



June 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on CMS's Interim Final Rule (CMS-1744-IFC) on Medicare and Medicaid Programs;
Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

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 30,000 children and adults in the United States. It is a complex, multi-system disease that requires targeted, specialized care to preserve health and well-being. Development of the CF care model, paired with genetically-targeted therapies that address the underlying cause of the CF, have contributed to dramatic improvements in life expectancy 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.

We commend the Centers for Medicare & Medicaid Services (CMS) for providing flexibility and expanded services in the Medicare program, particularly around home health care and telehealth, during the COVID-19 pandemic. These flexibilities are especially important for those with CF and other underlying health conditions which, according to the Centers for Disease Control and Prevention (CDC), are at increased risk of developing serious illness if they become infected with the coronavirus disease.

The CF Foundation appreciates the opportunity to provide feedback on CMS's policy and regulatory revisions during the public health emergency.

Clarification of Homebound Status Under the Medicare Home Health Benefit

The CF Foundation commends the Centers for Medicare & Medicaid Services for clarifying the standards for qualifying as homebound during the COVID-19 public health emergency, which allows more people with CF to receive care in their home and avoid potential exposure to coronavirus. **The expanded qualifications for homebound status are absolutely critical during the COVID-19 pandemic, including**

during phased state re-openings when the virus is still circulating. People with CF are susceptible to infections from bacteria, viruses, and fungi because abnormally thick, sticky mucus traps these organisms in the airways. Furthermore, the mucus and airway liquid in an individual with CF do not have the same infection-fighting properties as normal mucus. Thus, many individuals with the disease and members of their household are practicing strict social distancing and, in some cases, self-isolation during the pandemic.

We deeply appreciate the expanded definition of homebound in the interim final rule which explains that the definition of “confined to the home” allows patients to be considered homebound “if it is medically contraindicated for the patient to leave the home” or if the physician determines that it is “medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.” This clarification of the definition of homebound status will permit people with CF to receive reasonable and necessary home health services and enable people with CF to more safely continue their ongoing CF care while lessening their exposure to COVID-19.

Care at home may be safer for Medicare beneficiaries with CF and potentially less costly to the Medicare program than delivering care in an inpatient setting. **We urge the agency to ensure these flexibilities are extended for the CF population and others at high risk of infection as long as COVID-19 remains a threat.**

Flexibility to Ensure Coverage of Pump for Home Administration of Antibiotics for People with Cystic Fibrosis

CMS has taken steps in this interim final rule released on March 30, 2020 and the interim final rule released on April 30, 2020 to improve access to drugs delivered to patients at home. In the March 30, 2020 interim final rule, the agency provided flexibilities regarding the physician supervision requirement for incident-to drugs and clarified how physician practices might facilitate the home infusion of Part B drugs. These steps make home infusion of Part B drugs a possibility, if the physician and patient determine it is the best option for drug administration in the COVID-19 pandemic.

We urge the agency to apply flexibility to coverage of external infusion pumps for home IV administration of antibiotics for people with CF. Medicare beneficiaries with CF too often encounter coverage obstacles for external infusion pumps for antibiotic infusion. If physicians recommend home IV infusion and the drug is covered under the patient’s prescription drug plan, the agency should cover the equipment and supplies for home IV antibiotic administration. Especially during the public health emergency, when people with CF are advised to remain at home, access to home IV administration of antibiotics should be assured.

Telehealth flexibilities in Medicare

The CF Foundation commends CMS for recognizing the critical role of telehealth during the COVID-19 pandemic and providing temporary regulatory flexibility around these services. Over the past couple of months, the agency has taken steps to expand access to telehealth services for Medicare beneficiaries including the implementation of new coverage and reimbursement policies and expansion of reimbursement-eligible services. These changes have helped mitigate the effects of the coronavirus

pandemic by facilitating the widespread use of virtual telehealth visits to reduce unnecessary exposure to the virus for both patients and providers. Recognizing the need for strict adherence to social distancing guidelines and taking into account special considerations for their patient population, CF care teams have responded rapidly to changes in care delivery and are embracing telehealth in their clinics. Today, nearly all of the 130 CF care centers in the U.S. are providing some form of telehealth services to their patients.

Telehealth modalities

The interim final rule clarifies that for the duration of the public health emergency, devices with two-way audio and video capabilities, including smartphones, meet the definition of “interactive telecommunications systems” and services delivered through these devices are therefore reimbursable under Medicare. This flexibility has enabled patients and providers to leverage more accessible technology and telehealth platforms, thereby expanding access to needed care during the pandemic.

We recognize that the agency further expanded this offering in its interim final rule dated April 30, 2020 by offering reimbursement for behavioral health and E/M services delivered via audio-only platforms. The importance of reimbursing for audio-only telehealth services cannot be overstated. By expanding this benefit, CMS has helped ensure patients without access to the internet, a computer, or smartphone are still able to receive needed care while it is not safe to be seen in-person. This flexibility is especially critical for providers that serve rural or low-income populations; for instance, a CF clinician from Tucson, AZ said that most of her patients do not have access to the internet and many are relying on audio-only telehealth visits with their care team during the pandemic. **We urge CMS to permanently allow for telehealth visits to be conducted via audio-only platforms as well as expanded audio/visual devices (e.g., smartphones).**

Coverage for remote monitoring devices

Cystic fibrosis is a complex, chronic disease that requires regular physiologic monitoring. CF clinicians use key health indicators to monitor patients, most notably lung function. **To experience the full benefits of CMS’s telehealth expansions people with CF need access to remote monitoring devices, particularly home spirometers and pulse oximeters. Further, CF providers should be reimbursed for time spent on remote monitoring for their patients.**

Option to waive cost-sharing

The CF Foundation commends CMS for reiterating that providers will not be penalized for reducing or waiving any cost-sharing obligations beneficiaries may owe for telehealth services. This is and will continue to be an important option for care teams as the out-of-pocket costs associated with CF care can weigh heavily on patients, especially during high levels of unemployment caused by the pandemic, causing some to delay or forgo care altogether.

Making telehealth flexibilities permanent

We recognize that the flexibilities detailed in this interim final rule and subsequent COVID-19-related rules expire at the end of the current public health emergency, as declared by Secretary Azar. However, patients with cystic fibrosis and other severe underlying diseases will need to be conscientious about potential exposure to the virus even after the initial threat has passed and will therefore require access

to telehealth services for longer than the general population. Furthermore, beyond its immediate role in the short-term pandemic response, telehealth—if covered more broadly on a longer-term basis—can help ensure access to care for some patients who face logistic or financial challenges (e.g., transportation costs) visiting the clinic in-person. **We believe the use of telehealth services in CF holds great promise for continued delivery of high-quality CF care.**

We encourage CMS to start an ongoing dialogue with patients and providers to understand how to provide expanded access to telehealth services over the long-term. The CF provider community and the CF Foundation are conducting quality improvement programs, investigating patient and provider satisfaction, and refining best practices for telehealth delivery of cystic fibrosis care. **CMS has made great progress in adjusting existing regulations to reflect new realities in care delivery and we urge the agency to work with patient communities to capitalize on these ongoing learnings and extend temporary telehealth flexibilities beyond the coronavirus pandemic.**

Thank you for the opportunity to weigh in on these important changes.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mary B. Dwight', with a stylized flourish at the end.

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