CYSTIC FIBROSIS FOUNDATION®

December 23, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Tennessee *TennCare II Demonstration Amendment 42*

Dear Secretary Azar:

Thank you for the opportunity to comment on Tennessee's Medicaid Waiver Amendment 42. On behalf of more than 700 people with cystic fibrosis (CF) in Tennessee, we write to express our continued concerns regarding several provisions in the proposed waiver amendment application—including the request to change TennCare's funding structure, adopt a closed formulary, reduce federal oversight of TennCare, and divert funds to other initiatives. We oppose this proposal and ask you to reject this application.

Cystic fibrosis (CF) is a life-threatening genetic disease that affects 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-system condition, CF requires targeted, specialized treatment and medications. Many patients follow an extensive daily treatment regimen, 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. If left untreated, infections and exacerbations caused by cystic fibrosis can result in irreversible lung damage and the associated symptoms of CF lead to early death, usually by respiratory failure. Medicaid is a crucial source of coverage for patients with serious and chronic health care needs, including those with CF.

In the TennCare II Demonstration Amendment 42 application, Tennessee proposes drastic changes to TennCare's financing and formulary structure and asks for unilateral authority to alter core elements of the program. These changes could reduce access to care for those with CF enrolled in Medicaid and have a devastating impact on their health and well-being. Therefore, despite the clarifications made by the state, we continue to have serious concerns with this waiver application and urge you to reject this proposal.

Block Grant Funding Model

We have serious concerns 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 intentions to preserve existing benefits, the state 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.

The waiver also contains new financial incentives for Tennessee to reduce program spending. Under the current financing system, Tennessee saves 35 cents in state funds for every dollar it cuts from TennCare. If approved, this demonstration would significantly increase the incentive for the state to cut TennCare funds by allowing Tennessee to also recoup 50 percent of unspent federal funds—saving more than 67 cents for the state for every dollar cut from the program. Tennessee already has the fifth lowest per-person Medicaid spending in the country. We remain concerned that this "shared savings" funding structure, coupled with the proposals we address below, would incentivize the state to further reduce program funding by adding program barriers to enrollment or reducing provider rates.

Beyond our above concerns, we also believe the 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) itself recently acknowledged to North Carolina, we do not believe the state's proposed funding structure is approvable under federal law.[3,4]

We understand that the state is required by Tennessee state statute to submit this waiver, but continue to assert that, under federal statute, CMS is not legally permitted to approve this waiver. We ask the Secretary to adhere to federal statute and reject the request to implement this funding structure.

"Commercial-style" Closed Formulary

Tennessee is also requesting "to adopt a commercial-style 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 protections 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 life-saving, therapies is at stake—the state must provide a much more detailed proposal about how such a process would work.

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[1] Social Security Act § 1115(a)

[2] Hannah Katch, Judith Solomon, and Aviva Aron-Dine, "Tennessee Block Grant Proposal Threatens Care for Medicaid Beneficiaries," Center on Budget and Policy Priorities, September 25, 2019, https://www.cbpp.org/research/health/tennessee-block-grant-proposal-threatens-care-for-medicaid-beneficiaries

[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-medicaid-reform-demo-demo-appvl-20181019.pdf.

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 or is new-to-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.

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 details 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]

Waived Oversight and Elimination of Accountability

Tennessee is also requesting increased program authority to waive federal managed care requirements and modify various program elements without federal approval or public input, which could result in inadequate coverage for people with CF who rely on TennCare. While the CF Foundation recognizes the state's assertion that it would not be permitted to make reductions to the TennCare benefit package, we worry that giving a state unchecked authority to waive managed care requirements and modify these program elements could negatively impact eligibility and access to care.

We are troubled by the state's proposal to waive federal managed care requirements, which set standards for provider network adequacy, access to care, actuarially sound rates, appeals processes, and quality improvement. By waiving federal standards and oversight, the state could unilaterally make changes that would weaken coverage for people with CF who rely on TennCare. For example, if these standards are waived, a managed care organization may limit the number of providers in their network or only contract with specialist in certain regions of the state. For individuals with CF who require regular access to specialists and complex treatments, these limitations could be devastating.

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[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/state-releases/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-masshealth-demo-amndmnt-appvl-jun-2018.pdf.

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

In addition, the state is asking to "modify enrollment processes, service delivery systems, and comparable program elements" without federal approval. The state does not specify the purpose of these modifications. We have serious concerns about giving any state unlimited authority to alter these elements of its Medicaid program without the protection of federal oversight or public input.

Given the additional financial incentives to cut TennCare funding, we worry about the potentially damaging changes the state could make to the program. We therefore reemphasize our position that increased flexibility cannot come at the expense of safeguards for people with complex conditions like CF, and request that you deny the state's request for unilateral authority to make changes without federal review and public comment.

Diverting funds to non-TennCare Initiatives

This waiver application also gives Tennessee the authority to divert Medicaid dollars to fund other health care initiatives that may not specifically assist the TennCare population. This proposal lacks clear details about what projects could be supported with this funding. While we appreciate and support the state's desire to invest in nutritional assistance, rural healthcare transformation, and other initiatives that can improve health outcomes across the state, we are concerned that funding intended for low-income TennCare beneficiaries would shift outside the program. Furthermore, while the state notes several potential areas of priority, it does not limit itself to those specific projects. It is therefore difficult to share fully informed comments on this proposal.

Given the ambiguity of this proposal, we urge you to direct the state to include detailed, comprehensive list of funding priorities and ensure that federal Medicaid dollars are used specifically to support TennCare beneficiaries.

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 health care landscape continues to evolve, we look forward to working with the state of Tennessee to improve the lives of all people with cystic fibrosis. Please consider us a resource moving forward.

Sincerely,

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