



June 26, 2020

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Alexander:

We appreciate the opportunity to comment on the recommendations in your white paper, *“Preparing for the Next Pandemic,”* on public health preparedness and pandemic response. On behalf of the Cystic Fibrosis Foundation, we urge Congress to enact policies to address enhanced paid leave, antibiotic incentives, expanded telehealth coverage, and adequacy and affordability of health insurance for people with chronic conditions.

Background on cystic fibrosis and COVID-19

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. Like many other patient populations with underlying conditions, people with CF may be particularly vulnerable to complications from the ongoing coronavirus disease 2019 (COVID-19) pandemic. People with CF face a heightened life-long risk of both viral and bacterial infections because of the thick sticky mucus in the lungs that is characteristic of the disease. Unfortunately, infections can lead to losses in lung function, and many people with CF battle difficult-to-treat infections for which there are no effective antimicrobial drugs available.

Because patients with cystic fibrosis are particularly vulnerable to infections, the impacts of the COVID-19 pandemic on the CF community have been wide-ranging. The pandemic has affected how CF community members keep safe while engaging in normal activities of daily living, including accessing necessary specialty care and navigating the workplace. Thanks in part to the highly specialized care that patients with CF receive at their accredited care centers, people with CF are leading longer, more productive lives. However, the COVID-19 pandemic continues to disrupt patient access to necessary routine cystic fibrosis care. Job loss can be particularly hard for those living with CF, as many in the community rely on employer-sponsored insurance to cover the high health care costs associated with caring for a chronic illness; the high costs of CF care can be exceptionally burdensome on families struggling to make ends meet. Regardless of their circumstances in life, people with cystic fibrosis must have continued access to adequate, affordable coverage, especially during the current pandemic and any future public health crisis.

While we are encouraged by the swift actions Congress has taken to date to provide much-needed support for people across the nation impacted by this pandemic, more must be done to protect patients with serious underlying conditions like cystic fibrosis in the current pandemic and beyond.

Paid family and medical leave is a necessity for the CF community

Congress should expand paid leave to minimize vulnerable populations’ exposure to coronavirus, as well as to protect patients during future public health crises. The Centers for Disease Control (CDC) has advised those at

high-risk for severe illness from COVID-19 to continue to shelter in-place to protect their health during the current pandemic. However, under emergency policies enacted in the Families First Coronavirus Response Act (FFCRA), workers are only eligible for up to two weeks of financial support and job protection through expanded paid sick leave. Additionally, the expanded paid family medical leave program only provides support to those with children or adults with disabilities whose local school district or usual care providers are closed due to the pandemic for up to 10 weeks. Further exemptions, including exemptions for large employers and for essential workers, make this program inaccessible to a significant number of individuals.

At this time of great uncertainty in our country, it is important to understand that certain individuals are at much higher risk of adverse health events and death associated with COVID-19 than the rest of the population. Although recent research indicates the overall fatality rate from COVID-19 is around two percent, individuals with certain underlying health conditions experience a greater rate of severe complications and have higher fatality rates from COVID-19.^{1,2} Existing paid leave policies do not meet the needs of the many Americans who are at increased risk of complications due to COVID-19, including those living with cystic fibrosis. The lack of viable paid leave options for individuals who live with significant health conditions forces these individuals to face a devastating choice: place their health or their loved one's health at risk by going back to work or lose their job and likely their health insurance.

A number of patients and families in our community have shared their experience with balancing employment and the need to protect their health or their loved one's health during this time. One such individual with CF living in Tennessee, who has run out of options with her employer, shared that she faces a difficult decision to either lose her position as a nurse practitioner or return to in-person work at great risk to her health.³ We have also heard from families who are forced to live apart to protect vulnerable members in their household. To protect his daughter with CF, one father who is an essential worker has been staying in his family's camper to avoid exposing his family to COVID-19. These stories illustrate just a few examples of how inadequate protections are forcing vulnerable workers and their families to choose between their livelihood and their safety.

As Congress develops policy proposals for the next pandemic and continues to work on responding to COVID-19, we urge Congress to make changes to the paid family and medical leave program created by FFCRA. Eligibility for paid family leave should be expanded to ensure that anyone who has been advised by their physician to remain at home during this time because of a serious health condition can do so. Additionally, those who have been advised by a physician to remain home because there is a member of their household with underlying conditions must also be covered. Finally, the existing time limit on paid leave must be removed to ensure that these individuals can remain home as long as the COVID-19 pandemic poses a serious risk to their health and wellbeing, and this program must apply to employers of all sizes and types to prevent arbitrary gaps in eligibility.

Antibiotic incentives are urgently needed to address market failures

Congress should take immediate action to address the failing antibiotics market to help protect against drug-resistant infections both now and in the future. The coronavirus pandemic has demonstrated the urgency of ensuring the nation's readiness to combat dangerous infectious diseases. Beyond the immediate threat of the

¹ <https://erj.ersjournals.com/content/early/2020/03/17/13993003.00547-2020>

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https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_ABX_Guide/540747/all/Coronavirus_COVID_19_SARS_COV_2

³ <https://fox17.com/news/local/at-risk-workers-left-without-protections>

coronavirus outbreak, treatment-resistant secondary bacterial infections can further complicate care and recovery for patients with COVID-19. Addressing growing infectious disease threats – both viral and bacterial – will be crucial for preventing or mitigating the impacts of public health crises in the future.

Because many patients with cystic fibrosis struggle with both acute and chronic bacterial infections, routine use of antibiotics in CF care is medically necessary. Unfortunately, too many people with cystic fibrosis find themselves battling difficult-to-treat infections for which existing antibiotics are not effective. These experiences are not limited to the CF community; each year, 2.8 million Americans acquire serious infections caused by antibiotic-resistant bacteria, and 35,000 of them die as a result.⁴

Unfortunately, we are severely underprepared to meet the growing threat of antibiotic resistance. Because the effectiveness of antibiotics can wane over time as bacteria become resistant to available treatments, a robust antibiotic development pipeline is a necessary part of ensuring continued access to antibiotics that work. However, only a handful of new antibiotics are developed each year, leaving many antibiotic treatment needs unmet. This is in part due to the financial challenges associated with bringing a new antibiotic to market and keeping it there. Antibiotics rarely command a high price, and many antibiotic developers are struggling just to cover the costs of manufacturing their products. In 2019 alone, two antibiotic companies – Achaogen and Melinta – went bankrupt *after* successfully bringing antibiotic products to the market. Modernization in payment for these essential medical products is needed now more than ever to ensure novel antibiotic development continues.

Early development phase interventions, while beneficial, have alone not been enough to stabilize the antibiotics drug development pipeline. Products in the antibiotics pipeline need to be supported by a robust ecosystem of incentives to combat the low market, high societal value of these goods. A recent report from the U.S. Government Accountability Office highlighted the importance of government action on postmarket incentives, including market entry rewards and reimbursement reform, to prevent the continued decline of the antibiotics market.⁵

Congress should act now to reform reimbursement and market incentives for antibiotics. Current drug reimbursement methods fail to incentivize novel antibiotic development while reducing concerns about inappropriate use of these critical products; payment methods that de-link sales volume from revenue can help. One such model, sometimes referred to as the ‘Netflix’ subscription model, would provide consistent payments over a period of time to drug developers for access to their product. Innovative subscription contracts have been used to secure access to treatments important to public health efforts, such as in the case of Louisiana entering into a subscription contract to pay for hepatitis C treatments. Additionally, some countries such as the United Kingdom are already exploring how these innovative payment models may work for antibiotic products at a national level.

Another reimbursement fix, put forward in the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act (S. 1712, H.R. 4100), would carve out antibiotics from Medicare inpatient reimbursement and provide a separate additional payment for novel antibiotics. This measure would provide some immediate relief to antibiotic companies that are struggling to stay in business. Furthermore, innovative incentives like a market entry reward for novel antibiotics may increase interest in this development space. We

⁴ <https://www.cdc.gov/foodsafety/newsletter/antibiotic-resistance-threats-11-13-19.html#:~:text=CDC%20estimates%20that%20more%20than,660%2C900%20resistant%20infections%20each%20year.>

⁵ <https://www.gao.gov/assets/710/705578.pdf>

urge Congress to invest in solutions such as these to ensure access to antibiotics that work both now and in the future.

Telehealth services protect access to specialty care for vulnerable populations

Thank you for acknowledging the importance of building on recent changes to make telehealth more accessible to patients. We encourage Congress to work with Centers for Medicare and Medicaid Services (CMS) to ensure telehealth remains available as long as COVID-19 is a threat to people with CF and in the event of future pandemics.

Access to telehealth services during the coronavirus pandemic has been especially important for those living with CF, who may be at increased risk for developing serious illness related to COVID-19. 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 Foundation-accredited care centers in the U.S. are providing some form of telehealth services to their patients.

It is imperative that telehealth remains available to people with CF for as long as they need to follow social distancing guidelines and in the event of another pandemic. To ensure telehealth is accessible for people with CF, we urge the permanent removal originating site restrictions to ensure a patient's home can serve as the site of care. This enables infected patients to receive care without spreading the virus and allows other patients—including those with underlying conditions like CF—to receive care without putting themselves at increased risk of coronavirus infection.

Additionally, coverage for telehealth visits conducted via devices like smartphones and for certain services using audio-only platforms has been critical for ensuring widespread access to telehealth, and Congress should work with CMS to provide continued access via these technologies. CMS's 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. CMS has further expanded this offering in its interim final rule dated April 30, 2020 by providing reimbursement for behavioral health and E/M services delivered via audio-only platforms. 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, Arizona 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. Congress should work with CMS to ensure coverage for telehealth visits conducted via audio-only platforms as well as expanded audio/visual devices such as smartphones for as long as COVID-19 remains a threat to people with CF and establish mechanisms to provide these flexibilities in future pandemics.

Finally, for patients with CF to experience the full benefits of CMS's telehealth expansions, people with CF will also need access to remote monitoring devices, particularly home spirometers, pulse oximeters, and scales. These devices allow for collection of important data to help inform physicians on the health status and care needs of their patients. Further, CF providers should be reimbursed for time spent on remote monitoring for their patients given the importance of these services. Congress should work with the Administration to ensure reimbursement for remote monitoring devices and provider reimbursement for remote monitoring services.

All patients need adequate, affordable coverage

The current pandemic underscores the need for all Americans to have adequate, affordable health insurance. People with chronic conditions who are at increased risk of severe illness from COVID-19 rely on the rest of the population to take preventive measures to help reduce the spread of coronavirus, which requires all Americans to have access to testing and treatment.

Congress and the administration took several actions to ensure access to testing and treatment for COVID-19 during the emergency declaration, but these steps, while important, are not a replacement for comprehensive, affordable coverage. The FFCRA stated, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act clarified, that diagnostic testing be provided with no-cost sharing under Medicaid, Medicare, TRICARE, VA, and other coverage. FFCRA also created an option for Medicaid to cover diagnostic testing for the uninsured at 100 percent federal match, and the administration used its authority to reimburse providers treating uninsured patients with COVID-19. While these were necessary actions, this piecemeal approach does not ensure all Americans have access to COVID-19 testing and treatment. Only 21 states have adopted the option to provide diagnostic testing through Medicaid.⁶ The requirements do not apply for those enrolled in short-term limited-duration plans and other non-ACA-compliant coverage. It is also not clear whether the Provider Relief Funds used to reimburse providers treating uninsured patients with COVID-19 will be sufficient to cover their costs.

All Americans—and especially those with chronic conditions—are at increased risk of serious illness or death if they cannot get the testing and treatment needed during a pandemic. While we appreciate Congress's efforts to expand access to care in the midst of the COVID-19 crisis, we should prepare for the next pandemic by ensuring adequate, affordable coverage for all Americans so we are better protected going forward.

Once again, we thank you for this opportunity to provide input on public health preparedness and pandemic response. There are important opportunities for collaboration and discussion on reforms to improve on the nation's readiness for future emergencies and public health crises. We stand ready to work with Congress on the challenges ahead. Thank you for your consideration.

Sincerely,



Mary B. Dwight

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⁶ <https://www.kff.org/coronavirus-covid-19/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19/>; <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/>