December 27, 2019

VIA ELECTRONIC SUBMISSION

The Honorable Alex Azar, Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: TennCare II Demonstration, Amendment 42

Dear Secretary Azar:

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and under-served people. We appreciate the opportunity to provide these comments on Tennessee's TennCare II Demonstration Amendment.

NHeLP recommends that the Department of Health & Human Services (HHS) reject Tennessee's request for § 1115 waivers that would dismantle federal oversight and restructure financing of Tennessee's Medicaid program. The proposed changes do not comply with § 1115 of the Social Security Act.

I. HHS should not have certified this application as complete and should formally review it as a new application.

As explained in our letter to CMS dated November 26, 2019, HHS should not have certified this application as complete.[1] The application is extremely vague on many of the specifics of what Tennessee is proposing to do and how those proposals will affect stakeholders. Without more information, we are unable to submit meaningful comments on significant aspects of the project and believe this will be a problem for others as well. Simply put, the application does not allow a notice and comment process that is "sufficient to ensure a meaningful level of public input."[2]

While the document is labeled an "Amendment," it is effectively an application for a new project, and the federal Medicaid regulations governing review of a new § 1115 project should apply. And even if this document is considered an Amendment, HHS still needs to provide a meaningful public comment process because it has committed to the public to do this.[3] Moreover, such a process is also required by the Special Terms and Conditions of the approved TennCare waiver—conditions which, notably, are not met by the State's current application.[4] For the foregoing reasons, and to comply with 42 C.F.R. § 431.408, CMS should return the document to the State due to its lack of specificity and significant impacts.

II. HHS authority and § 1115.

For the Secretary to approve the project pursuant to § 1115, it must:

- propose an "experiment[], pilot or demonstration;"
- be likely to promote the objectives of the Medicaid Act;
- waive compliance only with requirements in 42 U.S.C. § 1396a; and
- waive compliance only "to the extent and for the period necessary" to carry out the experiment.[5]

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[1] Letter from Jane Perkins, Nat'l Health Law Program, to Seema Verma, Administrator Ctrs. for Medicare & Medicaid Servs. (Nov. 26, 2019), https://9kqpw4dcaw91s37kozm5jx17-wpengine.netdna-ssl.com/wp-content/uploads/2019/11/TennCare-Letter-for-publication.pdf.
[2] 42 U.S.C. § 1315(d)(2)(C), 42 C.F.R. § 431.408.
[3] *See*, *e.g.* CMS, *Re: Revised Review and Approval Process for Section 1115 Demonstrations* 5 (Apr. 27, 2012) (SHO# 12-001), https://www.medicaid.gov/federal-policy-guidance/downloads/sho-12-001.pdf.
[4] *See* Letter to Gabe Roberts, Director, TennCare, from CMS Acting Deputy Admin. & Director, CMS--Special Terms and Conditions III.7 at 14 (July 2, 2019) https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-ca.pdf.
[5] 42 U.S.C. § 1315(a).

The purpose of Medicaid is to enable states to furnish medical assistance to individuals whose income is too low to meet the costs of necessary medical care and to furnish such assistance and services to help these individuals attain or retain capability for independence or self-care.[6]

Tennessee's request to circumvent the requirements that Congress placed in the Medicaid Act for oversight and financing of Medicaid programs, as well as coverage of Medicaid services, is inconsistent with the Medicaid Act and § 1115 and should not be approved.

III. Tennessee should implement Medicaid expansion.

In its application, Tennessee describes a wide range of objectives for this project, including: improving health outcomes; increasing prevention and wellness; supporting rural health care infrastructure; helping combat the opioid crisis; and increasing rural health care access.[7] As described in detail below, the proposed project is improper and will not achieve these goals. If Tennessee were serious about achieving these objectives, it would take the path that Congress set forth, Medicaid expansion, and thereby draw down upon the billions of dollars – $22.5 billion over ten years – in available federal Medicaid expansion funds.[8] Unlike the speculative federal dollars the State hopes to control through this unprecedented project, the Medicaid expansion dollars are a certainty.

Tennessee's application is correct to identify rural health infrastructure as a critical problem: Tennessee has the nation's highest rate per capita of rural hospital closures.[9] Rejection of the expansion funds is especially damaging for Tennessee because Medicaid is the principal source of health coverage in rural communities.[10] Entire areas of the State have suffered the economic devastation, as well as loss of health care access, that result

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[6] *See id*. § 1396-1.
[7] TennCare II Demonstration Amendment 42, iii, 3, 16, 24 (Nov. 20, 2019), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/tn-tenncare-ii-pa10.pdf [hereinafter Tennessee Application].
[8] Stan Dorn et al., Urban Inst., *What Is the Result of States Not Expanding Medicaid?* (Aug.2014), https://www.urban.org/sites/default/files/publication/22816/413192-What-is-the-Result-of-States-Not-Expanding-Medicaid-.PDF.
[9] Ayla Ellison, *State-by-State Breakdown of 102 Rural Hospital Closures,* Becker's Hospital Review (March 20, 2019), https://www.beckershospitalreview.com/finance/state-by-state-breakdown-of-102-rural-hospital-closures.html.
[10] Joan Alker, et al., Georgetown University Center for Children and Families, *Medicaid in Small Towns and Rural America: A Lifeline for Children, Families, and Communities* (June 2017), https://ccf.georgetown.edu/wp-content/uploads/2017/06/Rural-health-final.pdf.

from rural hospital closures.[11] By refusing to expand Medicaid, Tennessee leaves its rural hospitals at a six-fold higher risk of closing, compared to states that have implemented expansion, and is depriving the rural communities they serve of urgently needed health resources.[12]

Research also shows that Medicaid expansion leads to a range of other positive outcomes, including: (1) a reduction in the rate of low-income individuals who are uninsured;[13] (2) increased access to and utilization of services (*e.g.*, cancer diagnosis rates, prescriptions for medications to treat opioid use disorder, use of smoking cessation medications);[14] (3) a reduction in out-of-pocket medical spending and medical debt;[15] and (4) improved self-reported health and positive health outcomes for infants.[16] A recent study from the Kaiser Family Foundation found that nonelderly adults with opioid use disorders (OUD) covered by Medicaid were more likely than those with other coverage to have received treatment in 2017.[17] Another recent study of West Virginia demonstrated that, following Medicaid expansion, more people in the State accessed treatment for OUD.[18]

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[11] Brett Kelman, *Tennessee's rural hospitals are dying off. Who's next?*, Nashville Tennessean (May 15, 2019), https://www.tennessean.com/story/news/health/2019/05/16/tennessee-rural-hospitals-closing-medicaid-expansion-ballad-health/3245179002/; Jade Lin, *The cascading health and economic impacts of hospital closures on rural communities*, Global Resilience Institute (Nov. 8, 2018), https://globalresilience.northeastern.edu/2018/11/the-cascading-health-and-economic-impacts-of-hospital-closures-on-rural-communities/.

[12] Richard C. Lindrooth et al., *Understanding The Relationship Between Medicaid Expansions And Hospital Closures*, Health Affairs Blog (Jan. 2018), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0976**;** Joan Alker, et al., Georgetown University Center for Children and Families, *Health Insurance Coverage in Small Towns and Rural America: The Role of Medicaid Expansion* (Sept. 2018), https://ccf.georgetown.edu/wp-content/uploads/2018/09/FINALHealthInsuranceCoverage_Rural_2018.pdf.

[13] Larisa Antonisse et al., Kaiser Family Found., *The Effects of Medicaid Expansion under the ACA: Updated Findings from a Literature Review* (Aug. 2019), http://files.kff.org/attachment/Issue-brief-The-Effects-of-Medicaid-Expansion-under-the-ACA-Findings-from-a-Literature-Review.

[14] *Id*. at 4-6. *See also* Benjamin D. Sommers et al., *Changes in Utilization and Health Among Low-Income Adults After Medicaid Expansion or Expanded Private Insurance*, 176 JAMA Internal Med. 1501, 1505-06 (2016), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2542420.

[15] Larisa Antonisse et al., Kaiser Family Found., *The Effects of Medicaid Expansion under the ACA: Updated Findings from a Literature Review* 7(Aug. 2019), http://files.kff.org/attachment/Issue-brief-The-Effects-of-Medicaid-Expansion-under-the-ACA-Findings-from-a-Literature-Review.

[16] *Id.* at 8.

[17] Kendal Orgera & Jennifer Tolbert, Kaiser Family Found., *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment* (May 2019), http://files.kff.org/attachment/Issue-Brief-The-Opioid-Epidemic-and-Medicaids-Role-in-Facilitating-Access-to-Treatment.

[18] Brendan Saloner et al., *The Affordable Care Act In The Heart Of The Opioid Crisis: Evidence From West Virginia*, 38 Health Aff. 633 (2019) (attached). *See also* German Lopez, "Obamacare's Medicaid expansion is helping fight West Virginia's opioid epidemic," Vox.com (Apr. 3, 2019), https://www.vox.com/policy-and-politics/2019/4/3/18290820/obamacare-medicaid-expansion-opioid-epidemic-west-virginia.

And another report concluded that expansion states nationwide saw substantially greater gains in access to opioid treatment than non-expansion states.[19]

Medicaid expansion also ensures that women receive health care throughout their reproductive years.[20] A recent national study found that half of women who were uninsured nine months prior to delivery were insured by Medicaid for delivery.[21] However, particularly in non-expansion states, many women continue to lack coverage before and after a pregnancy. Receiving care prior to pregnancy is essential for prevention, early detection, and treatment of conditions that increase risks for pregnancy-related complications, such as diabetes, hypertension, and cardiovascular disease. By increasing access to these needed services, expanding Medicaid can reduce maternal morbidity.[22] What is more, recent studies show that expanding Medicaid under the ACA led to significant improvements in receipt of prenatal care for first-time mothers, including increases in prenatal screens and prenatal vitamins.[23] Medicaid expansion also reduced infant mortality rates compared to non-expansion states, with the greatest declines among African American infants, showing that expansion can also reduce racial disparities.[24]

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[19] Lisa Clemans-Cope et al., Urban Inst. *Rapid Growth in Medicaid Spending and Prescriptions to Treat Opioid Use Disorder and Opioid Overdose from 2010 to 2017*, (Mar. 2019), https://www.urban.org/sites/default/files/publication/99798/rapid_growth_in_medicaid_spending_and_prescriptions_to_treat_opioid_use_disorder_and_opioid_overdose_from_2010_to_2017_2.pdf; *see also* Gaby Glavin, *Report: Expanding Medicaid Improves Access to Opioid Addiction Treatment*, U.S. News & World Report (Feb. 21, 2019), https://www.usnews.com/news/best-states/articles/2019-02-21/states-can-improve-access-to-opioid-addiction-treatment-by-expanding-medicaid-report-says.

[20] Guttmacher Inst., *Gains in Insurance Coverage for Reproductive-Age Women at a Crossroads* (Dec. 4, 2018), https://www.guttmacher.org/article/2018/12/gains-insurance-coverage-reproductive-age-women-crossroads.

[21] Jamie Daw et al., *Women In The United States Experience High Rates Of Coverage 'Churn' In Months Before And After Childbirth*, 36 HEALTH AFF. 598 (2017).

[22] Usha Ranji, Ivette Gomez & Alina Salganicoff, Kaiser Family Found., *Expanding Postpartum Medicaid Coverage* (May 2019) https://www.kff.org/womens-health-policy/issue-brief/expanding-postpartum-medicaid-coverage/; Adam Searing & Donna Cohen Ross, Georgetown University Center for Children and Families, *Medicaid Expansion Fills Gaps in Maternal Health Coverage Leading to Healthier Moms and Babies* 6-7 (May 2019) https://ccf.georgetown.edu/wp-content/uploads/2019/05/Maternal-Health-3a.pdf.

[23] Adam Searing & Donna Cohen Ross, *supra* note 22, at 6-7; L.R. Wherry, *State Medicaid Expansions for Parents Led to Increased Coverage and Prenatal Care Utilization among Pregnant Mothers*, 53 HEALTH SERVICES RESEARCH 3569 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6153180/.

[24] Chintan B. Bhatt & Consuelo M. Beck-Sagué, *Medicaid Expansion and Infant Mortality in the United States*, 108 AM. J. PUB. HEALTH 565 (2018) https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2017.304218.

Medicaid expansion has other benefits for children's wellbeing. One recent study found that after adjusting for confounding variables, there were 422 fewer cases of neglect per 100,000 children under age 6 reported in expansion states than in non-expansion states.[25]

In addition, studies have found that expanding Medicaid has positive economic effects for states, including budget savings, increased revenue, and job growth.[26] Specifically, research has shown that state Medicaid spending in expansion states grew by half as much as spending in non-expansion states.[27] Moreover, the increase in federal funds can help preserve state general funds, which are often used for programs and services for the uninsured. Arkansas, for instance, saved $15.2 million in spending for services for pregnant women, representing a 50 percent decrease in spending, by covering women through the expansion and receiving the enhanced federal match.[28]

In its application, Tennessee hints that it could "[c]over additional low-income persons not otherwise eligible for coverage under the Title XIX State Plan or TennCare demonstration," though it is not clear who this population is.[29] The implication is that the additional population Tennessee proposes to consider covering includes members of the Medicaid expansion group. Yet, allowing Tennessee to implement a partial expansion would run counter to congressional intent. The Medicaid Act (§ 1396a(a)(10)(A)(i)) requires states to cover "all individuals" in a given mandatory eligibility group. In enacting the ACA, Congress made the Medicaid expansion population a mandatory eligibility group. While the Supreme Court decision in *NFIB v. Sebelius* effectively gave states the option to decide whether to take up the Medicaid expansion population, it did not otherwise change the structure of the Medicaid program in any way for mandatory eligibility categories, including those individuals described in subsection VIII. As a result, for the individuals who fall within the new eligibility group and are described at 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII), there is no way to construe Tennessee's requested limitations on eligibility and enrollment as promoting the goals of the program.

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[25] Emily C. Brown et al., *Assessment of Rates of Child Maltreatment in States With Medicaid Expansion vs States Without Medicaid Expansion*, JAMA NETWORK OPEN (June 14, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2735758.

[26] Larisa Antonisse et al., *supra* note 13, at 9-10, 13-14. *See also* Mark A. Hall, Wake Forest Univ. School of Law, *Do States Regret Expanding Medicaid?* (2018), http://news.law.wfu.edu/files/2018/03/Medicaid-regret-Issue-brief.pdf; Benjamin D. Sommers & Jonathan Gruber, *Federal Funding Insulated State Budgets from Increased Spending Related to Medicaid Expansion*, 36 HEALTH AFF. 938 (2017)(attached).

[27] Deborah Bachrach et al., Robert Wood Johnson Found., *States Expanding Medicaid See Significant Budget Savings and Revenue Gains*, 1-2 (2016), https://www.rwjf.org/en/library/research/2015/04/states-expanding-medicaid-see-significant-budget-savings-and-rev.html.

[28] *Id.* at 3.

[29] Tennessee application at 24, 26.

Nor would a partial expansion qualify as an experiment, pilot, or demonstration, as required under § 1115. Starting in the early 1990s, states began to obtain § 1115 waivers to implement demonstration projects that expanded Medicaid to the adult population group, and by 2008, 18 states had received such approvals.[30] Congress followed this demonstration history with the ACA Medicaid expansion to 133% of FPL. In other words, this experiment is over as Congress has *already* acted to implement a new statute in light of these past waiver projects.

IV. Tennessee's waiver requests are not approvable under Section 1115.

A. Matching structure

42 U.S.C. § 1396b sets forth how the federal government is to reimburse states for a portion of their Medicaid expenditures. Under that provision, HHS covers 65% of Tennessee's Medicaid spending with no maximum limit to federal funding.[31] Tennessee appears to be asking HHS to deviate from that formula. However, § 1115 only permits waivers of provisions located in 42 U.S.C. § 1396a and only authorizes use of the matching payments structure.

CMS confirmed these legal limits in a recent 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.[32]

This confirms that CMS cannot (1) waive the financing provisions in 42 U.S.C. §§ 1396b and 1396d, (2) change the *way* states are paid (*i.e.*, it only allows CMS to turn on the light switch), or (3) provide Tennessee with money that is not connected to matching state spending on medical assistance.

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[30] *See* Keavney Klein & Sonya Schwartz, Nat. Acad. For State Health Policy, *State Efforts to Cover Low-Income Adults Without Children* 3 (2008), https://nashp.org/wp-content/uploads/sites/default/files/shpmonitor_childless_adults.pdf.

[31] Kaiser Family Foundation State Health Facts, *Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier*, https://www.kff.org/medicaid/state-indicator/federal-matching-rate-and-multiplier/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last accessed Dec. 23, 2019).

[32] CMS, Approval Letter for North Carolina Medicaid Reform Section 1115 Demonstration 6 (October 19, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicaid-Reform/nc-medicaid-reform-demo-demo-appvl-20181019.pdf.

Some of these legal limits are also acknowledged in CMS's recent decision to phase out the Designated State Health Program waiver model.[33] That model allowed states to use § 1115 "savings" to fund non-Medicaid state health programs, essentially what Tennessee has requested to do (see further discussion below). CMS correctly concluded that the DSHP model was "inconsistent with the overall federal-state financial relationship under the Medicaid statute."[34]

In sum, Medicaid's longstanding financing mechanism was legislated by Congress and can only be changed by Congress. CMS must observe the textual limits that Congress has set when deciding whether to approve waiver applications pursuant to § 1115. The structure of the Medicaid Act reveals that Congress did not grant CMS the authority to waive the program's funding mechanism. Indeed, Congress could not, consistent with the separation of powers, have made such an open-ended delegation that would authorize CMS to transform the Medicaid program in this manner. *See*, e.*g.*, *King v. Burwell*, 135 S. Ct. 2480, 2488–89 (2015) (Congress is presumed not to delegate to an agency the authority to resolve major questions of fundamental importance to the statutory scheme, without an express statement).

B. 42 C.F.R. Part 438 Managed Care Regulations

Tennessee's proposal to waive managed care regulations is not consistent with the purpose of Medicaid, is not experimental, is not necessary to the demonstration, and attempts to waive regulations that are not waivable under § 1115. The request is also too broad to provide informed comments – there is no indication of what managed care provisions the State wants to waive or why.

Will not promote the objectives of Medicaid nor is it experimental

Tennessee's request to waive the managed care regulations will not promote the objectives of Medicaid and is not experimental. In fact, a waiver of the Medicaid managed care regulations directly contradicts the objectives of Medicaid because it will inevitably reduce access to health care. Furthermore, there is already evidence showing the results of this "experiment" would be negative.

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[33] CMS, Dear State Medicaid Director (Dec. 15, 2017) (SMD # 17-005) (guidance on phase-out of expenditure authority for Designated State Health Program (DSHP) in Section 1115 Demonstrations), https://www.medicaid.gov/federal-policy-guidance/downloads/smd17005.pdf.
[34] *Id*. at 2.

To begin with, the 42 CFR Part 428 regulations were specifically promulgated in 2002 to address many coverage and accountability problems that existed in Medicaid managed care prior to 2002. For example, Tennessee itself experienced provider payment and solvency issues with *two* of its three largest managed care plans in the few years before the 2002 regulations were implemented.[35] CMS updated the 2002 regulations in 2016, and for good reason: in the interim years, CMS and other government agencies had identified numerous, on-going problems in state Medicaid programs.

For example, in 2014 OIG identified serious defects in state network adequacy standards.[36] A study in 2014 by HHS's Inspector General found only half the doctors listed in official plan directories were taking new Medicaid patients; among those doctors who were, one-fourth could not see patients for a month.[37] CMS's 2016 managed care regulations include a comprehensive approach to addressing these widescale network adequacy problems. Among other things, the regulations establish provider-specific network adequacy standards and require that external quality review processes validate network adequacy for MCOs, PIHPs, PAHPs and PCCM entities.[38] This is responsive to two separate OIG reports highlighting the need, efficacy, and importance of validating Medicaid provider networks for compliance, access, and availability.[39]

The Medicaid managed care regulations also incorporate reference to antidiscrimination laws that help address longstanding problems with discrimination.[40] Discrimination on any number of bases creates barriers to accessing medically necessary care–either by discriminatory plan practices (*e.g.*, in enrollment, covered and excluded services, medical necessity definitions, utilization controls), provider refusals, or avoiding treatment of certain populations because the provider does not want to serve them.[41] For example, LGBT individuals with insurance too often struggle to find a culturally competent provider and it is

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[35] *See infra* notes 52-54.
[36] HHS, Office Inspector Gen. ("OIG"), *State Standards for Access to Care In Medicaid Managed Care* 8-9 (Sept. 2014) ("CMS and States need to do more to ensure that all States have adequate access standards and strategies for assessing compliance."), http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf.
[37] HHS OIG, *Access To Care: Provider Availability In Medicaid Managed Care* 9-10 (Dec. 2014), https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf.
[38] 42 C.F.R. § 438.68.
[39] HHS OIG, *State Standards for Access to Care in Medicaid Managed Care* (Sept. 2014), http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf; HHS OIG, *Access to Care: Provider Availability in Medicaid Managed Care* (Dec. 2014), https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf.
[40] 42 C.F.R. § 438.3(f)(1).
[41] *See* Inst. of Med. of The Nat'l Acads. *The Health Of Lesbian, Gay Bisexual, and Transgender People: Building A Foundation For Better Understanding* 234 (2011), https://www.ncbi.nlm.nih.gov/books/NBK64806/pdf/Bookshelf_NBK64806.pdf.

also well documented that language barriers affect access to health care.[42] The TennCare proposal asks CMS not to apply these protections to TennCare enrollees. Indeed, the breadth of the waiver request means that *any* important managed care protections are at risk. For example, the Medicaid managed care regulations also include numerous protections to ensure individuals have access to reproductive health services. The regulations require states to ensure that every capitated plan demonstrates that "its network includes sufficient family planning providers to ensure timely access to covered services" and require capitated plans to allow women to directly access women's health specialists for routine and preventive services.[43] Tennessee asks CMS for permission to ignore these basic protections for women.

Instead of reducing accountability for Tennessee Medicaid managed care standards in the ways highlighted above, CMS should and must maintain the existing regulatory standards. Evidence suggests that even when states adopt generous consumer protections in Medicaid managed care aimed at ensuring access to services, access can fall short when compliance with those standards is not adequately monitored or enforced.[44]

Notably, even after 2016, the GAO has repeatedly noted problems with Medicaid managed care.[45] The GAO recommends that CMS to engage in more – not less –

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[42] *See id*. at 226; Laura R. Redman, *Outing the Invisible Poor: Why Economic Justice and Access to Care is an LGBT Issue*, 37 GEORGETOWN J. ON POVERTY LAW & POLICY 451, 457 (2010); Inst. Of Med. The Nat'l Acads., *Unequal Treatment: Confronting Racial and Ethnic Disparities In Health* 17 (2002), https://www.ncbi.nlm.nih.gov/books/NBK220358/pdf/Bookshelf_NBK220358.pdf.

[43] 42 C.F.R. § 438.206(b)(4), (b)(7).

[44] See, e.g., Elaine M. Howell, Cal. State Auditor, *Improved Monitoring Of Medi-Cal Managed Care Health Plans Is Necessary To Better Ensure Access to Care* (2015), https://www.auditor.ca.gov/pdfs/reports/2014-134.pdf.

[45] Government Accountability Office, *Medicaid Managed Care: Improvements Needed to Better Oversee Payment Risks* (July 2018), https://www.gao.gov/assets/700/693418.pdf; Government Accountability Office, *Medicaid Managed Care: Additional CMS Actions Needed to Help Ensure Data Reliability* (Oct. 2018), https://www.gao.gov/assets/700/695069.pdf; Government Accountability Office, *Medicaid: CMS Has Taken Steps to Address Program Risks but Further Actions Needed to Strengthen Program Integrity* (Aug. 2018), https://www.gao.gov/assets/700/694029.pdf; Government Accountability Office, *Medicaid: Actions Needed to Mitigate Billions in Improper Payments and Program Integrity Risks* (June 2018), https://www.gao.gov/assets/700/692821.pdf; Government Accountability Office, *Medicaid: CMS Should Take Steps to Mitigate Program Risks in Managed Care* (May 2018), https://www.gao.gov/assets/700/691619.pdf; Government Accountability Office, *Medicaid: Opportunities for Improving Program Oversight* (April 2018), https://www.gao.gov/assets/700/691209.pdf; Government Accountability Office, *Medicaid Managed Care: CMS Should Improve Oversight of Access and Quality in States' Long-Term Services and Supports Programs* (Aug. 2017), https://www.gao.gov/assets/690/686550.pdf; Government Accountability Office, *Medicaid Managed Care: Improved Oversight Needed of Payment Rates for Long-Term Services and Supports* (Jan. 2017), https://www.gao.gov/assets/690/681946.pdf; Government Accountability Office,

oversight over Medicaid managed care and demonstrations.[46] And, the GAO is not alone. A 2018 report from the Medicaid Access and Payment Commission (MACPAC) identifying considerable divergence among states in monitoring access in Medicaid managed care concludes that "oversight, both by CMS and by state agencies, can and should be further strengthened with more timely and consistent data collection and program evaluation."[47]

Tennessee's proposal to *reduce* oversight of its § 1115 demonstration is all the more improper because GAO has found that even the baseline level of oversight of state demonstrations needs to be *increased*. In its report highlighting "Further Actions Needed to Strengthen Program Integrity," CMS specifically identifies demonstrations as one of three "broad areas of risk to Medicaid program integrity."[48] One of the other three broad areas of risk is "improper payments," and Medicaid managed care is the leading concern in that area.[49]

Medicaid: Key Issues Facing the Program (July 2015), https://www.gao.gov/assets/680/671761.pdf; Government Accountability Office, *Medicaid Program Integrity: Increased Oversight Needed to Ensure Integrity of Growing Managed Care Expenditures* (May 2014), https://www.gao.gov/assets/670/663306.pdf; Government Accountability Office, *Medicaid: Service Utilization Patterns for Beneficiaries in Managed Care* (May 2015) (showing wild variation in services per adult beneficiary across states, from 13 to 55 services per person), https://www.gao.gov/assets/680/670548.pdf; Government Accountability Office, *Medicaid - High Risk Issue*, https://www.gao.gov/key_issues/medicaid_financing_access_integrity/issue_summary (noting that oversight in Medicaid can be "challenging, given its size and complexity," designating Medicaid as a "high risk" government area, and specifically identifying Medicaid managed care "risks related to … state MCO payments and risks with payments from MCOs to providers.") (last accessed Dec. 23, 2019).

[46] Government Accountability Office, *High Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas* (Mar. 2019), https://www.gao.gov/assets/700/697245.pdf; Government Accountability Office, *Medicaid: Program Oversight Hampered by Data Challenges, Underscoring Need for Continued Improvements* (January 2017), https://www.gao.gov/assets/690/681924.pdf; Government Accountability Office, *Medicaid: Additional CMS Data and Oversight Needed to Help Ensure Children Receive Recommended Screenings* (Aug. 2019), https://www.gao.gov/assets/710/700958.pdf; Government Accountability Office, *Medicaid Eligibility: Accurate Beneficiary Enrollment Requires Improvements in Oversight, Data, and Collaboration* (Oct. 2019), https://www.gao.gov/assets/710/702410.pdf; Government Accountability Office, *Medicaid Demonstrations: Actions Needed to Address Weaknesses in Oversight of Costs to Administer Work Requirements* (Oct. 2019), https://www.gao.gov/assets/710/701885.pdf; Government Accountability Office, *Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures* (Jan. 2018), https://www.gao.gov/assets/690/689506.pdf.

[47] Medicaid & CHIP Payment and Access Comm'n, *Monitoring Access to Care in Medicaid* (Mar. 2017), https://www.macpac.gov/wp-content/uploads/2017/03/Monitoring-Access-to-Care-in-Medicaid.pdf.

[48] Government Accountability Office, *Medicaid: CMS Has Taken Steps to Address Program Risks but Further Actions Needed to Strengthen Program Integrity* (Aug. 2018), https://www.gao.gov/assets/700/694029.pdf.

[49] *Id.*

Medicaid managed care regulations include numerous provisions that are also important to preventing fraud and abuse. In a 2018 report, HHS's Office of Inspector General noted numerous regulatory cites that are important to preventing fraud and abuse, and identified weaknesses in "efforts to identify and address fraud and abuse" in Medicaid managed care.[50]

Given its history, Tennessee has demonstrated that it should not be allowed to operate managed care without especially close oversight and accountability. Tennessee implemented the first TennCare managed care section 1115 project in 1994.[51] Soon after that, Tennessee became one of only three states to be denied accreditation by the National Association of Insurance Commissioners because it could not meet NAIC accreditation standards.[52] In 1999, Xantus Healthplan, the TennCare program's third largest MCO, was placed in receivership, and taxpayers ended up on the hook for many of the plan's unpaid bills.[53] The following year, Access MedPlus, TennCare's largest MCO, was placed under administrative supervision for failing to pay providers.[54] As these plans fell behind in paying providers, enrollees experienced coverage loss as providers dropped out of the plans' provider networks, and there was nowhere for patients to turn. At an April 2001 emergency hearing, a federal court received dramatic testimony about Access MedPlus patients suffering and even dying as they searched in vain for care.[55] The court ordered the State to create an emergency process for meeting the most urgent needs of the plan's patients. A few months later, the plan went bankrupt, leaving $100 million in unpaid debts to hospitals, doctors, and other creditors. The State spent millions more, and 350,000 Tennesseans struggled to find new providers, as Access MedPlus's patients were reassigned to new plans. Unfortunately, there was never a full accounting of where

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[50] HHS OIG, *Weaknesses Exist in Medicaid Managed Care Organizations' Efforts To Identify and Address Fraud and Abuse* (July 2018), https://oig.hhs.gov/oei/reports/oei-02-15-00260.pdf.
[51] Tennessee Division of Tenncare, Tenncare Timeline, https://www.tn.gov/tenncare/information-statistics/tenncare-timeline.html (last visited Dec. 23, 2019).
[52] Meg Fletcher, *Accreditation Withdrawal Sparks Debate,* Business Insurance (June 4, 2000), https://www.businessinsurance.com/article/20000604/story/10002631/accreditation-withdrawal-sparks-debate.
[53] Bill Carey, *Taxpayers may Dish Out $20 Million More for Xantus Creditors*, Nashville Post (June 6, 2000), https://www.nashvillepost.com/home/article/20446965/taxpayers-may-dish-out-20-million-more-for-xantus-creditors.
[54] Cyril F. Chang and Stephanie C. Steinberg, *TennCare Timeline: Major Events and Milestones from 1992 to 2016* 8 (Sept. 2016), https://www.memphis.edu/mlche/pdfs/tenncare/tenncare_bulleted_timeline.pdf.
[55] Memorandum Order, *Grier v. Neal*, Case No. 3:79-3107, (M.D. Tenn., June 20, 2001.), https://www.tnjustice.org/wp-content/uploads/2019/12/760-Memorandum-and-Order-6-21-01.pdf.

millions of taxpayer dollars had gone, but [t]he lack of oversight may have also facilitated corruption in TennCare contracting.[56]

HHS cannot waive provisions outside of 42 U.S.C. § 1396a.

Tennessee's waiver request appears to go far beyond anything the Secretary has authority to approve. The Medicaid statute contains numerous detailed managed care authorities and requirements that exist outside of 42 U.S.C. § 1396a – including in sections 1396b, 1396d, 1396n, and 1396u-2. Moreover, as the regulations themselves provide, CMS, at most, has legal authority to waive only those limited portions of part 438 that apply to requirements for PIHPs and PAHPs that flow from § 1396a(a)(4) (and are not independent required by another provision outside of § 1396a).[57]

As a specific example, § 1396b includes actuarial soundness requirements that are implemented through the 42 C.F.R. Part 438 regulations. The actuarial soundness requirements, based in § 1396b, cannot be waived under § 1115. Actuarial soundness is a cornerstone of Medicaid managed care, Congress put the requirement in a non-waivable provision of the law, and it certainly would not promote the objectives of Medicaid to allow states to underfund the entire delivery system.

The waiver of managed care regulations is not necessary to the TennCare project.

Tennessee has not provided a clear explanation as to how or why the waiver of *all* managed care regulations is related to the block grant project, much less how it is *necessary* to the project, as the statute requires.

In addition, by its own fashioning, Tennessee's waiver request is, by definition, not entirely necessary to its proposed project because some subsets of TennCare are *not* subject to the block grant (for example dual eligible and prescription drug costs). Tennessee is requesting managed care waivers impacting the entire TennCare population, when the demonstration does not impact many individuals. The managed care waiver request is thus overbroad and not necessary to the waiver.

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[56] Associated Press, *TennCare contractors were slow to divulge deals with Ford* (June 6, 2005) http://www.iclassifiedsnetwork.com/contentitem/74145/1259/tenncare-contractors-were-slow-to-divulge-deals-with-ford.

[57] 42 C.F.R. § 438.1(a)(1).

C. "Modify enrollment processes, service delivery system, and comparable program elements."

Tennessee's proposed waiver to "[m]odify enrollment processes, service delivery system, and comparable program elements" without amendments is not consistent with the purpose of Medicaid, is not experimental, and would waive provisions, *e.g.* 42 U.S.C. § 1396w-3, that are not waivable under § 1115. The proposal is also so vague that there is no way to provide meaningful comments.

Modify enrollment process

Tennessee has requested a waiver to modify enrollment processes without oversight or accountability. There is no legitimate reason to allow Tennessee to avoid this oversight, particularly given its long history of enrollment problems, which have resulted in reduced coverage.

Properly operating enrollment systems are vital for Medicaid coverage -- many people eligible for Medicaid are not actually enrolled. Among the nonelderly uninsured nationally, 6.7 million are in fact eligible for Medicaid or CHIP.[58] Enrollment rates vary significantly by state, and over 20% of eligible parents are *not* enrolled in Tennessee.[59] Although insurance enrollment rates skyrocketed nationally in the years after the ACA, from December 2017 to July 2019, Medicaid enrollment actually *fell* nationally by 2.6%.[60] In Tennessee, the trend was far worse: enrollment dropped by 6% over the same period.[61] Allowing Tennessee to change its enrollment systems unchecked risks exacerbating this serious, ongoing problem.

Recent analyses find that administrative burdens and faulty redetermination processes are contributing to declining enrollment. Evidence shows that national enrollment declines are too large to be explained by improving economy, and there is no correlation between

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[58] Jennifer Tolbert et al., Kaiser Family Found., *Key Facts about the Uninsured Population* 9 (Dec. 2019), http://files.kff.org/attachment/Issue-Brief-Key-Facts-about-the-Uninsured-Population.

[59] Kaiser Family Found., Medicaid/CHIP Parent Participation Rates,https://www.kff.org/medicaid/state-indicator/medicaidchip-parent-participation-rates/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Dec. 23, 2019); Kaiser Family Found., Medicaid/CHIP Child Participation Rates, https://www.kff.org/medicaid/state-indicator/medicaidchip-child-participation-rates/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Dec. 23, 2019).

[60] Kaiser Family Found., *Analysis of Recent Declines in Medicaid and CHIP Enrollment* (Nov. 2019) http://files.kff.org/attachment/Fact-Sheet-Analysis-of-Recent-Declines-in-Medicaid-and-CHIP-Enrollment.

[61] *Id.*

changes in state unemployment rates and Medicaid enrollment declines.[62] An in-depth analysis of Tennessee and three other states identified major administrative burdens in Medicaid redeterminations, some in violation of law.[63] Another report found that "[r]ecent state experiences suggest that one factor that may be contributing to Medicaid and CHIP enrollment declines is barriers associated with maintaining coverage due to renewal processes and periodic eligibility checks in some states."[64] The report pointed to issues with paper-based renewal processes in Tennessee.[65] All of this data confirms longstanding evidence that administrative barriers reduce enrollment and that burdensome enrollment processes are the greatest barrier to enrollment. [66][67]

Past and recent history shows that these concerns are particularly acute for Tennessee, as the State has repeatedly used its eligibility and enrollment systems to suppress enrollment. [68] During the 1990s, the State froze TennCare enrollment, cutting off access to health coverage for many low-income adults and children.[69] In 2005, the State dropped 170,000 people from TennCare due to budget pressures; research shows this enrollment drop may have delayed the detection of breast cancer in lower income women.[70]

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[62] Matt Broaddus, Center on Budget and Policy Priorities, *Research Note: Medicaid Enrollment Decline Among Adults and Children Too Large to Be Explained by Falling Unemployment* (July 17, 2019) https://www.cbpp.org/sites/default/files/atoms/files/7-17-19health.pdf.
[63] Families USA, *The Return of Churn: State Paperwork Barriers Caused More Than 1.5 Million Low-Income People to Lose Their Medicaid Coverage in 2018* (April 2019), https://familiesusa.org/wp-content/uploads/2019/09/Return_of_Churn_Analysis.pdf.
[64] Samantha Artiga & Olivia Pham, Kaiser Fam. Found., *Recent Medicaid/CHIP Enrollment Declines and Barriers to Maintaining Coverage* 4 (Sep. 24, 2019), http://files.kff.org/attachment/Issue-Brief-Recent-Medicaid-CHIP-Enrollment-Declines-and-Barriers-to-Maintaining-Coverage.
[65] *Id*. at 5.
[66] Kaiser Fam. Found., *Key Lessons from Medicaid and CHIP for Outreach and Enrollment under the Affordable Care Act* (June 2013), http://files.kff.org/attachment/key-lessons-from-medicaid-and-chip-for-outreach-and-enrollment-under-the-affordable-care-act-issue-brief.
[67] Michael Perry et al., Kaiser Fam. Found., *Medicaid and Children: Overcoming Barriers to Enrollment – Findings from a National Survey* (Jan. 2000) https://www.kff.org/wp-content/uploads/2013/01/medicaid-and-children-overcoming-barriers-to-enrollment-report.pdf.
[68] Christopher Coleman, Tennessee Justice Center, *How Tennessee Became an Outlier in the Rising Number of Uninsured Children and What Must Happen to Reverse the Trend* (July 26, 2019), https://www.tnjustice.org/wp-content/uploads/2019/07/How-Tennessee-Became-an-Outlier-in-the-Rising-Number-of-Uninsured-Children-and-What-Must-Happen-to-Reverse-the-Trend-1.pdf.
[69] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Issues in Developing Programs for Uninsured Children: A Resource Book for States. TennCare* (March 2, 1998), https://aspe.hhs.gov/report/issues-developing-programs-uninsured-children-resource-book-states/tenncare.
[70] Emily Siner, *TennCare's Big Cuts in 2005 May Have Delayed Breast Cancer Diagnoses, Study Suggests*, Nashville Public Radio (June 27, 2017), https://www.nashvillepublicradio.org/post/tenncare-s-big-cuts-2005-may-have-delayed-breast-cancer-diagnoses-study-suggests#stream/0.

More recently, in 2014, Tennessee was one of only six states that had to submit mitigation plans due to Medicaid application backlogs.[7172] Media at the time reported that "Tennessee received the harshest letter from the agency, with CMS charging that the state was not meeting six of seven 'critical success factors' to fulfill Medicaid and CHIP eligibility and enrollment rules."[73] In 2014 Tennessee was sued in a class action lawsuit for its delayed application processing – ultimately resulting in a preliminary injunction against the State that was affirmed by the Court of Appeals for the Sixth Circuit.[74] In the aftermath of the class action, over a two year span at least 128,000 children were terminated from their health coverage; one of the leading reasons was that families received 49 page forms which were not pre-populated as the law requires.[7576] From 2016 to 2017, Tennessee was one of only nine states to have a statistically significant increase of uninsured children – see a whopping 22.4% increase in the uninsurance rate.[77]

The unmistakable conclusion since 2014, and prior to that, is that Tennessee's eligibility and enrollment system is in desperate need of federal oversight and accountability measures – not unchecked permission to make changes. The clear result of this recent history is loss of coverage and delayed access to treatment—neither of which is consistent with the objectives of Medicaid. Nor is this waiver likely to yield any useful information. It is incomprehensible that a state, which, as the evidence shows, has failed for years to implement an enrollment system that can comply with *minimum* legal requirements, could be granted a waiver of enrollment oversight based on the notion that the State will use that power to be an enrollment *innovator*.

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[71] Rachana Pradhan, *CMS Targets Six States Over Ongoing Backlogs In Medicaid Enrollment*, Inside Health Policy (July 9, 2014), https://insidehealthpolicy.com/cms-targets-six-states-over-ongoing-backlogs-medicaid-enrollment-0; Rachana Pradhan, *States Outline Tactics, Timelines To Fix Medicaid Enrollment Backlogs*, Inside Health Policy (July 15, 2014), https://insidehealthpolicy.com/states-outline-tactics-timelines-fix-medicaid-enrollment-backlogs.

[72] Tom Wilemon, *How Tenncare Gave Control to Feds,* Tennessean (Oct. 5, 2014), https://www.tennessean.com/story/news/health/2014/10/05/tenncare-handed-control-feds/16778299/.

[73] Rachana Pradhan, *States Outline Tactics, Timelines To Fix Medicaid Enrollment Backlogs*, Inside Health Policy (July 15, 2014), https://insidehealthpolicy.com/states-outline-tactics-timelines-fix-medicaid-enrollment-backlogs.

[74] Wilson v. Gordon, 822 F.3d 934 (6th Cir. 2016), https://caselaw.findlaw.com/us-6th-circuit/1736153.html.

[75] Christopher Coleman, Tennessee Justice Center, *How Tennessee Became an Outlier in the Rising Number of Uninsured Children and What Must Happen to Reverse the Trend* (July 26, 2019), https://www.tnjustice.org/wp-content/uploads/2019/07/How-Tennessee-Became-an-Outlier-in-the-Rising-Number-of-Uninsured-Children-and-What-Must-Happen-to-Reverse-the-Trend-1.pdf.

[76] Brent Kellman, *Tennessee erased insurance for at least 128,000 kids. Many parents don't know*., Tennessean (Apr. 1, 2019), https://www.tennessean.com/story/news/health/2019/04/02/tennessee-tenncare-coverkids-medicaid-erased-health-care-coverage-for-children/3245116002/.

[77] Joan Alker & Olivia Pham, Georgetown University Center for Children and Families, *Nation's Progress on Children's Health Coverage Reverses Course* (Nov. 2018), https://ccf.georgetown.edu/wp-content/uploads/2018/11/UninsuredKids2018_Final_asof1128743pm.pdf.

Modify "service delivery system, and comparable program elements"

Tennessee's waiver request to modify "service delivery system" and "comparable program elements" without oversight is so vague that we do not know what is being proposed and, thus, make the following comments guessing at what might be at stake. For example, "service delivery system" could mean structural system design issues that are so significant that it could not possibly be proper to approve them at all … and certainly not through a demonstration amendment. For example, the original TennCare program itself was a change to the delivery system that, of course, necessitated a new waiver application. Now Tennessee is requesting authority that would ostensibly allow it to again overhaul the delivery system, not only without filing a new demonstration, but without even filing an *amendment* to the project. This is precisely the type of amendment that GAO was concerned would evade public *comment*. Now, Tennessee is seeking to evade both public comment and HHS review.[78] Service delivery system changes, whether small or large, almost always directly impact "eligibility, enrollment, benefits, cost-sharing, or financing" of care for enrollees.[79] As such, CMS cannot abdicate its oversight over such important functions.

The term "comparable program elements" is totally unintelligible and could literally mean anything. CMS cannot approve such a waiver or effectively delegate discretion to a state in this way.

Finally, for the "enrollment processes, service delivery system, and comparable program elements" Tennessee requests to waive, there is no explanation of why these are necessary to the demonstration, and the waivers would be overbroad in that they would impact populations and services that are not part of the block grant calculation.

D. Closed formulary

Tennessee's proposed waiver to implement a closed formulary is not consistent with the purpose of Medicaid, is not experimental, is not necessary to the demonstration, and attempts to waive provisions that are not waivable under § 1115.

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[78] Tennessee application at 20, 25.
[79] *See* 42 U.S.C. § 1315(d)(1).

Unprecedented Changes to Prescription Drug Coverage.

Tennessee has proposed sweeping and unprecedented changes to prescription drug coverage. Tennessee seeks to limit access to outpatient prescription drugs in its Medicaid program by imposing a "closed formulary," with at least one drug available per therapeutic class.[80] The proposal would restrict outpatient prescription drug access across *all* Medicaid eligibility categories, exclude drugs based upon a vaguely worded fiscal prudence or cost effectiveness standard, and allow Tennessee to second-guess the safety and efficacy of FDA-approved medications.[81]

HHS should reject Tennessee's request. Congress has established comprehensive, specific coverage requirements for Medicaid outpatient prescription drugs that work in conjunction with the requirement for generous manufacturers' rebates. HHS should improve its oversight over the current requirements.[82] HHS has no authority to selectively waive these provisions, which rest outside of 42 U.S.C. § 1396a (in § 1396r-8) through § 1115. In addition, HHS should reject Tennessee's proposal because there is nothing experimental in denying access to medically necessary outpatient prescription drugs through "commercial-style closed formularies." Moreover, HHS rejected a near identical "closed formulary" proposal from Massachusetts last year.[83]

Outpatient prescription drug protections may not be waived through § 1115.

HHS has no authority to waive Medicaid outpatient prescription drug coverage provisions and protections. As noted above, § 1115 may only be used to waive requirements of 42 U.S.C. § 1396a. Congress placed the Medicaid outpatient prescription drug requirements in 42 U.S.C. § 1396r-8.

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[80] Tennessee application at 14-16.
[81] Tennessee application at 15.
[82] MACPAC, Report to Congress, *Improving Operations of the Medicaid Drug Rebate Program* (June 2018), https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf; Government Accountability Office, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight* (March 2015), https://www.gao.gov/assets/670/669188.pdf; Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018), https://www.gao.gov/assets/700/692697.pdf.
[83] CMS, Approval Letter for Massachusetts MassHealth Section 1115 Demonstration Amendment (Jun. 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.

With that provision, Congress established broad coverage requirements to ensure access to outpatient prescription drugs for low-income Medicaid enrollees.[84] States that elect to provide outpatient prescription drug coverage must cover all FDA-approved drugs that are offered by any manufacturer that agrees to provide rebates.[85] In exchange for having all their FDA-approved medications covered by Medicaid, the manufacturers enter into rebate agreements, which allow Medicaid programs to purchase prescription drugs at a significantly lowered cost.[86]

Tennessee's proposal to waive the broad coverage requirements, while retaining manufacturers' rebates, would upend the fundamental structure of these interdependent statutory provisions. HHS has no authority to waive 42 U.S.C. § 1396r-8.[87] HHS recognized that rebates provided under the Medicaid Drug Rebate Program (MDRP) work in conjunction with the broad coverage requirements under § 1396r-8 when it rejected the "closed formulary" proposal from Massachusetts last year.[88] HHS suggested that states would have to forgo rebates under the MDRP to exclude drugs and negotiate prices directly with manufacturers. However, Tennessee disregarded that advisory and is instead proposing the same "closed formulary" concept that HHS has rejected.

In addition, given CMS's willingness to approve cookie-cutter waiver, such a waiver would set a dangerous precedent and would lead to a race-to-the bottom whereby other states would seek to limit Medicaid prescription drug coverage to the detriment of low-income and vulnerable enrollees.

There is nothing experimental about closed formularies.

There is nothing experimental about closed formularies. Research confirms that they do not yield savings but cause significant harm to enrollees, especially persons with chronic conditions and persons with disabilities who rely on prescription drug access.

In fact, the very premise of Tennessee's proposal, that allowing commercial-style, closed formularies in Medicaid will lead to lower drugs costs, has already been proven incorrect. MACPAC recently released an in-depth analysis comparing the cost of prescription drugs

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[84] H.R. Rep. 101-881, 101st Cong. 2nd Sess. 1990, 1990 U.S.C.C.A.N. 2017.
[85] 42 U.S.C. § 1396r-8(k)(2)(i).
[86] 42 U.S.C. § 1396r-8(a)(1).
[87] *Pharmaceutical Research and Mfrs. of America v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001).
[88] *See* CMS, Approval Letter for Massachusetts MassHealth Section 1115 Demonstration Amendment (Jun. 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.

in Medicaid, commercial plans with closed formularies, and Medicare. Medicaid offers much broader coverage and pays far less, or at least the same, for most drugs when compared to commercial plans and Medicare.[89] MACPAC's findings are consistent with a wealth of evidence showing that formulary restrictions have either a negative effect or no effect at all on pharmacy and medical costs.[90] And again, since there is nothing experimental with commercial-style closed formularies, HHS may not use § 1115 to waive Medicaid's broad coverage requirements for outpatient prescription drugs.

Tennessee's application carves prescription drug coverage out of the block grant, so this waiver is also not necessary to the project. Tennessee's risk for the cost of prescription drugs is not changing under this project, so the waiver is unrelated and unnecessary.

Closed formularies harm persons with disabilities and those with serious or chronic conditions.

According to researchers, the consequences of limiting prescription drug access are well-known and predictable – fewer prescriptions will be filled, resulting in increased non-adherence in the treatment of potentially serious medical conditions.[91] Gaps in treatment can have deadly consequences for some, including people living with HIV/AIDS where "even short interruptions of care can threaten health and undermine prevention effects."[92]

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[89] Medicaid and CHIP Payment and Access Comm'n, *Findings from Phase 2 of Analysis on Medicaid Drug Formularies: Effects on Utilization and Spending* (Sept. 2019), https://www.macpac.gov/publication/findings-from-phase-2-of-analysis-on-medicaid-drug-formularies-effects-on-utilization-and-spending/.

[90] Yujin Park et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review,* 23 J. MANAGED CARE & SPECIALTY PHARM. 893, 898 (2017) (reviewing 59 unique studies and observing that the majority of "studies that included total or medical costs (in addition to pharmacy costs)… showed either negative effect on total, medical, or pharmacy costs or no effect on pharmacy costs"); Laura E. Happe et al., *A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization,* 20 J. MANAGED CARE & SPECIALTY PHARM. 677, 681 (2014) (reviewing 93 studies and concluding "there was no distinct trend in the direction of association of economic outcomes with formulary restrictions").

[91] David Ridley & Kirsten Axelsen., *Impact of Medicaid Preferred Drug Lists on Therapeutic Adherence,* 24 *PHARMACOECONOMICS* 65 (2006), http://www.ncbi.nlm.nih.gov/pubmed/17266389. *See also* Laura Happe et al., *A Systematic Literature Review Assessing the Direction Impact Of Managed Care Formulary Restrictions On Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resources Utilization*, 20 J MANAGED CARE SPECIALTY PHARM. 677 (July 2014); C. Daniel Mullins et al., *Persistence, Switching, and Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, and Citalopram*, 25 PHARMACOTHERAPY 660 (May 2005).

[92] *See Drug Resistance*, AIDS INFO (Jan. 28, 2019), https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance; Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 *Health Affairs*, 430 (2014).

In managing HIV, physicians express a need to tailor individual therapy for patients by trying multiple drugs in the same therapeutic class.[93] For these patients, less restrictive formulary designs yield better outcomes and reduce costs.[94]

Formulary restrictions have been associated with lower medication adherence and poorer health outcomes in general.[95] A closed formulary in Medicaid would be particularly harmful for individuals with chronic and complex conditions. For example, decreases in medication utilization due to closed formularies are even more severe for patients with chronic illness.[96] Such outcomes would not promote the objectives of Medicaid.

Tennessee's closed formulary proposal would leave enrollees with inadequate prescription drug coverage.

In its proposal, Tennessee argues that establishing a closed formulary would align its Medicaid prescription drug benefit with commercial plans.[97] Instead of providing most FDA-approved medications where a manufacturer has entered into a rebate agreement, under Tennessee's proposal, prescription drug coverage could be limited to one drug per class.

In fact, this coverage standard is significantly lower than the prescription drug formulary required of many commercial plans sold through the individual and small group markets in Tennessee. These plans are subject to the Essential Health Benefits (EHB) coverage standards, established by a benchmark plan selected by Tennessee officials.[98] In Tennessee, the EHB benchmark plan is the Small Group Shop HDHP plan sold by BlueCross BlueShield of Tennessee, and it covers far more than the minimum of one drug

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[93] See *Formulary Decision-Making Challenges in HIV*, AM. J. MANAGED CARE (March 19, 2018), https://www.ajmc.com/peer-exchange/special-considerations-in-hiv-management/formulary-decisionmaking-challenges-in-hiv.
[94] James Baumgardner et al., *Modeling the Impacts of Restrictive Formularies on Patients With HIV,* 24 AM. J. MANAGED CARE (SPECIAL ISSUE NO. 8) SP322, SP325 (2018).
[95] *See* Laura E. Happe et al., *A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization,* 20 J. MANAGED CARE & SPECIALTY PHARM. 677, 681 (2014); Seth A. Seabury et al., *Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid* 20 AM. J. MANAGED CARE e52, e58 (2014); Yujin Park et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review,* 23 J. MANAGED CARE & SPECIALTY PHARM. 893, 898 (2017).
[96] *See* Brenda R. Motheral & Rochelle Henderson, *The Effect of a Closed Formulary on Prescription Drug Use and Costs*, 36 INQUIRY 481, 485 (1999-2000).
[97] Tennessee application at 15.
[98] *See* 42 U.S.C. § 300gg–6(a); 45 C.F.R.§ 147.150; 45 CFR § 156.100. *See also* 29 C.F.R.§ 2590.715-1251(c)(1).

per class proposed by Tennessee.[99] The EHB prescription drug coverage standard is one drug per USP class and category, or the benchmark plan, whichever is greater.[100]

For example, enrollees in individual and small group plans subject to EHB standards have over thirty anti-retrovirals used to treat HIV.[101] Medicaid enrollees living with HIV would have 1-5 medications available, depending on what classification system Tennessee decides to use. Tennessee's EHB benchmark plan provides at least ten forms of insulin; whereas TennCare's closed formulary might only provide one.[102]

Tennessee provides insufficient detail on its formulary design and exceptions process.

And while some of the bottom lines are stated (e.g., one drug per class), most of Tennessee's drug coverage proposal lacks sufficient detail for stakeholders to provide meaningful comment. For example, it states that the "closed formulary" would provide at least one drug per therapeutic class, but fails to specify what drug classification system it would use.

Tennessee promises an exceptions process to cover medically necessary drugs not on the formulary. However, the State fails to provide sufficient detail for stakeholders to be able to provide meaningful comment.

Furthermore, Tennessee fails to provide sufficient detail regarding how it will evaluate drugs for inclusion or exclusion from its closed formulary. The application mentions "market prices," but that term is not explained.[103] It could mean anything from average manufacturers prices, best private, wholesale acquisition cost, or a host of other pharmaceutical pricing standards.

Tennessee also mentions "cost effectiveness" as it proposes excluding drugs from its closed formulary. But again, the details are missing. CMS should reject any application proposing to employ quality-adjusted life years (QALYs), a metric sometimes used to

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[99] *See* CMS Center for Consumer Information & Insurance Oversight (CCIIO), Tennessee 2017 EHB Benchmark Plan, https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2017_Benchmark-Summary_TN.zip (last visited Dec. 19, 2019).
[100] 45 C.F.R. § 156.122.
[101] CMS Center for Consumer Information & Insurance Oversight (CCIIO), Tennessee 2017 EHB Benchmark Plan 6, https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2017_Benchmark-Summary_TN.zip (last visited Dec. 19, 2019).
[102] *Id*. at 7.
[103] Tennessee application at 15.

calculate cost-effectiveness of a drug or other medical intervention, and one that the National Council on Disability (NCD), an independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families, recently concluded, based on this evidence, is discriminatory or potentially discriminatory.[104] This is consistent with HHS' prior rejection of the State of Oregon's request for demonstration authority to use QALYs to allocate resources in their Medicaid program in the early 1990s.[105] Congress also prohibited the use of QALYs in Medicare and the Patient Centered Outcomes Research Institute (PCORI) within the Affordable Care Act.[106]

In sum, we are not able to comment on Tennessee's proposal without further information on the metrics the State will use, and equally important, without this baseline information, CMS is not in a position to be able to assess whether the proposal complies with section 1115's requirements.

Tennessee fails to fully utilize lawful strategies to address high drug costs.

Tennessee has provided no explanation as to why its proposed closed formulary waiver is even necessary given the ample Medicaid flexibility for formularies and preferred drug lists (PDLs) already available in federal law.[107] (TennCare's pharmacy advisory committee website provides no evidence that the State is currently employing Medicaid formulary exclusions provided under current law.[108]) CMS should not approve this waiver because the State already has equivalent or better flexibilities that would help it save money *without causing such serious harms to enrollees*.

States already have ample authority under current law to establish a formulary and exclude drugs from Medicaid coverage. A state's Medicaid formulary must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals

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[104] Nat'l. Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series* (Nov. 6, 2019), https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.
[105] *Id.* at 45-46
[106] *Id*. at 46
[107] 42 U.S.C. §§ 1396r-8, 1396o, 1396o-1, 1396u-7.
[108] *See* Tennessee Division of Tenncare, TennCare Pharmacy Program: Welcome to the Magellan Health Services Portal, https://tenncare.magellanhealth.com/tenncare_portal/spring/main;jsessionid=477nd7MLnLyNFTpLz0H9pDGZ7DGhQq21Mr3SSG4GyBl8mGgRMmhq!-221643383?execution=e1s1 (last accessed Dec. 19, 2019).

appointed by the Governor or the state's drug use review board.[109] If a state decides to exclude an outpatient prescription drug from its formulary, it may only do so after finding the drug does not have a significant, clinical therapeutic advantage over other drugs, and the state must explain the basis for the exclusion in writing.[110] Even if a state excludes an outpatient prescription drug from its formulary, the state must permit coverage of excluded pursuant to a prior authorization program and on a case-by-case basis.[111]

Federal law also allows states to designate "preferred" and "non-preferred" drugs and charge Medicaid enrollees copayments, similar to a formulary tiering structure, subject to limitations.[112] States can also negotiate supplemental rebates with pharmaceutical manufacturers in exchange to placement on the states PDL list.

Tennessee argues that its proposal for a closed formulary "would allow the state to negotiate more favorable rebate agreements with manufacturers, since—for each therapeutic class—the state could offer manufacturers an essentially guaranteed volume in exchange for a larger rebate."[113] However, the State fails to describe how such authority would yield any greater rebates than it can achieve through negotiating supplemental rebates (which do not harm enrollees). According to CMS, Tennessee is currently under-utilizing its supplemental rebate authority. CMS reports that Tennessee entered into a Supplemental Rebate Agreement (SRA) almost twenty years ago.[114] However, an increasing number of states have entered into purchasing pools to leverage their buying power and negotiate higher supplemental rebates – again, without harming enrollees.[115] Tennessee has not joined any multi-state rebate agreements with pharmaceutical manufacturers, whereby states leverage their buying power to lower prescription drug

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[109] 42 U.S.C. § 1396r-8(d)(4)(A). These are often called Pharmacy and Therapeutics (P&T) committees. *See also* David Bergman et al., National Academy for State Health Policy (NASHP), *State Experience in Creating Effective P&T Committees* (March 2006), https://nashp.org/wp-content/uploads/sites/default/files/medicaid_pandt.pdf.
[110] 42 U.S.C. § 1396r-8(d)(4)(C).
[111] 42 U.S.C. § 1396r-8(d)(4)(C); see also *Pharmaceutical Research and Mfrs. of America v. Meadows*, 304 F.3d 1197, 1207-08 (11th Cir. 2006).
[112] 42 U.S.C. §§ 1396o, 1396o-1. *See also* David Machledt and Jane Perkins, National Health Law Program, *Medicaid Premiums and Cost Sharing* (March 26, 2014), https://9kqpw4dcaw91s37kozm5jx17-wpengine.netdna-ssl.com/wp-content/uploads/2014/03/NHeLP_IssueBriefMedicaidCostSharing_03262014.pdf.
[113] Tennessee application at 15.
[114] Ctrs. for Medicare & Medicaid Services, *Medicaid Pharmacy Supplemental Rebate Agreements (SRA) as of September 2019*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.
[115] *See* Rachel Dolan, Kaiser Fam. Found., *Understanding the Medicaid Prescription Drug Rebate Program* 8 (Nov. 2019), http://files.kff.org/attachment/Issue-Brief-Understanding-the-Medicaid-Prescription-Drug-Rebate-Program.

costs.[116] Of note, according to MACPAC, only 16.5% of Tennessee's current Medicaid spending is on brand name prescription drugs.[117] The lion's share of outpatient prescription drug spending is for generics, where states have ample opportunity to negotiate supplemental rebates and enter into purchasing pools with other states to lower costs.

From what it has made available to the public about the proposal, it is clear that it will harm enrollees, have no experimental value, and is not necessary. CMS should not approve this waiver and should instead require Tennessee to use the existing flexibility to pursue similar polices with less harm to enrollees.

Tennessee may not supplant the FDA drug approval process.

HHS has no authority under § 1115 to allow Tennessee to replace the FDA drug approval process with its own determination whether outpatient prescription drugs are safe and effective.[118] In its application, Tennessee argues that excluding new drugs approved through the FDA's "accelerated approval pathway" will help protect enrollees since "many of them have not yet demonstrated actual clinical benefit and have been studied in clinical trials using only surrogate endpoints."[119]

By definition, a "covered outpatient drug" is a drug which is approved for safety and effectiveness as a prescription drug under the federal Food, Drug, and Cosmetic Act.[120] Tennessee's proposal suggests (without evidence) that FDA is approving drugs that have not demonstrated clinical benefit — which, if true, would directly violate the agency's own requirement that drug companies conduct studies to confirm clinical benefit prior to approval.

In response to comments provided at the state-level, Tennessee notes that "[i]t is not the state's intent to duplicate the FDA's approval process," but it would use its own P&T

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[116] Ctrs. for Medicare & Medicaid Services, Medicaid Pharmacy Supplemental Rebate Agreements (SRA) as of September 2019, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.
[117] Medicaid and CHIP Payment and Access Comm'n, *MACStats Exhibit 27. Medicaid Drug Prescriptions by Delivery System and Brand or Generic Status, FY 2018* (Dec. 2019) https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-27.-Medicaid-Drug-Prescriptions-by-Delivery-System-and-Brand-or-Generic-Status-FY-2018-thousands.pdf.
[118] See also *Edmonds v. Levine*, 417 F.Supp.2d 1323, 1336 (S.D. Fla. 2006), finding that Florida's Medicaid program could not establish its own criteria for approved off-label uses.
[119] Tennessee application at 15.
[120] 21 U.S.C. § 355(c); 42 U.S.C § 1396r–8(k)(2)(A). The 21st Century Cures Act, Pub. L. No. 114-255 (2016), amends the Food, Drug, and Cosmetic Act to create fast track approval.

committee review to establish prior authorization and medical necessity criteria.[121] Tennessee does not need a § 1115 waiver to conduct such reviews. Tennessee and all state Medicaid programs that provide the optional outpatient prescription drug benefit are obligated under federal law to review drug use and utilization.[122]

E. Termination and lockout for fraud

Tennessee's proposed waiver to terminate and lockout Medicaid for individuals engaging in alleged "fraud" is not consistent with the purpose of Medicaid and is not experimental.

In its application, Tennessee is seeking permission to terminate and impose a twelve-month lockout period on individuals who commit "TennCare fraud."[123] The application's focus on enrollee fraud is misplaced, as estimates suggest that enrollees commit only 10% of all health care fraud.[124] In addition, existing federal law already gives Tennessee comprehensive authority and extensive flexibility to address fraud among Medicaid enrollees – in fact, federal law *requires* states to take some actions. For example, states must refer cases of suspected fraud to law enforcement officials.[125]

Significantly, Tennessee's application mischaracterizes its existing authority to address fraud. The application avers that, "historically the federal government has not allowed states to take the most basic and obvious corrective action of terminating or suspending a member's eligibility when he has been determined to have committed fraud or abuse against the Medicaid program," and that "[t]his federal policy defies common sense, demonstrates a distressing lack of concern for public resources, undermines the integrity of the Medicaid program, and does nothing to disincentivize the misuse of public resources dedicated to provide assistance to needy individuals and families."[126] In fact individuals convicted of Medicaid fraud face substantial fines and imprisonment, and (in statutory provisions that are not waivable), Congress has *already* established states' authority to prohibit them from enrolling in Medicaid for up to one year.[127] Thus, Tennessee's request is either unnecessary or it is based on something left unstated. Notably, "TennCare fraud" is undefined in the application. Perhaps the State wants to

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[121] Tennessee application at 35.
[122] 42 U.S.C. § 1396r-8(g).
[123] Tennessee application at 18.
[124] Sara Rosenbaum et al., George Washington Univ. Dep't of Health Policy, *Health Care Fraud*: *An Overview* 2 (2009), https://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_EFDAD1BC-5056-9D20-3D3D36632A4F2163.pdf.
[125] 42 C.F.R. § 455.15.
[126] Tennessee application at 18.
[127] 42 U.S.C. § 1320a-7b(a).

terminate individuals who have not actually been convicted of the listed fraudulent offenses. [128] Indeed some of Tennessee's grounds for termination and lockout include outcomes that are, by definition, less than conviction, including an "individual's agreement to enter into participation in a first offender, deferred adjudication, or other arrangement where judgment of conviction has been withheld."[129] Other terms used by Tennessee are unclear and may also include dispositions short of conviction ("a finding of guilt" and "a plea of guilty or *nolo contendere* by the individual that has been accepted," as distinguished from a "judgment of conviction entered").[130] Research shows that, if approved, these grounds will lead to improper coverage losses. Two studies of individuals who were wrongly convicted showed that about 10% of wrongful convictions involved individuals who actually *plead guilty*.[131] Terminations for nolo contendere will impact even greater percentages of individuals who lack the resources to defend themselves or fear bias from the justice system.

Tennessee justifies these harms by claiming that the penalties will "disincentivize the misuse of public resources."[132] But there is simply no evidence to suggest that the broadened lockout penalty is more likely than the existing consequences (which include fines, imprisonment, and enrollment prohibition) to discourage fraudulent conduct. In short, Tennessee already has authority to penalize Medicaid fraud and the State's unnecessary request will increase harm.

F. Amount, duration, and scope, optional services, and targeted benefits

Tennessee's requests to waive the review process for changes to amount, duration, and scope and optional services, and to implement targeted benefits, should not be approved because they do not promote the objectives of Medicaid and could result in discriminatory health coverage policies. These benefits provisions are also not waivable because they are outside of 42 U.S.C. § 1396a.

The State portrays these requests as "routine," but they are so broadly stated that the accuracy of that statement cannot be determined. And, it is not difficult to imagine how adding a benefit with arbitrary limits or restrictions could also lead to discriminatory benefit

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[128] *Id*.
[129] Tennessee application at 19.
[130] *Id*.
[131] Jeff Adachi & Yali Corea-Levy, The San Francisco Public Defender, *The Right to Plea No Contest in a Criminal Case* (July 20, 2018), https://sfpublicdefender.org/news/2018/07/the-right-to-plea-no-contest-in-a-criminal-case/.
[132] Tennessee application at 18.

design or insufficient amount, duration, and scope of coverage. Under Tennessee's proposal, if Tennessee wishes to add an optional benefit that does not comport with Medicaid amount, duration, or scope standards, HHS will not be in a position to hold the State accountable as it would during the State Plan Amendment review process. Indeed, CMS review of SPAs is critical to identify legal deficiencies, such as services that are not actually reimbursable under Medicaid law (*e.g.*, the case of some Targeted Case Management programs.)[133] In one case, CMS denied a SPA from Maryland for TCM in part because "it restricted beneficiary freedom of choice by limiting providers to employees of public welfare agencies."[134] This kind of discriminatory targeting is exactly why CMS must continue to conduct oversight of state SPAs, even those that add new benefits.

Tennessee's proposal to unilaterally establish targeted benefits in absence of federal oversight amplifies these concerns. The Medicaid statute's comparability requirement is designed to prevent discrimination in benefit design. Although the State claims the current federal policy framework for targeting benefits is "unnecessarily limiting," it notes two paragraphs later that the State "already has significant experience with waivers of comparability."[135] The Secretary regularly grants states waivers to implement pilot projects for targeted benefits. In fact, the State's example, targeted dental coverage, is already part of § 1115 demonstrations in several states, as are other targeted benefits like pre-natal home visit programs.[136]

However, these specific waiver requests must be evaluated by the Secretary for experimental value and potential discriminatory effects, and they are subject to oversight and evaluation requirements. We have already seen other states inappropriately propose to use § 1115 to target richer benefit packages to, for example, people who work a certain

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[133] HHS OIG, *Missouri Claimed Some Unallowable Medicaid Payments of Targeted Case Management Services* (Mar. 2019), https://oig.hhs.gov/oas/reports/region7/71703219.pdf; HHS OIG, *Colorado Claimed Some Unallowable Medicaid Payments of Targeted Case Management Services* (Apr. 2018), https://oig.hhs.gov/oas/reports/region7/71603215.pdf. North Dakota, Minnesota, and Georgia have previously been found to have inadequate oversight to ensure that TCM services were appropriate for federal financial participation.

[134] Congressional Research Service, *Medicaid Targeted Case Management (TCM) Benefits*, fn 13 (Mar. 2008), http://www.ncsl.org/print/health/CRSTCM.pdf.

[135] Tennessee application at 17.

[136] *See*, *e.g.*, Maryland's Health Choice 1115 Waiver provides dental for pregnant women and for dual eligibles. Other states target services through managed care flexibilities. For example, some health plans in West Virginia offer adult dental services to pregnant women as a value-added service. *See*, Kaiser Family Foundation, *Medicaid Benefits: Dental Services*, fn9, https://www.kff.org/medicaid/state-indicator/dental-services/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Dec. 19, 2019).

number of hours.[137] Tennessee's proposal seeking permission to target benefits based on undefined "medical factors or other considerations" would potentially encompass exactly this sort of discriminatory benefit design.[138]

The HHS Secretary may not delegate § 1115 approval authority to a state to develop its own experiments with federal Medicaid funds without federal oversight. The Secretary has a responsibility to ensure that § 1115 projects are specific, comport with the law, and are likely to promote the objectives of the Medicaid program. If Tennessee has innovative ideas for targeting benefits eligible for federal financial participation, it must adhere to the existing approval and evaluation processes, whether through a § 1115 amendment or through other mechanisms available under the statute, including 42 U.S.C. § 1396n(i), Medicaid managed care, health home programs, and alternative benefit plans.

G. Using Medicaid for "health related" spending

Tennessee has requested waiver authority to "[s]pend federal block grant dollars on items or services not otherwise reimbursable under Title XIX but which have an impact on enrollee health."[139] This request is excessively broad and vague. Interventions that promote the objectives of Medicaid are ones that furnish medical assistance, that is, that promote health *coverage*.

What is more, states have a long and unscrupulous history of using Medicaid as a slush fund to finance objectives unrelated to health coverage. The GAO has repeatedly identified state efforts to improperly re-purpose federal Medicaid money for non-Medicaid expenditures.[140] In 2004, a GAO inquiry that looked at six states found that, "one state used the funds to help finance its education programs, and others deposited the funds into state general funds or other special state accounts that could be used for non-Medicaid purposes."[141] Although HHS has worked to curb such abuses, a 2015 GAO report specific to § 1115 raised serious concerns regarding the way that five states were using Medicaid

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[137] *See, e.g.,* Nebraska Medicaid Section 1115 Heritage Health Adult Expansion Demonstration (Dec. 12, 2019), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ne/ne-hha-pa.pdf (excerpt attached).
[138] Tennessee application at 17.
[139] Tennessee application at 25.
[140] Government Accountability Office, *Medicaid: Intergovernmental Transfers Have Facilitated State Financing Schemes* (March 2004), https://www.gao.gov/new.items/d04574t.pdf; Government Accountability Office, *Medicaid Demonstrations: Approval Criteria and Documentation Need to Show How Spending Furthers Medicaid Objectives* 29 (April 2015), https://www.gao.gov/assets/670/669582.pdf.
[141] Government Accountability Office, *Medicaid: Intergovernmental Transfers Have Facilitated State Financing Schemes* i (March 2004), https://www.gao.gov/new.items/d04574t.pdf.

DSHP funding, a financing model similar to what Tennessee proposes (see further DSHP discussion below):

> Several state programs approved for federal Medicaid funds in these states appeared, on their face, to be only tangentially related to improving health coverage for low-income individuals and lacked documentation explaining how their approval was likely to promote Medicaid objectives. For example, among the programs approved were a program that funds insurance for fishermen and their families at a reduced rate.[142]

Tennessee, in particular, has a history of diverting and hoarding federal Medicaid dollars. For example, like other states, Tennessee received temporary additional federal funding during the great recession under the American Recovery and Reinvestment Act of 2009 (ARRA), P.L. 111-5. Because the funds – hundreds of millions of dollars – were meant to immediately benefit depressed communities and affected households, ARRA provided that, "[a] State is not eligible for an increase in its FMAP … if any amounts attributable (directly or indirectly) to such increase are deposited or credited into any reserve or rainy day fund of the State."[143] Nonetheless, Tennessee deposited the entire ARRA Medicaid increase in the State reserve fund, thereby diverting it to purposes completely unrelated to Medicaid.[144]

Tennessee's spending of its federal TANF block grant funding also evidences abuses. Despite being among the states with the highest rates of children living in extreme poverty, Tennessee hoarded its TANF allotment, accruing $772 million in unexpended reserves, by far the most in the nation.[145] Instead of using TANF reserves to relieve childhood poverty, the State adopted a law in 2018 that diverts part of the reserves to fund a Medicaid work requirement that is projected to remove 68,000 parents from the TennCare program.[146]

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[142] Government Accountability Office, *Medicaid Demonstrations: Approval Criteria and Documentation Need to Show How Spending Furthers Medicaid Objectives* 29 (April 2015), https://www.gao.gov/assets/670/669582.pdf.

[143] Section 5001(f)(3), https://www.congress.gov/111/plaws/publ5/PLAW-111publ5.pdf.

[144] Declaration of David Manning, *Crabtree v. Goetz*, No. 3-08-939, (M.D. Tenn., May 15, 2009), https://www.tnjustice.org/wp-content/uploads/2019/12/2009-5-15-Manning-Declaration-re.-TN-ARRA-funds-diversion.pdf.

[145] Children's Defense Fund, *Child Poverty in America 2018: State Analysis* (Sept. 26, 2019), https://www.childrensdefense.org/wp-content/uploads/2019/09/Child-Poverty-in-America-2018-State-Factsheet.pdf; *Tennessee's $732M in welfare reserves the biggest in nation*, Tennessean (Oct. 30, 2019), https://www.tennessean.com/story/news/2019/10/31/tennessee-tanf-fund-732-m-welfare-reserves-biggest-nation-families-first/2496808001/.

[146] Tenn. Code Ann. § 71-5-1 (1968), https://www.tn.gov/content/dam/tn/tenncare/documents2/PublicChapter869.pdf; Joan Alker and Olivia Pham, Georgetown University Center for Children and Families, *Work Reporting Requirement for Tennessee Parents Would Harm Low-Income Families with Children* (Jan. 2019),

When the TANF reserves recently came to light, the governor and legislative leadership continued to refuse to spend the money, eventually relenting only in the face of a public backlash.[147]

Given this history, CMS should not now allow the State to spend money on initiatives that are not related to health coverage and "are not [even] specifically targeted at the TennCare population."[148] Though the State disavows any intention of using funds on projects such as highway maintenance, this does not rule out expenditures in countless other unrelated areas. And while the State describes some ostensible "priorities" for new spending, nothing in this application prevents the State from financing interventions unrelated to health care that have speculative or unsubstantial impacts on health.

V. The TennCare II "block grant" is not experimental or legitimate.

A. The project is not a valid experiment.

HHS already runs block grant programs, established by Congress.

The facts that Congress has already established numerous block grant programs and is well familiar with their operation makes it clear that Congress has nothing to learn from Tennessee's proposed experiment. HHS runs numerous block grant programs, including a large national health insurance block grant program (CHIP).

More importantly, evidence from HHS's own block grant programs has already demonstrated that the impact of block grant programs is not improved access to services or innovation, but in fact the opposite, reduced access to services and regression. In 1996, at the end of the AFDC program, 67% of Tennessee families in poverty were receiving cash assistance.[149] By 2017, only 23% of Tennessee families were receiving

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https://ccf.georgetown.edu/2019/01/30/work-reporting-requirement-for-tennessee-parents-would-harm-low-income-families-with-children/.

[147] Natalie Allison, *Gov. Bill Lee Defends Tennessee's Decision to Sit on $732M in Reserves for Poor Working Families,* Nashville Tennessean (Oct. 25, 2019), https://www.tennessean.com/story/news/politics/2019/10/24/governor-bill-lee-defends-tennessee-choice-hold-732-m-poor-working-families-tenncare-block-grant/4086524002/; Mike Reicher et al., *$1 Billion of Federal Funds Unspent in Tennessee: Here's What We Know So Far*, Nashville Tennessean (Nov. 8, 2019), https://www.tennessean.com/story/news/2019/11/08/tanf-tennessee-heres-what-we-know-so-far-unspent-funds/2517962001/.

[148] Tennessee application at 14.

[149] Center on Budget and Policy Priorities, *TANF Financial Assistance to Poor Families Is Disappearing in Tennessee* (2018), https://www.cbpp.org/sites/default/files/atoms/files/tanf_trends_tn.pdf.

services, a staggering 44 point drop.[150] This decrease represented over 70,000 less families receiving services, the vast majority of them living in poverty.[151] Even the families that had services received a remarkably low benefit in Tennessee, $185 compared to the national median of $450.[152] In Tennessee, even when the TANF and SNAP benefits are added together, families remain below 40% of the poverty level – the second lowest level in the country.[153] From 2001 to 2017 Tennessee reduced over two-thirds of its investment in child care and over one-third for work activities though "the number of families with children below 50 percent of the poverty line remained high."[154] Despite alarming levels of poverty in the State (for example, the nation's sixth highest poverty rate for young children), Tennessee has taken advantage of the block grant mechanism to hoard a large pool of unspent funds instead of meeting the needs of Tennesseans.[155]

In addition, national research shows that the formula of block grants plus "flexibility" is a recipe for disaster. For example, Kansas exploited "virtually unfettered flexibility to set eligibility policies and processes in TANF" to minimize coverage far below that in other states (setting a 24 month time limit compared to the 60-month limit most states use).[156] Most families that left the program did so because they were cut off, not because they no longer needed assistance.[157] Data show a steady increase in extreme poverty from 1996 (when AFDC was replaced by TANF block grants) to 2012.[158] In Maine, a study found that families that lost assistance due to new flexibility policy "face[d] multiple barriers to work and experience[d] severe hardships as a result of losing TANF assistance."[159] In Washington state, data shows that 36% of families who lost TANF were homeless at the time, including 2,000 homeless children, and that of those losing TANF due to time limits,

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[150] *Id*.
[151] *Id*.
[152] *Id*. Tennessee's benefit was subsequently increased, and is still far below the 2017 national median.
[153] Ashley Burnside and Ife Floyd, Center on Budget and Policy Priorities, *More States Raising TANF Benefits to Boost Families' Economic Security* (Dec. 2019),https://www.cbpp.org/research/family-income-support/more-states-raising-tanf-benefits-to-boost-families-economic-security.
[154] Center on Budget and Policy Priorities, *Tennessee TANF Spending* (2018), https://www.cbpp.org/sites/default/files/atoms/files/tanf_spending_tn.pdf.
[155] LaDonna Pavetti, Center on Budget and Policy Priorities, Tennessee Should Use Its TANF Funds to Lessen Child Poverty (Nov. 14, 2019), https://www.tnjustice.org/wp-content/uploads/2019/11/Using-TANF-to-Lessen-Child-Poverty.pdf; Center on Budget and Policy Priorities, *Tennessee TANF Spending* (2018), https://www.cbpp.org/sites/default/files/atoms/files/tanf_spending_tn.pdf.
[156] Tazra Mitchell et al., Center on Budget and Policy Priorities, *Life After TANF in Kansas: For Most, Unsteady Work and Earnings Below Half the Poverty Line* (Feb. 2018), https://www.cbpp.org/research/family-income-support/life-after-tanf-in-kansas-for-most-unsteady-work-and-earnings-below.
[157] *Id*.
[158] Arloc Sherman, *Under $2 a Day in America, Part 1*, Center on Budget and Policy Priorities Off the Charts (March 5, 2012), https://www.cbpp.org/blog/under-2-a-day-in-america-part-1.
[159] Sandra Butler, *TANF Time Limits and Maine Families: Consequences of Withdrawing the Safety Net* (March 2013), https://www.mejp.org/sites/default/files/TANF-Study-SButler-Feb2013.pdf.

about 70% had mental health needs and nearly half had serious mental illness.[160] National data also shows that work sanctions in TANF were also harmful with negligible benefits.[161]

There is no experiment – Tennessee is not taking on any risk beyond the current demonstration.

In its application, Tennessee states that its "innovative proposal reimagines the Medicaid financing structure" and will "convert the federal share of its Medicaid funding relating to providing its core medical services to its core population to a block grant."[162] However, the actual content of the application taken on its face does not do this. Instead, the application indicates that the State will continue using its existing financing structure.

TennCare has been in operation as a § 1115 waiver project for about two decades. Like all § 1115 projects, TennCare is subject to the Department's budget neutrality limit. And, under the terms of the project, the federal government will not provide TennCare financing in excess of that budget neutrality limit, which is trended annually based on a CBO trend rate.[163] In other words, TennCare already has an effective cap, as do all comprehensive § 1115 projects. Tennessee's "block grant" application explicitly implements – more accurately, preserves – the exact same CBO trend rate in the proposed project.[164] Tennessee's risk of losing federal funds remains unchanged for its current demonstration (potential for gains will be discussed shortly). This "block grant" is not an innovative experiment – it is par for the course in § 1115 projects.

A comparison between the projected costs and actual spending for TennCare (based on the State's quarterly report for the first quarter of 2019) illustrates that the block grant is illusory. For example, children and adults under the age of 65 are by far the two most

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[160] Washington State Budget and Policy Center, Harmful WorkFirst Cuts Worsen Washington's Homelessness and Mental Health Crises (2019), https://budgetandpolicy.org/wp-content/uploads/2019/01/Workfirst-homelessness-behavioral-health-fact-sheet-2019-V8.pdf; Washington State Department of Social and Health Services, *Temporary Assistance For Need Families Pre-2011 Workfirst Policies* (Dec. 2018), https://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?fileName=WorkFirst%20Pre%202011%20Policies%20Legislative%20Report_99990320-7163-4562-90b0-954db40ef616.pdf.

[161] LaDonna Pavetti, Center on Budget and Policy Priorities, *TANF Studies Show Work Requirement Proposals for Other Programs Would Harm Millions, Do Little to Increase Work* (Nov. 2018), https://www.cbpp.org/research/family-income-support/tanf-studies-show-work-requirement-proposals-for-other-programs-would.

[162] Tennessee application at iii. Note, Tennessee's block grant includes an adjustment for enrollment, effectively making it a per capita cap. *See* Tennessee application at iv.

[163] Tennessee application at 5-6.

[164] *Id*.

numerous groups in TennCare and account for well over half the spending.[165] The projected costs for children and adults (DY 16) were $535.50 and $1,111.34 (PMPM), respectively.[166] As the quarterly report show, however, the actual costs are only about $384 and $608, respectively.[167] As a result of lavish, front-end projections, even after factoring in all costs, the Tennessee demonstration ran a *surplus* of over $770 million in just one quarter, over total costs of $2.8 billion (meaning the projection gives the State a whopping cushion of 27% above the actual spending trajectory).[168] The generosity of the projection in Tennessee's application, together with financing assumptions made by the State, have all but assured that it could never reach the cap and that it has no chance of helping control federal funding growth as a cap, making the entire "experiment" a charade.

This stands in stark contrast to true spending cap proposals, such the Better Way: Our Vision for a More Confident America (2016), American Health Care Act (2017), and Better Care Reconciliation Act of 2017 proposals. These proposals *were* designed to control federal funding growth and took the exact opposite (though equally misguided) approach: they deliberately set the projections *below* actual spending. For example, the long term trend rate for Better Way and BRCA was based on CPI-U.[169] The long-term estimate for CPI-U is only 2.4%, well below current spending growth.[170] As a result, these proposals were estimated to result in massive *reductions* in federal spending, for example $841 billion for Better Way and $457 billion for AHCA.[171] The proposals also would have resulted in tens of millions of more uninsured individuals.[172] In short, Tennessee's

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[165] Division of TennCare, *TennCare II, STC 44, Quarterly Progress Report (January – March 2019)* Attachment A (May 30, 2019), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/TennCare-II/tn-tenncare-qrt-rpt-jan-mar-2019.pdf.

[166] Letter to Gabe Roberts, Director, TennCare, from CMS Acting Deputy Admin. & Director, CMS-- Special Terms and Conditions III.7 at 14 (July 2, 2019).

[167] Division of TennCare, *TennCare II, STC 44, Quarterly Progress Report (January – March 2019)* Attachment A (May 30, 2019), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/tn/TennCare-II/tn-tenncare-qrt-rpt-jan-mar-2019.pdf.

[168] *Id*.

[169] Matthew Buettgens, *Senate health bill would lower the Medicaid per capita cap rate, causing greater state budget shortfalls*, Urban Wire Health and Health Policy, (June 20, 2017), https://www.urban.org/urban-wire/senate-health-bill-would-lower-medicaid-capita-cap-rate-causing-greater-state-budget-shortfalls.

[170] Medicaid and CHIP Payment and Access Comm'n, *Design Issues in Medicaid Per Capita Caps: An Update* 9 (July 2017), https://www.macpac.gov/wp-content/uploads/2017/07/Design-Issues-in-Medicaid-Per-Capita-Caps-An-Update.pdf.

[171] John Holahan et al., Urban Institute, *The Impact of Per Capita Caps on Federal and State Medicaid Spending* (Mar. 2017), https://www.urban.org/research/publication/impact-capita-caps-federal-and-state-medicaid-spending.

[172] Linda J. Blumberg et al., Urban Institute, *State-by-State Coverage and Government Spending Implications of the Better Care Reconciliation Act* (June 2017), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2017/rwjf438332; Linda J. Blumberg et al., Urban Institute, *State-by-State Coverage and Government Spending Implications of the American Health Care Act*

purported block grant experiment looks nothing like a block grant proposal, and the risk of financial loss is indistinguishable from its existing project. HHS should not approve the waiver to allow a block grant – there is no experiment because there is no block grant.

We also note that first, Tennessee proposes to adjust the block grant upwards if enrollment increases, but not downwards if enrollment decreases.[173] This clearly depicts the one-sided deal Tennessee proposes and heightens the State's gain if it finds a way to suppress enrollment. Second, as if to dispel any doubt that the "block grant" is imaginary, Tennessee actually proposes that, "[i]f during the course of the demonstration the state's actual expenditures exceed the amount projected by the block grant such that the federal contribution to the state's Medicaid program would fall below the amount otherwise required by statute, the demonstration would be discontinued."[174]

In short, Tennessee's purported block grant experiment looks nothing like a block grant proposal, and the risk of financial loss is indistinguishable from its existing project. HHS should not approve the waiver to allow a block grant – there is no experiment because there is no block grant.

B. Tennessee's shared savings proposal is improper and profiteering.

While the Tennessee application would not change the State's risk of federal funding losses, it would result in a funding boon for the State. Tennessee requests a shared savings payment of half of the difference between the inflated spending cap and their actual spending.[175] Since the spending cap is inflated, the State is assured it will get shared savings payments. There are numerous problems with this.

As discussed earlier, there is no legal authority for these payments, which are in essence federal payments untethered to any kind of state spending. The lack of limits on how a state could spend such a payment also raise legal and accountability problems for HHS. (State spending is discussed further below.) It is fiscally irresponsible for HHS to give away Medicaid dollars. Because the trend rate is inflated, CMS will continue to pay its share of the actual spending, but then will be making an additional large and gratuitous shared savings payment. Far from a block grant that helps control federal spending, CMS will be giving away money.

(June 2017), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2017/rwjf438332/subassets/rwjf438332_1.

[173] Tennessee application page iv.

[174] *Id*. at 11.

[175] *Id*. at 10.

Even more troubling is that the shared savings provision creates an incentive for the State to slash spending at all times. (The only way that CMS actually could control its spending growth under this scheme is if the State slashes spending to such an abysmally low level that the reduction in CMS payments actually grew larger than the shared savings payment.) Tennessee's FMAP is 65%.[176] For every dollar the State does not spend on Medicaid, Tennessee will recover the 35 cents it would have spent *and* pocket 32.5 cents that the federal government would have paid. Tennessee will effectively turn a profit for *not* providing health care. In short, the shared savings provision will result in Tennessee getting free federal dollars and reward the State for cutting its own health care spending—when Tennessee has provided absolutely no evidence that its spending is inefficient or improper.

Finally, the profiteering character of Tennessee's proposed financing mechanism is exacerbated by the State's request to spend the money on anything that has an "impact" on health. That provision (addressed in greater detail above), would effectively allow the State to use the shared savings windfall to fatten its general fund and support a wide range of state budget objectives that have nothing to do with furnishing medical assistance – the objective of Medicaid.

When three major dots above are connected on the Tennessee proposal, it becomes clear that it is an attempted cash grab for the State as opposed to a block grant or other attempt to create a responsible arrangement with the federal government. First, the proposal would give the State a windfall of cash (for no action) *and* an incentive to slash spending. Second, by waiving managed care regulations it would give the State unprecedented power to reduce spending and care – allowing the State to cut capitation with actuarial impunity and allowing managed care plans to reduce coverage (network adequacy, utilization management, care coordination, etc.) to compensate for lost capitation. And third, it would allow the State to use the money to essentially prop up its general fund. No part of this promotes the objectives of Medicaid or has a valid experimental purpose. CMS does not have the authority under § 1115 to give away money or abdicate its role in holding states accountable for federal funding.

Tennessee's proposal would also violate CMS policy.

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[176] Kaiser Family Foundation State Health Facts, *Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier*, https://www.kff.org/medicaid/state-indicator/federal-matching-rate-and-multiplier/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last accessed Dec. 23, 2019).

As proposed, Tennessee's illusory block grant would violate CMS policy. In its application, Tennessee assumes that it can capture demonstration "savings" (*i.e.*, savings relative to the high without waiver cap), that those savings accrue over time, and that they can be spent on anything "impacting" health. However, in August 2018 guidance, CMS set clear limits on the ability of a state to "roll over" savings over time, and more importantly, CMS added a requirement that demonstration without waiver estimates be rebased (recalculated) "[b]eginning with the next demonstration extension approval period starting on or after January 1, 2021."[177] At regular intervals, financing for a new period must be adjusted downwards to account for *actual* spending in the prior period. Tennessee cannot accumulate savings indefinitely as proposed, and CMS cannot approve such an application under its own policies.

Furthermore, approval of this project would appear to contradict CMS's 2017 policy guidance phasing out Designated State Health Program (DSHP) § 1115 demonstrations.[178] DSHP demonstrations allow states to capture savings, similar to the way Tennessee has proposed and then apply those savings towards existing state-funded programs, effectively freeing up state dollars (which can then be used to draw additional federal matching funds). Tennessee's proposed financing scheme is essentially similar to the DSHP model – making it inconsistent with CMS policy. In that guidance, CMS cites concern that the DSHP model "in effect, results in increased federal expenditures without a comparable increase in the state's investment in its demonstration" – precisely what Tennessee has proposed.[179] CMS correctly notes that such a relationship "is inconsistent with the overall federal-state financial relationship under the Medicaid statute."[180]

Equally important is the fact that CMS re-evaluated the propriety of the DSHP model in response to "interest" from GAO and Congressional oversight committees.[181] It would not be appropriate for CMS to phase out the DSHP mechanism due to well-founded legal and oversight concerns and then re-establish the same financing mechanism under a new name. In fact, the Tennessee scheme should be of *greater* concern to CMS than the DSHP model it is phasing out. The DSHP model is less subject to abuse in that it supports an identifiable program (identifiable in advance) that the state is actually funding, and any subsequent federal money comes pursuant to state spending that is *matched*. Tennessee's proposal would require no state spending to obtain a federal windfall and would not involve supporting any pre-identifiable objective – CMS would only learn after

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[177] CMS Dear State Medicaid Director Letter, *Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects* 8 (Aug. 2018), https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf.
[178] CMS Dear State Medicaid Director Letter, *Phase-out of Expenditure Authority for Designated State Health Programs (DSHP) in Section 1115 Demonstrations* (Dec. 2017), https://www.medicaid.gov/federal-policy-guidance/downloads/smd17005.pdf.
[179] *Id*. at 2
[180] *Id*.
[181] *Id*.

the fact how the State chose to spend its gift. Such an arrangement diverts from CMS's stated policy and principles for accountability for the people's taxpayer dollars (as well as Medicaid's statutory financing structure.

VI. The TennCare block grant is not consistent with the objectives of Medicaid.

A. A block grant could lead to substantial "coverage" losses.

As discussed above, despite calling itself a block grant, the content of the application filed by Tennessee appears to result in a windfall of federal funding and CMS abdicating oversight over Tennessee's Medicaid program. If, however, Tennessee is actually intending to implement a true block grant, or CMS interprets the application as requesting a true block grant or otherwise rejects material assumptions Tennessee makes in the application, the approval would have a devastating impact on Tennessee's Medicaid program. For example, Tennessee assumes that (1) its generous budget neutrality limit will effectively serve as its block grant cap, and (2) it will not be subject to regular rebasing of its budget neutrality "savings" as CMS policy requires. If CMS rejects either (or both) of these assumptions in approving the project, then it will not have approved the application that Tennessee submitted and that CMS put out for public comment. Of additional concern, it could dramatically increase the State's risk of losing federal funds. In short, a project implementing a true block grant could all but force Tennessee to cut coverage and/or access to services.

State could lose fed funding.

Under a true block grant, the TennCare Amendment 42 project would set a hard cap on the federal funding available to the State. Although Tennessee attempts to compensate for enrollment increases, the State would be fully at risk for increases in per capita costs. If those costs increased, once the State hit the cap it would lose millions or billions in federal funding. Tennessee's could see an increase in per capita costs and sustain large federal funding losses for numerous reasons.

New technologies could dramatically increase the per capita costs of providing care. For example, two CAR-T immunotherapies were approved for certain types of cancer in 2017, at costs that range from an estimated $160,000 to almost $800,000, depending on

complications.[182] Per person costs can also increase because of health epidemics.[183] For example, the opioid epidemic is a serious issue in Tennessee and could drive up per capita costs.[184] One study showed that per capita Medicaid expenditures in 2013 for patients with OUD averaged *twice* that of a matched comparison group without OUD, and that spending was mostly due to increased inpatient and outpatient spending (not prescription drugs).[185] As another example, a Zika crisis could add dramatic costs. Treatment, care, and services for an infant born with microcephaly may be well over $4 million dollars and may reach as much as $10 million over their lifetime.[186] Over 4,800 pregnancies in the U.S. territories had a lab result showing confirmed or possible Zika from 2016-2018 and about 1 in 7 of those babies had birth defects or neurodevelopmental abnormalities potentially caused by Zika.[187]

Natural disasters may also increase per capita spending. For example, in 1999, Hurricane Floyd led to a significant increase in per-capita costs for Medicaid enrollees in the year after the storm.[188] In 2016, flooding in Baton Rouge led to an increase in behavioral health claims for at least 10 months.[189]

Another reason that per capita caps create risk is that they are inherently difficult to set. Selecting a base year value and then setting a trend rate for growth amounts to an imprecise prediction filled with assumptions and relying on incomplete data. As MACPAC

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[182] Jeffrey A. Tice et al., Institute for Clinical and Economic Review, *Chimeric Antigen Receptor T-Cell Therapy for B-Cell Cancers: Effectiveness and Value* 179 (Mar. 2018), https://icer-review.org/wp-content/uploads/2017/07/ICER_CAR_T_Final_Evidence_Report_032318.pdf.
[183] Candace Gibson, *How Per Capita Caps Harm the Prevention and Treatment of New Viruses*, National Health Law Program, (June 22, 2017), https://healthlaw.org/resource/how-per-capita-caps-harm-the-prevention-and-treatment-of-new-viruses/.
[184] National Institute on Drug Abuse, *Tennessee Opioid Summary* (Mar. 2019), https://www.drugabuse.gov/node/pdf/21986/tennessee-opioid-summary.
[185] Douglas Leslie et al., American Journal of Managed Care, *The Economic Burden of the Opioid Epidemic on States: the Case of Medicaid* (July 2019), https://www.ncbi.nlm.nih.gov/pubmed/31361426.
[186] Transcript for CDC Telebriefing, Centers for Disease Control and Prevention, Zika Summit Press Conference, (Apr. 1, 2016), https://www.cdc.gov/media/releases/2016/t0404-zika-summit.html; Daniel Chang, *One in 10 Pregnant Women With Zika Had Fetus or Baby with Birth Defects, CDC Says*, MIAMI HERALD, Apr. 4, 2017, http://www.miamiherald.com/news/health-care/article142594664.html.
[187] Centers for Disease Control and Prevention, *Vital Signs: Zika-Associated Birth Defects and Neurodevelopmental Abnormalities Possibly Associated with Congenital Zika Virus Infection — U.S. Territories and Freely Associated States, 2018* (Aug. 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731e1.htm?s_cid=mm6731e1_w.
[188] Marisa Elena Domino et al., American Journal of Public Health, *Disasters and the Public Health Safety Net: Hurricane Floyd Hits the North Carolina Medicaid Program* (2003), https://ajph.aphapublications.org/doi/pdfplus/10.2105/AJPH.93.7.1122.
[189] Stephen W. Phillippi et al., American Journal of Public Health, *Medicaid Utilization Before and After a Natural Disaster in the 2016 Baton Rouge–Area Flood* (2019), https://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2019.305193.

has noted, "utilization and eligibility data are often incomplete and can be subject to a substantial data lag" and "[d]ecisions about trend rates also involve several assumptions for which there may be a range of appropriate responses."[190] As the CMS Office of the Actuary noted in its own 2017 report predicting Medicaid's financial outlook:

> Like any projection of future health care costs, the Medicaid projections presented here are necessarily uncertain. Actual numbers of enrollees, the number of services used, and the reimbursement levels per service will depend on all of the factors described previously—none of which can be predicted with certainty. Past increases in Medicaid and other health care costs have often been relatively volatile, adding to the difficulty of correctly anticipating future trends.[191]

The construction of per capita caps also raises another risk. Even when separate caps are designed for distinct populations that have different costs, the case mix within each population still can create risks. MACPAC notes that "enrollees who use long-term services and supports (LTSS) are ten times more expensive than enrollees who do not use LTSS," and thus "[d]emographic changes within an eligibility group (*e.g.*, an increasing share of aged enrollees using LTSS) could put external pressure on average spending within an eligibility group."[192] In addition to risk of cost for a state, this also creates harmful incentives: states have a disincentive to enroll (or provide services to) such an enrollee who uses LTSS if per capita payment is based on a lower level of need.[193]

A per capita cap structure also creates a disincentive for states to make strategic investments in health care that reduce long term spending and improve outcomes. For example, health homes for dual eligibles in Washington state required significant up-front investments, but have generated a 4-to-1 return on investment.[194] While most studies confirm that patient-centered medical homes decrease costs, it takes time after practice

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[190] Medicaid and CHIP Payment and Access Comm'n, *Setting Per Capita Caps: Significant Differences Between Current Methods and Those Anticipated Under Financing Reforms* (Mar. 2017), https://www.macpac.gov/wp-content/uploads/2017/03/Setting-per-capita-caps.pdf.

[191] Centers for Medicare & Medicaid Services Office of the Actuary, *2017 Actuarial Report on the Financial Outlook for Medicaid* 47 (2017), https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf.

[192] Medicaid and CHIP Payment and Access Comm'n, *Design Issues in Medicaid Per Capita Caps: An Update* 5 (July 2017), https://www.macpac.gov/wp-content/uploads/2017/07/Design-Issues-in-Medicaid-Per-Capita-Caps-An-Update.pdf.

[193] For more discussion, *see* David Machledt, *Per Capita Caps: The Devil is in the Details*, National Health Law Program (June 21, 2017), https://healthlaw.org/per-capita-caps-the-devil-is-in-the-details/.

[194] Medicaid and CHIP Payment and Access Comm'n, *September 2019 Public Meeting Transcript* 245-46 (Sept. 2019), https://www.macpac.gov/wp-content/uploads/2018/03/September-2019-Meeting-Transcript.pdf.

transformation for those savings to be realized.[195] The immediate fiscal pressure and funding cliff created by a hard cap makes it difficult for states to engage in smart, efficient up-front spending.

State takes on more countercyclical risk.

Some of the drivers of increased per capita costs described above – such as natural disasters or health epidemics – will have negative economic impacts on a state. This means that at the same time that state costs *increase*, the State's revenues to pay for health care costs *decrease*. This "countercyclical" risk is a well-known aspect of the Medicaid program.[196] Congress's matching structure for Medicaid is designed to provide some insulation for this countercyclical nature of the program; when state costs increase, federal funding increases. Under a per capita cap, however, the State is fully exposed to the countercyclical risk: so, after the flood, the State has more costs, and at the same time less state dollars and federal funding stops (at the cap).

Even under a matching payment structure, countercyclical risk is a serious problem for states in Medicaid. Congress has temporarily increased federal matching payments during recessions on two occasions to prop up state Medicaid programs (and economies).[197] The GAO has recommended *more*, not less, countercyclical protection for states.[198] A per capita cap for the TennCare demonstration risks doing the exact opposite, abandoning the State's Medicaid program *exactly* when it needed assistance the most.

The State will be forced to cut eligibility, services, and/or provider rates.

If Tennessee suffers large losses of federal funding from a block grant (or per capita cap), the State will have no choice but to cut eligibility, services, and/or provider rates. MACPAC has noted that in "responding to changing economic conditions, states … decide whether to cover optional eligibility groups and services, determine provider payment methods and

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[195] Yalda Jabbarpour et al., Patient-Centered Primary Care Collaborative, *The Impact of Primary Care Practice Transformation on Cost, Quality, and Utilization*, 14 (July 2017), https://www.pcpcc.org/sites/default/files/resources/pcmh_evidence_report_08-1-17%20FINAL.pdf.
[196] Laura Snyder and Robin Rudowitz, Kaiser Family Foundation, *Medicaid Financing: How Does it Work and What are the Implications?* (May 2015), https://www.kff.org/medicaid/issue-brief/medicaid-financing-how-does-it-work-and-what-are-the-implications/.
[197] *Id*.
[198] Government Accountability Office, *Medicaid: Key Issues Facing the Program* (July 2015), https://www.gao.gov/assets/680/671761.pdf.

rates, define coverage parameters for covered services, and adopt strategies to address the volume and intensity of services."[199]

The sheer size of the federal funding reduction under a real block grant would mean Tennessee would be forced to cuts to eligibility and services – which would directly harm enrollees. Cuts to provider rates decrease provider participation in the program and make it hard for enrollees to find providers – which of has harmful impacts on enrollees.[200]

History shows Tennessee cuts care when there is budget pressure.

Tennessee's past actions confirm that the State cuts care in response to budget pressure. In 2005, the State dropped 170,000 people from TennCare due to budget pressure.[201]

VII. Conclusion

We have included numerous citations to supporting research, including direct links to the research. We direct HHS to each of the studies we have cited and made available through active links, and we request that the full text of each of the studies cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these citations part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

We appreciate your consideration of our comments. If you have questions about these comments, please contact Leonardo Cuello (cuello@healthlaw.org).

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[199] Medicaid and CHIP Payment and Access Comm'n, *Report to Congress on Medicaid and CHIP* 24 (June 2016), https://www.macpac.gov/wp-content/uploads/2016/06/June-2016-Report-to-Congress-on-Medicaid-and-CHIP.pdf.

[200] Diane Alexander and Molly Schnell, *Closing the Gap: The Impact of the Medicaid Primary Care Rate Increase on Access and Health* (Apr. 2018), https://economics.stanford.edu/sites/g/files/sbiybj9386/f/alexander_schnell_2018.pdf; Suk-fong S. Tang et al., Pediatrics, *Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians* (Jan. 2018), https://pediatrics.aappublications.org/content/pediatrics/141/1/e20172570.full.pdf.

[201] Emily Siner, *TennCare's Big Cuts in 2005 May Have Delayed Breast Cancer Diagnoses, Study Suggests,* Nashville Public Radio (June 27, 2017), https://www.nashvillepublicradio.org/post/tenncare-s-big-cuts-2005-may-have-delayed-breast-cancer-diagnoses-study-suggests#stream/0.

Sincerely,

Jane Perkins
Legal Director