



October 18, 2019

Gabe Roberts
Director
Division of TennCare
310 Great Circle Road
Nashville, TN 37243

RE: Tennessee *TennCare II Demonstration Amendment 42 “Block Grant Waiver”*

Dear Director Roberts:

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 serious concerns regarding several provisions in the proposed waiver 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 the proposal to implement block grant funding and ask the state to not submit the proposed waiver provisions not required by state law.

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. Medicaid is a crucial source of coverage for patients with serious and chronic health care needs, including those with CF. Decreased access that could result from funding reductions, benefit restrictions, or other program changes would be devastating to those who rely on high-quality CF care to maintain their health and well-being.

In the TennCare II Demonstration Amendment 42 application, Tennessee proposes drastic changes to the program’s financing, benefit structure, and program safeguards. Given how these changes could impact those with CF in Medicaid, we have serious concerns with this waiver application.

Block Grant Funding Model

We have serious concerns that the block grant funding proposal creates a framework for Tennessee to restrict TennCare funding—both because this model relies on a rigid funding structure that is not responsive to changes in program costs and because the waiver contains incentives for Tennessee to reduce program spending that may have negative consequences for the CF population.

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, the state may not be able to provide the additional funds needed to cover cost increases and may look to cut benefits, eligibility, and/or provider rates. Such threats are particularly acute given the additional flexibilities the state is requesting around benefits and managed care plan oversight, as discussed below. For patients with serious chronic conditions like CF, such cuts could mean Medicaid no longer provides access to their care provider or covers the complex, specialized care they need. Lack of proper care could lead to an



increase in hospitalizations, decrease in lung function, or decrease in Body Mass Index, all dire consequences for someone with cystic fibrosis.

The waiver also contains an incentive for Tennessee to find ways to reduce program spending. Tennessee already has the fifth lowest per-person Medicaid spending in the country. Under the current financing system, Tennessee loses federal funding when it reduces Medicaid spending. This proposal would effectively reverse the incentives for the state by allowing Tennessee to recoup 50 percent of unspent federal funds for every dollar cut from TennCare—creating a financial reward for cutting Medicaid spending. This “shared savings” model encourages the state to maximize savings by cutting benefits or adding program barriers to enrollment.

Beyond our above concerns, we also believe the request for block grant funding 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}

“Commercial-style” Closed Formulary

Tennessee is also requesting the flexibility “to adopt a commercial-style closed formulary with at least one drug available per therapeutic class.” CFF appreciates 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, inappropriate based on the availability of existing data, and could create barriers to life-saving treatments.

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—in which patients’ access to clinically beneficial, sometimes life-saving, therapies is at stake—the state must provide a detailed proposal about how such a process would work.

We also caution the state that cost-effectiveness assessments are limited by the availability and 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

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.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicare-Reform/nc-medicare-reform-demo-demo-appvl-20181019.pdf>.



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 of patients and should not be the sole basis for coverage decisions.

Additionally, 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

State Flexibility and Waived Oversight

Tennessee is also requesting increased program flexibility that could result in reduced benefits and protections for people who rely on TennCare.

Tennessee is seeking new authority to change its TennCare benefits package, including through the addition or elimination of optional benefits and changes in the amount, duration, and scope of covered benefits without federal approval. This flexibility would permit the state to cap services, such as hospitalizations, or limit critical services for only certain individuals. While the state presents this as a way to increase services to some beneficiaries, the flexibility requested by the state could result in abrupt cuts to services for beneficiaries, including people with severe and chronic conditions like CF, without any federal oversight to ensure the program is meeting its core objectives.

We are also concerned with 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. All TennCare beneficiaries, including people with CF, are enrolled in managed care. These safeguards protect their access to services and their ability to appeal treatment denials. For someone with cystic fibrosis who requires access to specialty care centers and complex therapies, these protections are vital. Waiving federal regulations would eliminate core safeguards that ensure people with CF who rely on TennCare are provided with a minimum standard of coverage.

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. 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

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/masshealth-demo-amndmnt-appvl-jun-2018.pdf>.

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



beneficiaries would shift outside the program – resulting in benefit reductions. We therefore urge you to ensure that federal Medicaid dollars are used specifically to support TennCare beneficiaries.

In conclusion, we oppose the above-mentioned policies and ask you to withdraw all proposals in this waiver not required by state law. 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,

Mary B. Dwight

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