January 31, 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

Re: Request for Information; Essential Health Benefits (CMS-9898-NC)

Dear Secretary Becerra:

The Cystic Fibrosis Foundation thanks the Department of Health and Human Services (HHS) for the opportunity to respond to the Request for Information (RFI) on issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (ACA). 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.

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

Typical Employer Plans:

> *We seek comment on changes in the scope of benefits offered by employer plans since plan year 2014. In particular, we are interested in comments that discuss the relative generosity of the current typical employer plans, and whether they are reflective of the scope of benefits provided under employer plans offered in more recent plan years, or whether employer plans offered since plan year 2014 are more or less generous.*

The CF Foundation has seen an erosion of the once gold standard employer plan and with each plan year, employers offer less and less generous options. Employers have sought to combat the rising cost of health

care prices by shifting the financial burden to employees through a combination of higher cost-sharing, benefit restrictions, and limited provider networks. According to the Kaiser Family Foundation, about a third of working adults covered through employer sponsored insurance face an annual deductible of about $2,000 or more, and employee premium contributions have risen by about 300% since 1999.[1] In 2022, fewer than half of employers offering health benefits believe their provider network in the plan had a sufficient number of behavioral health providers to ensure timely access to services for their workers, and one-third reported that they did not know.[2] For people with CF that are trying to manage a complex, chronic condition, this shift is extremely problematic.

Self-funded, or self-insured, insurance plans are especially concerning. According to a recent Kaiser Family Foundation study, 65% of covered workers are in a plan that is self- funded and as fully insured risk pools, they are incentivized to adjust their benefits when even one enrollee has a high-cost condition. Many offer a prescription drug benefit, which is subject to ACA regulations of EHBs. Under current law, employer health plans are allowed to deem certain categories of prescription drugs as "non-essential," even if they are necessary for people with serious, chronic conditions, like CF. When a covered drug is deemed "non-essential," the payer will not count any cost-sharing towards the enrollee's deductible and out-of-pocket maximum. In this system, people with CF in a "typical employer plan" could pay hundreds or thousands of dollars in out-of-pocket costs for necessary medicines and never hit their out-of-pocket maximum. Further, we are seeing some employer plans eliminate coverage of certain specialty medications altogether. Cystic fibrosis treatments rarely have lower-cost generic alternatives and, when employer plans refuse to cover specialty CF medications, people with CF face the difficult choice of foregoing these necessary treatments, changing to an often more costly insurance plan from the ACA marketplace, or in some cases making career sacrifices and seeking alternate employment.

Over the last 20 years, insurers, pharmaceutical manufacturers, and pharmacy benefit managers (PBMs) have been ratcheting up subversive tactics, resulting in the patient being put in the middle. More and more employers use high-deductible plans to manage rising costs. As a result, patients have turned to manufacturer copay assistance to hit their deductible and lower their out-of-pocket spending. In response, employers are now implementing the programs that limit the effect of copay assistance for patients financially at the same time, drug manufacturers can dictate the amount of copay assistance is available for patients, making this an unsustainable option as there maintains a risk of running out of assistance and being unable to afford medications. Self-insured payers are at the forefront of the programmatic changes because they operate differently from other types of payers and have more ability to directly control cost. This systemic debate between payers, PBMs, and pharmaceutical manufacturers about drug pricing puts patients' health and financial wellbeing at risk and forces patients to consistently need to adapt and navigate a confusing, opaque, ever-changing landscape.

As a result of these practices, people with CF are left with few options. In a study conducted using the Cystic Fibrosis Foundation's case management data, people with CF enrolled in self-funded employer plan regularly experienced gaps in care, lack drug coverage, or the need to change insurance due to cost.[3] CFF asks HHS to work with other agencies and Congress to establish better standards for employer coverage, including self-funded plans, and to better regulate the norms and practices of pharmaceutical manufacturers, insurers, and PBMs that put patients at risk. Moreover, because these plans are less

[1] https://www.kff.org/report-section/ehbs-2022-section-1-cost-of-health-insurance/
[2] *Ibid.*
[3] https://www.cysticfibrosisjournal.com/pb-assets/Health%20Advance/journals/jcf/Abstracts-of-the-2022-North-American-Cystic-Fibrosis-Conference-1671118809317.pdf , S214

generous than previously evaluated, HHS needs to review and update the EHB benchmark and framework more regularly, which we address below.

Review of Essential Health Benefits:

> *The ACA requires HHS to periodically review the EHB to determine: (1) whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost; (2) whether EHB need to be modified or updated to account for changes in medical evidence or scientific advancement; (3) information on how EHB will be modified to address any such gaps in access or changes in the evidence base; and (4) the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations.*

As noted above, much has changed in health needs and care since HHS implemented EHB requirements in 2014. In order to conduct a thorough and regular review, HHS should establish a process that is evidence-based, transparent, operates with clearly articulated timeframes for reviewing and reporting, allows for public input, and includes consumer and patient representatives. Such a review would identify barriers to accessing services due to coverage and cost, changes in medical evidence and scientific advancement, and any gaps in coverage for needed services.

> ***Utilization Management for Controlling Costs:*** *What strategies have consumers and providers seen plans implement to reduce utilization and costs, such as use of prior authorization, step therapy, etc.?*

Utilization management tools such as prior authorization can be a time-consuming process that burdens providers, diverts valuable resources away from direct patient care, and causes delays in patient access to needed treatment.[4] This process is particularly onerous on the CF community as people with CF must adhere to intensive, ongoing treatment plans in order to stay healthy. Adults with CF require an average of seven therapies every day, and as many as twenty.[5] Many of these medications are taken year after year, and in most cases, for life. When medications are indicated for specific diseases and not widely prescribed, a one-size-fits-all utilization approach does not work. This is important to note for the CF population, as modulators are based on specific genetic mutations and therefore the risk of abuse is low. Unnecessary prior authorizations can delay the start or continuation of needed treatments, leading to adverse health outcomes. Since CF is a progressive disease, interruptions in care put patients at risk of irreversible lung damage and costly hospitalizations.

Furthermore, prior authorizations can also cause significant administrative burden for CF providers and are often redundant for medications that people with CF must take indefinitely to maintain their health. The vast majority of people with CF are treated at centers of excellence by experts in CF management. In a 2019 Cystic Fibrosis Foundation survey of over 100 CF care center directors, 60 percent cited the time and resources required for PAs as one of the biggest barriers they face in supporting access to care and treatment. This process diverts valuable time and resources away from direct patient care.

In reviewing EHB, we urge HHS to ensure any utilization management is grounded in medical and scientific guidelines and is not used as a tool to restrict access to EHB. EHB's promise to provide access to a

[4] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2680350/

comprehensive set of benefits will be undermined if insurers are able to use plan rules and care review programs to limit access to those services. Therefore, we recommend HHS explore polices that are a clinically based alternative to prior authorization, such as "gold carding," to streamline the administrative process, ensure timely access to medications and reduce delays in care. "Gold carding" or other alternative approaches to utilization management, allow providers to meet certain criteria and then receive an exemption that waives prior authorization requirements. This will streamline the process and reduce the cost and administrative burden for patients and providers who manage chronic, lifelong conditions.

> ***Telehealth:*** *How could telehealth utilization better address potential gaps in consumer access to EHB for behavioral health services or other health care services? What other strategies have plans implemented to broaden access to telehealth services?*

We support HHS's goal to research the expanded use and availability of telehealth as well as the continuous efforts to collect data on the uses and outcomes of telehealth, including data to measure access and outcomes across different demographic groups. As the Department continues to evaluate the benefits of telehealth services, people with CF and their families should retain the right and ability to choose between receiving care in-person or via telehealth.

While telehealth 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 video or audio-only services. 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. Such access could help patients better maintain and manage their care, leading to more consistent and better outcomes.

> ***Advancing Health Equity:*** *How should the EHB advance health equity by taking into consideration economic, social, racial, or ethnic factors that are relevant to health care access (for example, access to appropriate language services)? In what ways could EHB better address health conditions that disproportionately affect underserved populations or large parts of the American population? For example, how could EHB address nutrition-related health conditions for the American population? How has the medical evidence regarding nutrition-related health conditions changed since 2014? How can EHB better improve nutrition-related health outcomes for the populations that are most likely to benefit from coverage of nutrition-related care, such as people with diabetes?*

Regular review of EHB is critical to identify advances in health equity that should be incorporated into EHB. While HHS has data reporting mechanisms available about plan coverage denials, appeals, delays in care and results from plan administrative process, these data points are not standardized across all HHS health programs (Medicare, Medicare Advantage, Medicaid, and Marketplace). HHS should establish standardized reporting metrics and that data should be made publicly available and be stratified by insurer. Moreover, HHS should explore avenues through essential health benefits to require plans to regularly screen for social risk factors, make referrals for support services, and track the outcomes of those referrals. It is important for plans to monitor enrollee use of referred services in order to better understand and address barriers to access. This data will also help ensure that the referrals placed are for sustainable interventions. To further enhance essential benefits, it will be critical to ensure access to appropriate language services and other accommodations that make services available to all, regardless of preferred language or ability. In providing EHB, insurers must be held to strong standards under section 1557.

Furthermore, with regard to addressing nutrition-related health conditions, food insecurity is prevalent in the CF community with one in three people with CF reporting experiencing food insecurity: three times the national average.[6] This is particularly problematic as people with CF often have increased caloric needs due to pancreatic insufficiency. The CF Foundation has evaluated intervention options to increase access to affordable food for the community, including exploring supplemental benefits – such as coverage of medically tailored meals – offered by health plans. In recent efforts, the CF Foundation facilitated a collaboration between CF clinicians and a local community organization providing medically tailored meals. This pilot intervention has been positively received by the CF community, with users reporting increased access to food, improved diet quality, increased energy, and savings of time and money.

Non-CF-specific research on medically tailored meals has found numerous benefits for both the recipients of medically tailored meals and their insurers, including fewer inpatient admissions, lower healthcare costs, improved diet quality, and lower rates of food insecurity.[7,8] One study that evaluated benefits for individuals dually eligible for Medicare and Medicaid found that individuals receiving medically tailored meals had 50% fewer inpatient admissions and 70% fewer emergency department visits than similar patients not enrolled in the meal program. Researchers found an average net savings of $220 per patient per month (16% savings on total medical expenditures) after factoring in the costs of the medically tailored meals.[9]

While some of the existing medically tailored meal programs rely on private donations, many also rely on health plans and systems partnering to provide meal interventions to their members. HHS should evaluate the effectiveness of these programs across chronic disease types to better understand how coverage could be incorporated in EHBs.

> ***Medical Evidence and Scientific Advancement****: What changes in medical evidence and scientific advancement have occurred since 2014 that are not reflected in the current EHB-benchmark plans? Are there benefits widely covered as EHB that are not supported by current medical evidence? Are there other barriers to incorporating changes in medical evidence and scientific advancement into the EHB? How can the EHB better track with changes in medical evidence and scientific advancement? What steps should be taken to address EHB that are not supported by current medical evidence?*

A systemic, evidence-based review would help identify other advances in care and medicine that should be included in any updated EHB. Coverage in most healthcare plans has been found to be more restrictive than national diseases specific guidelines and practices. As it stands, there is no clear guidance for plans on coverage for therapeutic medical advancements.

> ***Gaps in Coverage:*** *Are there examples of benefits that are essential to maintaining health, including behavioral health, that are insufficiently covered as EHB but that are routinely covered by other specific health plans or programs, such as employer-sponsored plans, Medicare, and Medicaid?*

Coverage of chronic disease management is uneven and often inadequate. For some programs, not all providers are covered (such as social workers or coordinators), and third-party organizations like the CF

[6] https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/59/
[7] https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/59/
[8] https://pubmed.ncbi.nlm.nih.gov/30421335/
[9] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0999

Foundation must help provide funding to ensure patients have the opportunity to access chronic disease management services. It is unclear what types of services are being covered within this category and when plans are covering them for a comprehensive range of chronic diseases. We would also like to note that coverage of services does not equal access; the total cost of medications and care will drive people to make tradeoffs between disease management or other needs such as housing or food.[10] We therefore urge HHS to set and enforce standards for what must be covered for this EHB.

Coverage of Prescription Drugs as EHB:

> *We seek comment on whether CMS should consider using an alternative prescription drug classification standard for defining the EHB prescription drug category, such as the USP DC or others, in the future.*

The Department seeks comment on whether it should consider using an alternative prescription drug classification standard for defining the EHB prescription drug category in the future. Plans currently satisfy EHB standards for prescription drugs if, among other things, they cover the greater of one drug per U.S. Pharmacopeia Medicare Model Guidelines (USP) class and category or the number of such drugs included in the state's benchmark plan. This standard has not been updated since the EHB rules came into effect in 2014 and life changing CF drugs have been brought to market since then. HHS suggests transitioning to the USP Drug Classification (USP DC) system; however, while more therapies are included, access challenges will remain. The CF Foundation recommends HHS reform to strengthen the prescription drug standard and require coverage of a minimum of two drugs per USP class and category or the number covered by the benchmark plan, whichever greater. Furthermore, plans should be required to cover, "all or substantially all" drugs in certain specified classes that are critical to certain vulnerable populations.

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The CF Foundation appreciates the opportunity to provide comments on the proposed rule. We look forward to working with HHS 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

[10] https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1058&context=sphhs_policy_briefs