September 9, 2021

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

Re: TennCare III Medicaid Section 1115 Demonstration

Dear Secretary Becerra:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on Tennessee's TennCare III demonstration, and we applaud the Administration for opening this comment period. Given the fact that this waiver proposes sweeping and significant changes, it is essential to consider the concerns of experts, advocates and stakeholders through the proper notice and comment rules required. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

ACS CAN appreciates Tennessee's goal of promoting the health of low-income Tennesseans, but we oppose the changes to the program funding structure, as approved by the Centers for Medicare and Medicaid Services (CMS) on January 8, 2021. We also have serious concerns about the approved "flexibilities" for administering the program. More than 41,980 Tennesseans are expected to be diagnosed with cancer in 2021[1] and there are nearly 326,530 cancer survivors in the state[2] – many of whom are receiving health care coverage through the TennCare program. ACS CAN wants to ensure that cancer patients and survivors in Tennessee will have adequate access and coverage under the Medicaid program, and that program requirements do not create barriers to care for low-income cancer patients, survivors, and those who will be diagnosed with cancer.

The proposed aggregate funding cap and operational flexibilities could seriously limit eligibility and access to care for some of the most marginalized Tennesseans, including those with cancer, cancer survivors, and those who will be diagnosed with the disease. We strongly urge CMS to consider stakeholder comments and revoke approval of the elements of the TennCare III Demonstration detailed below:

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[1] American Cancer Society. *Cancer Facts & Figures 2021*. Atlanta, GA: American Cancer Society; 2021.
[2] American Cancer Society. *Cancer Treatment & Survivorship Facts & Figures 2019-2021*. Atlanta, GA: American Cancer Society; 2019.

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Financing Model

Aggregate Cap Structure

ACS CAN strongly opposes Tennessee's plans to change the traditional Medicaid financing structure to an aggregate cap model. This plan would fundamentally alter the Medicaid program in Tennessee, shifting the funding from a percentage match, whereby the program's funding adjusts automatically to account for the number of enrollees and rising health care costs, to one where annual funding for the program would be capped. While the per capita costs for enrollee groups will adjust based on national trends, we believe this funding will still not be sufficient to meet the health care needs of low-income Tennesseans. Moving forward with the aggregate cap model could significantly reduce low-income cancer patients', survivors', and their families' access to affordable, comprehensive health care in the state.

Funding Model Unable to Respond to Unexpected Medical Cost Growth

Tennessee's aggregate cap model is based on *historical* (pre-TennCare) spending per enrollee category and inflated annually using a pre-determined growth rate (using an inflation factor based on the Congressional Budget Office's (CBO) projections for growth in Medicaid spending). Health care costs are often greater than projected, as increases in medical expenses and health coverage needs are difficult to predict. For example, a new breakthrough cancer treatment or an unexpected health care emergency could cause health care costs to increase significantly. If projected costs are more than estimated in the base period enrollment, the state would be left paying a greater portion of the costs than they would under a federal match, putting significant pressure on the state's budget. In 2017, the non-partisan CBO estimated that applying a block grant funding model would significantly reduce federal Medicaid revenue to states and lead to an estimated three quarters of program enrollees becoming uninsured.[3] The likelihood of more Tennesseans becoming uninsured contradicts the objective of the Medicaid program, which is to improve the health and wellness needs of vulnerable and low-income individuals and families.[4]

Additionally, further economic downturns or a major state disaster – like the devastating floods last month – could create greater need for Medicaid coverage among state residents. Even with the approved funding increase for enrollment increases in the state greater than 1%, the state could still be responsible for costs above those garnered through enrollment increases. Under a traditional Medicaid funding model, when these unexpected incidents occur the matched federal funding automatically adjusts to cover additional state spending to help meet actual state enrollment and needs.

[3] Congressional Budget Office. *Impose caps on federal spending for Medicaid. Budget Options*. Published December 8, 2016. Accessed December 2019. https://www.cbo.gov/budget-options/2016/52229.
[4] Medicaid.gov. About section 1115 demonstrations. Accessed December 2019. https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html.

Capped Funding Could Mean Reduced Federal Funds for Hospitals, Providers, and Health Centers
We are concerned the state may choose to cut payments to providers to help keep spending under the new aggregate cap amount so that they can "share" the resulting savings with the federal government.[5] These cuts could make it harder for patients with serious and chronic health conditions – who rely on prompt access to primary care providers as well as specialists – to access providers who can help them find the best treatments and manage their conditions. If the state reduced provider payments, it is very likely that fewer providers would participate in the program or they would stop taking new Medicaid patients, seriously limiting enrollees' access to care. Providers operating in low-income and rural areas in Tennessee, which traditionally have a high number of Medicaid enrollees and uninsured individuals, would likely be impacted the most. Reduced provider payments could also contribute to more hospital closures in the state and have a harmful impact on access for Medicaid enrollees.

In addition, reduced federal financial support through a block grant could result in a shift of additional costs to Tennessee hospitals, health systems, providers, and enrollees through increased uncompensated care. Many public hospitals, children's hospitals, rural providers, and federally qualified health centers (FQHCs) make up the safety net for low-income individuals and families, including those battling cancer. These health systems greatly rely on Medicaid revenue to provide services. There are 29 community health center organizations in Tennessee[6] that serve nine percent of Medicaid enrollees in the state and 22 percent of the state's uninsured.[7] Without current federal and state funding levels, hospital systems, FQHCs, and providers may have to limit the number of Medicaid or uninsured patients they treat due to lower reimbursement rates and higher uncompensated care costs. Not only would this mean reduced access for Medicaid enrollees and the uninsured, but it could also hinder efforts to improve health outcomes in the state – which would be antithetical to the state's goal to continue to improve the health of its residents through the waiver. Again, the Division should consider the impact an aggregate cap structure would have on Tennessee residents, Medicaid enrollees, and health care systems in the state and reconsider plans to implement the approved changes.

State Flexibilities
The previous administration granted Tennessee unprecedented flexibilities without the need for federal approval as part of its TennCare III Demonstration. The state noted that "it is not the intention of the state to enumerate in detail in this document every innovation, reform, or policy change that might take place over the life of the demonstration, since the purpose of the block grant is precisely to give the state a range of autonomy within which it can make decisions about its Medicaid program."[8] At the same time, the demonstration approval states that these flexibilities will only be used when adding services or benefits. ACS CAN fears that by providing unlimited flexibility – without seemingly any CMS

[5] The state proposes that in any year in which the state underspends its block grant, the state and the federal government share 50/50 in the resulting savings. This proposal is discussed more below under "Other Proposals of Concern."
[6] National Association of Community Health Centers. Community Health Center Chartbook. Published January 2019. Accessed December 2019. http://www.nachc.org/wp-content/uploads/2019/01/Community-Health-Center-Chartbook-FINAL-1.28.19.pdf.
[7] Ibid.
[8] TennCare III Medicaid Section 1115 Demonstration. Title XIX No. 11W00369/4. Pg. 14.

or public oversight – there is little preventing the Division from imposing additional barriers to important services at some point in the future to save state dollars, making it more difficult for patients to access the care they need.

Aggregate Funding Caps Could Restrict Patients' Access to Care

Because the state may see a significant reduction in overall federal funding under the approved funding arrangement, the state may be forced to use other cost-saving measures that are otherwise prohibited by the current Medicaid program including enrollment freezes, waiting lists, and increased cost sharing for impacted enrollees. This is antithetical to the purpose of the Medicaid program, which is to provide comprehensive health coverage to low-income individuals that need it. Multiple studies have shown that individuals are less likely to seek health services, including life-saving preventive screenings (e.g., mammograms and colonoscopies), when they must pay for those services out-of-pocket.[9,10,11] Deterring a low-income person from accessing care by charging cost-sharing or instating enrollment freezes or waiting lists could result in higher costs later, which the state may have to bear.

For a person with cancer, enrollment freezes, waiting lists, and out-of-pocket cost sharing – which could be implemented under the approved waiver – could mean a later-stage diagnosis when treatment costs are higher, and survival is less likely. Ultimately, changing the funding structure for Medicaid raises serious issues about the program's ability to offer low-income Tennesseans quality, affordable, and comprehensive health care coverage, particularly for those suffering from cancer. Therefore, we strongly urge the Division to consider the impact this change could have on low-income cancer patients and survivors who need health care coverage to fight and hopefully survive their disease and to deny the state from moving forward with this harmful proposal.

Access to Prescription Drugs is Essential for Cancer Patients

Closed formulary: The state was granted authority by the previous administration to implement a "commercial-style" closed formulary with at least one drug available per therapeutic class and exclude "certain new drugs" from its formulary. ACS CAN opposes the adoption of a closed drug formulary for TennCare. There is no single oncology drug that is medically appropriate to treat all cancers. Cancer is not just one disease, but hundreds of diseases. Cancer tumors respond differently depending on the type of cancer, stage of diagnosis, and other factors. As such, oncology drugs often have different indications, different mechanisms of action, and different side effects – all of which need to be managed to fit the medical needs of an individual. Oncologists take into consideration multiple factors related to expected clinical benefit and risks of oncology therapies and the patient's clinical profile when making

[9] Solanki G, Schauffler HH, Miller LS. The direct and indirect effects of cost sharing on the use of preventive services. *Health Services Research.* 2000; 34: 1331-50.
[10] Wharam JF, Graves AJ, Landon BE, Zhang F, Soumerai SB, Ross-Degnan D. Two-year trends in colorectal cancer screening after switch to a high-deductible health plan. *Med Care.* 2011; 49: 865-71.
[11] Trivedi AN, Rakowsi W, Ayanian JA. Effect of cost sharing on screening mammography in Medicare health plans. *N Eng J Med.* 2008; 358: 375-83.

treatment decisions. For example, one fourth of cancer patients have a diagnosis of clinical depression,[12] which may be managed with pharmaceutical interventions that may limit cancer treatment options because of drug interactions or side effects. As such, when enrollees are in active cancer treatment, it can be particularly challenging to manage co-morbid conditions.

Allowing for the use of a closed formulary would severely restrict a physician's ability to prescribe the medically appropriate treatment for an individual without going through a lengthy appeals process. Denying enrollees access to medically appropriate therapies can result in negative health outcomes, which can increase Medicaid costs in the form of higher physician and/or hospital services to address the negative health outcomes.

Impact on tobacco cessation: ACS CAN is also concerned about the implications a closed formulary will have on individuals' access to smoking cessation products. Currently, there are seven Food and Drug Administration (FDA)-approved tobacco cessation medications available to help people quit. Multiple options are necessary because different treatments work for different people. Tobacco users are disproportionately low-income[13] and have a higher risk for chronic diseases associated with tobacco addiction, including lung cancer.[14] Limiting access to a panoply of tobacco cessation products will hinder individuals' ability to break their dependence on tobacco.

Tennessee's proposal to duplicate FDA process: In addition, the waiver proposed granting the state flexibility to exclude new drugs from its formulary "until market prices are consistent with prudent fiscal administration or the state determines that sufficient data exist regarding the cost effectiveness of the drug."[15] We are concerned that this policy would hinder cancer patients' access to innovative cancer therapies. Additionally, "until market prices are consistent with prudent fiscal administration" is a completely arbitrary designation and would allow the state to essentially make up their own definition of what they consider to be "prudent fiscal administration."

The FDA is the world standard for drug approval. The agency employs physicians, statisticians, chemists, pharmacologists, and other scientists to ensure that drugs that are approved can clinically demonstrate safety and effectiveness.[16] The agency also invests significant resources in research, development, and technology to aid in this evaluation and review process. The waiver proposal appears to seek to allow

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[12] American Cancer Society, *Coping with Cancer: Anxiety, Fear, and Depression*. Available at https://www.cancer.org/treatment/treatments-and-side-effects/emotional-side-effects/anxiety-feardepression.html.
[13] Jamal A, Phillips E, Gentzke AS, et al. Current Cigarette Smoking Among Adults — United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2018;67:53–59. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a1
[14] U.S. Department of Health and Human Services. *The Health Consequences of Smoking – 50 Years of Process: A Report of the Surgeon General*, 2014. Available at https://www.surgeongeneral.gov/library/reports/50-years-of-progress/.
[15] Division of TennCare, TennCare II Demonstration. Project No. 11-W-00151/4. November 20, 2019. Pg. 15. https://www.tn.gov/content/dam/tn/tenncare/documents2/Amendment42FinalVersion.pdf
[16] Food and Drug Administration. *Drug Development and Approval Process*. Updated June 13, 2018. Accessed December 2019. https://www.fda.gov/drugs/development-approval-process-drugs.

the state to supplant the FDA's federal role in drug safety and effectiveness. This creates an unnecessary administrative burden as the state would attempt to duplicate existing federal responsibilities. The state lacks the resources necessary to duplicate those already conducted by the FDA.

Furthermore, we are concerned that even if the state were to conduct its own determination as to the effectiveness of a new drug, the waiver provides no information regarding what process the state will use to make that determination and how timely such a determination would be made. Requiring a state to undergo a duplicative approval process to the FDA's process will result in delayed access to innovative treatments. In addition, allowing the state to make its own determination regarding the efficacy of a drug takes the clinical care decision away from the physician-patient relationship and places it on the state.

Inclusion of prescription drugs in block grant financing: We are also concerned that CMS's January 2021 demonstration approval incorporates the prescription drug benefit into the aggregate cap financing structure. Including the prescription drug benefit in the aggregate cap will further limit federal funding to the state and, with the request to limit oversight of this demonstration, could allow the state to make draconian cuts to the Medicaid program. Tennessee's application requested that CMS allow the state to exclude certain expenses from the funding model calculation and continue to be financed through the federal match structure, including outpatient prescription drugs. This is a clear acknowledgement from the Division that the aggregate cap financing structure does not protect the state nor its Medicaid enrollees, including cancer patients and survivors, from financial risk from medical or other unexpected events.

Exceptions process: While we appreciate the proposal states the program will maintain an exceptions process to cover drugs not on the formulary when medically necessary, we urge CMS to require greater clarification (if implemented) of how long the exceptions process will take before a drug can be approved to be covered. Cancer patients undergoing an active course of treatment for a life-threatening health condition need uninterrupted access to the prescription drugs that are most medically appropriate for their condition. Disruptions in cancer treatment or adjuvant therapy, such as hormone therapy, can result in negative health outcomes. Additionally, switching patients' medications mid-treatment can provoke undue anxiety and uncertainty for patients and can negatively impact their chance of survival.

Therefore, we strongly urge CMS to revoke approval of Tenncare's plans to implement a closed formulary with a minimum of only one drug per therapeutic class, as it would severely impact cancer patients' access to medically appropriate treatments needed to fight their cancer diagnosis.

Program Lockout for Member Fraud

The state plans to suspend or terminate the eligibility of individuals who have been determined to be guilty of fraud and to prevent them from re-enrolling for up to 12 months. ACS CAN supports state efforts to reduce or eliminate fraud from health care programs. However, we are concerned that suspending or terminating the eligibility of individuals without a robust appeal process in place could place a substantial financial burden on enrollees and cause significant disruptions in care, particularly for

individuals in active cancer treatment. During the proposed suspension or termination period, low-income cancer patients will likely have no access to health care coverage, making it difficult or impossible to continue treatment. For those cancer patients who are mid-treatment, a loss of health care coverage could seriously jeopardize their chance of survival. Being denied access to one's cancer care team could have a significant impact on an individual's cancer prognosis and the financial toll that the lock-out would have on individuals and their families could be devastating. Therefore, we urge CMS to require the Division to provide details of a robust appeal process before implementing plans to suspend or terminate the eligibility of individuals who have been determined to be guilty of fraud.

Other Proposals of Concern

The state has not provided any estimates on the number of people impacted or any fiscal analysis of the plans. We are concerned that the funding arrangement incentivizes the state to cut or reduce its Medicaid spending, which could be achieved through measures to restrict utilization of TennCare enrollees' benefits and services, and allocate the state's 55% share of these "savings" on "items and services not otherwise covered under TennCare, or not otherwise eligible for federal match, if the state determines that such expenditures will benefit the health of members or are *likely* to result in improved health outcomes [emphasis added]."[17]

The approval also allows these savings to be used for public health initiatives that **are not** specifically targeted at the TennCare population. While we appreciate Tennessee including priorities for program innovation in the CMS waiver application and support the state wanting to improve the lives of rural Tennesseans through a rural health initiative, we do not believe federal funds meant for Medicaid enrollees' health care services should be spent on programs that do not directly impact Medicaid enrollees.

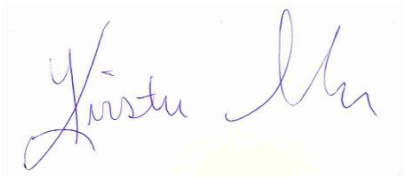
Conclusion

We appreciate the opportunity to provide comments on the TennCare III Demonstration. The preservation of eligibility and coverage through the TennCare program remains critically important for many low-income Tennesseans who depend on the program for cancer and chronic disease prevention, early detection, diagnostic, and treatment services. We ask CMS to reconsider its approval of the elements of the Demonstration detailed above in light of the potential impact of an aggregate cap funding structure and closed formulary could have on low-income Tennesseans' access to lifesaving health care coverage, particularly those individuals with cancer, cancer survivors, and those who will be diagnosed with cancer during their lifetime.

Maintaining access to quality, affordable, accessible, and comprehensive health care coverage and services is a matter of life and survivorship for thousands of low-income cancer patients and survivors, and we look forward to working with the Division to ensure that all people are positioned to win the fight against cancer. If you have any questions, please feel free to contact my staff at Jennifer.Hoque@cancer.org.

[17] Division of TennCare, TennCare II Demonstration. Project No. 11-W-00151/4. November 20, 2019. Pg. 14. https://www.tn.gov/content/dam/tn/tenncare/documents2/Amendment42FinalVersion.pdf

Sincerely,



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