The Honorable Eric Hargan  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

January 5, 2018

Dear Acting Secretary Hargan:

Thank you for the opportunity to comment on the amendment to North Carolina’s 1115 waiver application. While we recognize the need to put the state’s medical assistance program on a sustainable funding path, the Cystic Fibrosis Foundation recommends that the state pay special attention to the needs of individuals with rare genetic diseases who require multidisciplinary specialty care in any reform effort.

Cystic fibrosis (CF) is a life-threatening genetic disease that affects 954 people in North Carolina and 30,000 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. As a complex, multi-organ condition, CF requires targeted, specialized treatment and medications. Given the role that Medicaid plays in helping this patient population access the high-quality care and treatment they need to maintain or improve their health, we urge the state to ensure the needs of CF patients are met as the state makes changes to its Medicaid program. Within the 1115 demonstration waiver application amendment, we are concerned particularly with the following provisions:

**Employment requirements**
We appreciate the state’s decision to exempt from employment requirements those who are deemed “medically frail,” which reflects the important reality that health status can significantly affect an individual’s ability to search for and sustain employment. As the state works to define these exemptions, North Carolina should clarify the medically frail definition to include conditions such as cystic fibrosis. Some people with cystic fibrosis may not qualify for disability but their ability to work may vary over their lifetimes. While many can work full or part-time, others are not able to maintain employment due to their health status or the amount of time they need to spend on their treatments. Many patients bear a significant treatment burden, amounting to hours of chest physiotherapy, delivery of nebulized treatments, administration of intravenous antibiotics, and/or other activities required to maintain or improve their health, which can interfere with their ability to work. For these reasons, many people with CF experience periods when they are unable to work or attend school, despite being ineligible for disability benefits.

In addition to providing specificity on qualifying “medically frail” conditions, we urge the state to articulate a clear process for applying for an exemption based on “medically frail” status, as well as a timeline for determination. Clear rules around the application process, eligibility requirements, and timeframes will help ensure that eligible individuals are able to get an exemption.

**Monthly premiums**
We are concerned that the proposal to implement premium payments for people with incomes greater than 50 percent of the poverty level and to terminate coverage for failure to make a premium payment for 60 days may create barriers to care. Our research shows that while 99% of people with CF have insurance, one-quarter of
people delay or skip care due to cost concerns. Such actions seriously jeopardize the health of people with CF and can lead to costly hospitalizations and fatal lung infections. We encourage you to reject cost-sharing provisions for this medically and financially vulnerable population.

Additionally, the process of making a premium payment can pose challenges for a population that may not have easy ways to pay bills, which makes coverage termination a particularly punitive consequence for failing to pay premiums. For instance, an analysis of Indiana’s Medicaid program found that nearly 30 percent of enrollees never enrolled in coverage or were disenrolled from coverage because they failed to make premium payments during the study period. The analysis found 22 percent of individuals who never enrolled because they did not make the first month’s payment cited affordability concerns, and 22 percent said they were confused about the payment process. Moreover, researchers found that many beneficiaries in Michigan used money orders to pay their premiums, as money orders are a common form of payment for individuals without a bank account or credit card, and beneficiary advocates and enrollment assisters noted that money order fees could sometimes equal or exceed the amount of premiums or copayments owed.

For people with cystic fibrosis, losing coverage because they are unable to make a premium payment could eliminate their access to vital, life-saving care. We urge you to reject the monthly premium requirement and associated coverage termination.

Public comment period and reporting
We are concerned that the state comment period ended four business days before the close of the federal comment period. Federal rules require that extension applications include a public comment period and a “federal report of the issues raised by the public during the comment period and how the State considered ‘the comments when developing the demonstration extension application.’” We are concerned that the amendment is not subject to the full public notice and comment process. The public should have the opportunity to weigh-in on significant changes to the Medicaid program, such as the work requirements and premiums, that are sought in North Carolina.

The Cystic Fibrosis Foundation appreciates the opportunity to provide input on these important policy changes. As the health care landscape continues to evolve, we look forward to working with CMS and the state of North Carolina to ensure access to high-quality, specialized CF care and improve the lives of all people with cystic fibrosis. Please consider us a resource moving forward.

Sincerely,

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Cystic Fibrosis Foundation

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Cystic Fibrosis Foundation

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