

December 23, 2019

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

Dear Secretary Azar:

The undersigned organizations appreciate the opportunity to comment on Tennessee's proposed amendment to its section 1115 demonstration project, known as the TennCare II Demonstration. Tennessee's proposal would fundamentally transform Tennessee's Medicaid program by giving Tennessee a lump sum of federal dollars with significantly reduced federal oversight and accountability for beneficiary protections. *We strongly urge you to reject the proposal in its entirety.*

Tennessee's submission has serious procedural flaws, which should have led you to return it to Tennessee as incomplete. First, the proposal should not be treated as an amendment but a new proposal subject to full transparency requirements. In April, the Government Accountability Office (GAO) issued a report finding weaknesses in your policies for ensuring transparency of proposals for Medicaid demonstrations, including the failure to explore the full impact of amendments to existing demonstrations.¹ *This proposal, which would radically change the financing and federal oversight of Tennessee's Medicaid program, wouldn't just amend Tennessee's program but would completely overhaul its operations.* Treating it as an amendment ignores the GAO's findings and recommendations for adherence to Medicaid transparency requirement. Any overhaul of this magnitude should not be considered as an amendment to an existing waiver.

Second, the proposal is vague and lacks a full description of the impact it would have on 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. Yet the proposal fails to fully explain how Tennessee plans to use this new authority, making it impossible for stakeholders to determine its full potential impact and effectively comment.

Approval of Tennessee's Proposal for a Lump Sum Payment of Federal Funds Would Violate Federal Law

Tennessee's proposal would radically change its Medicaid program:

- Tennessee would receive a lump sum of federal funds based on the state's projected costs of covering children, parents and people with disabilities without its waiver ("without waiver" costs). The lump sum would increase if enrollment rose above its 2016-2018 average — but would not decrease if enrollment fell.
- If Tennessee spends less than the capped lump sum, it would keep half the unspent federal funds. If costs exceed the capped amount, Tennessee would be responsible for the full excess.

¹ Government Accountability Office, "Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency" GAO 19-315, April 2019, <https://www.gao.gov/assets/700/698608.pdf>

- Tennessee could spend at least a portion of federal Medicaid funds on anything that the state determines would improve beneficiaries' health, which could include social services or public health infrastructure that the state already funds with state dollars.

Tennessee's proposal, like any block grant, is not 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.

Altering Medicaid's financing structure, including the formula that sets out the rate at which states draw down federal Medicaid funds, requires a waiver of a provision in section 1903 of the Social Security Act, which governs how Medicaid is financed. Section 1115 does not give the Secretary authority to waive section 1903, so giving Tennessee a lump sum of federal funds isn't allowable.

Moreover, Tennessee proposes to draw down 50 percent of unspent federal funds if its expenditures amount to less than the block grant, which is based on its projected "without waiver" costs. Tennessee has always spent considerably less than its "without waiver" projections, so Tennessee is certain to receive more federal funds than it would receive under current law, thereby effectively increasing its federal matching rate.

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 regarded as federally matchable. *It does not allow applicable federal match rates to be altered.*"² [emphasis added]

The TennCare 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

² 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>.

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. That means 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 Threaten Beneficiary Access to Care

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.

Tennessee lists several specific areas of the regulations from which it requests “relief.” The statutory authority for these provisions is outside section 1902, so the Secretary lacks authority to approve Tennessee’s request.³

- 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,
- 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 fails to explain how any changes in federal oversight and state accountability for Medicaid funds would affect beneficiaries. 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 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

³ 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.

practices, in violation of the rights of enrollees under the *Olmstead v. L.C.* Supreme Court decision, and in conflict with federal law.⁴

- 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.⁵ For example:

- In 1999, Xantus Healthplan, an MCO operating under TennCare, was placed into receivership and was believed to owe \$87 million to health care providers.⁶
- In 2000, Access MedPlus, TennCare’s second largest MCO, was placed under administrative supervision after failing to meet payment requirements.⁷
- In 2001, a lawsuit was filed citing irreparable harm after Access MedPlus enrollees died or were denied essential care due to an inadequate provider network.⁸
- Meanwhile, these plans fell behind in their provider payments, and a federal court ordered the state to create an emergency process to provide care to Medicaid enrollees who were unable to access care through their MCO. It was only a few months until the emergency plan went bankrupt and left \$100 million in unpaid claims to providers.⁹
- In 2008, a state senator was found guilty of receiving more than \$800,000 in kickbacks from TennCare contractors.¹⁰

⁴ *Olmstead v. L.C.*, 119 S.Ct. 2176, 1999; Social Security Act, § Section 1902(a)(29)(B).

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

⁶ Tennessee State Government, Division of TennCare, “TennCare Timeline,” <https://www.tn.gov/tenncare/information-statistics/tenncare-timeline.html>; see also Bill Carey, “Taxpayers May Dish Out \$20 Million More for Xantus Creditors,” Nashville Post, June 9, 2000, <https://www.nashvillepost.com/home/article/20446965/taxpayers-may-dish-out-20-million-more-for-xantus-creditors>.

⁷ John Commins, “Access MedPlus Put Under Supervision,” Nashville Bureau, May 11, 2000, <https://web.archive.org/web/20000620001532/http://www.timesfreepress.com/2000/MAY/11MAY00/NEWSACC01.html>

⁸ *Grier v. Neel*, United States District Court for the Middle District of Tennessee, Nashville Division, June 20, 2001, <https://www.tnjustice.org/wp-content/uploads/2019/12/760-Memorandum-and-Order-6-21-01.pdf>

⁹ Tennessee Justice Center 2019, *op cit*.

¹⁰ The Associated Press, “Testimony Ends in Ford Corruption Trial,” WMC5 Action News, July 16, 2008, <https://www.wmcactionnews5.com/story/8685046/testimony-ends-in-ford-corruption-trial/>; see also The Associated Press, “Tennessee: Ex-Lawmaker Guilty,” New York Times, July 19, 2008, <https://www.nytimes.com/2008/07/19/us/19brfs-003.html?partner=rssnyt&emc=rss>

Tennessee’s Closed Prescription Drug Formulary Proposal Would Not Promote the Objectives of the Medicaid Program

Tennessee proposes an unprecedented change to Medicaid coverage of prescription drugs by waiving the requirement that the state comply with 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 2018.¹¹

Section 1927 is not waivable under Section 1115.¹² Moreover, Section 1115 gives the Secretary authority to waive sections of the statute for demonstration projects that are “likely to assist in promoting the objectives of [Medicaid].” Tennessee does not explain how its proposal would promote the objectives of the Medicaid program, such as by expanding coverage or access to care.

The proposed closed formulary threatens to significantly restrict Medicaid beneficiaries’ access to needed prescription drugs. Like the Massachusetts waiver proposal that CMS rejected, there is a significant risk that Tennessee could use this authority to deny coverage of a clinical breakthrough drug solely because of cost, 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 does not provide any 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).

The Proposed Amendment Includes Additional Proposals Likely to Weaken Coverage

Tennessee proposes unprecedented authority in two additional areas which would weaken accountability and that are likely to expose beneficiaries to unnecessary risk.

First, the state requests broad, undefined authority to “modify enrollment processes, service delivery systems, and comparable program elements without the need for a demonstration amendment.” The state does not define the statutory source of the authority it 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.

¹¹ 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>.

¹² *PhRMA .v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).

However, each of these areas of program administration have essential, clearly defined federal requirements to ensure beneficiaries are protected and federal funds are used appropriately. For example, federal requirements do not permit states to make Medicaid enrollment or renewal burdensome for beneficiaries in specific respects, such as requiring unnecessary paperwork, in-person interviews, or overly frequent redeterminations. As noted above, the federal government has clear requirements for the ways in which state Medicaid programs deliver health care services, including broad requirements for Medicaid managed care administration. The state's proposal is not clear whether it is seeking authority to change any of these or similar aspects of its Medicaid requirements — which could threaten access to care for TennCare enrollees.

Second, the proposal would allow the state to add benefits without going through the federal approval 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. For example, Tennessee could favor certain providers through geographic restrictions on benefits or put arbitrary limits on the benefits it decides to provide.

Conclusion

All in all, Tennessee's proposal seeks significantly more federal funds with significantly less federal oversight and accountability. Approval of Tennessee's proposal would leave 1.4 million Tennessee Medicaid beneficiaries at risk of losing benefits, consumer protections, and even coverage. Section 1115 doesn't give the Secretary authority to pay states more for doing less to ensure people eligible for Medicaid get the care they need.

Our comments include numerous citations to supporting research, including direct links to the research for HHS' benefit in reviewing our comments. We direct HHS to each of the studies cited and made available to the agency through active hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the administrative record in this matter for purposes of the Administrative Procedure Act.

Thank you for your willingness to consider our comments. If you need additional information, please contact Judy Solomon (Solomon@cbpp.org) or Joan Alker (jca25@georgetown.edu).

American Art Therapy Association
American Federation of Labor and Congress of Industrial Organizations
American Federation of State, County, & Municipal Employees
Autistic Self Advocacy Network
Center on Budget and Policy Priorities
Children's Defense Fund
Community Catalyst
Epilepsy Foundation
Families USA
Family Voices
First Focus on Children
Georgetown University Center for Children and Families
Legal Action Center
March of Dimes
Mental Health America
National Alliance on Mental Illness
National Association of Pediatric Nurse Practitioners

National Association of Social Workers
National Employment Law Project
National Family Planning & Reproductive Health Association
National Health Care for the Homeless Council
National Multiple Sclerosis Society
Professor Pamela Herd, Professor of Public Policy, Georgetown University
Raising Women's Voices for the Health Care We Need
Service Employees International Union