CCD

CONSORTIUM FOR CITIZENS
WITH DISABILITIES

December 27, 2019

The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 2020

Dear Secretary Azar:

On behalf of the Consortium for Citizens with Disabilities (CCD) Health Task Force we urge you to reject Tennessee's proposed amendment, known as the TennCare II Demonstration Amendment 42. Tennessee's proposal would fundamentally undermine the Tennessee's Medicaid program by significantly reducing federal oversight and accountability for beneficiary protections. The Health Task Force opposes the conversion of the federal Medicaid program to a block grant, and we oppose the conversion of any portion of Tennessee's TennCare program to a block grant.

The Consortium for Citizens with Disabilities (CCD) is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society. The Health Task Force promotes policies that increase access to health care and promote health, independence and improved functioning. For many people with disabilities, being able to access timely needed health care is a life or death matter.

The Health Task Force has major concerns about the Tennessee proposal. This proposal, like any block grant, is not legally approvable under federal law. Section 1115 of the Social Security Act authorizes the Secretary of Health and Human Services to waive provisions in section 1902 of the Social Security Act, which defines whom states must (and can opt to) cover, what benefits they must (and can opt to) provide, the processes for determining eligibility, various beneficiary protections, and various requirements and options for delivering health care services. The proposal attempts to waive a number of other sections of the Social Security Act that are not allowable including the sections describing Medicaid financing, matching rate, and other sections of the law.

In addition, § 1115 requires the Secretary to ensure that 1115 projects are likely to promote the objective of the Medicaid Act – to provide medical assistance to low-income individuals and families. The proposed radical change to Medicaid financing, along with the requested waivers of key Medicaid beneficiary protections and program integrity measures, would endanger coverage and access to benefits for thousands of Tennesseans with disabilities, and so would not promote the objectives of the Act. For this reason also, Tennessee's proposed block grant may not be approved legally through § 1115 authority.

The Tennessee proposal does not define key terms and lacks a full description of the impact it would have on people with disabilities and other Medicaid beneficiaries. Tennessee seeks a block grant of federal funds and new authority to bypass federal beneficiary protections on how managed care organizations operate, how benefits including prescription drugs are provided, and how beneficiaries enroll. The lack of explanation and vagueness makes it impossible for people with disabilities, their family members, service providers and other stakeholders to determine its full potential impact and effectively comment. The State offers vague promises and repeatedly couches its statements about its "intent" to maintain benefits and enrollment with qualifications that render the promises meaningless. The weak maintenance of effort promise provides no assurances for specific populations and does not specify the mechanism to grow the minimum spending per year.

The state proposes to generate a pool of federal dollars based on the difference between CMS's projection of what a state might spend without a waiver and what the state actually spends on care. This scheme falls well outside the statutory parameters for federal financial participation because the funds would not be tied to actual, specific Medicaid-reimbursable services or administrative activities. Moreover, Tennessee requests permission to remove federal oversight over the state's distribution of these extra funds. This structure reflects bad fiscal policy that invites abuse and threatens to dilute limited Medicaid resources beyond focusing on Medicaid beneficiaries. In its proposal, Tennessee suggests it might use these federal Medicaid funds to cover public health and other activities that target a broader population than eligible Medicaid beneficiaries, so long as some Medicaid beneficiaries might also benefit. Among other problems, this raises several oversight questions, including whether the state will primarily use these funds to shift existing state-funded services, like IMDs and public health, to federal Medicaid funding without meaningfully increasing access to care for Medicaid beneficiaries.

The Health Task Force strongly objects to the potentially devastating changes Tennessee proposes for its Medicaid prescription drug benefit. Allowing TennCare to adopt a commercial-style closed formulary, which may cover only one drug in each therapeutic area, would likely have limited effect on drug pricing, but might have serious consequences for beneficiary health. In many cases, people cannot tolerate or do not benefit from one drug in a therapeutic class, and therefore need an alternative that may be restricted under this new policy. While the state proposes to allow alternatives through an exceptions process, studies have shown that such work arounds are often poorly understood and difficult to access. One survey of Medicaid-enrolled persons with psychiatric disability found that nearly half had been unable to initiate or refill clinically indicated medication prescriptions at least once in the past year, and they were 3.6 times more likely to experience an adverse event.[1] If finalized, this provision—even assuming it were legal (which it is not)--would force many beneficiaries to switch on to the sole medication available per class. Switching medications for non-medical reasons can be greatly destabilizing

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[1] Joyce C. West et al., *Medicaid Prescription Drug Policies and Medication Access and Continuity: Finding from Ten States*, 60 *Psychiatric Services* 601 (2009).

to health. For example, in one study of people with epilepsy, people who had their medication switched had a 16.7% rate of seizure reoccurrence over 6 months, compared to 2.8% among those who were not switched.[2] Especially for conditions like epilepsy where treatment failure can lead to serious health consequences, restricting access to one drug per class is especially dangerous.

Even more egregious, the State requests authority to unilaterally delay covering potentially life-saving new medications "until market prices are consistent with prudent fiscal administration."[3] This would endanger the health and wellbeing of people with disabilities and serious health conditions who rely on broad access to medications. Because many people with disabilities live with relatively rare conditions, new treatments often come with a high price tag. For example, the FDA recently approved a new, potentially life-changing treatment for the 30,000 people who live with cystic fibrosis, but it costs hundreds of thousands per year.[4] Nearly half (45%) of the 30,000 are on Medicaid.[5] Medicaid law requires broad prescription drug coverage precisely to ensure that states cover such new treatments. But Tennessee's proposal seeks permission to unilaterally deny or indefinitely delay coverage for such new treatments in the name of its budget.

Finally, the state also proposes to delay coverage of medications until data on "cost effectiveness" is sufficient. Many cost effectiveness studies today are based on discriminatory Quality-Adjusted Life Year (QALY) calculations, and the amendment does not prohibit using such measures. In 1990, the Bush Administration found QALYs to violate the Americans with Disabilities Act and denied the state of Oregon's request to use QALYs to determine services in Oregon's Medicaid program.[6] The federal government has already determined that QALY-based cost effectiveness measures are discriminatory and violate federal law in a Medicaid context.

Critical beneficiary protections and oversight requirements are threatened by the proposed sweeping waiver of Federal managed care regulations. Tennessee requests waivers from several areas of the regulations, including:

- federal approval of state contracts with managed care organizations (MCOs),
- federal approval of directed payments to providers by MCOs,
- limits on Medicaid payments to IMDs,

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2 Finamore, J.M., Sperling, M.R., Zhan, T., Nei, M., Skidmore, C.T., & Mintzer, S. (2016). Seizure outcome after switching antiepileptic drugs: A matched, prospective study, Epilepsia 57(8), 1294-300. Retrieved from https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13435.

3 TN Proposal, at 15.

4 U.S. Food & Drug Admin., *FDA Approves New Breakthrough Therapy for Cystic Fibrosis* (Oct. 21, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-new-breakthrough-therapy-cystic-fibrosis.

5 Vijaya Iyer, *Disease Worsening, High Healthcare Costs Seen in CF Patients Insured by Medicaid*, Cystic Fibrosis News Today (July 31, 2018), https://cysticfibrosisnewstoday.com/2018/07/31/cf-patients-medicaid-experience-pulmonary-exacerbations-higher-healthcare-costs/.

6New York Times, *Oregon Health Plan is Unfair to the Disabled*, (Sept. 1, 1992), https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html

- federal approval of MCO payment rates to ensure actuarial soundness, and
- reports to CMS that include information on MCOs including their financial performance; beneficiary grievances, appeals, and hearings; access standards; network adequacy; and sanctions.

Many of these provisions were established because of failures in the states to protect the health and civil rights of people with disabilities. Recent updates to the federal Medicaid managed care regulations included numerous new requirements directly related to improving oversight and care quality for managed Long-term Services and Supports (MLTSS) programs used by people with disabilities. These include new network adequacy requirements, quality reporting for HCBS measures, beneficiary support systems, requirements to improve care transitions and care coordination, improvements to provider directories and the accessibility of plan materials, and more. Tennessee's broad, unspecified request would allow it to waive compliance with any or all of these Medicaid managed care requirements. Section 1115 statute permits the Secretary to waive only requirements in section 1902 of the Social Security Act "to the extent and for the period he finds necessary to enable such State or States to carry out such project." Blanket waivers of whole sections of the Medicaid statute may not be approved. Moreover, the statutory authority for these key protections lies outside section 1902. The Secretary lacks authority to approve Tennessee's request.[7]

Tennessee also does not explain why it needs to waive these rules other than stating they are unnecessary and that the state needs "flexibility" to operate within a capped financing structure. But what the state claims are unnecessary requirements are essential program integrity and beneficiary protections that were established to protect the health and civil rights of people with disabilities and waiving them raises serious concerns:

- Without federal approval of state MCO contracts, Tennessee could allow MCOs to significantly restrict access to benefits, such as by failing to require MCOs to ensure their networks provide adequate access to a full range of providers within an appropriate geographic area.
- Without federal limits on Medicaid payments to IMDs, the state could provide payment for extended institutionalization of Medicaid enrollees, in conflict with evidence-based practices, in violation of the rights of enrollees under the *Olmstead v. L.C.* Supreme Court decision, and in conflict with federal law.[8]
- Without federal approval of MCO payment rates to ensure actuarial soundness, TennCare could pay MCOs rates that would not be sufficient to provide the care enrollees need, forcing them to ration care — without the backstop of the other federal requirements that would ensure beneficiary access to care.

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[7] The basis for the managed care regulation is provided in 42 CFR §438.1. Except for a minor provision applying the rules to certain arrangements that don't meet the definition of a managed care organization, which Tennessee doesn't seek to waive, all the rules are based on provisions outside section 1902.

[8] *Olmstead v. L.C.,* 119 S.Ct. 2176, 1999; Social Security Act, § Section 1905(a)(B).

- Without reports to CMS on information on MCOs' performance, CMS would have little information about beneficiary access to care or program integrity, and advocates might lack access to critical data on the efficacy of Tennessee's managed care program

The Health Task Force is concerned that the state is requesting broad but undefined authority to change enrollment processes, service delivery systems, and other changes without the need for an amendment to the demonstration. While the lack of specificity of the proposed changes make it difficult to provide meaningful comments, we are concerned that the state may create administrative burdens that disproportionately affect people with disabilities, making it more difficult for them to enroll and keep their health coverage. Some examples of burdensome provisions include requiring unnecessary paperwork, in-person interviews, and overly frequent redeterminations to maintain eligibility. Because nearly everyone in TennCare, including those in 1915(c) waivers, is covered through managed care, any changes the state implements related to enrollment, benefit design, or quality oversight could affect all Medicaid beneficiaries with disabilities.

We are concerned that the state's request for authority to waive comparability or to forego CMS approval for adding optional benefits or adjusting the amount, duration, or scope of existing benefits could lead to discriminatory benefit design with little or no federal oversight. The state passes these requests off as "routine," but it is not difficult to imagine how adding a benefit with arbitrary limits or restrictions could also lead to discriminatory benefit design or inappropriate levels of amount, duration, and scope. The statute's comparability requirement is partly intended to prevent such discrimination. And though the state claims the current policy framework is "unnecessarily limiting," it notes two paragraphs later that the state "already has significant experience with waivers of comparability."[9] The Secretary regularly grants states waivers to implement pilot projects for targeted benefits. In fact, the state's example, targeted dental coverage, is already part of 1115 demonstrations in several states.[10] However, these requests must be specific and evaluated by the Secretary for experimental value, potential discriminatory effects, and they are subject to oversight and evaluation requirements.

Federal oversight has been critical to protecting people with disabilities because states have not done the right thing for this population. It took the federal Justice Department's lawsuits against the state's Arlington and Cloverbottom Developmental Centers, and ongoing federal oversight, for Tennessee to begin offering community-based services for people with I/DD. The Americans with Disabilities Act (ADA) was and is necessary because states didn't voluntarily make buildings accessible. The Individuals with Disabilities Education Act (IDEA) was and is necessary because states did not see the need to provide a free and appropriate public education to children with disabilities.

Overall the Tennessee proposal establishes a dangerous precedent and undermines Medicaid's program integrity by limiting federal oversight. Allowing the state to operate the program with limited federal oversight and information is particularly threatening to people with disabilities. If harmful or discriminatory policies are implemented by the state, or the managed care

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9 Proposal, at 17.

10 See, e.g., Maryland HealthChoice Waiver.

organizations, there are few avenues to address the issue. The limited public review and comment ensures that people with disabilities, their family members, providers and other advocates have little influence over how policies are developed and whether they will meet their needs.

The Health Task Force urges CMS to reject this dangerous proposal. If you have any questions please contact Rachel Patterson (rpatterson@efa.org).

Sincerely,

The Health Task Force Co-Chairs:

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Epilepsy Foundation

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