Opportunity to Strengthen Access to Hepatitis C Treatment Through Section 1115 Justice-Involved Reentry Initiative Demonstrations

Civil Rights Litigation Clearinghouse[1]
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Introduction

Individuals who are justice involved have disproportionately high rates of Hepatitis C virus. At least 2.4 million individuals in the United States are living with Hepatitis C[2] and up to one-third of these individual have spent time in a correctional facility in any given year.[3] On April 17, 2023, the Centers for Medicare & Medicaid Services (CMS) released a State Medicaid Director Letter (SMDL), "Opportunities to Test Transition-Related Strategies to Support Community Reentry and Improve Care Transitions for Individuals Who Are Incarcerated." The SMDL provides guidance on how states can design Section 1115 Demonstrations to provide targeted Medicaid-financed services to justice-involved individuals prior to release to support their reentry into the community.[4] Section 1115 Justice-Involved Reentry Initiative Demonstrations provide a new opportunity to strengthen access to treatment for Hepatitis C by testing the hypothesis that providing targeted Medicaid services to individuals with Hepatitis C while they are incarcerated can increase access to needed treatment and improve overall health outcomes upon their reentry into the community. This opportunity may be especially important for people with shorter stays in a jail or prison setting, as to whom the period immediately preceding release may be the best or only window to offer such care. (Of course, under no circumstances should someone otherwise eligible for or in need of treatment at an earlier time be delayed for no reason other than to await eligibility for these pre-release services.)

Until now, due to a provision of federal Medicaid law known as the "inmate exclusion," inpatient hospital care was the only service that could be covered by Medicaid for individuals considered "inmates of a public institution."[5] The SMDL outlines the opportunity for states to waive the inmate exclusion and receive federal financial participation (FFP) for expenditures for certain pre-release healthcare services, including treatment for Hepatitis C, provided to individuals who are incarcerated and otherwise eligible for Medicaid prior to their release. As of October 2023, 14 states had pending Section 1115 Demonstrations that included Reentry Initiative related requests; [6] Reentry Initiative Demonstrations have been approved in California and Washington.[7]

This document lays out the required sections that must be included in a state's Section 1115 Demonstration application[8] and identifies where and how a state can be explicit about its intent to address the health care needs of individuals with Hepatitis C as part of its Justice-Involved Reentry Initiative. It follows the Clearinghouse's recent publication *Policies for Expanding Hepatitis C Testing and Treatment in United States Prisons and Jails*, which offers policies for expanding testing, evaluating and monitoring the disease, universalizing access to direct acting antiviral medication, supporting successful treatment outcomes, and recordkeeping to enhance the oversight and accountability essential to any successful scale-up.

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Required Component of a Section 1115 Demonstration	**Hepatitis C-Specific Considerations for Each Section**
Section I – Program Description	
States are required to provide a summary of the proposed Demonstration program, and how it will further the objectives of title XIX and/or title XXI of the Social Security Act (the Act). States must also provide a rationale for the Demonstration.	**Objectives and Rationale** • In this section a state will lay out its overall objectives and rationale for implementing a Justice-Involved Reentry Initiative. • Specifically, a state would detail its goals of improving health outcomes and supporting reentry into the community for justice-involved individuals by providing a targeted set of Medicaid services during the pre-release period. As part of laying out the rationale for pursuing the Demonstration, this section should describe the disproportionate behavioral health and physical health needs of individuals who are justice-involved. This can include the disproportionate rates of justice-involved individuals with Hepatitis C, including related risk of transmission during and following incarceration, and the unique opportunity to test and treat this high-concentration, high-risk (and often hard-to-treat) population in this setting. The section may also describe the overlap between individuals with Hepatitis C and individuals with opioid use disorders and the importance of providing treatment to address both health care needs. **Covered Services**. This section should include the scope of covered services that will be provided to individuals who are enrolled in Medicaid during the pre-release period. o At a minimum, per the CMS SMDL, states are required to provide: ▪ Case management to assess and address physical and behavioral health care needs and health-related social needs; ▪ Medications for Opioid and Alcohol Use Disorders , as clinically appropriate, with accompanying counseling for all types of substance use disorders; and, ▪ 30-day supply of medications, as clinically appropriate based on the medication dispensed and the indication, provided to the individual immediately upon release from the correctional facility. o At state option and based on other states' approved Section 1115 Demonstration requests[9] and the SMDL, states may also provide the following additional services:

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	▪ Medications during the pre-release period, including direct-acting antiviral treatment for Hepatitis C; and ▪ Physical and behavioral health clinical consultation to stabilize individuals during the pre-release period and support reentry, including evaluation and management of Hepatitis C. **Eligible Individuals.** Per the SMDL, Medicaid- and CHIP-eligible individuals who are currently incarcerated may be included as eligible populations in the Demonstration. States have flexibility to target subsets of the incarcerated population and establish identification criteria. For example, states can define a target population to include individuals with specific mental health, substance use, and physical health care conditions, including individuals who have Hepatitis C. In the alternative, states can make all individuals who are both eligible for Medicaid or CHIP and incarcerated eligible for pre-release services. **Eligible Correctional Facilities**. The section should lay out the eligible correctional facilities where individuals will receive pre-release services which can include, per the SMDL, state and/or local prisons, jails, and/or youth correctional facilities. **Pre-Release Time Period**. Per the SMDL, states generally are expected to cover demonstration services beginning 30 days immediately prior to the individual's expected date of release. CMS will also approve Demonstration authority to begin coverage up to 90 days prior to the expected date of release. States may wish to request the longer 90-day pre-release period in order to maximize the time for testing and treating Hepatitis C; 90 days could enable a full course of direct acting anti-viral treatment, although follow up to confirm sustained virological response would be necessary upon return to the community.
States must lay out the hypotheses that will be tested/evaluated during the Demonstration's approval period and the plan by which the State will use to test them.	To address the healthcare needs of justice-involved individuals, the SMDL lays out the following goals of Reentry Initiative Section 1115 Demonstrations that will be tested by a state. At a minimum, state Demonstrations should seek to: • Increase coverage, continuity of coverage, and appropriate service uptake of Medicaid.

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	• Improve access to services prior to release and thereby improve transitions and continuity of care into the community upon release. • Improve coordination and communication between correctional systems, Medicaid systems, managed care plans, and community-based providers. • Increase additional investments in healthcare and related services aimed at improving the quality of care for enrollees in carceral settings and in the community to maximize successful reentry post-release. • Improve connections between carceral settings and community services upon release to address physical health, behavioral health, and health-related social needs (e.g., assistance with food and housing). • Reduce all-cause deaths in the near-term post-release. • Reduce the number of emergency department (ED) visits and inpatient hospitalizations among recently incarcerated Medicaid enrollees through increased receipt of preventive and routine physical and behavioral healthcare. In addition to these goals, states can include Hepatitis C-specific objectives such as: • Improving the rates of initiation and engagement of Hepatitis C care during the pre-release period and ensuring continuity of care post-release. • Promoting data-sharing with community health providers to facilitate this continuity of care and follow up. • Strengthening clinical education and training for providers related to screening, diagnosis, and treatment of Hepatitis C. • Reducing transmission rates of Hepatitis C in the correctional setting and upon return to the community. • Expanding access to Hepatitis C testing and, in particular, direct acting treatment, including for people who have otherwise been excluded from access because of drug use—which must not be disqualifying—or because the disease was not sufficiently advanced. • Increasing accountability and oversight over Hepatitis C testing and treatment programs, including by strengthening cooperation, information sharing, and joint-treatment efforts with community health care partners.

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States must describe where the Demonstration will operate, i.e., statewide, or in specific regions within the State. If the Demonstration will not operate statewide, states must indicate the geographic areas/regions of the State where the Demonstration will operate.	• There are no Hepatitis C-specific considerations for this section.
States must describe the proposed timeframe for the Demonstration.	• There are no Hepatitis C-specific considerations for this section.
States must describe whether the Demonstration will affect and/or modify other components of the State's current Medicaid and CHIP programs outside of eligibility, benefits, cost sharing or delivery systems	• There are no Hepatitis C-specific considerations for this section.
Section II – Demonstration Eligibility	
The Demonstration application must include a chart identifying populations whose eligibility would be affected by the Demonstration.	• This section should include information on the Medicaid and CHIP eligibility groups that will participate in the Demonstration, including each eligibility group's income eligibility level. • States should include eligibility groups that are most likely to have Hepatitis C such as Medicaid expansion adults, parents, aged, and disabled.
Section III – Demonstration Benefits and Cost Sharing Requirements	
States are required to describe whether there are: (1) any proposed changes to benefits that are different from what is provided under the Medicaid and/or CHIP State Plan; and (2) any proposed changes to cost sharing that are different from those that are applied under the Medicaid and/or CHIP State Plan.	• There are no Hepatitis C-specific considerations for this section.
Section IV – Delivery System and Payment Rates for Services	
States are required to include information on the means by which benefits will be provided to Demonstration participants, such as whether services will be delivered via fee-for-service, managed care, or multiple delivery systems.	• This section should include whether services will be delivered via fee-for-service, managed care, or a combination. • This section should also describe whether treatment for Hepatitis C will be provided by correctional facility and/or community-based pharmacies and note that all

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	pharmacies will be required to enroll in Medicaid in order to bill and claim Medicaid for medications that are provided during the pre-release period.
Section V – Implementation of Demonstration	
States must describe the anticipated implementation date as well as the approach that a state will use to implement the Demonstration. Specifically, this should include an implementation schedule, such as a phased-in approach, and how individuals will be notified/enrolled in the Demonstration.	• There are no Hepatitis C-specific considerations for this section.
Section VI – Demonstration Financing and Budget Neutrality	
This section should include a narrative of how the Demonstration will be financed as well as the expenditure data that accompanies this application. The State must include 5 years of historical data, as well as projections on member month enrollment. In addition to providing a narrative a part of the Demonstration applications, states will also be required to provide financing and budget neutrality forms.	• There are no Hepatitis C-specific considerations for this section.
Section VII – List of Proposed Waivers and Expenditure Authorities	
This section lays out the preliminary list of waivers and expenditure authorities related to Title XIX and XXI of the Social Security Act that the state believes it needs to operate its Demonstration.	States may request the following expenditure and waiver authorities to enable the provision of pre-release services, none of which are specific to treating individuals with Hepatitis C. • **Expenditure Authority:** Expenditures for pre-release services, provided to qualifying Medicaid and CHIP beneficiaries for up to [insert 30-90 days] immediately prior to the expected date of release from a participating [insert eligible correctional facility. • **Waiver Authorities:** o Statewideness (Section 1902(a)(1)): To enable the state to provide pre-release services, as authorized under the demonstration, to qualifying

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	enrollees on a geographically limited basis, in accordance with the state's Reentry Initiative Demonstration Implementation Plan. o Amount, Duration and Scope of Services and Comparability (Section 1902(a)(10)(B): To enable the state to provide only a limited set of pre-release services to qualifying enrollees that is different than the services available to other enrollees outside of the carceral settings in the same eligibility groups authorized under the State Plan or the Demonstration. o Freedom of Choice (Section 1902(a)(23)(A)): To enable the state to require qualifying enrollees to receive pre-release services through only certain providers.
Section VIII – Public Notice	
This section provides information on how the state solicited public comments during the development of the application in accordance with the requirements under 42 C.F.R. 431.408.	• There are no Hepatitis C-specific considerations for this section.
Section IX – Demonstration Administration	
States must include point of contact information for the Demonstration application.	• There are no Hepatitis C-specific considerations for this section.

[1] We are grateful for the contributions of Kinda Serafi, Partner, Manatt Health; the Center for Health Law and Policy Innovation at Harvard Law School; and the National Viral Hepatitis Roundtable. For more on this topic, see *Pre-Release Medicaid Coverage and New Opportunities to Combat Hepatitis C*, Hepatitis C: State of Medicaid Access, https://stateofhepc.org/wp-content/uploads/2023/10/SOHC_1115andPreReleaseCoverage_BriefGuide.pdf.

[2] *See* State of Medicaid Access, Center for Health Law and Policy Innovation, Harvard Law School & National Viral Hepatitis Roundtable (June 2023), https://stateofhepc.org/; *see also* Brian R. Edlin, et al., *Toward a more accurate estimate of the prevalence of hepatitis C in the United States*, 62 HEPATOLOGY 1353 (2015), *available at* https://pubmed.ncbi.nlm.nih.gov/26171595/ (indicating that estimates of Hepatitis C prevalence are likely even higher than reports suggest).

[3] Tessa Bialek & Matthew J. Akiyama, *Policies for Expanding Hepatitis C Testing and Treatment in United States Prisons and Jails* (2023), *available at* https://clearinghouse.net/resource/3872/.

[4] Social Security Act § 1115. Section 1115 of the Social Security Act gives the Secretary of Health and Human Services the authority to approve experimental, pilot or demonstration projects that are likely to assist in promoting the objectives of the Medicaid program.

[5] Social Security Act § 1905(a)(3); 42 C.F.R. § 435.1009; 42 C.F.R. § 435.1010.

[6] Arizona, Illinois, Kentucky, Massachusetts, Montana, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Utah, Vermont, and West Virginia.

[7] See 11-W-00193/9, "California CalAIM Demonstration", January 26, 2023, available at https://www.dhcs.ca.gov/provgovpart/Documents/California-Reentry-Demonstration-Initiative-Amendment-Approval.pdf; 11-W-00304/0 and 21-W-00071/0, "Washington State Medicaid Transformation Project 2.0," June 30, 2023, *available at* https://www.medicaid.gov/sites/default/files/2023-06/wa-medicaid-transformation-ca-06302023.pdf.

[8] Centers for Medicare and Medicaid Services, "Section 1115 Demonstration Program Template," *available at* https://www.medicaid.gov/sites/default/files/2020-02/fillable-1115-demo-10-12v2.pdf

[9] *Supra* note 3.