September 9, 2021

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

Re: TennCare III Section 1115 Demonstration

Dear Secretary Becerra,

The undersigned organizations appreciate the opportunity to comment on the special terms and conditions of Tennessee's section 1115 demonstration, "TennCare III" (Project Number 11- W-00369/4), which was approved on January 8, 2021. Meaningful public input is an essential part of the 1115 demonstration design process, and we applaud your commitment to transparency in allowing public comment on the demonstration. The original federal comment period on the state's November 20, 2019 amendment to its TennCare II demonstration, which began the day before Thanksgiving and closed two days after Christmas, was inadequate. Even though the federal comment portal malfunctioned for about two days during this period, CMS did not provide an extension. As for the extension of TennCare II, CMS did not post, accept, or consider any public comment.

TennCare III would not promote the objectives of the Medicaid program, as section 1115 requires. To the contrary, its provisions for an aggregate cap on federal funding, a closed prescription drug formulary, and the elimination of 3-month retroactive coverage would undermine Medicaid coverage. As such, they are also inconsistent with the President's Executive Order 14009 on Strengthening Medicaid and the Affordable Care Act, which requires review and eventual suspension or rescission of agency actions that undermine Medicaid.[1] Moreover, TennCare III would likely increase, rather than reduce, systemic barriers that underserved communities in Tennessee experience in accessing Medicaid coverage, in violation of the President's Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities.[2] Finally, the ten-year approval of these provisions conflicts with section 1115, which does not allow approvals or extensions to last longer than five years.

In light of these egregious defects, we urge you to rescind the TennCare III demonstration and maintain Medicaid coverage and benefits in Tennessee while giving the state an opportunity to propose an extension of TennCare II, which is "subsumed" in TennCare III, or a new amendment or demonstration that promotes Medicaid's objectives and advances racial equity.

The Aggregate Cap on Federal Funding Undermines Medicaid in Tennessee

Under TennCare III, federal Medicaid matching payments are subject to an aggregate cap, adjusted for enrollment changes above or below a certain level. The special terms and conditions

[1] Executive Order No. 14009, 86 CFR 7793 (2021), https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act.
[2] Executive Order No. 13985, 86 CFR 7009 (2021), https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.

make explicit that this cap shifts financial risk to the state: "Tennessee shall be at risk for the aggregate cap and the state accepts risk for both enrollment and per capita costs, subject to the enrollment risk corridors describe *[sic]* in these STCs" (STC 78). If in a given year the state's demonstration expenditures are above the cap amount, the state will pay 100 percent of the excess. If the state's demonstration expenditures are less than the cap amount, the state will be able to draw down up to 55 percent of the federal government's savings depending on its performance on quality metrics that it selects. The state may use these so-called "shared savings" to fund certain programs that are currently paid for with state dollars. The federal dollars free up the state dollars to be used for whatever purpose the state decides.

This aggregate cap, coupled with the so-called "shared savings" mechanism, represents a radical change in Medicaid financing. Shifting risk to Tennessee through the imposition of an aggregate cap, and at the same time rewarding it with additional federal funds if it cuts its spending below the cap amount, creates a powerful financial incentive for the state to reduce coverage. TennCare III gives it two primary pathways for doing so: limiting access to prescription drugs through a closed formulary (see below) and freezing or cutting provider payment rates. Reducing provider rates discourages provider participation, degrading provider networks, which is already a problem in the TennCare program, and impairing beneficiaries' access to care. The existing barriers to care resulting from network inadequacy will only be made worse by TennCare III's financial incentives and are especially troubling given the state's high rates of infant and maternal mortality, especially among Black individuals.[3] By incentivizing the state to reduce Medicaid coverage, this financing structure undermines the Medicaid program.

As you know, the Medicaid program, through its open-ended federal matching structure, is designed to share the risk of providing health and long-term care services for low-income Americans between the federal government and participating states. If a state makes a payment on behalf of an eligible individual for a covered service, the federal government will match that payment at the statutory rate (in Tennessee's case, 66.10 percent this year). Conversely, if the state does not make such a payment, the federal government will not match it. Section 1115 does not give the Secretary the authority to modify the long-standing financing provisions of section 1903 of the Social Security Act to change a state's matching rate or to modify the open-ended matching structure of the program. Nor does section 1115 authorize the Secretary to create a "shared savings" arrangement under which, if the state does not make a Medicaid expenditure, and the federal government therefore does not match that expenditure, the state nonetheless gets to extract up to 55 percent of the amount that the federal government did not spend.

The use of section 1115 demonstration authority to create powerful financial incentives for a state to reduce coverage undermines the Medicaid program. We urge you to reject the aggregate cap and "shared savings" mechanism as they do not promote the objectives of Medicaid and are inconsistent with Executive Order 14009.

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[3] Kinika Young, "Rooted in Racism: An Analysis of Health Disparities in Tennessee," Tennessee Justice Center, July 27, 2020, https://www.tnjustice.org/wp-content/uploads/2020/07/Rooted-in-Racism-An-Analysis-of-Health-Disparities-in-Tennessee.pdf.

The Closed Prescription Drug Formulary Undermines Medicaid in Tennessee

TennCare III allows Tennessee to sharply restrict what drugs are covered for adults age 21 and over by permitting the state to cover only one drug per class, unless the state's benchmark plan used for its marketplace covers more. The only exceptions would be for drugs in six "protected" classes — anti-depressant, anti-convulsant, anti-psychotic, immunosuppressive, cancer, and HIV/AIDS drugs — for which the state would be required to cover nearly all drugs, as is the case in Medicare Part D today. While the state would be required to establish an appeals process allowing beneficiaries to obtain off-formulary drugs if the drugs are "clinically appropriate," this process may not be meaningful because it is entirely in the discretion of the state to define when an off-formulary drug would be "clinically appropriate." The exceptions process also creates more red tape barriers for patients and providers, discouraging busy prescribers and further suppressing provider participation in TennCare.

As explained above, the aggregate cap and "shared savings" provisions of TennCare III give the state a powerful incentive to cut Medicaid spending. The closed formulary provision is one of the main pathways available to the state for cutting spending. The fiscal logic for the state will be to limit the number of drugs per non-protected class to one, and to define "clinically appropriate" for purposes of the exceptions process narrowly. It could, for example, use its new formulary authority to eliminate or limit coverage of certain new and existing drugs solely due to their high cost, even if those drugs are clinically effective and required to treat beneficiaries' serious medical conditions.

Restricting beneficiary access to prescription drugs by imposing a closed formulary does not promote the coverage objectives of Medicaid; it undermines it. In particular, a closed formulary has no legitimate experimental purpose. The potential benefit—leveraging lower prices from pharmaceutical manufacturers—is highly implausible in a state with a relatively small Medicaid program with limited purchasing power that already enjoys the purchasing power of the national Medicaid Drug Rebate Program (discussed further below). On the other hand, the potential harm to beneficiaries with serious medical conditions who need high-cost drugs is predictable and immediate. Not only does the approval provide very few details about the formulary, and none about the exceptions process, under its terms, CMS will have no opportunity to review these details when they do become available. Nor does the approved demonstration afford CMS real-time access to utilization data that would enable it to determine whether the operation of the formulary and exceptions process are having a disproportionate impact on underserved communities, including persons of color and individuals with disabilities, and if so, to suspend the approval.

Finally, by allowing the state to operate a closed formulary yet continuing to require drug manufacturers to provide rebates to the state, TennCare III threatens to destabilize the highly successful Medicaid Drug Rebate Program. Under that program, drug manufacturers pay rebates in exchange for an agreement that all states offering Medicaid drug coverage will maintain open formularies of FDA-approved drugs. Medicaid already obtains the lowest prices under the Rebate Program, net of rebates and discounts, compared to other federal programs and agencies, according to the Congressional Budget Office.[4] And nearly all states, including Tennessee, already use tools like preferred drug lists and prior authorization to negotiate supplemental rebates on top of the federally

[4] Congressional Budget Office, "A Comparison of Brand-Name Drug Prices Among Selected Federal Programs," February 18, 2021, https://www.cbo.gov/publication/56978.

required rebates.[5] By unilaterally breaking this social contract, the approval of TennCare III calls into question the trustworthiness of Medicaid as a purchaser and HHS as a steward, undermining the program at the same time it restricts coverage. We urge you to withdraw approval of the closed formulary.

The Waiver of 3-Month Retroactive Coverage Undermines Medicaid in Tennessee

Under TennCare III, Medicaid beneficiaries except for infants and children under 21 and pregnant and post-partum women don't have the financial protection of retroactive coverage for three months prior to a determination of eligibility. Waiving retroactive coverage reduces coverage for most adult Medicaid beneficiaries and thereby undermines the Medicaid program and fails to promote the principal objective of the program, as required for approval under section 1115. We urge you to reject this waiver.

Rejection is particularly compelling in the case of Tennessee, which has been granted a waiver of 3-month retroactive coverage since the first TennCare demonstration in 1994. Even if the waiver initially had a legitimate experimental purpose, that purpose has been accomplished during the past 27 years. Whatever lessons the waiver of 3-month retroactive coverage with respect to traditional Medicaid populations, expansion adults, or both, in Tennessee and 13 other states was to have taught policymakers have been learned, and there is evidence from these waivers that they undermine Medicaid's objectives. Removal of the coverage leaves beneficiaries exposed to medical bankruptcy and creates uncompensated care for hospitals. At this point, the waiver of retroactive coverage functions as an unauthorized amendment to the Medicaid statute for Tennessee and the 13 other states that have been granted waivers of 3-month retroactive coverage for traditional and expansion populations. That policy choice is one for the Congress to make; section 1115 does not give the Secretary the authority to make it.

Paying Providers for Uncompensated Care Delivered to Uninsured People with Statutory Pathways to Coverage Undermines Medicaid

TennCare III continues the state's use of an Uncompensated Care Fund for Charity Care as a a substitute for providing coverage to low-income Tennesseans who would qualify for Medicaid if the state took up the option to cover adults with incomes at or below 138 percent of the federal poverty level (FPL). Under TennCare III, the state is allowed to use the Uncompensated Care Fund for "health care costs that are incurred by the state, hospitals, or health care clinics to furnish uncompensated medical care as charity care for low-income individuals that are uninsured." Low-income uninsured individuals include those with incomes below 200 percent of FPL, a population that overlaps the Medicaid expansion population that Tennessee has elected not to cover.

Uncompensated care pools like Tennessee's Uncompensated Care Fund for Charity Care do not promote coverage for Medicaid-eligible individuals with incomes at or below 138 percent of FPL because Congress, by statute, has clearly delineated how they should be covered: through Medicaid expansion. Nor do such pools have any continued experimental purpose.

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[5] CMS, "Medicaid Pharmacy Supplemental Rebate Agreements (SRA) as of June 2021," https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.

In 2019, there were 119,000 uninsured Tennesseans in the Medicaid coverage gap, and 30 percent of these individuals were people of color (26 percent Black and 4 percent Latino).[6] Tennesseans in the coverage gap have no pathway to coverage, and many rely on receiving care from safety net hospitals and clinics. The Uncompensated Care Fund will reimburse some providers for some of the charity care they furnish to some of these uninsured Tennesseans, with the decision as to who receives charity care entirely at the unreviewed discretion of each provider. Given the well-documented influence of implicit bias in provider decision-making, the state's reliance on a Fund rather than Medicaid coverage is likely to result in inequities in access and quality of care.[7] Many other individuals in the coverage gap may lack access to care because of where they live, a lack of transportation, the type of care they need, and other factors. Access to care for all Tennesseans in the coverage gap falls short of what they would be entitled to under Medicaid.

Expenditures under the Uncompensated Care Fund are capped, so it provides no guarantee that low-income Tennesseans will get the health care they need, a guarantee they would have if they were enrolled in Medicaid. Individuals with coverage under Medicaid have access to the full range of health services needed to stay healthy – including wellness and preventive care, as well as chronic, specialty, rehabilitative, habilitative, and acute care. Uncompensated care pools like Tennessee's Uncompensated Care Fund for Charity Care do not provide an individual with that full range of coverage. Without true coverage, individuals dependent upon charity care go without most of the health services they need to stay healthy, and even the services that are eligible often result in insurmountable bills and bankruptcies, or great stress until the debt is forgiven, if they are lucky enough to qualify for charity care.

Simply put, reimbursing providers for charity care is a grossly inadequate way to furnish health care to individuals. That is why Congress designed Medicaid as a coverage program. Furthermore, Medicaid coverage payments sustain the providers that enrollees prefer based on the high-quality and accessible services that they offer, whereas uncompensated care pool payments often reward providers based on opaque factors disconnected from what enrollees truly value. Section 1115 authorizes the Secretary to approve demonstration projects that are likely to assist in promoting Medicaid's objectives. By substituting charity care reimbursement for actual coverage for Medicaid expansion adults, TennCare III undermines Medicaid by undercutting its principal objective: coverage.

We are not suggesting that uncompensated care pools should never be approved as part of a demonstration, but that they should not be used to provide limited access to health care for people who could have Medicaid coverage and get the care they need when they need it. If Tennessee expanded Medicaid, there would still be large numbers of Tennesseans who would not qualify for Medicaid or other public coverage, so mechanisms such as Tennessee's Uncompensated Care Fund for Charity Care may be appropriate to help ensure the financial viability of safety net providers who serve uninsured Tennesseans.

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[6] Gideon Lukens and Breanna Sharer, "Closing the Medicaid Coverage Gap Would Help Diverse Group and Narrow Racial Disparities," Center on Budget and Policy Priorities, June 14, 2021, https://www.cbpp.org/research/health/closing-medicaid-coverage-gap-would-help-diverse-group-and-narrow-racial.

[7] William J. Hall, *et. al*, "Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review, *American Journal of Public Health*, December 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4638275/#; Shantanu Agrawal and Adaeze Enekwechi, "It's Time To Address The Role Of Implicit Bias Within Health Care Delivery," Health Affairs, January 15, 2020, https://www.healthaffairs.org/do/10.1377/hblog20200108.34515/full/.

Tennesseans who are ineligible for any form of coverage should be able to get their health care needs addressed. But payments for charity care should be carefully designed and targeted for this purpose and should not be used as a substitute for direct coverage for people who would be eligible for Medicaid if Tennessee expanded. We urge you to revise any approval for Tennessee's Uncompensated Care Fund for Charity Care in light of these considerations.

TennCare III Would Do Nothing to Address Systemic Barriers to Medicaid Access for Underserved Communities

EO 13895 directs the Federal Government to "pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality." This includes assessing whether, and to what extent, an agency's programs and policies "perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups." HHS should assess section 1115 demonstrations through this lens, especially those like TennCare III that affect entire state Medicaid programs and their beneficiaries. As approved, TennCare III will do little if anything to improve health equity in Tennessee and may over the next decade result in increased disparities.

People of color in Tennessee experience health disparities. The infant mortality rate for Black infants (11.4 per 1,000 lives births) was over twice as high as that for White infants (5.4) in 2018.[8] And between 2017 and 2019, non-Hispanic Black women were almost four times as likely to die from pregnancy-related causes as non-Hispanic White women.[9] Disparities in outcomes like these are related to disparities in coverage: in 2019, the rates of uninsurance among Black Tennesseans (12.3 percent) and Hispanic Tennesseans (36.5 percent) were both higher than that for White Tennesseans (10.0 percent).[10]

The harmful effects of the waiver provisions discussed above will fall disproportionately on people of color, individuals with disabilities and rural residents, deepening the disparities in health care access and health status of those disadvantaged Tennesseans.

TennCare III does not speak to these disparities. In fact, neither the 228-page initial approval (January 8, 2021), nor the 214-page technical correction (January 20, 2021), contains the terms "equity," "health equity," "disparities," "health disparities," or "racial disparities." A fundamental issue for TennCare is that it cannot produce beneficiary data disaggregated by race and ethnicity; the CMS DQ Atlas ranks the state's data as "unusable."[11] The approval simply ignores this problem.

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[8] Kaiser Family Foundation, State Health Facts: Infant Mortality By Race/Ethnicity, https://www.kff.org/other/state-indicator/infant-mortality-rate-by-race-ethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[9] Tennessee Department of Health, "2021 Maternal Mortality Annual Report," https://www.tn.gov/content/dam/tn/health/program-areas/maternal-mortality/MMR_Annual_Report_2021.pdf.

[10] Kaiser Family Foundation, State Health Facts: Uninsured Rates for the Nonelderly by Race/Ethnicity, https://www.kff.org/uninsured/state-indicator/nonelderly-uninsured-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[11] Medicaid and CHIP Business Information Solutions (MACBIS), "CMS DQ Atlas Beneficiary Information: Race and Ethnicity," Centers for Medicare and Medicaid Services, available at https://www.medicaid.gov/dq-atlas/landing/topics/single/map?topic=g3m16&tafVersionId=16.

Similarly, it does not explain how an aggregate cap on federal funding, combined with a closed formulary and a waiver of 3-month retroactive coverage, will address Tennessee's current health disparities. Nor does it explain why the fiscal incentives for the state to reduce coverage will not worsen the current disparities or perhaps create new ones over the next ten years. We urge you to reject these and other provisions of TennCare III that are inconsistent with HHS's responsibilities under E.O. 13985.

Ten-Year Section 1115 Demonstration Project Extensions are Not Permitted Under Federal Law

Section 1115 of the Social Security Act allows the Secretary to approve state demonstration projects that promote the objectives of Medicaid. Section 1115 demonstrations can only be approved "for the period…necessary" for the state to carry out the project and are generally approved for no more than five years. Subsections (e) and (f) of section 1115 are clear that initial and subsequent extensions of an approved demonstration are limited to three or five-year periods depending on the type of demonstration project.

Despite the clear direction from Congress that extensions be limited to periods no longer than three or five years, CMS issued guidance in November 2017, stating that it "may approve the extension of routine, successful, non-complex section 1115(a) waiver and expenditure authorities in a state for a period up to 10 years." As our comments on the aggregate cap, closed formulary, 3-month retroactive coverage, uncompensated care funds, and systemic barriers to access make clear, TennCare III is far from a "non-complex" demonstration, so even in the absence of a statutory prohibition on extensions longer than three or five years, TennCare III should not be approved for 10 years. To lock in these policies for 10 years is not only inconsistent with section 1115 but also with Executive Orders 13895 and 14009.

Conclusion

If TennCare III, as approved, is allowed to continue, over 1.4 million Medicaid beneficiaries in Tennessee will be at risk for reductions in their coverage and increased systemic barriers to access. We urge you to rescind the approval of TennCare III and maintain Medicaid coverage and benefits in Tennessee while giving the state an opportunity to propose an extension of TennCare II, which is "subsumed" in TennCare III, or a new demonstration that promotes Medicaid's objectives and advances racial equity.

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

Sincerely,

American Psychological Association
Autistic Self Advocacy Network
Center for Medicare Advocacy
Center on Budget and Policy Priorities
Epilepsy Foundation
Family Voices
First Focus on Children

Georgetown University Center for Children and Families
HIV Medicine Association
March of Dimes
Medicare Rights Center
National Academy of Elder Law Attorneys
National Alliance on Mental Illness
National Association of Pediatric Nurse Practitioners
National Family Planning & Reproductive Health Association
National Multiple Sclerosis Society
Primary Care Development Corporation
United Way Worldwide