



September 9, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: TennCare III - Approval Special Terms and Conditions

Dear Secretary Becerra,

Thank you for the opportunity to provide comments on the Special Terms and Conditions approved on January 8, 2021 for the TennCare III demonstration waiver. On behalf of people with cystic fibrosis (CF) living in Tennessee, we write to express our serious concerns with this waiver application. We oppose the state's proposal to adopt a closed formulary and are concerned with the continuation of Tennessee's Medicaid Managed Care program and waiver of retroactive coverage. We fear these policies will jeopardize patient access to quality and affordable healthcare and therefore urge that the Department of Health and Human Services (HHS) remove these harmful provisions.

Cystic fibrosis is a life-threatening genetic disease that affects more than 30,000 people in the United States, including over 750 in Tennessee. Roughly a third of adults living with CF in the state rely on Medicaid for some or all of their health care coverage. 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-system condition, CF requires targeted, specialized treatment and medications. 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.

In the most recent TennCare III section 1115 waiver, Tennessee proposes drastic changes to the program's financing and formulary structure and utilizes harmful block grant funding. Given how these changes could impact those with CF on Medicaid, we have serious concerns with this proposal.

Block Grant Funding Model

We are concerned that the block grant funding proposal creates a framework for Tennessee to restrict TennCare funding—this model is not responsive to changes in program costs and the waiver contains incentives for Tennessee to reduce program spending, which may result in access barriers for the CF population. Given federal statute, we also challenge the legality of this proposal.

While the proposal includes an adjustment for unexpected enrollment growth, it does not account for other changes in program needs. Tennessee would remain responsible for other unexpected increases in per-person TennCare costs, such as increased costs due to public health crises or innovations in medical treatment. In these situations, despite the state's intention to preserve existing benefits, it may not be able to provide the additional

funds needed to cover cost increases and may look to alter eligibility, reduce provider rates, or make other changes to save money at the expense of patients' access to care. Such threats are particularly acute given the authority the state is requesting around managed care plan oversight and other program elements, as discussed below. For patients with serious chronic conditions like CF, these changes could mean that Medicaid no longer provides access to their care provider or covers the complex, specialized care they need. Lack of proper care could severely compromise the health of a person with cystic fibrosis by leading to an increase in hospitalizations, reduction in lung function, or decrease in nutritional status.

Beyond our above concerns, we also believe the proposed block grant funding structure violates federal statute. Under Section 1115 of the Social Security Act, the Secretary of Health and Human Services has the authority to waive compliance with multiple sections of the Act when they are "likely to assist in promoting the objectives" of the Medicaid program.¹ However, the Medicaid payment model and match rates are outlined in Sections 1903 and 1905, sections notably absent from the list of waivable provisions under Section 1115.² As the Centers for Medicare and Medicaid Services (CMS) wrote in its letter to North Carolina in response to the state's 2018 waiver application requesting similar authority, we do not believe the state's proposed funding structure is approvable under federal law.^{3,4}

"Commercial Style" Closed Formulary

Tennessee is also requesting the authority to adopt a closed formulary with at least one drug available per therapeutic class. CFF recognizes the reality that growth in drug costs contributes to the increasing strain on state budgets. However, we are concerned that the state's proposal to adopt a closed formulary based on cost-effectiveness reviews is underdeveloped, lacking in detail and sufficient protection for patients, and unlawful based on existing federal statute.

The state's plan to implement a closed formulary and base coverage decisions on cost-effectiveness reviews is woefully underdeveloped. Tennessee provides no details as to how it would determine when "market prices are consistent with prudent fiscal administration," nor does the state outline any process for how it would conduct cost-effectiveness reviews or what data would be considered during such discussions. If Tennessee is serious about such an endeavor—one in which patients' access to clinically beneficial, sometimes lifesaving, therapies is at stake—the state must provide a much more detailed proposal about how such a process would work.

We also caution that cost-effectiveness assessments are limited by the quality of data available at the time the review is conducted. This can significantly impact the outcome of such assessments, especially when cost-effectiveness is evaluated when a drug enters the market. In such circumstances, long-term outcomes and patient experience data do not yet exist. Even when clinical evidence is available, current assessments incorporate very limited patient-relevant information such as real-world evidence, patient experience, and patient survey data, if any. Thus, these assessments often undervalue long-term benefits and real-world outcomes and should not be the sole basis for coverage decisions

¹ Social Security Act § 1115(a)

² Joan Alker. Pending CMS Guidance on Medicaid Block Grants: Executive Overreach Strikes Again. Georgetown University Center for Children and Families. June 27, 2019. Available at: <https://ccf.georgetown.edu/2019/06/27/pending-cms-guidance-on-medicaid-block-grants-executive-overreach-strikes-again/>

³ Social Security Act § 1115(a)

⁴ Centers for Medicare & Medicaid Services, North Carolina Medicaid Reform Demonstration Approval, October 19, 2018, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicaid-Reform/nc-medicaidreform-demo-demo-appvl-20181019.pdf>

Moreover, the waiver application notes TennCare would seek to ensure that the new, limited formulary meets the needs of the “vast majority of members” and would create an exceptions process for obtaining off-formulary drugs “similar to the existing authorization process”—neither of which are sufficient protections for people with CF. The commitment to meet the needs of the “vast majority” of TennCare members is an insufficient and empty assurance for individuals with rare and chronic conditions who rely on complex care regimens to maintain their health. TennCare’s formulary must meet the medical needs of all beneficiaries, not simply the majority. Furthermore, regarding the exception process, this proposal once again lacks clear detail and fails to specify exactly how this process will work or how the state would ensure patient access. Simply noting that the process will be “similar” to the current process is ambiguous and does not provide enough detail for public comment. For instance, patients need information about response time requirements and standards for determining medical necessity in order to evaluate the sufficiency of this proposed process.

Finally, the administration has made its position on this issue clear: in a 2018 notice, the Department of Health and Human Services stated that any drug manufactured by a company with a Medicaid National Drug Rebate agreement “is covered by the Medicaid Drug Rebate Program (MDRP) and is to be covered by state Medicaid programs.”⁵ CMS also rejected a comparable proposal submitted by Massachusetts in 2017, citing a similar rationale.⁶ Thus, Tennessee’s proposal to restrict drug coverage as proposed in this waiver is not a viable option under federal statute.⁷ Therefore, we encourage CMS to revoke approval for the closed formulary in the special terms and conditions.

Removal of Retroactive Eligibility

The CF Foundation opposes Tennessee’s decision to continue to waive retroactive coverage in TennCare. Retroactive eligibility helps ensure continuous coverage for people with CF who experience changes in insurance status and become Medicaid eligible. There are many reasons why Tennesseans, including people with CF, may not be able to submit a timely Medicaid application when they become eligible. Someone with CF may be consumed by a complicated medical situation—such as an extended hospitalization—that can make it difficult to complete an application. Applications can be burdensome and confusing, and people may not realize their coverage has lapsed until they seek care.

Retroactive eligibility helps adults living with CF in Tennessee who rely on Medicaid avoid gaps in coverage and costly medical bills and is an especially important safeguard for those who have lost their job or are experiencing changes in their insurance status as a result of the COVID-19 pandemic. Without it, people with CF may face significant out-of-pocket costs. Cystic fibrosis care and treatments are costly, even with coverage. According to a survey conducted by George Washington University of 1,800 people living with CF and their families, over 70 percent indicated that paying for health care has caused financial problems such as being contacted by a collection agency, having to file for bankruptcy, experiencing difficulty paying for basics like rent and utilities, or having to take a second job to make ends meet. And while 84 percent received some form of financial assistance in 2019 to pay for their care, almost half reported still having problems paying for at least one medication or service in that same year. We urge CMS to rescind approval for the waiver of retroactive eligibility.

⁵ Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program Notice Release No. 185, June 27, 2018, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/staterelases/state-rel-185.pdf>

⁶ Centers for Medicare & Medicaid Services, MassHealth Demonstration Amendment Approval, June 27, 2018, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealthdemo-amndmnt-appvl-jun-2018.pdf>.

⁷ Social Security Act § 1927(d), 42 U.S.C. § 1396r-8.

Cost-Sharing Requirements

The CF Foundation oppose Tennessee's decision to continue their Medicaid Managed Care program, which requires individuals with incomes above 100 percent of the federal poverty level to pay monthly premiums and coinsurance for select services, including non-emergency use of the emergency department.

Under this program, an individual's failure to pay their monthly premiums result in disenrollment. This policy will continue to increase the number of enrollees who lose Medicaid coverage, as nominal premiums are often unaffordable for low-income beneficiaries and the process of making a premium payment can create barriers to care for a population that may not have bank accounts or credit cards. For example, when Oregon implemented a premium in its Medicaid program, with a maximum premium of \$20 per month, almost half of enrollees lost coverage. An analysis of Indiana's Medicaid program also found that nearly 30 percent of enrollees either never enrolled in coverage or were disenrolled from coverage because they failed to make premium payments. 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.⁸

Research has also shown that even relatively low levels of cost-sharing for low-income populations limit the use of necessary healthcare services.⁹ The program's cost sharing requirement for low-income beneficiaries would also have been a significant financial burden for patients. People with CF bear a significant cost burden and out-of-pocket costs can present a barrier to care. According to the above-mentioned survey of people living with CF and their families, while 98 percent of people with CF have some type of health insurance coverage, 58 percent have postponed or skipped necessary medical care or treatments due to cost concerns. Such actions seriously jeopardize the health of people with CF and can lead to costly hospitalizations and fatal lung infections.

Conclusion and Policy Recommendation

We oppose the above-mentioned policies and ask you to reject this waiver application. The Cystic Fibrosis Foundation appreciates your attention to these important issues. As the healthcare landscape continues to evolve, we look forward to working with you to improve the lives of all people with cystic fibrosis. Please consider us a resource moving forward

Sincerely,



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⁸ Lewin Group. Healthy Indiana Plan 2.0: POWER Account Contribution Assessment. March 31, 2017. Retrieved from <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan2/in-healthy-indiana-plan-support-20-POWER-acct-cont-assesmnt-03312017.pdf>

⁹ Samantha Artiga, Petry Ubri, and Julia Zur, "The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings," Kaiser Family Foundation, June 2017. Available at: <https://www.kff.org/medicaid/issue-brief/theeffects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/>