

## Advancing Hepatitis C Elimination: Implementation Strategy for the Proposed National Program

Millions of Americans suffer from chronic hepatitis C, which remains the leading cause of liver cancer and liver transplantation, despite the availability of diagnostic tests and curative therapies. The Biden Administration has proposed a national program for hepatitis C elimination that prioritizes the development of point of care diagnostics, broad access to curative DAA therapy, and comprehensive and coordinated efforts across public health and health care programs to engage, inform, identify, and treat individuals with hepatitis C.<sup>1</sup> Consequently, there is unprecedented interest in developing a feasible implementation pathway to ensure maximum impact of new federal investments needed to implement such a program. This policy brief outlines recommendations for an implementation strategy for this national program.

Although most people with hepatitis C have Medicaid or Medicare insurance, many of these patients as well as uninsured Americans with hepatitis C have been underserved by the nation's existing health care infrastructure. Thus, an implementation strategy should include mechanisms to both reach patients and promote continuity of treatment through accountable test-to-treat pathways. Hepatitis C treatment programs have traditionally been implemented through public health organizations including the CDC, state, and local health departments. However, most Americans with hepatitis C receive care through health care programs supported by Medicare and Medicaid. Promising programs to inform a national initiative have also been implemented through health care programs, including certain state Medicaid plans, notable tribal programs, and the Veterans Administration. Additionally, learnings from the COVID-19 pandemic national response, which implemented test-to-treat and vaccination strategies across all traditional and non-traditional sites of care, can also advance hepatitis C test to treat approaches. Finally, the national program can benefit from medical progress that has made it feasible for primary care practices – including safety-net providers – to oversee the full scope of screening, testing, treatment, and prevention in the populations they serve. National progress in provider payment and care delivery reforms that support more effective collaboration between health care, public health, and other public and private community resources can increase the adoption of capabilities to identify, screen and treat hepatitis C – creating a more robust, permanent capacity to prevent and manage hepatitis C for the future.

In collaboration with stakeholders and experts, the Duke-Margolis Center developed a [strategic framework](#) for a national hepatitis C elimination program with the goal of informing an implementation pathway for the Administration's proposal. The framework reflected learnings from a broad range of successful local and regional programs as described above, including "test to treat" initiatives embedded in community based primary care models; effective management of COVID-19 and other respiratory pathogens resulting from improved diagnostic technologies and public health analytics; and provider payment reforms with greater accountability for important population health outcomes.

Components of the strategic framework include:

- Accelerating the development, regulatory review, and FDA approval of rapid point-of-care (POC) tests and expanding the use of reflex testing to facilitate a single-visit test to treat model.

- Expanded surveillance through collaborations between health care and public health.
- Population-level procurement models to ensure availability of diagnostics and direct-acting antivirals (DAAs) at low costs.
- Training and supporting primary care providers in managing the overall care pathway and building capacity in community-based organizations.
- Provider and public education about hepatitis C and accessibility of testing and treatment.

Here, we focus on a specific set of implementation strategies of the aforementioned framework that could significantly increase sustained impact of the national program:

**1. Encouraging and providing financial support for large-scale procurement models for DAAs.**

Procurement of DAAs at affordable cost will support long term sustainability of an elimination program. The Administration has proposed a novel federal subscription model, with more details expected soon, for individuals who are enrolled in Medicaid, incarcerated, uninsured, or served by the Indian Health Service. The intent of such a broad-based model is to achieve lower per-person and overall cost and enhanced access, while reducing state budget spending on DAAs. This approach is based on the experience of novel, population-based procurement of DAAs such as the expenditure cap models in Louisiana and Washington, which have limited the state budget impact of expanded purchases of DAAs for Medicaid beneficiaries and some other at-risk populations. States that are interested in opting out of a federal model for their Medicaid populations could be offered model state plan amendments and incentives for a population-based procurement model for medications – although this could be more costly to the states than the proposed federal model. A similar procurement model – which holds promise for other therapeutics as well -- could also provide lower-cost access to “single visit” diagnostic tests. CMS could also provide templates or guidance to Part D plans and Medicare Advantage plans, in conjunction with performance measures and financial incentives for Medicare providers, to implement similar population-based procurement models to expand access of DAAs to Medicare beneficiaries.

**2. Implementing community-based models for expanded treatment access, harm reduction and co-location models.**

Many individuals at higher risk of contracting hepatitis C, or already infected, receive care at Federally-qualified health centers (FQHCs), rural health centers (RHCs), safety-net hospitals, and other specialized settings (e.g., a Ryan White clinic). An effective and sustainable long-term elimination effort should support the implementation of comprehensive screening, testing, treatment and prevention models in these and other diverse primary care settings. Key resources to enable large-scale implementation in primary care practices include model piloting and guidance, workforce education and training, task shifting and support through specialist-to-primary care telehealth programs, and straightforward consultation and referral processes for the small share of patients that may require more significant specialty care. These resource supports could be coupled with the further adoption of payment reforms in Medicaid and Medicare to encourage the adoption of these capabilities in primary care practices.

**3. Implementing accountable payment mechanisms to support hepatitis C management capabilities in primary care settings.**

Availability of DAA treatment will translate into greater impacts on hepatitis C outcomes if payment models are aligned with screening, treatment, and prevention models that can be readily set up and sustained in stretched primary care practices. Performance-based payments and alternative payment models for primary care providers are one way to support and sustain expanded screening, diagnosis and treatment completion within Medicare and Medicaid. CMS has already identified screening, treatment, and prevention as

major population health opportunities and is developing screening and treatment performance measures and steps to support comprehensive hepatitis C care models, including in safety-net clinics.<sup>ii</sup> These performance measures could be combined with supports for implementing care models and with hepatitis C care coordination payments for screening and completing treatment in Medicare and Medicaid. Aligned reforms in other key financial supports for safety-net providers could reinforce these supports. For example, as part of the initiative, some additional payments through the HRSA Health Center Program Quality Improvement Initiatives to implement these care models could be aligned with Medicare and Medicaid reforms to advance hepatitis C primary care models, including aligned accountability metrics. By leveraging Medicare, Medicaid, and other existing funding sources, the new federal funding could go further to help HRSA-funded and other Federally-funded facilities reach uninsured patients, incarcerated individuals, and other underserved patients.

- 4. Strengthening surveillance infrastructure to track elimination metrics.** Successful hepatitis C programs have benefitted from enhanced surveillance networks to identify positive cases, treatment progress and reinfection. These surveillance efforts can be supplemented by data from health care providers' electronic data systems, building on existing programs for health care-public health data sharing. Supported by CMS, CDC, and the Office of the National Coordinator for Health Information Technology, partnerships across public health agencies and health care organizations can be relatively inexpensive ways to enable informed and timely actions to screen and treat patients while monitoring overall program effectiveness.<sup>iii</sup>

### **Developing an Implementation Strategy that Aligns Federal and State-level Efforts**

A sustainable implementation strategy will also include specific short-term actions that can be achieved through existing federal authorities through CMS, HRSA, CDC and state-level avenues to strengthen the impact of the areas identified above. Alongside this focus on innovative uses of existing funding streams to build capacity for hepatitis C elimination, we will also refine ways to leverage new federal support (e.g., to provide financial incentives for states and safety-net providers to adopt these new payment and care models). Below are specific research and development areas that will inform the implementation strategy.

#### *State Reforms*

There are many examples of state level programs, approved through Medicaid waivers and State Plan Amendments, that have been implemented to provide aligned financial and infrastructure support for expanded screening, treatment, and care coordination for conditions such as HIV, SUD, and behavioral health conditions. These models offer templates that can be used to expand critical screening, treatment, and care coordination, coupled with tracking and performance monitoring to account for screening and treatment completion. Models can also support use of data captured through the treatment programs, especially data that tracks screening and treatment progress, in local and regional surveillance efforts.

Example models include the modified subscription or drug expenditure cap models for DAA procurement in [Louisiana](#) and [Washington](#), and alternative payment models to advance longitudinal, coordinated care such as the [HIV Special Needs Plan](#), [Health Homes](#) for chronic disease management, [HIV Case Management](#), the [Pediatric Healthcare Recovery Program](#), [Public Health Provider Charity Care Program](#), [Transition Care for Inmates](#), and Certified Community Behavioral Health Clinics. Many states are also implementing more comprehensive, advanced primary care models in Medicaid through [accountable care reforms](#), which can include explicit steps related to hepatitis C screening and treatment (Medicare examples are described below).

These models have been used to expand access to screening, treatment, and prevention for Medicaid eligible individuals, the uninsured, and more recently, the incarcerated. To help accelerate implementation, these models will provide a basis for specific guidance and payment models through Medicaid and HRSA to support implementation by frontline primary care practices, FQHCs, and harm reduction sites.

Additional financial incentives could accelerate state efforts to implement these approaches. Some of these reforms can be implemented through existing authorities, such as infrastructure investments may already qualify for enhanced FMAP support. Additional supports for these programs, to make them more attractive for states and primary care providers, could be provided through limited additional Federal appropriations.

### *Medicare Reforms*

Medicare also offers a set of opportunities to expand access to care and treatment for hepatitis C, including through provider education, performance measures in Traditional Medicare and Medicare Advantage, modifications to Medicare's major alternative payment models for primary care providers, drug payment reforms and other payment reforms supported by the Innovation Center.

In particular, there are ongoing efforts to update hepatitis C performance measures in the Merit Based Incentive Payment System (MIPS) and to implement such measures in the Medicare Shared Savings Program (Traditional Medicare's main program for accountable care organizations) and Medicare Advantage. An existing measure that evaluates the percentage of patients screened is being refined to extend to follow up for the patient to indicate treatment initiation or referral for care.<sup>iv</sup> This existing effort presents an opportunity to develop a measure to indicate treatment completion, which, combined with the existing MIPS measures, can facilitate a test to treat pathway with financial support linked to treatment and completion. As the CMS foundational quality measurement strategy suggests, these kinds of performance measures can be aligned with measure development and implementation for state Medicaid programs.

In addition, CMMI has outlined some potential prescription drug payment reform pilots that address related issues to those described here, including the diabetes drug access model, and the Cell and Gene therapy Access Model, both of which provide incentives for providers to adopt alternative drug payment and coverage models like those used in some state Medicaid programs.

### *Expanding Access to Care in Non-traditional Care Settings*

Many individuals at higher risk of contracting or currently infected with hepatitis C access basic healthcare services in "safety net" settings like FQHCs or in outside of traditional care settings, if they have a regular care provider at all. Many of these individuals face disparities in social determinants of health as well as other significant health concerns such as substance use disorder and behavioral health issues. Additional Federal funding to provide financial and technical support for such care models, combined with accountability for screening and successful treatment, could help advance longitudinal, coordinated primary care for such patients. A combined effort across HRSA, other public health agencies, and the CMS hepatitis C initiatives described above would facilitate scalable care models for these high-risk and underserved populations for example by providing hepatitis C care alongside social services and other

wraparound services through tele-health augmented, mobile, or even co-located services to reach and maintain continuity with these patients.

Appropriations will be necessary to implement and sustain such care models, but by leveraging existing coverage programs and directionally aligned reforms to strengthen primary care, especially in the safety net, the programs would be built into routine health care delivery and financing, significantly diminishing the need for additional funding to implement such care models. Next steps will identify ways to leverage existing programs to help make new funding sustainable. These steps are synergistic with CMS and broader HHS initiatives to provide longitudinal, coordinated primary care for Americans who receive care in safety-net settings.

### *Improving Data Capture to Strengthen Surveillance*

Data standards and data sharing can power efforts to advance hepatitis C elimination. To improve existing data capture, CMS could collaborate with ONC to implement national standards in EHRs to more easily capture and construct reports on whether at-risk patients have been tested, whether results were positive, and whether the patients completed treatment. These national standards would enable health care practices to substantially augment current fragmented and uneven public health tracking of hep C testing and prevalence, and enable more informed public health/health care collaboration in implementing and refining the national initiative.

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<sup>i</sup> Fleurence RL, Collins FS. A National Hepatitis C Elimination Program in the United States: A Historic Opportunity. *JAMA*. 2023;329(15):1251–1252. doi:10.1001/jama.2023.3692

<sup>ii</sup> <https://innovation.cms.gov/innovation-models/aco-reach>

<sup>iii</sup> <https://healthpolicy.duke.edu/publications/future-public-health-public-health-30-and-accountable-population-health>

<sup>iv</sup> [https://qpp.cms.gov/docs/QPP\\_quality\\_measure\\_specifications/CQM-Measures/2023\\_Measure\\_400\\_MIPSCQM.pdf](https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_400_MIPSCQM.pdf)