



December 18, 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 submit comments on Tennessee's TennCare II Demonstration Amendment 42.

The undersigned organizations represent millions of individuals facing serious, acute and chronic health conditions across the country. Our organizations have a unique perspective on what individuals need to prevent disease, cure illness and manage chronic health conditions. The diversity of our groups and the patients and consumers we represent enables us to draw upon a wealth of knowledge and expertise and serve as an invaluable resource regarding any decisions affecting the Medicaid program and the people that it serves. We urge the Department of Health and Human Services (HHS) to make the best use of the recommendations, knowledge and experience our organizations offer here.

The purpose of the Medicaid program is to provide healthcare coverage for low-income individuals and families, and our organizations are committed to ensuring that CMS and Tennessee provide adequate, affordable and accessible healthcare coverage through the TennCare program. Unfortunately, our organizations fear that by changing the financing structure of TennCare to a block grant, the state will jeopardize access to quality and affordable care for patients with serious and chronic health conditions. The block grant will include vulnerable eligibility groups such as children and people with disabilities and requests unprecedented changes that could make it harder for patients to get the treatments and services that they need. Our organizations urge you to reject the waiver and offer the following comments on specific aspects of the proposal.

Block Grant Structure

Our organizations remain extremely concerned with the lack of detail in Tennessee's block grant proposal. Such a drastic change in Tennessee's Medicaid program will undoubtedly have a dramatic impact on patients, but without additional details, it is difficult for our organizations to fully comment on all of the possible impacts of a block grant and the waiver's additional requests on the patients we represent.

However, even based on the limited information available, it is clear that Tennessee's block grant could reduce access to quality and affordable healthcare for patients with serious and chronic health conditions by preventing the state from accessing matching federal funds. Furthermore, the financing structure proposed by Tennessee will not protect either the state or patients from financial risk. For example, the per capita adjustments to the block grant will not be sufficient to address increases in per person healthcare costs. There are many ground-breaking treatments in development for patients with serious and chronic illnesses. If an expensive but highly effective treatment became available to treat or even cure one of these illnesses, Tennessee's spending could rise, creating an incentive for the state to impose additional barriers for that treatment. Additionally, a public health crisis like the opioid epidemic or an infectious disease outbreak could greatly increase healthcare costs above Tennessee's projections. Similarly, a natural disaster such as a hurricane or wildfire would likely increase the need for medical care – including costly services like emergency room visits and hospitalizations – again driving up Tennessee's spending and again putting treatments and services for patients at risk.

Tennessee may also choose to cut payments to providers to help control spending under the new block grant. Our organizations are concerned that these cuts could affect provider participation in the program and make it harder for patients – who rely on prompt access to primary care providers as well as specialists – to get appointments with providers who can help them find the best treatments and manage their conditions. As the gap between the block grant and actual costs of patient care increases over time, the pressure on Tennessee to limit enrollment, reduce benefits or increase cost-sharing for patients will only increase. These cuts are unacceptable for our patients.

While the waiver does include a brief maintenance of effort proposal regarding the state's financial contribution towards the block grant, our organizations are concerned that this vague pledge will not ensure that current and future administrations commit adequate funding for the healthcare needs of patients in the TennCare program. Since the state is also requesting authority to use Medicaid funding for other initiatives related to public health, social determinants of health and rural healthcare, it would be able to meet this requirement by counting spending on other programs and still cut its spending on traditional TennCare expenses. Additionally, the proposal does not specify the growth rate for the state's share of the funding. If the growth falls below the growth in healthcare costs, the TennCare program will face even greater pressures to cut benefits and services for patients.

Finally, changing TennCare to a block grant through the 1115 waiver process is illegal. The Secretary of Health and Human Services does not have the authority to waive Sections 1903 and 1905, where the financing structure of the Medicaid program is located, through these types of waivers, as multiple experts have noted.^{1,2} Such a change would require congressional authority, yet Congress has repeatedly declined to pass legislation on this issue, most recently during the debate over repealing and replacing the Affordable Care Act in 2017.

Additional Waiver Requests

Tennessee has requested broad and unprecedented changes as part of its move to a block grant financing structure. Again, many of these requests are incredibly vague and will not advance the goal of furnishing coverage in the Medicaid program, instead making it harder for patients to access the treatments and services they need.

Managed Care Changes

Tennessee is asking to be exempt from federal standards and requirements for its managed care program, including the managed care rule. This important safeguard helps to ensure that Medicaid Managed Care Organizations (MCOs) meet certain requirements related to patient care. Patient struggles to access care through managed care organizations have been well documented in several states, including Iowa,³ Kansas⁴ and Texas.⁵ This rule is especially important in Tennessee, where 100 percent of beneficiaries receive their care through MCOs.

The managed care rule sets standards related to adequate networks, so patients can actually see the appropriate providers and receive the care they need. Without these federal requirements, an MCO could limit the number of specialists in its network or only contract with specialists in one part of the state. For a patient with a serious health condition, this could be fatal. Additionally, the managed care rule also sets standards about MCOs' communications with enrollees, ensuring that provider directories are updated regularly and that information is accessible for individuals with limited English proficiency and disabilities. If CMS permits Tennessee to waive compliance with these standards, it is unclear whether adequate protections will be left in place for patients to help them access the care they need. These are just some examples of the many important safeguards protecting patients' access to care in MCOs that are in jeopardy under Tennessee's proposal.

Amount, Duration and Scope Changes

Tennessee is also asking to change the "amount, duration, and scope" of benefits, which could allow the state to put caps on services or only cover critical services for certain individuals. Such broad authority to make these types of changes to critical benefits could negatively impact patient care and outcomes. For example, TennCare could limit the number of doctor's visits per year for certain patients. For patients with serious or chronic conditions, this would be unacceptable. While the state claims that "it is not its intent under this proposal to reduce covered benefits for members below their current level," this ambiguous statement – in combination with the broad waivers the state continues to request – is not sufficient to ensure that current or future administrations will not make changes to benefits that could harm our patients.⁶ In reality, the financial pressures of a block grant would increasingly incentivize the state to roll back benefits and jeopardize patients' access to care.

In previous situations where Tennessee was under pressure to cut its budget, patients' coverage and access to services were in fact jeopardized. In 2005, Tennessee changed its eligibility rules to disenroll 170,000 individuals from its Medicaid program due to budgetary pressures, one of only two states to ever go through a large-scale disenrollment of this nature.⁷ Subsequent research found that after this loss of coverage, individuals' self-reported health and access to care declined, visits to doctors and dentists decreased and the use of public and free clinics increased.⁸ Additionally, earlier this year, the Tennessee Department of Health proposed to cut an HIV screening program and a program that pays for medications for patients with hemophilia and renal failure in response to pressure to cut two percent from its budget.^{9,10} Our organizations are particularly concerned about the changes the state might make with the requested authority given this troubling track record.

Prescription Drug Access

Our organizations oppose the proposal to create a closed formulary with as few as one drug per class and exclude prescription drugs approved through the Food and Drug Administration's (FDA) accelerated approval process. Limiting access to medications will be detrimental to our patients.

Diseases present differently in different patients. Prescription drugs have different indications, different mechanisms of action and different side effects, depending on the person's diagnosis and comorbidities. A closed formulary would limit the ability of providers to make the best medical decisions for the care of their patients, effectively taking the clinical care decisions away from the doctor and patient and giving them to the state. Additionally, as a result of new breakthroughs in treatment, physicians are increasingly testing patients for biomarkers to help match patients to medications such as targeted therapies or immunotherapies which may result in better outcomes. However, medications that treat patients with different characteristics might still be in the same medication class. A robust, open formulary needs to be part of TennCare so that patients can benefit from these advancements and access the treatments their doctor believes are best for them.

Allowing TennCare to exclude prescription drugs approved through FDA's accelerated processes will also harm patients by restricting access to novel and lifesaving therapies. In the past few years, many new treatments have been approved through an accelerated approval process that benefit patients. For example, cancer treatments have been approved that target specific tumor mutations or provide options for patients who did not respond to their first- or second-line treatment. All patients enrolled in TennCare should have the opportunity to access treatments that could extend or improve their quality of life.

While TennCare has stated that there will be an exceptions process for medically necessary drugs that are not included in the formulary, the proposal remains vague and fails to include important details about the how long the appeal process would take or what beneficiaries would be required to do through the appeals process. Research shows that administrative hurdles such as prior authorization for drugs can lead patients to delay or abandon treatment altogether.¹¹ For a patient with a serious or chronic health condition, a pause or delay in treatment could result in their disease worsening irreversibly.

Finally, Tennessee's proposal makes a number of comparisons to the commercial market and the tools that it uses to control prescription drug costs. The Medicaid population does not have the luxury of shopping around for health plans, unlike participants in the commercial insurance market. As a result, commercial insurance tools are completely inappropriate for this population. Instead, the TennCare program already has access to the Medicaid Drug Rebate Program – which lowered Medicaid prescription drug costs for the federal and state governments by 51.3 percent in 2016 – to help control its prescription drug costs.¹²

Healthcare Spending

Tennessee's proposal includes a request to use Medicaid funding for other public health initiatives and investments in rural healthcare, which may not be targeted at TennCare enrollees. While our organizations support efforts to address social determinants of health and improve access to care in rural areas, we are concerned about diverting funding that should be spent on healthcare services for patients to these other worthy goals. Again, the financial pressures of a block grant could incentivize the state to use TennCare funding to fill in other holes in its budget and ultimately reduce access to treatments and services for the patients we represent.

Fraud

Tennessee also requests authority to lock out individuals convicted of fraud from the Medicaid program for up to 12 months. While our organizations support the goal of reducing fraud in healthcare programs, we oppose lock outs as they would jeopardize access to care for patients with serious, acute and chronic health conditions. People who are in the middle of treatment for a life-threatening disease, rely on regular visits with healthcare providers or must take daily medications to manage their chronic conditions cannot afford a sudden gap in their care – physically or financially. The state has provided no detail in its application regarding whether there will be an appeals process and if so, how challenging it will be for patients to make an appeal if they need immediate access to treatments and services. We therefore have serious concerns about how this proposal would impact our patients’ access to care.

Additional Changes

Finally, Tennessee has asked for authority to change “enrollment processes, service delivery systems and comparable program elements” without seeking additional CMS approvals in the future. Again, these requests lack any detail and yet could make it harder for patients to get the treatments and services they need. For example, changes in enrollment and eligibility systems in Tennessee have recently led to a major loss of coverage through the state’s Medicaid program.¹³ As a result, the uninsured rate for children rose more rapidly in Tennessee in 2018 than in any other state.¹⁴ The changes requested by Tennessee could have a similarly devastating impact on coverage for the patients we represent.

Alternative Approaches

If Tennessee is truly concerned about containing costs while making TennCare a “stronger and more effective program”, the state could submit a state plan amendment to fully expand Medicaid to 138 percent of the federal poverty level and receive a 90 percent match from the federal government for all expenses for the adult expansion population. This policy would both benefit the state financially and extend access to care to more low-income individuals in need of coverage, a core objective of the Medicaid program.

Tennessee has included a list of examples in which the state could improve care using block grant funding under this waiver. These include covering additional needy individuals, increasing programs available to individuals with disabilities, promoting tobacco cessation and addressing the opioid epidemic. However, the state has not made any actual, concrete requests related to these goals in its application. Again, the best way for Tennessee to both extend coverage to more people and include more benefits for enrollees while bringing in more federal dollars is to fully expand Medicaid under the Affordable Care Act.

Medicaid expansion helps patients with serious and chronic illnesses access the comprehensive healthcare coverage that they need to manage their conditions and stay healthy. This coverage includes essential health benefits like emergency care, hospitalizations and prescription drugs. Individuals also receive access to important preventive services like tobacco cessation treatment and cancer screenings at no cost.

The evidence is clear that Medicaid expansion has important health benefits for patients and consumers.¹⁵ For example, research has found an association between Medicaid expansion and early stage cancer diagnosis, when cancer is often more treatable.¹⁶ Medicaid expansion states have experienced increased utilization of prescription drugs, especially for patients with diabetes and cardiovascular disease.¹⁷ This will help patients manage their conditions and avoid more expensive care

in emergency departments and hospital settings. Another study found that Medicaid expansion is associated with a reduction in preventable hospitalizations for patients with respiratory conditions, diabetes complications and bacterial pneumonia.¹⁸ Medicaid expansion is associated with improvements in quality measures, including those for asthma management, BMI assessment and hypertension control, at federally qualified health centers, critical healthcare providers for low-income patients.¹⁹ Another notable study showed Medicaid enrollees in Medicaid expansion states are utilizing tobacco cessation treatment at a higher rate than their peers in non-expansion states.²⁰ Medicaid expansion is also playing an important role in addressing health disparities; one recent study found that states that expanded Medicaid under the ACA eliminated racial disparities in timely treatment for cancer patients.²¹

Medicaid expansion also improves the financial well-being of individuals and communities. An evaluation of Medicaid expansion in Ohio found that enrollees are less likely to have medical debt than their non-enrolled counterparts.²² Additionally, Medicaid expansion has helped state economies and has been associated with a reduced risk of hospital closures, especially in rural areas.²³ Once again, our organizations strongly believe that the best way to both furnish coverage to more people and improve the fiscal sustainability of the state's Medicaid program is for Tennessee to expand Medicaid.

Other Issues

Both by eliminating review requirements for future changes in benefits and services and by requesting to make this demonstration permanent, the state is proposing to remove important opportunities for the public to provide feedback on how TennCare is working for key stakeholders before any policies are implemented or continued. It is especially important that beneficiaries impacted by the demonstration waiver continue to have the ability to provide feedback to the state and CMS. TennCare is a joint venture between Tennessee and CMS. Both entities, as well as the people it serves, deserve a voice in how the program is administered.

Tennessee has also failed to provide a complete budget neutrality estimate with details of the projected changes in spending with the waiver and any impact on coverage. The federal rules at 431.408 pertaining to state public comment process require at (a)(1)(i)(C) that a state include an estimate of the expected increase or decrease in annual enrollment and expenditures if applicable. The intent of this regulation is to allow the public to comment on a Section 1115 proposal with adequate information to assess its impact. Given that this waiver represents a fundamental change to Tennessee's demonstration, CMS should require the state to include these projections and their impact on budget neutrality provisions.

The core objective of the Medicaid program is to furnish healthcare to low-income and needy populations. This waiver does not further that goal and our organizations strongly oppose this proposal. Thank you for the opportunity to provide comments.

Sincerely,

American Lung Association
American Kidney Fund
Chronic Disease Coalition
Crohn's & Colitis Foundation
Epilepsy Foundation
Family Voices
Hemophilia Federation of America

Leukemia & Lymphoma Society
Lutheran Services in America
March of Dimes
National Alliance on Mental Illness (NAMI)
National Health Council
National Hemophilia Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Patient Advocate Foundation
Susan G. Komen

¹ Joan Alker. Pending CMS Guidance on Medicaid Block Grants: Executive Overreach Strikes Again. Georgetown University Center for Children and Families. June 27, 2019. Available at: <https://ccf.georgetown.edu/2019/06/27/pending-cms-guidance-on-medicaid-block-grants-executive-overreach-strikes-again/>.

² Nicholas Bagley. Tennessee wants to block grant Medicaid, Is that legal? The Incidental Economist. Sept. 17, 2019. Available at: <https://theincidentaleconomist.com/wordpress/tennessee-wants-to-block-grant-medicaid-is-that-legal/>.

³ Tony Leys and Stephen Gruber-Miller. (2019) 'Iowa agrees to give Medicaid management companies 8.6% raises', *Des Moines Register*. 10 July. Accessed at: <https://www.desmoinesregister.com/story/news/health/2019/07/10/iowa-medicaid-privatization-managed-care-companies-amerigroup-centene-iowa-total-care-mcos-increase/1691928001/>

⁴ Karen Henry. *KanCare enrollees with mental illness report gaps in Medicaid managed care program*. September 20, 2019. The University of Kansas. Accessed at: <https://news.ku.edu/2017/09/20/kancare-enrollees-mental-illness-report-gaps-medicaid-managed-care-program>

⁵ J. David McSwane and Andrew Chavez. (2018) 'Managed-care companies overstate the number of physicians available to treat the state's sickest patients', *Dallas News*. 4 June. Accessed at: <https://interactives.dallasnews.com/2018/pain-and-profit/part3.html>

⁶ Sara Rosenbaum, Alexander Somodevilla, Morgan Handley and Rebecca Morris. "Inside Tennessee's Final 1115 Medicaid Block Grant Proposal." (December 6, 2019). Health Affairs Blog. Accessed at: <https://www.healthaffairs.org/doi/10.1377/hblog20191205.927228/full/>

⁷ Melinda B. Buntin, Ph.D. "Tennessee's Opening Bid for a Medicaid Block Grant." (October 31, 2019) *New England Journal of Medicine*. Accessed at: <https://www.nejm.org/doi/full/10.1056/NEJMp1913356?query=TOC>

⁸ Thomas DeLeire, "The Effect of Disenrollment from Medicaid on Employment, Insurance Coverage, Health and health Care Utilization," (August 2018). NBER Working Paper No. 24899. Accessed at: <https://www.nber.org/papers/w24899>

⁹ Stephen Elliot, "Lee de-emphasizes service cuts as he considers health budget," (January 30, 2019) *The Nashville Post*. Accessed at: <https://www.nashvillepost.com/politics/state-government/article/21045321/lee-deemphasizes-service-cuts-as-he-considers-health-budget>

¹⁰ Brett Kelman, "Tennessee mulls cutting medication support for renal failure, hemophilia," (January 29, 2019). *The Tennessean*. Accessed at: <https://www.tennessean.com/story/news/2019/01/29/tennessee-health-department-medication-coverage-state-budget-cuts/2712961002/>

¹¹ The American Medical Association, "2017 AMA Prior Authorization Physician Survey." Accessed at: <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf>

¹² Medicaid and CHIP Payment and Access Commission, "MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016," December 2017. Accessed at: <https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/>.

¹³ Brett Kelman and Mike Reicher. At least 220,000 Tennessee kids faced loss of health insurance due to lacking paperwork. *The Tennessean*. July 14, 2019. Available at <https://www.tennessean.com/story/news/investigations/2019/07/14/tenncare-coverkids-medicaid-children-application-insurance-denied/1387769001/>.

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- ²¹ American Society of Clinical Oncology, "Racial Disparities in Access to Timely Cancer Treatment Nearly Eliminated in States with Medicaid Expansion." American Society of Clinical Oncology Annual Meeting. June 2, 2019. Access at: <https://www.asco.org/about-asco/press-center/news-releases/racial-disparities-access-timely-cancer-treatment-nearly>
- ²² Ohio Department of Medicaid, *2018 Ohio Medicaid Group VII Assessment: Follow-Up to the 2016 Ohio Medicaid Group VIII Assessment*, August 2018. Accessed at: <http://medicaid.ohio.gov/Portals/0/Resources/Reports/Annual/Group-VIII-Final-Report.pdf>.
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