



Dec. 27, 2019

Hon. Alex Azar  
Secretary, U.S. Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201

Re: Opposition to Amendment 42 to TennCare Section 1115 Demonstration Waiver

Dear Secretary Azar:

The Bazelon Center for Mental Health Law submits these comments in response to Tennessee’s proposed Amendment 42 to its TennCare Section 1115 Medicaid demonstration waiver. The Bazelon Center is a national non-profit legal advocacy organization that advances the rights of individuals with mental disabilities in all aspects of life, including health care, community living, housing, education, employment, parental and family rights, and other areas.

The proposed amendment would dramatically alter Tennessee’s Medicaid program, creating a federal block grant providing the state with a lump sum of federal dollars rather than federal reimbursement in accordance with the law concerning federal matching rates, and eliminating many aspects of federal oversight. This amendment would place Medicaid beneficiaries’ access to services at serious risk, and we urge you to reject it.

**The Proposal is Procedurally Deficient**

First, Tennessee’s proposed amendment fails to meet transparency requirements. The proposal is extremely vague and fails to meaningfully discuss the potential impact of the proposed amendments on beneficiaries—including eliminating federal protections for managed care enrollees, for the coverage of prescription drugs, and for enrollment, among other things. Indeed, Tennessee states that “it is not the intention of the state to enumerate in detail . . . every innovation, reform, or policy change that might take place over the life of the demonstration” because it should have “a range of autonomy” to make decisions about its Medicaid program.<sup>1</sup> But that is *precisely* what is required in order to meet federal transparency requirements and ensure that the potential impact of the proposal is explored and the public has a meaningful opportunity to comment on proposed changes. As the Government Accountability Office warned earlier this year:

Without a policy with robust transparency requirements for amendment applications with significant impacts, there is the potential that states and CMS will fail to receive meaningful public input on the amendment and thereby lack complete understanding of the impact. As

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<sup>1</sup> Application at 13.

a result, CMS may not be positioned to mitigate any potential risks in the demonstrations being amended or when other states request to test similar policies in the future.<sup>2</sup>

While Tennessee states that its proposed amendment is designed to promote “consumer empowerment and choice,” allowing members “to become better healthcare consumers,” ensuring that members receive “individualized care that is outcomes-oriented and focused on prevention, wellness, recovery, and maintaining independence,” it offers virtually no explanation of how the proposed changes will bring about these outcomes.

We urge you to heed the concerns raised by the GAO about the “limited transparency requirements” applied to states’ applications to amend existing demonstration waivers and its recommendation that CMS subject demonstration amendments that may have significant impact to the full transparency requirements for new demonstrations and extensions.<sup>3</sup> *See also* 42 C.F.R. § 431.412(c)(1) (“If an extension application includes substantial changes to the existing demonstration, CMS may, at its discretion, treat the application as an application for a new demonstration.”).

Tennessee’s proposed amendment would clearly make substantial changes to the existing demonstration and should be required to comply with full transparency requirements. Accordingly, we urge you not to approve the proposed amendment due to the failure to meet basic transparency requirements.

### **HHS Lacks Authority to Approve Tennessee’s Proposal**

HHS lacks the authority to approve this proposal. Section 1115 of the Social Security Act authorizes HHS to waive various provisions of the Social Security Act—specifically, 42 U.S.C. §§ 302, 602, 654, 1202, 1352, 1382, and 1396a. Tennessee’s proposed amendment, however, would require waiver of a number of provisions outside of these waivable provisions. For example, it would require waiver of the formula for the rate at which states draw down federal Medicaid funds set out in 42 U.S.C. § 1396b (due to its proposal to block grant federal funds and to draw down 50 percent of unspent federal funds if its expenditures amount to less than the block grant), protections for coverage of prescription drugs set out in 42 U.S.C. § 1396r-8 (due to its proposal for a closed prescription drug formulary), and the IMD rule set out in 42 U.S.C. § 1396d(a). Waiver of these provisions is not permissible under Section 1115.

In fact, CMS recently acknowledged that it lacks the legal authority to change a state’s federal Medicaid matching rate in a letter to North Carolina, stating:

“Section 1115(a)(i) waiver authority extends only to provisions of section 1902 of the Act, and does not extend to provisions of section 1905 of the Act, such as section 1905(b). Nor is CMS able to grant the state’s request by providing expenditure authority under section 1115(a)(2)(A) of the Act. Section 1115(a)(2)(A) only permits state expenditures to be

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<sup>2</sup> Government Accountability Office, “Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency” GAO 19-315, April 2019, at 24, <https://www.gao.gov/assets/700/698608.pdf>.

<sup>3</sup> *Id.* at 19, 34, <https://www.gao.gov/assets/700/698608.pdf>.

regarded as federally matchable. It does not allow applicable federal match rates to be altered.”<sup>4</sup>

### **Tennessee’s Proposal Would Not Promote the Objectives of Medicaid.**

Tennessee’s proposal would not promote Medicaid’s central objective of providing affordable coverage to low-income people. In fact, the proposal would provide incentives to the state to limit enrollment and benefits. Under Medicaid’s current financing structure, established by federal law, Tennessee receives 65 cents in federal reimbursement for every dollar it spends on allowable services for Medicaid enrollees. As a result, for every dollar the state reduces its Medicaid spending, it saves 35 cents, while the federal government saves 65 cents.

Under the proposal, Tennessee would get a lump sum of federal funds and keep 50 percent of any federal funds under its cap that the state it doesn’t spend. As a result, for every dollar the state reduced Medicaid spending, it would save 67.5 cents — 35 cents of state savings plus 32.5 cents, which is half the 65 cents the federal government would otherwise get back. This change would nearly double the state’s financial reward for cutting Medicaid spending on children, low-income parents, and people with disabilities, whether by shrinking enrollment or by cutting services.

Moreover, under the proposal, Tennessee could use these extra federal funds on anything it claims will improve health. For example, it could use these funds to supplant current state spending on public health or social services — effectively making the funds it saves available for highways or tax cuts. In particular, if the waiver were in place in the next recession or state budget crisis, it would create powerful new incentives and opportunities for Tennessee to balance its budget by cutting TennCare. And, as explained below, the unprecedented authorities Tennessee seeks would make it more likely that Tennessee would undermine coverage.

### **Tennessee’s Proposed Exemption From Federal Managed Care Regulations Would Place Beneficiaries’ Access to Care in Serious Jeopardy**

Tennessee’s request for a sweeping waiver of regulations protecting managed care Medicaid enrollees could have severe consequences for managed care enrollees’ access to services, and in light of Tennessee’s utter failure to explore and address these concerns, this proposal should be rejected. Coming on the heels of the mental health summit in which this Administration professed its concern about ensuring that individuals with psychiatric disabilities have access to the services they need, it would be ironic if HHS were to grant the waiver from managed care regulations sought by Tennessee.

Tennessee requests authority to “operate a managed care program that does not comply with the requirements of 42 [Code of Federal Regulations] Part 438.” Since virtually all of Tennessee’s Medicaid beneficiaries are provided care through a managed care plan, this is an issue of critical importance.

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

Tennessee lists several specific areas of the regulations from which it requests “relief.” The statutory authority for these provisions is outside the provisions that Section 1115 permits to be waived, so the Secretary lacks authority to approve Tennessee’s request.

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

Tennessee offers no explanation of how the requested changes in federal oversight and state accountability for Medicaid funds would affect beneficiaries. Nor does Tennessee explain why it believes that waiver of these rules is important other than stating they are unnecessary and that it wants “flexibility” to operate within a capped financing structure. Far from being unnecessary, these regulations are essential to preserve program integrity and protect beneficiaries:

- 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 with psychiatric disabilities, in conflict with evidence-based practices and in conflict with the Americans with Disabilities Act’s integration mandate and the Supreme Court’s decision in *Olmstead v. L.C.*, 527 U.S. 581 (1999). As noted above, the statutory IMD rule is not waivable, and in any event, Tennessee does not even pretend to comply with the length of stay and community services requirements of CMS’s 2017 and 2018 guidance documents concerning waiver of the IMD rule.
- 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.
- Without reports to CMS on information on MCOs’ performance, CMS would have little information about beneficiary access to care or program integrity.

As a rationale for its proposed exemption from the federal MCO regulations, the state claims, “Tennessee has a demonstrated history of effective administration of its managed care program.” However, Tennessee’s past administration of its managed care program has been mired in abuses and controversy.<sup>5</sup> The comments of the Center on Budget and Policy Priorities, the Georgetown

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<sup>5</sup> Tennessee Justice Center, “Back to the Future: Tennessee’s Experience with Medicaid *MIS*managed Care,” December 12, 2019, <https://www.tnjustice.org/managedcarehistory/>.

University Health Policy Institute's Center for Children and Families and others identify some examples. We also note that Tennessee's systemic failures to provide needed mental health services for children enrolled in TennCare was resolved only through litigation and 15 years of implementing a consent decree (*John B. v. Emkes*).

### **Tennessee's Closed Prescription Drug Formulary Proposal Would Not Promote the Objectives of the Medicaid Program**

As noted above, HHS lacks authority to grant Tennessee's request to institute a closed formulary. In addition, the proposal for a closed formulary would not promote the objectives of the Medicaid program.

Tennessee proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving Section 1927 of the Social Security Act, which requires Medicaid to cover Food and Drug Administration (FDA) approved drugs (subject to certain conditions and exclusions) if the manufacturer of such drugs has signed an agreement to pay rebates (i.e. discounts). Under current law, Tennessee can impose preferred drug lists that require prior authorization before a prescription drug may be covered under Medicaid. But except for certain classes of drugs that states may exclude, states are barred from imposing a fully "closed" formulary under which drugs cannot be covered under any circumstance.

Tennessee's proposal would allow the state to exclude FDA-approved drugs entirely "until market prices are consistent with prudent fiscal administration or the state determines that sufficient data exist regarding the cost effectiveness of the drug." The state would only have to offer just one drug per therapeutic class. Tennessee's proposal closely resembles a 2017 Massachusetts proposal to establish a closed formulary in its Medicaid program, which CMS rejected in 2018.<sup>6</sup>

The proposed closed formulary threatens to significantly restrict Medicaid beneficiaries' access to needed prescription drugs. Like the Massachusetts waiver proposal that CMS rejected, Tennessee's proposal would allow it to deny coverage of a clinical breakthrough drug solely because of cost, and not just in the case of low-value drugs that aren't more clinically effective than existing lower-cost drugs. The proposal states that "Tennessee is committed to ensuring that its Medicaid beneficiaries have access to needed medications," and now includes an exceptions process to cover off-formulary drugs when medically necessary. But the waiver provides no detail about when the clinical needs of a patient would justify access to drugs excluded from the formulary and thus it's unclear how meaningful this exceptions process will be. (The waiver only states that the procedures for seeking an exemption would be like the existing prior authorization process for non-preferred drugs).

A closed formulary is also particularly problematic for individuals with psychiatric disabilities. There are unique challenges in finding psychiatric medications that work effectively for any particular individual; even when individuals do find medications and dosages that are effective for them, that process frequently takes years. In addition, the serious side effects experienced by many

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



individuals taking psychiatric drugs make it difficult to find a medication that an individual will find acceptable. A closed formulary will make it far less likely that individuals will find psychiatric medications that work.

### **The Proposed Amendment Includes Additional Proposals Likely to Weaken Coverage**

Tennessee proposes unprecedented authority in two additional areas that would weaken accountability and expose beneficiaries to unnecessary risk: (1) it requests broad, undefined authority to “modify enrollment processes, service delivery systems, and comparable program elements without the need for a demonstration amendment,” and (2) it requests authority to add benefits without going through the federal process, which ensures that benefits are provided statewide, are of sufficient amount, duration or scope, and aren’t provided in a way that discriminates based on a person’s illness or diagnosis. The state does not identify the statutory source of authority for these requests or provide sufficient information to understand its intent and the full implications of these requests. Without additional information about the authorities requested and scope of changes the state proposes, it is impossible to comment on the amendment’s implications for beneficiaries, program integrity, or legality. HHS should not approve these requests absent additional information and a meaningful opportunity to provide public comment.

For the reasons above, we urge you to reject Tennessee’s proposed amendment.

Sincerely,

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