



January 17, 2020

Drew Snyder  
Executive Director  
State of Mississippi, Division of Medicaid  
550 High Street Suite 1000  
Walters Sillers Building  
Jackson, MS 39201-1325

Dear Mr. Snyder:

On behalf of the 40 adults living with cystic fibrosis (CF) enrolled in Medicaid in Mississippi, we write to you regarding the state's Medicaid prescription drug limit. We are concerned that this policy creates barriers to accessing medically necessary drugs for beneficiaries with CF, places a high administrative burden on people with cystic fibrosis—especially those with co-morbid conditions—and does not comply with federal Medicaid regulations. We therefore urge you to implement a medical necessity override and we request a meeting to discuss this issue.

### **About Cystic Fibrosis**

Cystic fibrosis is a life-threatening genetic disease that affects approximately 30,000 people 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. Because it is a complex, multi-system condition, eighty-six percent of CF patients also have at least one associated condition, including CF related diabetes or asthma. CF and its associated conditions require targeted, specialized treatment. It is crucial for patients that their health coverage—including Medicaid—provides access to needed therapies.

To treat CF and its associated conditions, most patients follow extensive daily regimens developed by their care teams. For many, this amounts to hours of chest physiotherapy, delivery of nebulized treatments, administration of intravenous antibiotics, and/or other activities required to maintain or improve their health. Prescription drugs are an essential component of this care regimen; people with cystic fibrosis may take drugs to help break up mucus in the lungs to make it easier to breathe, treat the bacteria that colonize in their airways, improve absorption of essential nutrients, treat comorbid conditions, or even correct the underlying genetic defect of the disease. If left untreated, the infections, exacerbations, or complications from associated conditions caused by cystic fibrosis can result in irreversible lung damage, declining health outcomes, and early death.

Given the complexity and life-threatening complications associated with CF, we trust that CF care teams are best positioned to determine their patients' medical needs, including prescription drug regimens. Most people with CF receive care at a CF Foundation accredited care center that provides multidisciplinary, specialized care in accordance with data-driven clinical practice guidelines.<sup>1</sup>

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<sup>1</sup> The Cystic Fibrosis Foundation accredits one adult and one pediatric care center in Mississippi. Both are located at the University of Mississippi Medical Center.

**We therefore ask that you revise your prescription drug limit policy to include a medical necessity override. This remedy would reduce the administrative burden and barriers to access that Medicaid patients experience as they navigate the program in Mississippi.**

### **Administrative Burdens and Barriers to Access for People with CF**

While we were encouraged when the Mississippi legislature removed the statutory monthly limit on prescription drugs, we are disappointed in the decision to only increase the limit by one drug, from five to six prescriptions. We recognize that the 90-day maintenance drug list allows for some additional flexibility and appreciate the state's decision to include many CF therapies on this list. However, we believe this is an insufficient safeguard and does not relieve the complex and overwhelming administrative burden for people with CF.

This issue is particularly acute for people with cystic fibrosis who have another significant medical condition, and therefore require a large number of medications each month. These patients must closely manage their prescriptions to ensure they are filling each prescription at the right time to avoid hitting the monthly limit. If they encounter a delay for any reason—such as an extended hospital stay—it can result in losing access to a needed medication.

We were recently made aware of several specific instances of CF patients with complex drug regimens going without needed medications or routinely paying out-of-pocket from their limited resources for prescriptions. One patient has significant mental health issues in addition to her CF. As a result, she takes 14 medications each month, many of which are not included on the 90-day maintenance list. Because of Mississippi's limit and her inability to pay for medications out-of-pocket, she often skips medications and regularly goes without essential CF therapies. This has resulted in avoidable hospitalizations and additional costs to the state. Another patient with a co-morbid condition takes 20 different medications each month. Although he has successfully maximized his drug coverage under the 90-day maintenance drug list through careful coordination, he still regularly pays out-of-pocket for as many as six drugs per month, resulting in a significant financial burden.

### **Compliance with Medicaid Regulations**

Furthermore, we believe Mississippi's current policy needs additional flexibility in order to comply with federal Medicaid regulations. Federal regulations at 42 CFR 440.230(b) require that within the Medicaid program, "[e]ach service must be sufficient in amount, duration, and scope to reasonably achieve its purpose."<sup>2</sup> An arbitrary limit on the number of prescriptions without a meaningful exception process for drugs in excess of the limit for medical necessity does not reasonably accomplish the purpose of covering prescription drugs. In a State Medicaid Director letter on September 4, 1998, CMS stated that a medical equipment "policy that provides no reasonable and meaningful procedure for requesting items that do not appear on a State's pre-approved list, is inconsistent with the federal law." CMS based this conclusion on the 42 USC §1396(a) (17) requirement that limitations on covered services be reasonable and on the 42 CFR 440.230(b) requirement that services achieve their purpose.<sup>3</sup>

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<sup>2</sup> Code of Federal Regulations. Available online: <https://www.gpo.gov/fdsys/pkg/CFR-2017-title42-vol4/xml/CFR-2017-title42-vol4-sec440-230.xml>

<sup>3</sup> Centers for Medicare & Medicaid Services, State Medicaid Director Letter, September 4, 1998. Available online: <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD090498.pdf>

We urge the Mississippi Medicaid program to act immediately to ensure it is consistent with the prescription drug needs of people with cystic fibrosis. While we recognize the need to carefully manage Medicaid spending, limiting essential therapies creates barriers to necessary care for people with chronic conditions like CF. We therefore urge the state to implement a medical necessity override process—which can ensure patients receive critical therapies and help Mississippi avoid unnecessary additional costs from patients skipping needed medications. We request a meeting to further discuss and work with you on this proposal.

We stand ready to partner with you to try to achieve the balance of cost control and appropriate patient access. Please contact Lauren Ryan, Senior State Policy Specialist, at [lryan@cff.org](mailto:lryan@cff.org) or (301) 841-2632 with your availability to discuss this issue further with CFF and local providers.

Sincerely,



**Mary B. Dwight**  
Senior VP of Policy & Advocacy  
Cystic Fibrosis Foundation



**Lisa Feng, DrPH**  
Senior Director of Policy & Advocacy  
Cystic Fibrosis Foundation