AMERICAN LUNG ASSOCIATION.

National President and CEO
Harold P. Wimmer

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 American Lung Association is the oldest voluntary public health association in the United States, currently representing the 35 million Americans living with lung diseases including asthma, lung cancer and COPD. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

The purpose of the Medicaid program is to provide healthcare coverage for low-income individuals and families. The American Lung Association is committed to ensuring that TennCare provides adequate, affordable and accessible healthcare coverage. Unfortunately, this waiver proposal will jeopardize patients' access to quality, affordable healthcare. The Lung Association opposes Tennessee's proposal and offers the following comments.

Block Grant Structure

The Lung Association opposes Tennessee's proposal to change the financing structure for its Medicaid program to a block grant. The Lung Association fears that the state will cut coverage for certain treatments

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completely or impose additional barriers to important services, making it more difficult for patients to access the care that they need.

Tennessee's proposal would include vulnerable eligibility groups such as children and people with disabilities in the block grant. This includes children with asthma and pregnant women who are trying to quit smoking. The Lung Association has serious concerns about how including these populations in the block grant will impact their care. All individuals in the TennCare program need comprehensive, quality healthcare coverage, and the financial pressures of a block grant would threaten access to this type of care.

For example, Tennessee may choose to cut payments to providers to help control spending under the new block grant. The Lung Association is concerned that these cuts could affect provider participation and make it harder for patients with lung disease – who rely on prompt access to primary care providers as well as specialists like pulmonologists and oncologists – 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.

Tennessee's proposed financing structure will not protect either the state or patients from financial risk. The per capita adjustments to the block grant will not be sufficient if an unexpected event, such as a public health crisis or natural disaster, increases per person healthcare costs. For example, there are many ground-breaking treatments in development for patients with serious and chronic illnesses. If an expensive but highly effective treatment became available, Tennessee's spending could rise, putting the state's budget at risk and creating an incentive for the state to impose additional barriers for that treatment.

While the waiver does include a brief maintenance of effort proposal regarding the state's financial contribution towards the block grant, the Lung Association is concerned that this structure 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 health-related programs and could 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. , 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.

Prescription Drugs

The Lung Association opposes 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 lung disease patients.

Diseases, including lung disease, 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.

The proposed closed formulary would compromise access to evidence-based care for lung disease patients. For example, an asthma patient may need multiple drugs in one class to control their symptoms. The National Asthma Education and Prevention Program (NAEPP) Guidelines for treating asthma discuss treatment as part of the stepwise approach. Depending on the severity of the patient's asthma, different medications are recommended and, in some cases, multiple medications are recommended. If the policy in the waiver was implemented, some asthma patients would not be able to access the medications they need to manage their condition.

This proposal would also harm lung cancer patients. As a result of new breakthroughs in treatment for lung cancer, physicians are increasingly testing tumors for biomarkers to help match patients to medications such as targeted therapies or immunotherapies which may result in better outcomes. However, medications that treat tumors with different characteristics might still be in the same medication class. In order to effectively treat patients, a robust, open formulary needs to

be part of the Medicaid program 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 two years, several new treatments have been approved through an accelerated approval process that benefit lung cancer patients, targeting specific tumor mutations or providing options for patients who did not respond to their first- or second-line treatment. Lung cancer 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 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. For a patient with a 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.

Managed Care

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, and this is especially important in Tennessee, where 100 percent of beneficiaries receive their care through MCOs. For example, 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 oncologists in its network or only contract with oncologists in one part of the state. For a lung cancer patient, this could be fatal. 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.

Amount, Duration and Scope

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 chronic conditions, including COPD and asthma, 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. In reality, the financial pressures of a block grant would increasingly incentivize the state to roll back benefits and jeopardize patients' access to care.

Additional Changes

Tennessee has asked for authority to change "enrollment processes, service delivery systems and comparable program elements" without seeking additional CMS approvals in the future. 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. As a result, the uninsured rate for children rose more rapidly in Tennessee in 2018 than in any other state. The changes requested by Tennessee could have a similarly devastating impact on coverage for the patients we represent.

Under this proposal, current and future administrations would not need to get approval to make changes to benefits and services beyond those outlined in this waiver proposal. Medicaid enrollees, by definition, are a low-income population and often lack the finances to access treatment beyond what Medicaid covers. For patients with lung disease, accessing healthcare can literally be the difference between life and death, and it is critical that TennCare continue to provide a robust set of benefits. For example, a benefit cut could result in COPD patients not being able to access supplementary oxygen or patients with asthma not getting nebulizers or

other devices they need to take their controller medications to manage their condition and live active, healthy lives. This broad authority to make additional policy changes without approval therefore puts patients' care at grave risk.

Finally, both by eliminating review requirements for 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.

Fiscal Sustainability

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 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.

Finally, the Lung Association is 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 to fully comment on all of the possible impacts of a block grant and the waiver's additional requests on the patients we represent.

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 the American Lung Association opposes the proposal. Thank you for the opportunity to submit comments.

Sincerely,

Harold P. Wimmer
National President and CEO
American Lung Association