NVHR
National Viral Hepatitis Roundtable

September 9, 2021

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

Re: TennCare III Project Approved Special Terms and Conditions

Dear Secretary Becerra:

The National Viral Hepatitis Roundtable (NVHR) appreciates the opportunity to comment on the approved special terms and conditions (STCs) of the TennCare III project. NVHR is a national coalition of more than 500 patients, providers, community-based organizations, advocates, and public health partners fighting for an equitable world free of viral hepatitis.

Hepatitis C is a pressing public health issue facing Tennessee. Between 2013 and 2016, there were an estimated 69,100 Tennesseans living with hepatitis C, half of whom may be unaware of their infection. The most recent data from the CDC shows that Tennessee has the third highest rate of newly reported hepatitis C infections in the nation, where the rate is 126.8 cases per 100,000 people.[i] The virus continues to claim the lives of Tennesseans every year, despite the availability of a cure. In 2017, the rate of hepatitis C related deaths was 7 deaths per 100,000 people, failing to meet the CDC's National Viral Hepatitis Progress Report 2025 goal of less than 3.0 deaths per 100,000 persons.

In partnership with Harvard Law School's Center for Health Law and Policy Innovation, NVHR tracks and documents access to HCV treatment across the country through our Hepatitis C: State of Medicaid Access project. HHS' Centers for Medicaid and Medicare Services issued a communication to states in 2015 which advised state Medicaid programs to design coverage policies for HCV drugs which are not unduly restrictive nor in conflict with the statutory aims of the Medicaid program under Section 1927 of the Social Security Act. In the intervening years, as costs of HCV drugs have fallen dramatically, several states have revised, eased, or in a few cases removed restrictions to access.

Yet, Tennessee still maintains harmful and inequitable barriers to HCV treatment in their Medicaid program. Specifically, access to curative therapy remains out of reach due to the requirement that patients abstain from drugs and alcohol for six months, despite injection drug use being the driving factor of new infections. Recent provisional data by the CDC found that the rate of reported drug related deaths in Tennessee surpassed the national average by 17.5 percent. To adequately address the opioid crisis, we need more – not less – access to care, including for infectious diseases associated with injection drug use.

NVHR has serious concerns that TennCare III will further restrict access to care for thousands of Tennesseans living with hepatitis C. We are concerned that TennCare III does not meet the requirements of section 1115 of the Social Security Act, restricts low-income Tennesseans' access to Medicaid coverage and services, and exacerbates existing racial health disparities in the State. We have described below our specific objections to the core features of the project.

Racial Equity

Due to the ongoing effects of structural racism and inequality, the poverty rate among Black and Hispanic Tennesseans is roughly twice as high as the poverty rate among white Tennesseans.[ii] As a result, nonwhite individuals are much more likely than white individuals to rely on Medicaid for their health care.[iii] By restricting access to Medicaid coverage and services, TennCare III disproportionately harms people of color.

In so doing, the project will also perpetuate and exacerbate existing racial health disparities in the State.[iv] For example, the rate of hepatitis C-related deaths in Tennessee was higher for Black Tennesseans as compared to white Tennesseans. In fact, Black Tennesseans account for 21% of hepatitis C-related deaths and only 17% of the population.[v] Even more concerning are the interruptions to historically under-resourced viral hepatitis prevention and treatment services during the COVID-19 pandemic. A survey conducted by NVHR and partners found that COVID-19 has forced clinical providers, community-based organizations, and health departments to limit hepatitis, HIV, and STI testing and treatment, further exacerbating the pre-existing syndemic and health inequities of hepatitis, HIV, STIs, and substance use. This stark reality coupled with growing liver cancer and mortality rates among baby boomers and Black, Indigenous, and People of Color presents an urgent need to remove all remaining barriers to the HCV cure.

COVID-19 has only created a greater need for Tennessee's Medicaid program. The waiver creates needless barriers to healthcare access critical to vulnerable and low-income individuals and their families. Instead of granting Tennessee waivers that perpetuate and exacerbate racial health disparities and inequities, CMS should encourage the State to reduce these gaps through Medicaid expansion. Tennessee is one of only twelve states that still deny their residents access to Medicaid under broadened eligibility rules established by the Affordable Care Act. Empirical research establishes conclusively that Medicaid expansion has reduced mortality and morbidity.[vi] It also enhances families' financial security, thereby contributing to their ability to address social determinants of health. Furthermore, as one of only thirteen states who require a period of abstinence to receive treatment for HCV, CMS should also convey the strongest possible stance towards facilitating removal of barriers to HCV treatment access in Tennessee.

Closed Prescription Drug Formulary

The approved STCs allow Tennessee to implement a closed prescription drug formulary for adult beneficiaries. Despite not covering prescription drugs as required by the Medicaid Act, Tennessee will continue to receive generous rebates from manufacturers. CMS should withdraw its approval of the closed formulary for several reasons.

First, Congress ensured that Medicaid enrollees have broad access to outpatient prescription drugs. Section 1396r-8 outlines the requirements for state Medicaid programs, including those that govern the development and use of a formulary. Since section 1115 only allows waivers of Medicaid provisions in section 1396a, HHS cannot waive provisions in 1396r-8.

Second, the closed formulary is not experimental and does not promote the objectives of the Medicaid Act. There is nothing novel about a closed formulary; they are ubiquitous in commercial plans. The consequences of limiting prescription drug access are well-known and predictable: enrollees have less access to curative and potentially life-saving medications. Fewer prescriptions will be filled, leading to lower medication adherence. Lower medication adherence is generally associated with poorer health outcomes, and ultimately, higher total health care costs.[vii] For people with hepatitis C or other significant health needs, decreased access to and utilization of medications under a closed formulary is especially harmful, making the CDC goal of eliminating viral hepatitis by 2030 out of reach. Every new HCV infection represents a failure to cure the index case, and a generation struggling

to survive the overdose crisis will face long-term health consequences from HCV if Medicaid policies do not facilitate access to treatment now.

While the approval does require Tennessee to implement an exceptions process, that process cannot be sufficient to ensure that beneficiaries have access to medically necessary drugs. Many individuals will not be aware of the exceptions process.[viii] Others will be aware of the process, but they (and/or their providers) will find it too cumbersome or time-consuming to navigate successfully. Existing exceptions processes such as prior authorizations pose significant challenges to people living with hepatitis C. They disproportionately restrict access to care for and unintentionally perpetuate stigma against the very communities who need treatment most. Choice of treatment, including the ability to prescribe shorter treatment regimens, is especially important for people living with hepatitis C due to clinically significant drug interactions and social determinants of health, such as housing instability, that may impact a patient's ability to successfully complete treatment. It is also critically important to ensure prompt and continuous access to medication for patients who have difficulty navigating the healthcare system.

Furthermore, prior authorizations place an undue administrative burden on prescribers, which takes away time and resources from other life-saving care. A study in Rhode Island found that the complete prior authorization process from prescription to DAA acquisition took 45-120 minutes per patient, longer with a protracted denial and appeals process.[ix] Another study conducted by the American Medical Association found that among the 1,000 primary and specialty care physicians surveyed, an average of two business days per week was devoted to prior authorization requests and the overwhelming majority (91%) felt that the prior authorization process had a negative impact on clinical outcomes.[x] Ultimately, exemption processes delay time-sensitive medications for our most vulnerable residents thereby increasing the risk of hepatocellular carcinoma, liver failure, and death.

Finally, federal law already gives Tennessee a number of tools for saving money on prescription drugs. For example, Tennessee is free to: (1) establish a formulary as permitted in section 1396r-8, which allows states to exclude drugs that do not have a "significant, clinically meaningful therapeutic advantage"; and/or (2) negotiate supplemental rebates with pharmaceutical manufacturers, including entering into multi-state purchasing pools. Tennessee has failed to pursue these well-established strategies to reduce outpatient prescription drug costs. There is no evidence Tennessee has sought to implement a formulary allowed under section 1396r-8. According to CMS, Tennessee has failed to negotiate supplemental rebates and last entered into a supplemental rebate agreement almost two decades ago. It has not joined one of the more recent multi-state agreements, through which states leverage their joint purchasing power to lower their prescription drug costs. CMS should rescind its approval of the closed formulary and direct Tennessee to the other less harmful mechanisms available for controlling prescription drug utilization and costs.

Aggregate Cap and Shared Savings

CMS should rescind its approval of the "aggregate cap" and shared savings financing structure because it conflicts with section 1396b and it does not promote the objectives of Medicaid.

Section 1396b establishes how the federal government must fund Medicaid programs in the states, and as previous administrations have pointed out, it is not waivable under section 1115. While the TennCare III approval did not grant a waiver of section 1396b, in effect, it permits CMS to deviate from the financing scheme set forth in that provision. For example, if Tennessee spends more than the aggregate cap, it will not receive federal reimbursement for its excess costs. That means that the State will receive an FMAP for its total expenditures on medical assistance that is lower than the FMAP Congress has required in section 1396b. Section 1115 does not give the Secretary the authority to make that change.

In addition, the aggregate cap and shared savings financing structure rewards Tennessee for reducing its Medicaid spending, placing beneficiaries' access to health care services at serious risk. If Tennessee spends less than the aggregate cap in any given year, it can earn up to 55% of the federal savings achieved. While the STCs require Tennessee to spend the savings on Designated State Investment Programs, they do not prevent the State from using the savings to supplant current state funding for DSIPs. In other words, the savings will free up state funding for Tennessee to use for any purpose.

Notably, Tennessee has a history of redirecting federal funding intended to benefit low-income individuals. During the Great Recession, the State improperly diverted hundreds of millions of additional federal Medicaid funding provided by the American Recovery and Reinvestment Act of 2009 away from Medicaid and into its reserve fund. Similarly, instead of using federal TANF funding to assist low-income families with children, Tennessee has hoarded the money. It has continued to grow its TANF reserve while more than 22% of children – and a shocking 40% of Black children – continue to live in poverty in the State. There is nothing to prevent Tennessee from using the TennCare III shared savings as a slush fund to pay for policy priorities that are unrelated to improving health care coverage for low-income and underserved individuals and communities. Given the State's recent history, there is every reason to fear that it will do so.

In an effort to maximize its shared savings, Tennessee will reduce its Medicaid spending. Under the approval, Tennessee cannot reduce the populations or services covered without amending the project and triggering a change in the aggregate cap. So, to reduce its spending, the State will have to reduce the capitated rates paid to managed care plans, leaving it to the plans to figure out how to cut their costs (while also fulfilling their fiduciary duty to maximize their profits).

So, we can well predict that, based on their historical performance, managed care plans, in turn, will use two principal avenues to reduce their spending: (1) cutting provider reimbursement rates; and/or (2) further restricting access to covered services. Both paths will harm Medicaid beneficiaries. When plans lower their reimbursement rates, fewer providers will contract with the plans, reducing beneficiaries' access to covered services. Imposing more stringent utilization controls also restricts beneficiaries' access to necessary care. Because aggressive utilization controls are costly to administer, and therefore only produce net savings if reserved for the most expensive services, the TennCare III approval will disproportionately harm beneficiaries who have the greatest medical need – children and adults with chronic, complex conditions.

These perverse incentives will have disproportionate impact on Tennessee Medicaid beneficiaries with chronic viral hepatitis, particularly those with a complex mix of medical, behavioral, and social needs. Management of patients with chronic viral hepatitis has benefited from the substantial evolution of pharmaceutical treatments, particularly for hepatitis C – with major advances in hepatitis B treatment expected over the next several years. However, a substantial proportion of patients – especially those concentrated in the Medicaid population – have significant histories of unstable housing, criminal justice system involvement, substance use, and fragmented engagement with the health care system. Similarly, Medicaid beneficiaries who have acquired hepatitis B and/or C infection in recent years through injection drug use may be heavily overrepresented in rural parts of Tennessee with longstanding barriers and challenges to health care infrastructure and access.

In other words, management of viral hepatitis to achieve population goals requires not only comprehensive coverage of medications and sufficient reimbursement rates to ensure an adequate supply of health care providers, but also sustained attention to – and financing of – care coordination, case management, and a range of other strategies and services (potentially including patient navigation, recovery coaches, adherence counseling, and harm reduction counseling and support) that address the challenging social needs of this population. Similarly,

promising population health strategies to improve hepatitis B vaccination rates and maternal/child outcomes, integration of routine hepatitis C screening in emergency departments, and co-location of integrated medical and behavioral health in both clinical and community settings represent important innovations with significant potential to both improve the health of Tennessee Medicaid beneficiaries and reduce long-term costs of undiagnosed and untreated chronic viral hepatitis.

Unfortunately, the aggregate cap and shared savings structure risks exerting downward pressure on overall covered services and reimbursement rates, with predictable negative consequences on care delivery for beneficiaries with complex medical and social needs. Innovative approaches towards designing health care systems and care pathways for patients with viral hepatitis necessarily require up-front investments and expansion of covered services which run counter to a financing system prioritizing short-term cost containment, even at the expense of long-term population health improvements. Under this waiver, providers and health care settings will be heavily discouraged from – if not actively penalized for – developing innovative models of care that address the complex social needs of patients with viral hepatitis and other diseases and conditions associated with racial/ethnic disparities and social determinants of health. Well-documented barriers to care – including those with equally well-established models and strategies for mitigation – would persist under the design and conditions of this waiver.

Conclusion

As health inequities and lack of access to sterile harm reduction supplies continue to drive rising HCV infection rates, we must continue to hold federal and state regulators accountable for ensuring that all people living with HCV have access to treatment consistent with established treatment guidelines and relevant federal and state laws. We have included numerous citations to supporting research, including direct links to the research. We direct CMS to review each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles 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 CMS is not planning to consider these materials 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 and articles into the record.

Thank you for the opportunity to comment on the TennCare III project. If you have further questions, please do not hesitate to reach out.

Sincerely,

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[i] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2019. https://www.cdc.gov/hepatitis/statistics/2019surveillance/index.htm. Published May 2021.

[ii] *State Health Facts, Poverty Rate by Race/Ethnicity, 2019,* Kaiser Family Found., https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited August 16, 2021).

[iii] *The TennCare Block Grant Makes Health Disparities Worse*, Tenn. Justice Ctr., https://www.tnjustice.org/blockgrant/ (last visited Aug. 19, 2021) (showing that at least 29.6% of Black Tennesseans are enrolled in TennCare, compared to 13.9% of white Tennesseans).

[iv] *See, e.g.*, Kinika Young, Tenn. Justice Ctr., *Rooted in Racism: An Analysis of Health Disparities in Tennessee* (2020), https://www.tnjustice.org/wp-content/uploads/2020/07/Rooted-in-Racism-An-Analysis-of-Health-Disparities-in-Tennessee.pdf ; Bill Frist & Andre L. Churchwell, *Discrimination and Disparities in Health: Examination of Racial Inequality in Nashville*, Tennessean (July 31, 2020), https://www.tennessean.com/story/opinion/2020/07/31/examination-racial-inequality-nashvilles-healthcare/5540680002/.

[v] Hall, E.W., Schillie, S., Vaughan, A.S., Jones, J., Bradley, H., Lopman, B., Rosenberg, E.S. and Sullivan, P.S. (2021), County-Level Variation in Hepatitis C Virus Mortality and Trends in the United States, 2005-2017. Hepatology, 74: 582-590. https://doi.org/10.1002/hep.31756

[vi] Matt Broaddus, et al.*, Medicaid Expansion Has Saved at Least 19,000 Lives, New Research Finds; State Decisions Not to Expand Have Led to 15,000 Premature Deaths* (2019); https://www.cbpp.org/research/health/medicaid-expansion-has-saved-at-least-19000-lives-new-research-finds.

[vii] *See, e.g.*, Kam Capoccia et al., *Medication Adherence with Diabetes Medication: A Systemic Review of the Literature*, 42 Diabetes Educator 34, 48 (2016), https://journals.sagepub.com/doi/pdf/10.1177/0145721715619038 (reviewing studies on the relationship between medication adherence among people with diabetes and outcomes and finding a significant decrease in "health care utilization, medical costs, A1C, and diabetes complications as adherence increased").

[viii] For example, when Arkansas implemented work requirements, repeated research revealed that a large percentage of beneficiaries had not even heard of the requirements and that the exemptions process was confusing and difficult to navigate. *See* Jessica Greene*, Medicaid Recipients' Early Experience With the Arkansas Medicaid Work Requirement*, Health Affairs Blog, Sept. 5, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180904.979085/full/; MaryBeth Musumeci et al., Kaiser Family Found., *Medicaid Work Requirements in Arkansas: Experience and Perspectives of Enrollees* (December 2018), http://files.kff.org/attachment/Issue-Brief-Medicaid-Work-Requirements-in-Arkansas-Experience-and-Perspectives-of-Enrollees; Benjamin Sommers et al., *Medicaid Work Requirements: Results from the First Year in Arkansas,* 381 N. Eng. J. Med. 1073 (2019), https://www.nejm.org/doi/full/10.1056/nejmsr1901772.

[ix] Duryea P, Habchi J, Sprecht-Walsh S, Thomas AM, Bratberg J, et.al. A Modifiable Barrier to Hepatitis C Virus Elimination in Rhode Island: The Prior Authorization Process for Direct-Acting Antiviral Agents. R I Med J. 2020;103(5):41-44. http://rimed.org/rimedicaljournal/2020/06/2020-06-41-hcv-duryea.pdf. Access July 21, 2021.

[x] American Medical Association. 2018 AMA prior authorization physician survey. https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf Accessed September 8, 2021.