in the United States. 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. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. 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. 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.

The CF Foundation appreciates the opportunity to submit comments on the Department of Health and Human Services (“HHS”) Strategic Plan for Fiscal Years 2022-2026.

Goal #1: Protect and strengthen equitable access to high quality and affordable healthcare

Objective 1.1: Increase choice, affordability, and enrollment in high-quality healthcare coverage

To achieve this objective, HHS will need to address financial and administrative barriers to care in Medicaid and Affordable Care Act (ACA) coverage.

Medicaid

Medicaid provides a vital source of coverage for half of children and one-third of adults with CF. For many individuals with CF, Medicaid helps them afford the treatments, medications, and inpatient and outpatient care they need. In one of his first executive orders on healthcare, President Biden directed HHS to re-examine “demonstrations and waivers under Medicaid and the ACA that may reduce coverage

or undermine the programs, including work requirements.”¹ We appreciate the steps the Centers for Medicare and Medicaid Services (CMS) have already taken to withdraw relevant guidance as well as revoke approvals of work and community engagement requirements in almost a dozen states. Additionally, the Foundation urges HHS to revoke or reject additional Section 1115 waivers that include barriers to care such as block grants, premiums and other excessive cost sharing, limitations on benefits like Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services and non-emergency medical transportation (NEMT), and elimination of retroactive coverage. These barriers create undue burden on beneficiaries and additional barriers to coverage for people with CF who rely on Medicaid to get the care they need. We urge you to consider a specific reference to ending demonstrations and waivers that reduce coverage and undermine the Medicaid program in the final strategic plan.

A crucial component of efforts to increase health coverage enrollment will be promoting uninterrupted coverage in the Medicaid program during the unwinding of the public health emergency. The Foundation appreciates the updates that CMS made to its guidance to states regarding the resumption of routine state Medicaid operations at the end of the COVID-19 public health emergency, and we have reached out to states to share our recommendations for how to ensure enrollees who remain eligible for Medicaid coverage maintain their access to care.

Insurance Marketplace

The majority of people with CF have private health insurance coverage; however, affordability of these plans remains a barrier, leading individuals to forgo or delay essential care and treatments. Federal affordability standards for employer-sponsored coverage should be updated to allow employees to purchase subsidized individual market coverage when their employer coverage is unaffordable. Fourteen percent of people with CF have a deductible of \$6,000 or more and this significant cost must be included in the calculation about what is “affordable.” We ask HHS to work with other Departments and update the federal employer-sponsored insurance affordability standards to more accurately reflect patient cost burden and include deductible costs.

Objective 1.2: Reduce costs, improve quality of health care services, and ensure access to safe medical devices and drugs

Medicare

With recent advancements in treatment options, more people with CF are aging onto Medicare than ever before. This development highlights the extraordinary advancements in care; however, the current Medicare delivery model, the current coverage policies, and the cost of care continues to be a barrier to accessing needed treatments and prescription drugs for people with CF. We ask HHS to work with Congress to identify solutions – particularly for Medicare’s prescription drug benefit and out of pocket costs – to address the substantial cost budget for Medicare beneficiaries with CF. One in ten people with CF enrolled in Medicare pay over \$10,000 in cost-sharing, not including their premiums or deductible. This extraordinary cost leads people to forgo or delay essential care and treatments. In the era of personalized medicine, this is an untenable and unsustainable model. Furthermore, there are significant coverage gaps for components of CF care that further compound the out-of-pocket cost burden for people with CF enrolled in Medicare. These include coverage of supplies for home infusion of antibiotics,

¹ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/28/fact-sheet-president-biden-to-sign-executive-orders-strengthening-americans-access-to-quality-affordable-health-care/>.

post-transplant drugs, adequate insulin testing supplies for people with CF-related diabetes, and mucolytic drugs that are an essential part of CF treatment. We look forward to working with HHS to improve Medicare coverage to better serve people with CF.

Telehealth

We support HHS' goal to research the expanded use and availability of telehealth as well as the department'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 policymaking regarding telehealth moves forward, we urge HHS to evaluate and expand the types of clinicians who can provide online assessment and management. People with CF rely on a multi-disciplinary, 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

Furthermore, the Foundation applauds CMS for establishing the benefit of audio-only telephone evaluation and management services during the time of the COVID-19 public health emergency. CMS has helped ensure patients without access to the internet or video platform – through a computer or smartphone – 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. For patients who do not have sufficient broadband to support video conferencing or do not have any internet access at all, telephonic visits with their care team are their only option for access remote care. Providers and patients also encounter technical issues with the platform or broadband, and some patients do not have the technological expertise to navigate video platforms—all of which can lead to the need for audio-only visits. Anecdotally, one CF physician in Indiana estimates that 25 to 30 percent of her telehealth appointments are conducted over the phone either because of broadband or other technological issues.

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. 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.

Objective 1.3: Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health

The CF Foundation strongly supports HHS' attention to health equity. As we focus on coverage and access to care, we particularly support the strategies to remove barriers to care and coverage for individuals who experience challenges due to underlying social determinants, which in turn lead to disparities in health outcomes.

Data Collection

In July, we joined other advocacy organizations in response to the Office of Management and Budget Request for Information regarding equity and underserved communities.² We support HHS' efforts to collect and disaggregate data to understand how policies impact communities differently and create inequalities in coverage and care. Within CMS, the agency should first evaluate data currently collected and the process for its collection. Where it is not already being done and where it is possible, state and federal entities should strive to collect self-reported data on race, ethnicity, gender, disability and sexual orientation. When collecting these data though, it should be made clear why data are being collected and how the data will be used. Individuals collecting this information should undergo cultural competency and skilled communication training to regain trust and minimize the trauma and stigma that underserved communities may experience when interacting with government entities. We also urge HHS to analyze proposed policies for their impacts on health equity.

ACA Section 1557

The CF Foundation also urges HHS to reinstate and improve the regulations implementing nondiscrimination provisions of Section 1557 of the Affordable Care Act.³ We particularly support reinstating protections against discriminatory benefit design and ensuring that the scope of the protection extends to all products offered by insurers who receive federal financial assistance. Such actions will help reduce discrimination in health care coverage and the health disparities that stem, in part, from this discrimination.

Network Adequacy

The CF Foundation is excited HHS intends to reexamine federal network adequacy standards for plans offered through the Federally Facilitated Marketplace (FFM) as it is critical to restore and strengthen protections for consumers. Federal law requires that marketplace health plans maintain an adequate network of providers, and up-to-date online provider directories. These protections are designed to ensure that marketplace enrollees have timely, meaningful access to the care and services they need, as well as accurate information to help them understand plans' networks and identify the plans and providers most likely to meet their needs.

For individuals with complex, chronic conditions like CF, which require a provider care team of specialists, it is vital to ensure that plans' provider networks are of sufficient size and composition, and that provider directories are accurate, informative, and clear. This is particularly important for patients from underserved communities, who have experienced discrimination in health care settings and systematically worse health outcomes. As HHS revisits network parameters for qualified health plans

² <https://www.cff.org/About-Us/Our-Approach-to-Federal-State-and-Local-Policy/Our-Policy-Priorities/Briefings-Testimonies-and-Regulatory-Comments/PPC-Response-to-OMB-RFI-on-Health-Equity-in-Federal-Programs.pdf>

³ <https://www.cff.org/About-Us/Our-Approach-to-Federal-State-and-Local-Policy/Our-Policy-Priorities/Briefings-Testimonies-and-Regulatory-Comments/Patient-Coalition-Media-Statement-on-1557-SDNY-Amicus-Brief.pdf>

(QHPs), we suggest networks should be evaluated on their ability to provide culturally- and linguistically-competent care as well as care accessible to people with disabilities. This means, among other things, a rigorous assessment of whether a network includes sufficient providers and/or provides sufficient access to appropriate language services to ensure limited English proficiency individuals can obtain timely care in their preferred language, as well as assessment of physical, language, and other accessibility. Further, networks must ensure access to culturally appropriate care reflecting the diversity of enrollees' backgrounds and attuned to traditionally underserved communities, including people of color, immigrants, people with disabilities, and LGBTQ individuals. To enable consumers to identify the plans and providers likely to meet their needs, all health plans must be required to indicate in their provider directories the languages of other than English spoken by any provider and/or their staff.

Goal #3: Strengthen Social Well-being, Equity, and Economic Resilience

Objective 3.1: Provide effective and innovative pathways leading to equitable economic success for all individuals and families

Social Determinants of Health

We share and support HHS' 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 HHS has identified social factors as key elements impacting access to services that are essential to CF care, treatment, and management. We look forward to partnering with the Department as it develops resources and facilitates coordination across federal and state programs.

Goal #4: Restore trust and accelerate advancements in science and research for all

Objective 4.1: Improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion

Clinical Trial Design

CF clinical trials of the future will be impacted by the diverging CF population – those without effective modulators or those with advanced lung disease who may have a greater desire to enroll in future clinical trials, and those who are healthier thanks to earlier intervention with modulator therapies who may be less inclined or unable to participate in trials. Drug sponsors will need to consider how changes in the CF population and accepted practices on where and how frequently clinical trial activities take place can and should impact clinical trial designs. The Foundation welcomes the opportunity work with the FDA to ensure a clear and supportive regulatory pathway for CF therapeutic development in the future.

Furthermore, not unlike other disease communities, CF has several subpopulations that face more onerous barriers to clinical trial participation than the average person. In particular, clinical trials for patients with CF can fail to effectively meet the needs of Spanish-speaking populations as well as those with limited or irregular income. For Spanish-speaking patients, language barriers remain a substantial

challenge to clinical trial participation. Informed consent forms and other participant-facing study materials are often not translated into Spanish, and research sites may lack proper language supports for non-English speakers. These barriers prevent individuals who primarily speak Spanish, as well as other non-English speakers, from taking full advantage of opportunities to participate in clinical trials and as a result impacts the representativeness of the study population.⁴

Patients with limited income as well as those without a reliable income source also face substantial barriers to clinical trial participation. Costs associated with clinical trials can be burdensome for many patients, and delays in reimbursement for travel can severely impact a person's finances and ability to continue participation in the trial. The amount of time a patient must take off from work, school, child or elder care, or other commitments for clinical trial activities can also be a major deterrent to participation. Travel can be especially challenging for patients with chronic diseases, and rare disease studies often require patients to travel much further than non-rare disease studies to reach a trial site.

The Food and Drug Administration (FDA) can offer further practical advice for drug sponsors on addressing challenges related to language barriers, reimbursement methods, reducing burden associated with trial visits, and the Foundation looks forward to working alongside the FDA in this endeavor.

Objective 4.2 Invest in the research enterprise and the scientific workforce to maintain leadership in the development of innovations that broaden our understanding of disease, healthcare, public health, and human services resulting in more effective interventions, treatments, and programs

Investing in a Diverse Biomedical Research Workforce

The CF Foundation shares and supports HHS' goal to address the systematic barriers that impact people of color's participation in biomedical research workforce. Cystic fibrosis affects many people of different racial and ethnic backgrounds. However, for many years there has not been adequate representation of people of color shared in the stories and descriptions of the disease by medical and public health entities, as well as by the CF Foundation and the CF community. Improving the representation of people of color within the CF community – including those in the CF research workforce – and addressing health disparities that exist within these groups is critical to the Foundation's mission of serving all people with CF.

Improving diversity of the CF research workforce is a necessary component of ensuring better engagement and support of people of color with CF in clinical trials. Much work remains in tackling systematic issues impacting diversity of the CF and broader research workforce. For the CF research field, the mischaracterization of CF as a disease that only impacts Caucasians can also dissuade researchers from diverse backgrounds from entering the CF research workforce and leads to a shortage of role models for researchers of color who may otherwise considering entering this field. In April, CF Foundation submitted comments to the National Institute of Health (NIH) which highlight the barriers to entering the research workforce and includes suggestions for improving institutional culture, increasing mentorship opportunities, and addressing gaps in health disparities research, all of which reflects

⁴ <https://www.cff.org/About-Us/Our-Approach-to-Federal-State-and-Local-Policy/Our-Policy-Priorities/Briefings-Testimonies-and-Regulatory-Comments/CF-Foundation-Response-to-NIH-RFI-on-Data-and-Biospecimen-Sharing.pdf>

feedback we received from members of the Foundation's external racial justice work group.⁵ We look forward to collaborating with HHS on these complex challenges.

The CF Foundation appreciates the opportunity to provide comment on HHS' Strategic Plan for Fiscal Years 2022-2026. We look forward to working with the department on these critical issues to ensure access and affordability for people with CF.

Sincerely,



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⁵ <https://www.cff.org/About-Us/Our-Approach-to-Federal-State-and-Local-Policy/Our-Policy-Priorities/Briefings-Testimonies-and-Regulatory-Comments/CF-Foundation-Comments-to-the-NIH-on-Advancing-DEI-in-the-Biomedical-Workforce.pdf>