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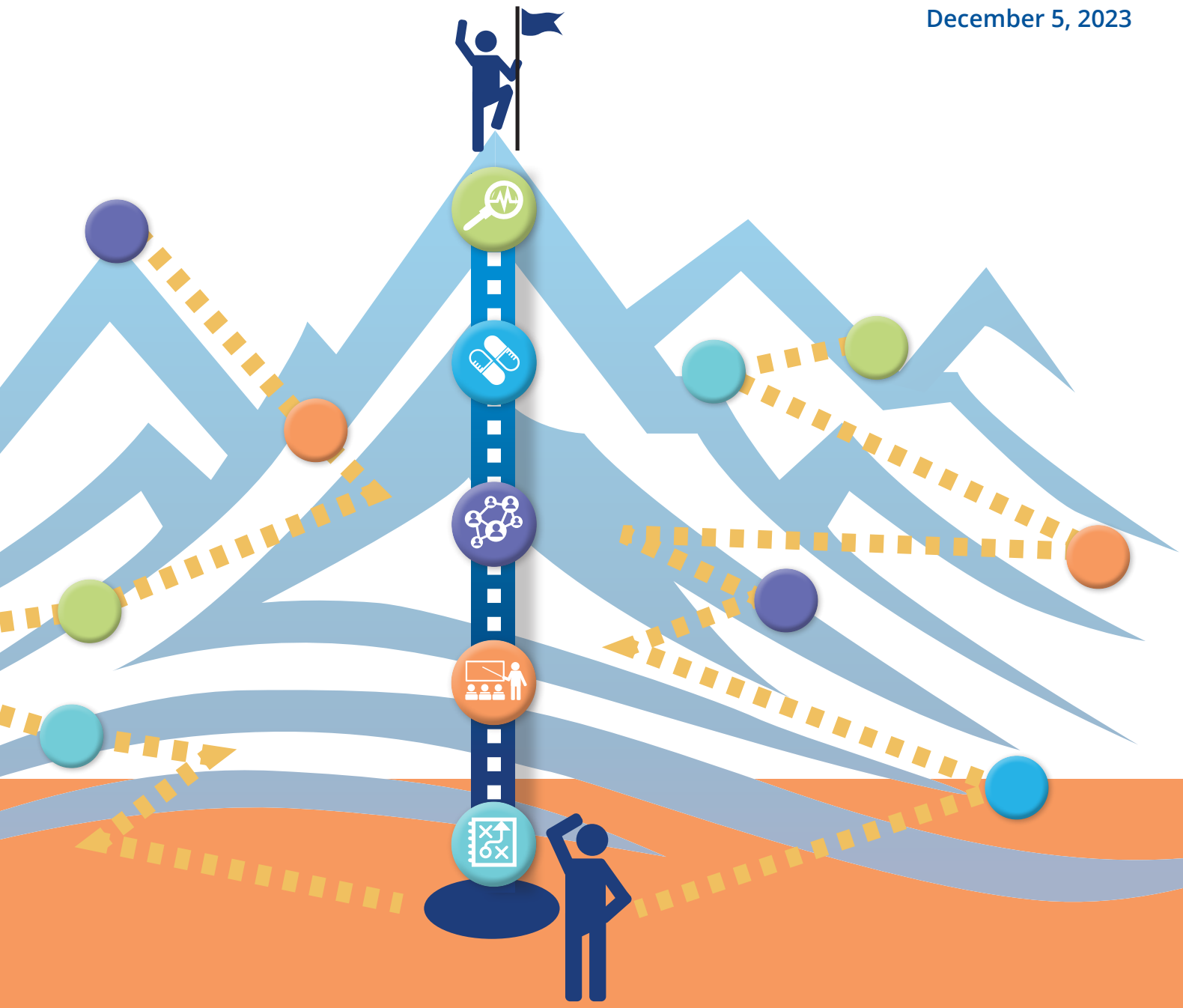

Advancing Hepatitis C Elimination:
A Coordinated Public Health and Health Care Strategy

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Executive Summary

Hepatitis C infection can lead to serious and costly complications including cirrhosis and liver cancer,[1] making it a persistent public health threat in the United States. Despite the availability of curative direct acting antiviral (DAA) therapies, the hepatitis C incidence rate increased 71 percent from 2014 to 2018.[2] While most impacted Americans have health insurance, particularly Medicaid or Medicare, populations disproportionately impacted by hepatitis C are underserved and may not have access to hepatitis C care.

The Duke-Margolis Institute for Health Policy has developed a framework and implementation pathway for the national program to eliminate hepatitis C that reflects independent analysis of past and current local and regional elimination programs, semi-structured stakeholder interviews, and expert workshops. This strategy coordinates public health initiatives and health care payment and delivery reforms to provide the infrastructure and sustainability needed for treating, containing, and eliminating hepatitis C.

The Biden Administration's 2023 proposal for a five-year initiative for hepatitis C elimination highlighted how federal support could enable rapid progress through public health agencies, community health centers, and other health care providers for higher-risk populations.[3] This directed federal program could achieve potentially offsetting savings from reducing hepatitis C complications. If enacted, this new funding would provide momentum and a bridge for implementing our proposed built-in supports to sustain effective hepatitis C prevention and treatment across public programs and treatment settings.

Our strategic framework reflects learnings from federal, state, and regional public health initiatives to overcome barriers to hepatitis C testing and care. It also reflects growing experience with innovative payments for medical products linked to population health goals, and health care payment and coverage reforms that support "test to treat" capabilities and better longitudinal data to identify and engage patients. These reforms to better integrate hepatitis C prevention, screening, testing and treatment into our nation's primary care system can reduce not only the burden of hepatitis C but also other infectious and chronic disease threats. The core components of the framework include:

1. Accelerated development, regulatory review, and FDA approval of rapid point-of-care (POC) tests and expanded use of "reflex" testing to enable testing and treatment in a single visit.
2. Expanded disease detection and monitoring through collaborations between health care and public health.
3. Population-level procurement models for availability of diagnostics and DAAs at low unit costs.
4. Financial and technical support for investments and sustainability for primary care services and community-based organizations to deliver the full cascade of hepatitis C prevention and treatment.
5. Provider and public education about hepatitis C and accessibility of testing and treatment.

Within this framework, we focus on strategies that can be implemented in Medicare, Medicaid, and other federal programs to enable sustainable hepatitis C care cascades in multiple treatment settings:

1. Using population-based DAA procurement models that reduce net costs per patient linked to the removal of prior authorization, prescribing restrictions, and low or no copays;
2. Scaling up primary care capacity to provide a streamlined and complete care experience for patients with hepatitis C in a range of care settings, so that drug procurement reforms reliably translate into large increases in hepatitis C cure and prevention, especially in underserved populations; and
3. Bolstering disease detection and monitoring activities using increasingly standardized and interoperable electronic health care and public health data to strengthen hepatitis C monitoring efforts and track program goals.

Background

Over two million Americans suffer from chronic hepatitis C. Between 2014 and 2018, the number of estimated annual acute infections increased from 0.7 per 100,000 people to 1.2 per 100,000 people, with two thirds of cases occurring among people impacted by the opioid crisis.[4] Individuals at greatest risk of contracting hepatitis C suffer from other health conditions such as substance use disorder (SUD), behavioral health, and human immunodeficiency virus (HIV) among others. Reported rates of acute hepatitis C infection were considerably higher in 2021 compared with 2006 for all race and ethnicity categories,[5] and rates of newly reported chronic hepatitis C were highest among American Indian/Alaska Native populations, with 68.9 cases per 100,000 people. Among other populations, rates were 27.9 for persons who are Black, 29.2 for persons who are white, and 10.0 for persons who are Hispanic. Of note, newly reported chronic cases occurred at a rate of 57.9 per 100,000 people for those living in rural areas.[6] Left untreated, hepatitis C results in serious and costly complications including hepatocellular carcinoma, cirrhosis, liver failure, and liver transplantation. Effective treatments are DAA therapies, which inhibit viral protein synthesis and prevent hepatitis C virus (HCV) replication. Since 2013, multiple DAA treatment options have become available that can cure hepatitis C in over 90 percent of cases.[7]

In the US, the care cascade for hepatitis C is complex and fragmented, with a two-step diagnostic process followed by prescription and adherence to curative DAA therapy, with supportive monitoring by a hepatologist required for complex cases. Gaps exist at nearly every stage of this care pathway. Many regions lack the disease detection and monitoring infrastructure for patient identification. There is insufficient education for both patients and providers around screening recommendations and transmission risk factors. Patients may face multiple challenges accessing treatment and care, which include provider shortages; lack of awareness of testing or treatment sites; coverage restrictions including prior authorization; stigma or discrimination by providers; and comorbidities that can make treatment adherence challenging.[8, 9]

Initially, drug procurement for large incident populations presented a barrier for purchasers to provide broad access to curative treatment. As multiple treatment options and generics have become available, net costs have fallen by 80 percent or more.[10, 11] However, out-of-pocket costs remain too high for many patients, and coverage restrictions remain for patients and prescribers, such as prior authorization and sobriety requirements. Patient populations disproportionately impacted by hepatitis C include Medicaid beneficiaries, populations in incarcerated settings, the uninsured, and Medicare beneficiaries. Even with insurance, many high-prevalence groups have been underserved by the nation's existing health care infrastructure and may not have access to regular primary care. As a result, even as DAA net prices and drug spending has fallen, so has the number of patients with hepatitis C who complete curative treatments.

Promising Programs to Inform a Hepatitis C National Strategy

Given these barriers, federal, state, and regional programs have implemented a range of strategies to strengthen the care cascade, with the goal of identifying and treating more patients. Evidence from these programs provides a foundation for a national strategy to contain and eliminate hepatitis C.

Strategies that have successfully addressed barriers to access to DAA treatment are population-based procurement contracts for DAAs. Louisiana, Washington, and Michigan piloted novel payment contracts with manufacturers to improve access to DAA therapies for Medicaid beneficiaries and populations in incarcerated settings. Likened to a "subscription" model, these state population-based procurement arrangements effectively establish annual expenditure caps for access to DAA treatment for a whole covered population. The selective state contract with a particular DAA manufacturer includes a supplemental drug rebate that reduces the net price to close to zero once a prespecified expenditure level is reached, typically based on the state's past "fee for service" drug expenses. This approach ensures budget predictability for drug spending, while improving access and maintaining drug revenues for the manufacturer in the negotiations. Preliminary findings from such reforms suggest that broad population-focused drug procurement models must be coupled with supports for improving access to testing and treatment to ensure treatment uptake in impacted populations. Many of these reforms were implemented shortly before the COVID-19 pandemic, which further complicated access to care. Notably, while implementation of these programs resulted in a sharp increase in patients diagnosed and treated, over time, overall numbers of patients treated has declined.[12]

Between 2014-2019, the Centers for Disease Control and Prevention (CDC) provided grant funding to hepatitis C reduction programs in the Seattle, Chicago, and Baltimore areas that had successes in identifying, screening and initiating treatment for more patients.[13,14,15] While each program was tailored for a specific region and/or population, overlapping programmatic features suggest that there are core activities that can address barriers to hepatitis C care. These features include comprehensive disease detection efforts to track patient and community progress, targeted educational and public awareness efforts, expanded screening sites, and linkage to care between diagnosis and treatment. Programs like the CDC initiatives also illustrate the value of sustainable, predictable long-term support that enables primary care providers to plan and build these capabilities into to routine workflows. The programs were grant funded for a limited period, and while they contributed to some necessary regional infrastructure, the temporary funding prevented seamless program continuation. Successful programs in Egypt, Australia and the United Kingdom have provided long-term support for integrating care pathways into primary care settings, especially settings that are easily and regularly accessible for high-risk populations.[16]

Most community health centers and other primary care settings need additional integrated support for prescribing DAAs and managing patients through their use. In the absence of such support, the practices are likely to refer patients to a liver care specialist, which incurs additional costs and may create logistical barriers, especially for patients in areas or health plans with limited access to specialty care. A range of programs can enable frontline provider training and support to create the capacity for primary care providers to offer hepatitis C care. These programs also include integrated specialty support for technical troubleshooting, managing complex cases, and managing referrals. For example, Project ECHO has provided specialist-to-frontline provider virtual training and consultation to support implementation of the full hepatitis C practice cascade in primary and community care settings.[17]

The successful Veterans Health Administration (VHA) National Viral Hepatitis Program supports the importance of integrated, sustainable reforms in drug procurement and straightforward and accessible care pathways to achieve major reductions in the prevalence of hepatitis C. The program combines a population-focused drug procurement component, clinical dashboard and registry surveillance system, and targeted and coordinated care pathway.[18] This program resulted in around 100,000 veterans being treated since 2014, with an estimated 25,000 remaining untreated.[19]

In March 2023, the Biden Administration proposed a framework for a five-year national program for hepatitis C elimination that prioritizes broad access to DAA treatment and development of POC diagnostics accompanied by

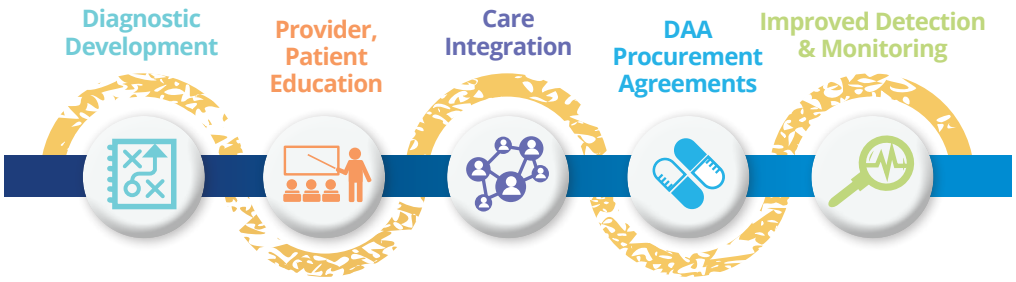
public health programming that focuses on educating physician and patient communities on hepatitis C.[20] This major five-year initiative will aim to provide resources for timely nationwide implementation of drug procurement, education, and support for effective care models for populations that remain at high risk for hepatitis C and with limited access to effective care pathways: Medicaid beneficiaries, uninsured populations, those who are incarcerated, and American Indians/Alaska Natives. These resources would potentially enable all states and more primary and community-care providers to make available more comprehensive hepatitis C care programs. Central to the proposed national elimination initiative is a procurement strategy which results in lower net price per drug course, enabling more patients to be treated. A report from the National Bureau of Economic Research projects that, based on expected costs averted for treating hepatitis C complications, the total cost savings for the Administration's proposal is an estimated $18.1 billion, of which $13.3 billion will be accrued by the federal government.[21] Congressional Budget Office evaluation of the short- and longer-term budget impact of an elimination program is pending.

To support such a national approach to hepatitis C elimination, and assure that this campaign or similar initiatives can transition to sustainable care models implemented routinely in primary and community care settings, Duke-Margolis developed a framework and implementation pathway for the national program to eliminate hepatitis C. The framework and implementation pathway reflect independent analysis of past and current local and regional elimination programs (as described above), semi-structured interviews with stakeholders, and expert workshops **(see Appendix).** Our focus is on opportunities to build in such supports in Medicaid and Medicare, which remain the main financing programs through which at-risk patients receive most care for hepatitis C as well as other infectious and chronic diseases. We also describe steps to align other public health agency initiatives for high-risk uninsured and underinsured populations with these goals.

A Framework for Sustainable Hepatitis C Containment and Elimination

A national elimination strategy will need to incorporate components that address barriers to care at each stage of the care cascade. As seen with successful hepatitis C programs, no single component will be sufficient on its own. A national program could leverage current policy reform directions to integrate and scale components from successful models of hepatitis C screening, testing, and payment, particularly to improve access and uptake for populations served by Medicaid and Medicare, as well as other high-risk individuals who are uninsured or underserved by the health care infrastructure.

Table 1 | Components of a National Program to Address Barriers to Care



Barrier in Care Cascade	National Program Component
Two-Step screening and diagnostic	Single visit test to treat treatment model
Limited disease detection and monitoring infrastructure	Expanded disease detection and monitoring
Coverage restrictions for DAA treatment	Broad population-based procurement for DAAs and diagnostics
Lack of patient and provider education on hepatitis C risk and screening	Awareness and education campaigns
Provider shortages	Care integration and coordination

The national program could consist of the following core components to address barriers to care:

- **Diagnostic Development:** A single visit, test to treat model is needed to increase the likelihood that patients will both initiate and complete treatment in a variety of clinical settings. Rapid POC tests, and alternative one-step diagnostic approaches such as reflex testing, are in development.[22] To accelerate validation testing and regulatory review in the United States, a new funding opportunity has emerged through the Independent Test Assessment Program, established as part of the National Institutes of Health Rapid Acceleration of Diagnostics Tech program. This program aims to facilitate expedited validation, authorization, and commercialization of POC hepatitis C ribonucleic acid quantitative diagnostics, by helping to assure that test validation evidence meets FDA authorization requirements, and that supporting evidence is developed quickly and efficiently.

- **Disease Detection and Monitoring:** Updates and expansion of existing disease detection infrastructure at the local community and state level coupled with networks that enable data sharing and data aggregation can inform clinical dashboards to support patient identification, planning, and program progress. Because most testing and treatment occurs through health care providers, these efforts benefit from timely, secure, and reliable interchange of

key data from health care providers' electronic data systems, which is a key objective of ongoing programs for health care-public health data sharing. Supported by Centers for Medicare and Medicaid Services (CMS), CDC, and the Office of the National Coordinator for Health Information Technology (ONC), clear pathways for implementing national standards and infrastructure support through electronic health records (EHRs) and public health agency infrastructure can enable informed and timely actions to screen and treat patients while monitoring overall program effectiveness.

- **Population-Based Procurement for DAAs and Diagnostics:** As described above, the Biden proposal will include federally driven population-based procurement, similar to those piloted in Louisiana and Washington. DAA procurement at the federal level would help overcome initial barriers to accessing treatment, especially if diagnostics are included in the model. Broader implementation of population-based procurement will lower per-person or unit costs of the treatment, which in turn can facilitate treating a greater number of patients while protecting purchaser budgets and providing opportunities for drug manufacturers to sustain net revenues. Broader adoption of procurement models through negotiated manufacturer and payer/purchaser agreements, coupled with expanded coverage policies will facilitate broader access to treatment. To succeed in substantially reducing or eliminating hepatitis C prevalence, these population-focused drug procurement models should be linked to clear, evidence-based strategies for increasing awareness and capacity to use these drugs in effective test to treat pathways in primary care and other community-based settings.

- **Awareness and Education:** Awareness and Education about hepatitis C and availability of testing and therapeutics can overcome the existing knowledge gaps around risk factors, patient/prescriber requirements, and test to treat options. Physician education through telehealth modules can address physician shortage challenges across the country. Finally, peer-led initiatives may help mitigate stigma, encourage patients to seek treatment, and support treatment adherence.

- **Care Integration:** Sustainable integration of the care cascade into routine primary care delivery is necessary to keep patients in the care flow. Primary care capabilities are needed to support diagnosis, linkage to care, disease assessment, treatment including efficient specialty guidance when needed, and follow-up in routine care to prevent recurrence. This may include care navigator and coordinator support, peer networks, and EHR data automation for following patients longitudinally. 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 including e-consultations.

Implementation Pathway for Hepatitis C Containment and Elimination

In our implementation pathway, we focus on three key strategies that can advance and sustain progress towards hepatitis C elimination through public health care programs, including:

1. Shifting to alternative DAA procurement models that rely on population-based payments with incentives for effective uptake and achieving cures, and moving away from fee-for-service barriers to treatment access.
2. Linking these procurement contracts to payment reforms that encourage and support enhanced primary care capacity for a more patient-centered care model/experience for patients with hepatitis C in a range of traditional and nontraditional care settings.
3. Leveraging ongoing programs to advance electronic data standards and interoperability incentives for disease detection and monitoring activities to improve the data infrastructure to track hepatitis C burden, identify gaps in response, support coordinated care, and improve capabilities for assessing the impact of hepatitis C initiatives and policy reforms.

Table 2 | Key Strategies That Can Direct Activities Under A National Elimination Program

Key Strategy	Actions
Drug and Diagnostic Procurement and Treatment Access	Appropriate coding and reimbursement mechanisms should be prepared for when a POC diagnostic nears authorization to ensure timely access.
	Population-based drug procurement models can permit removal of prior authorization requirements, prescribing restrictions, and copays for DAAs.
Increasing Primary Care Capacity	Payment incentives for hepatitis C diagnosis and treatment can build on recent Medicare and Medicaid payment reforms and incentives for diagnosis and treatment (with specialist coordination) of common health problems in primary care settings, especially in conjunction with alternative payment models to support advanced primary care.
	Implementation of care coordination and peer-navigation services can help navigate treatment pathways and connect patients to wraparound services to improve treatment adherence.
	Implementation of payment supports or incentives for use of Project ECHO and other telehealth supports for frontline clinicians can help deliver the full diagnostic and therapeutic pathway of services.
	Health care entities and community leaders/community-based organizations can partner and build relationships to increase community trust in and awareness of hepatitis C elimination programs.
	Alignment of grant efforts from the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), CDC, and others could improve provider and patient education, improve screening rates, and increase outreach to high-risk populations in non-traditional care settings.
	Alignment of quality measures and metrics across CMS, HRSA, SAMHSA could help encourage hepatitis C screening and treatment.
Disease Detection and Monitoring	Interoperability measures for EHRs could include a pathway toward standard approaches electronic case reporting for hepatitis C cases, aligned with a pathway to align such data sharing with state and local public health data systems for tracking cases, treatment, and outcomes.
	Universal reflex testing should occur across public and commercial labs.
	Federal grants can be directed towards prisons and jails to ensure capacity to implement opt-out hepatitis C testing.
	Lab reporting should be expanded to include both positive and negative hepatitis C lab values.
	CDC appropriations can provide support for alignment with health care data systems to track, report, and offer technical and capacity assistance to local and state health departments for improving infectious disease detection and monitoring.

The Role of Medicaid, Medicare, and Other Federal Authorities

Medicaid

Through Medicaid, there are existing models that can be used as templates to expand the scope and eligibility of hepatitis C care. The framework components can be implemented through Medicaid SPAs, waivers, and managed care contracts. These authorities address some of the key strategies for a hepatitis C elimination program, but not all **(see Table 3 below).** CMS can provide guidance, templates, and shared resources based on promising state reforms to accelerate adoption of these programs – especially if there is upfront federal support to encourage state adoption.

Table 3 | Mechanisms Through Medicaid To Support Key Strategies

Strategy	State Plan Amendment	Section 1115 Demonstration Waiver	Managed Care Contracts
Drug and Diagnostic Procurement Access	Population-based purchasing arrangements for DAAs with drug manufacturers, made available to Medicaid multi-state purchasing collaboratives.		
Increasing Primary Care Capacity	Include new coverage and payment methodologies for hepatitis C treatment and support services such as care coordination and peer navigation.	Target coverage expansion for hepatitis C services and include supplemental payments to mitigate uncompensated care costs among safety-net providers.	Enhance provider reimbursement through plan incentives for hepatitis C services.
	Expand types of providers recognized as reimbursable Medicaid providers for hepatitis C services such as pharmacists and Community Health Workers (CHW).	Extend coverage for a set of services to incarcerated individuals to engage them in hepatitis C care and support continuity of care upon transition to the community.	Leverage authorities such as in-lieu-of services and value-added services to reimburse social services that address health-related social needs.
	Extend reimbursement eligibility to non-traditional sites of care such as mobile clinics and harm reduction sites.	Implement demonstration programs that support broader payment reform and strengthen primary care services.	Utilize Performance Improvement Projects to set hepatitis C quality improvement goals and implement aligned and standardized quality measures to meet goals.

SPAs are an avenue to implement targeted reforms that support hepatitis C diagnosis and treatment for Medicaid beneficiaries. SPAs must abide by federal Medicaid regulations in order for states to access federal funds and can be used to shift the scope of services covered for particular populations through payment reforms, such as modifying fee schedules, reforming how services are covered, and implementing performance-based payments. SPAs to advance hepatitis C elimination could:

- *Support non-traditional care delivery models, such as pharmacist-led models, to further extend the reach of treatment.* Illinois had a SPA approved to allow pharmacists to provide patient care services related to HIV pre- and post-exposure prophylaxis, which could be similarly applied to hepatitis C.[23] Additionally, reimbursable electronic consultations between providers can be included in SPAs to support implementation of this sort of task-shifting approach.

- *Help engage individuals in treatment and facilitate care management by trusted community members.* Implementing reimbursement eligibility for CHWs may expand the inclusion of care management in routine hepatitis C treatment, in turn reducing patient attrition along the care cascade. Several states have already received approval for SPAs to reimburse CHWs and other nontraditional health care workers. Some have used more tailored approaches, such as providing coverage of CHW services for specific populations or through Health Homes, while others have made these services broadly applicable such as done in Louisiana and Rhode Island.[24] States can ensure coverage of a range of services including health care and resource navigation, counseling, screening and assessment and care planning.

- *Provide approval to states to receive wraparound social services for hepatitis C that offset potential costly downstream complications and improve quality of care, health outcomes, and patient experience.* To further ensure adherence to treatment for patients facing barriers to care, payment for in lieu of service or setting (ILOS) is also a mechanism through which Medicaid managed care organizations (MCOs) can substitute medical services, outlined in the state Medicaid plan, with services that address health related social needs, if they are deemed medically appropriate and cost effective.[25, 26]

- *Help states target support to sites serving a large number of individuals with complex health and social needs by extending reimbursement to non-traditional care settings.* A New York SPA allows the state to offer reimbursement for specific harm reduction services. New York Medicaid beneficiaries who have used or use drugs have access to the benefit at authorized syringe exchange programs.[27] This strategy allows for more frequent care touchpoints with people who inject drugs, which is a key population for hepatitis C elimination activities.

- *Advance more sustainable payment approaches that strengthen capacity for primary care, and provide the necessary care delivery infrastructure to engage patients in hepatitis C treatment.* In proposing Alternative Payment Methodology for federally qualified health centers (FQHCs), states have the flexibility to implement reimbursement models that shift focus to value rather than volume of services delivered. States can add payments on to baseline Prospective Payment System rates based on performance or have capitated per member per month payments linked to performance measures. These approaches would incentivize providers to deliver comprehensive primary care services needed to improve patient outcomes, including case management, and services to address health-related social needs.[28, 29] Hepatitis C measures can be included in measure sets to encourage the uptake of screening and treatment.

Section 1115 demonstration waivers are a more substantial mechanism for states to implement reforms in their Medicaid programs compared to SPAs alone. They are typically used to alter coverage and how care is paid for and delivered across a broader range of conditions and services for Medicaid, uninsured, and incarcerated populations. Given the lengthy application and approval process, 1115 waivers are utilized as an approach to implement more systemic reforms in Medicaid. These demonstrations, however, are temporary unless the waiver is renewed. While 1115 waivers may not be the most timely and feasible approach to advance hepatitis C reforms, states have used 1115 waivers to extend reimbursement and strengthen care delivery pathways for populations who have more restricted access to care, demonstrating potential applications for hepatitis C.

Section 1115 waivers have been used to direct supplemental payments for certain services to community clinics and local public health agencies to mitigate uncompensated care costs or target coverage expansion to provide a limited set of services to uninsured populations. For example, Maine implemented a Section 1115 demonstration waiver that offered a set of HIV services, including access to anti-retroviral therapies, for the treatment of HIV among low-income persons including some who did not qualify for Medicaid.[30] This approach may especially be effective in states with smaller populations or could be used among non-expansion states to cover hepatitis C and related services for uninsured populations.

While populations in incarcerated settings are not generally covered by Medicaid, several states have expanded limited coverage for incarcerated populations upon transition out of correctional facilities by implementing a partial waiver of the statutory Medicaid exclusion policy. California was the first state to receive a Section 1115 waiver to extend select Medicaid services to all Medicaid-eligible adults and youth in correctional facilities who meet certain health criteria 90 days prior to release and support with continuation

of care after-release.[31] Covered services are intended to leverage community-based partnerships and improve care coordination by connecting those transitioning with a CHW and local Medicaid-provider, case management services, physical and behavioral health clinical consultation services, laboratory and radiology services, medications, and medication-assisted treatment for SUD.

Within their Section 1115 waivers and associated plan amendments, states also have authorities through contracts with Medicaid managed care plans to incentivize hepatitis C services. Through managed care contract adjustments, states can encourage or direct MCOs to enhance support and incentives for primary care providers to implement effective hepatitis C care reforms. In particular, value-based payment arrangements or performance initiatives to support stronger primary care can incorporate financial incentives that link payments to quality metrics. MCOs can be held accountable for hepatitis-C related measures and have flexibility in how they increase hepatitis C services to meet performance improvement targets. For example, MCOs can use existing networks and resources or contract with outside entities for case management services, provider and patient outreach, and provider training to build primary care capacity for hepatitis C treatment. In some cases, partnerships include community-based organizations and MCOs use authorities, such as the before-mentioned ILOS as well as value-added services, to address health related social needs that support hepatitis C treatment access and adherence.[32]

Louisiana's previous initiatives in both HIV and hepatitis C provide an example of how states can direct MCOs to expand hepatitis C treatment access. Louisiana included hepatitis C in quality improvement goals and require managed care plans to report quality outcomes related to case management outreach, provider education, screening, and DAA treatment initiation outlined through PIPs.[33, 34] MCOs leveraged their own resources, such as case management and outreach teams to increase awareness among patients and providers toward improving hepatitis C awareness, diagnosis, and treatment. Quality measures focused on hepatitis C treatment not only supports providers to increase offerings of hepatitis C services, but help create uniformity in tracking and reporting among Medicaid managed care plans. Accordingly, these could also provide data on gaps where state public health initiatives can be used to improve outreach, screening, and treatment.

Medicare

CMS can support the three key elimination strategies through policies and reforms in both traditional Medicare and Medicare Advantage (MA) **(see Table 4 below).**

Table 4 | Opportunities To Support Key Strategies Through Medicare, Medicare Advantage

Strategy	Traditional Medicare	Medicare Advantage (MA)
Drug and Diagnostic Procurement	CMS guidance and encouragement of Part D plans through performance incentives for plans to utilize population-based procurement approaches for generic and lower-cost, high-cure rate DAAs, with preferred formulary placement.	CMS guidance on drug procurement and encouragement through performance incentives for plans to utilize population-based procurement approaches for generic and lower-cost, high-cure rate DAAs, with preferred formulary placement and aligned prescribing incentives for network providers.
	Implement a National Coverage Determination to provide coverage for hepatitis C screening for all Medicare beneficiaries without limitations to site of service to increase the number of patients screened and numbers of providers and sites offering screening.	
Increasing Primary Care Capacity	Implement incentives for telehealth, co-location of services, and streamlined hepatitis C diagnosis and treatment models through physician fee schedule reforms and alternative payment models including the Shared Savings Program that support advanced, accountable primary are.	Incentivize telehealth, co-location of services, and streamlined hepatitis C diagnosis and treatment models through performance measures (transparency) and payment incentives (e.g., relevant STARS measures for advanced primary care).
	Aligned performance measures for hepatitis C screening and treatment.	
Disease Detection and Monitoring	Promote data interoperability and data automation to streamline health data that goes to local health departments to support more complete disease detection and monitoring efforts.	

CMS has levers for encouraging DAA and diagnostic usage and procurement through Medicare. As of 2015, all Medicare Part D plans covered at least one DAA. However, DAAs are often placed in the highest tier of the drug formulary, resulting in substantial out-of-pocket (OOP) costs for patients that, along with prior authorization and dispensing limits, can complicate access. A recent report from the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that Medicare patients are less likely to receive the generic versions of the DAAs available than Medicaid patients, leading to higher OOP costs for Medicare beneficiaries, as well as higher overall spending for DAAs in the Medicare program.[35] Drug plan contracting guidance and incentives for Part D plans (standalone and MA) to implement population-based DAA procurement could encourage increased availability of DAAs in MA and Part D plans treatment and minimize OOP costs for beneficiaries, while still sustaining manufacturer net revenue (i.e., lower net drug cost per patient, but more patients treated, especially if implemented in conjunction with reforms to support broader access to streamlined diagnosis and treatment pathways). In this context, removing prior authorization in Medicare plans will make treatment more accessible for patients as well as reduce clinical burden.

CMS could also change the coverage for hepatitis C screenings for Medicare beneficiaries to support greater access to hepatitis C diagnostic testing for beneficiaries who are at elevated risk of infection. Medicare currently has a National Coverage Determination (NCD) in place that covers hepatitis C screening for adults at high risk for infection, as well as screening for those born between 1945 and 1965 when ordered by a primary care physician or practitioner within the context of a primary care setting.[36] United States Preventive Service Task Force (USPSTF) now has updated their recommendation to include screening

for all adults age 18-79, with a grade B rating. Hepatitis C screening is currently on the NCD waitlist.[37] The updated NCD should thus, at minimum, provide hepatitis screening to all adults. Accordingly, hepatitis C screening is on the waitlist for upcoming Medicare NCDs to align with more recent clinical guidances for screenings; expanded hepatitis C screening coverage would allow for screenings of a greater number of beneficiaries, support disease detection and monitoring efforts, and potentially influence private payers to expand coverage policies. CMS could consider covering hepatitis C diagnostics (and eventually, POC tests) ordered by providers outside of the primary care setting who are participating in coordinated testing and treatment programs.

Increased access for the Medicare population will require innovative models for care delivery and harm reduction in primary and community settings. CMS recently increased efforts to advance primary care for Medicare beneficiaries (including telehealth-based specialty coordination) through payment for capacity building and innovative payment models. The Center for Medicare and Medicaid Innovation announced its "Making Care Primary" model, which aims to build out care management, integration, and community connections to streamline care for beneficiaries.[38] CMS is prioritizing organizations with no prior experience with value-based care, involving FQHCs, and working with payers in eligible states to ensure there is alignment in goals for primary care services across payers and settings. The goals of this model are to improve care management, build and maintain relationships between primary and specialty care, and strengthen provider relationships with community entities to enable referrals for addressing social needs of patients. Because many people with hepatitis C also have unaddressed social needs, a model that focuses on community referrals and care management will help keep patients in the care cascade from diagnosis to treatment for hepatitis C. This model, as well as Medicare's other major accountable care programs – the Shared Savings Program and the Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health Model – all are well-suited to support more routine access to effective hepatitis C screening and treatment.

More broadly, CMS can also consider expanding financial supports for case management services, or clarifying that hepatitis C diagnosis and treatment fits within existing payments. Flexible reimbursement that would allow providers to reach high-risk patients more easily, such as through telehealth, co-location models, or mobile clinics, would also support access to care. For example, extending or making permanent telehealth flexibilities would help reach patients in rural settings, as well as reduce the number of patients lost to follow-up appointments with specialists due to issues with transportation or other social factors.[39] CMS has taken steps in this direction, with changes to the 2024 Physician Fee Schedule that allows additional providers to bill for telehealth, extends telehealth options for opioid treatment programs, and additions to what can be included in general care management billing codes.[40]

CMS also finalized in the Physician Fee Schedule for CY 2024 billing codes for community health integration services by health care personnel, including CHWs. The code includes person-centered assessments, facilitating access to social services, health care navigation, and facilitating emotional and social support when appropriate. CMS finalized codes for principal illness navigation services conducted by certified personnel, including peer navigators, who have been shown to help increase uptake and completion of hepatitis C treatment.[41] These codes are not intended for illnesses that require less than 60 minutes of care navigation per month, but CMS could clarify that such support is appropriate for some patients with hepatitis C. SUD-impacted populations—which have a significant overlap with hepatitis C populations—have one of the significant conditions supported by these reimbursements.

CMS could also develop a care management and coordination model for patients with hepatitis C and other undertreated infectious diseases. In an alternative payment pilot recently announced for beneficiaries with dementia,[42] CMS will provide payment for participants that offer evidence-based longitudinal care management and coordination, including person-centered assessments and care plans, care coordination, and 24/7 access to a dementia care support line. Care navigators will also be available to beneficiaries, and will assist with both clinical and non-clinical services. A similar model designed to support evidence-based longitudinal care with accountability for results for hepatitis C patients could aid beneficiaries with hepatitis C who also have substantial barriers to receiving care because of social determinants of health, comorbid conditions, or other factors.

These steps could be implemented alongside a pathway toward adoption of a limited number of validated, standard quality measures in Medicare to support the

hepatitis C care cascade. This could involve adding or changing Merit-Based Incentive Payment System (MIPS), performance measures in alternative payment models for advanced primary care, and STARS measures for MA plans. A hepatitis C screening or treatment measure or screening and treatment measure could also be added to the Healthcare Effectiveness Data and Information Set measure sets, which are applicable to a broad range of health plans. Standard performance measures for hepatitis C screenings and treatments would be easier to compare across plans, driving accountability by having screening and treatment information public,[43] consistent with the goals of CMS' National Quality Strategy.

There are three quality measures within MIPS designed to measure hepatitis C care performance:

- One-Time Screening for HCV for all Patients.[44] This measure quantifies the percentage of patients aged 18 years and older who received a one-time screening for hepatitis C virus infection during a performance period. It falls under the categories of Specialty Care, Family Medicine, Internal Medicine, and Nephrology.
- Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis.[45] This measure looks at the percentage of patients aged 18 years and older, with a diagnosis of chronic hepatitis C cirrhosis, who receive imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma at least once within the performance period. This falls under the Specialty, Family Medicine, Gastroenterology, and Internal Medicine categories.
- Annual HCV Screening for Patients who are Active Injection Drug Users.[46] This measure is the percentage of current injection drug users who received screening for HCV infection within the performance period. This measure falls under the Specialty, Family Medicine, and Internal Medicine categories.

None of the quality measures related to hepatitis C are considered "high-priority" measures, even though measures 400 and 401 are considered "core" measures developed through a CMS-supported, multi-stakeholder, consensus-based process.[47] The multi-stakeholder group last year identified gaps in the core set, including initiation of antiretroviral treatment for chronic hepatitis C, treatment adherence or completion, as well as measures that show an increased ability to treat hepatitis C. Clarifying a pathway for making a standard measure of screening and treatment high-priority, leading to broad implementation across Medicare payment programs, would incentivize screenings and care for hepatitis C as well as encourage adoption in commercial and Medicaid plans.

Consistent with this goal, CMS and the American Gastroenterological Association (AGA) are evaluating a change to existing MIPS performance measure #400, to require reporting on first time hepatitis C antibody tests, percentage of patients that have never received a test, percentage that receives an infection test, and the percentage that initiate treatment within three months or are referred to another clinician for treatment within one month of a positive test.[48] The AGA is working on an additional quality measure for future consideration into the quality payment program, which would record cases of sustained virologic response (SVR). This would help CMS keep track of how many cases of hepatitis C are cured, how many of the positive cases are new, and how many cases remain untreated—which could also inform disease detection and monitoring efforts. Since around half of all eligible Medicare beneficiaries are now enrolled in MA plans, these private plans could include similar performance measures and other quality improvement measures to have a standard set of reportable metrics to inform disease detection and monitoring and elimination program metrics.[49] CMS also recently finalized a MIPS Value Pathway for the "Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV."[50, 51] This pathway also utilizes the existing MIPS measures and would benefit from measures that reflect SVR.

CMS can support disease detection through promoting adoption and use of interoperability standards for relevant key health data reporting. For example, CMS in collaboration with the HHS ONC has developed required electronic medical record standards to support reporting of certain key clinical performance measures for its ACO programs including diabetes control, blood pressure control, and depression screening and treatment.[52, 53] Extension of such an approach over time for key hepatitis C data sharing using automated and interoperable standards would support both hepatitis C care improvement and streamline key health data sharing with health departments, supporting the goal of health care-public health collaboration to improve community outcomes.

Other Federal Programs

A key element to a national elimination strategy will be extending reforms to support effective diagnosis, treatment, and prevention in Medicaid and Medicare to those who do not have reliable longitudinal private or public coverage. Federal funding through public health programs and health care programs for additional populations has been critical for hepatitis C initiatives. In addition, federal support for state and local public health programs is critical for local situational awareness on hepatitis C burden and access to care, and thus for guiding further interventions. State and local health departments are responsible for case disease detection and monitoring, defining reportable conditions and lab values, and aggregating and analyzing data to create a case report that is sent to the CDC, and to support state and local initiatives to reduce hepatitis C burden. Given the different resources, infrastructures, and stages of state hepatitis C containment programs, the completeness, consistency, and timeliness of such data varies. New federal initiatives and funding could address these gaps more efficiently and sustainably if implemented in ways that coordinate with and advance aligned Medicaid and Medicare reforms.

Extending Reach Beyond Medicaid and Medicare

Important populations beyond those covered by Medicare and Medicaid would benefit from a nationwide elimination strategy. The VHA has already implemented a coordinated, integrated hepatitis C detection and elimination strategy with considerable impact, as noted above. We highlight below additional at-risk populations, including American Indian and Alaska Natives (AI/AN) who depend on Indian Health Service (IHS) capabilities for health care, and incarcerated individuals. Other uninsured individuals could also be reached through supporting capabilities in their primary and community care settings, building on the Medicaid reforms described above.

The IHS could benefit from additional federal funding to develop the infrastructure and capacity to sufficiently scale existing hepatitis C disease detection and treatment programs. Although the IHS is part of the big four federal agencies that receive the Federal Supply Schedule price for discounted drugs, a federal procurement plan or additional appropriations would support better care to support hepatitis C treatment. A 2017 GAO report found that IHS spending per capita was $4,078, just half of Medicaid spending per capita ($8,109), and less than half of what the VHA or Medicare spent per capita ($10,692 and $13,185, respectively).[54] Populations served by the IHS are also served by a number of other payers, including Medicare and Medicaid, so hepatitis C care reforms in those programs could have synergistic benefits for these populations. Additional funding could also extend services and build upon current programs. The Cherokee Nation Hepatitis C Elimination Program, for example, had great success in increasing screening rates from 21 percent to 38 percent and showed improvements in linkage to care.[55, 56] Program activities included universal screening, implementation of provider EHR prompts, implementation of a hepatitis C registry, a public awareness campaign, provider training, case management, and delivery of harm reduction services linked to opioid use disorder treatment. The didgʷálič Wellness Center in Washington on Swinomish Tribal lands also demonstrated success by co-locating care with a single point of treatment and integrating wraparound services to remove barriers to access. This program began as a center to treat alcohol dependence, then grew to offer services such as mental health care, primary health care, SUD treatment, medication assisted treatment, on-site social workers, and a hepatitis C treatment program.[57] These programs are potentially scalable for delivering tailored, culturally relevant care and social services to a historically hardly-reached population.

Disparities and limited access to hepatitis C diagnosis and treatment for populations in incarcerated settings have equity implications for a national elimination strategy. As of 2020, people who are Black were imprisoned at nearly five times the rate of those who are white, despite accounting for only 12 percent of the US population.[58, 59] People who are AI/AN are also incarcerated at disproportionate rates, with recent estimates showing AI/AN individuals are

incarcerated at a 38 percent higher rate than the national average. With both hepatitis C prevalence and mortality rates higher for Black and AI/AN populations, and with incarceration rates for these populations disproportionate compared to white individuals, a national elimination strategy that successfully treats incarcerated individuals will also help reduce some health disparities with hepatitis C.[60] The proposed federal hepatitis C elimination initiative includes a population-based procurement program to provide DAAs to individuals in prisons and jails. Block grants would also support public health efforts to address communicable disease within correctional facilities. A main barrier to screening and treatment for hepatitis C in correctional facilities is workforce shortages in general, not just medical personnel. Care delivery in prisons relies heavily on clinical pharmacists, meaning that expanding the number of patients screened and treated is limited based on staffing of clinical pharmacists. If new federal supports and incentives are available, states could allocate additional funding to departments of corrections (DOCs) for capacity building at prisons and jails to ensure enough personnel for testing and treating individuals. The Virginia DOC hired additional pharmacy staff and partnered with the Virginia HEPC program to treat more incarcerated individuals and refer individuals being released to community resources and medical counseling. As a result of these changes, 1,040 incarcerated individuals with chronic hepatitis C were treated in Virginia correctional facilities between January 2020 and January 2022, with a 97 percent cure rate.[61] Coupling this near-term capacity building with longer-term Medicaid reforms would provide a sustainable path for better care for hepatitis C and other health risks for incarcerated individuals.

Disease Detection and Monitoring

The CDC has created guidance and provides technical assistance to state health departments in areas of data acquisition, case investigation, outbreak detection, data analysis, data for public health action, and data sharing. The CDC is currently providing disease detection and monitoring funding in 59 states and jurisdictions—up from 14 in years prior—which has led to improvements in building capacity for disease detection and monitoring, which should support more complete data reporting on hepatitis C and other infectious diseases. In 2022, 80 percent of jurisdictions hired a full-time employee for viral hepatitis C disease detection and monitoring efforts compared to 68 percent in 2021 and jurisdictions with viral hepatitis elimination plans increased from 43 percent in 2021 to 70 percent in 2022.[62]

However, with current levels of funding and inconsistent integration with health care capabilities for consistent data sharing and effective hepatitis C care delivery, states have generally been unable to build capacity to the level needed to support robust disease detection and response. Increased state and federal funding could support advancement of a standardized data infrastructure that integrates key health care laboratory, case and treatment data and a local health department disease detection and monitoring infrastructure to complete data reporting, analysis, and local capacity to respond to outbreaks. Public health workforce support at the state and local level, in conjunction with Medicaid and Medicare payment reforms to support aligned work by health care organizations, is critical to support case investigation and data completeness and issue a public health response to actionable data. Furthermore, federal support for more sophisticated analyses based on better hepatitis C-related data, for example by leveraging the resources of the CDC's new Center for Forecasting and Outbreak Analysis, can enable a more complete understanding of populations affected, persistent inequities, and effective ways to target resources to address identified gaps. These analyses can feed into dashboards the track outbreaks, treatment and progress towards elimination.

Alignment of public health and health care toward a parsimonious set of meaningful performance measures for the hepatitis C care cascade is critical. New Uniform Data System (UDS) measures through HRSA for hepatitis C screening and treatment are intended to increase the uptake of hepatitis C services in safety-net clinics among many competing health priorities, as was done for HIV/AIDS. Adding any measures can be challenging as it is likely to add to existing reporting burden for stretched frontline health care providers. Yet, alignment of UDS measures implemented through HRSA with hepatitis C measures implemented by CMS would ease data collection and reporting burden. Financial incentives tied to a clear path to implementation of aligned measures across Medicare, Medicaid, and HRSA over time would leverage any new funding with financial supports from existing federal programs to provide a clearer business case for building more effective hepatitis C care pathways into primary care practices. Any new federal funding for this initiative can be targeted to regions and populations of greatest need. In 2020, the first year of Ending the HIV Epidemic-Primary

Care HIV Prevention, HRSA awarded $54 million to 195 health centers to increase the HIV prevention services including increasing counseling, testing, pre-exposure prophylaxis prescriptions, and successful linkage to care.[63]

Diagnostic Development

Federal policy efforts could also support diagnostic development, procurement, and usage. Hepatitis C screening is a USPSTF recommended service. This recommendation provides a foundation for coverage of hepatitis C tests—including one-step POC tests—without a copay for Medicaid, Medicare, and private insurance beneficiaries in eligible sites.[64] Reimbursement in non-traditional sites (such as mobile clinics) and for uninsured patients may require alternative procurement.

Alongside a path toward coverage of a new "single-visit" diagnostic test, prioritizing timely implementation of coverage and payment is important. Availability of CPT and PLA codes for the forthcoming test ensures a means for reimbursement for labs and providers. Existing application cycles for these coding sets suggest early code assignments following FDA approval which may affect time to access. There are mechanisms to expedite coding, such as the AMA giving POC tests provisional codes, which was used in the public health emergency for COVID-19 tests. Further, procurement of such tests should be prioritized for sites serving larger shares of individuals most likely to be lost to follow up during the diagnostic phase of the care cascade. This includes treatment of patients in decentralized settings, where hardly-reached populations are more likely to receive their care and sites that see significant drop offs in patient follow-up. Urgent care clinics, mobile care units, rural care sites, methadone clinics, and syringe service programs, for example, may most benefit from a POC test, as patients would not have to come back in to confirm their hepatitis C status. This may also enable immediate treatment or linkage to care. There are opportunities to enhance access to POC tests at such sites through establishing advance purchase contracts for diagnostic products that meet minimum specifications.

Alignment across Federal Agencies and Program Cost Implications

As evidenced by the Seattle, Chicago, and Baltimore programs, there is a substantial cost associated with implementing these approaches and a need for predictable aligned financial support to sustain them.

Our strategic framework, which is focused on ensuring long term impact and sustainability of hepatitis C elimination efforts, has highlighted the importance of aligning ongoing federal program efforts with any new federal resources and supports to provide a clear and predictable path for participating primary and community care organizations to make needed investments and workflow changes to embed the care cascade more effectively in their routine activities.

As we have noted, there will be additional upfront costs associated with setting up and implementing more reliable hepatitis C care cascades, and increasing awareness. However, these could in turn be offset by lower Medicaid and Medicare costs for treating hepatitis C complications like liver transplants and cancer. Whatever the net estimated impact, many of the steps described in our strategic framework can be implemented without legislation, are aligned with existing primary care and public health reforms and initiatives, and would increase the impact of any new hepatitis C-related appropriations.

It is important to note that population-based procurement would impact safety-net clinics participating in the 340B Drug Discount Program. While the proposed approach for federal procurement would lower some costs associated with 340B drug purchasing, there would still be a loss of 340B revenue. With the uptake of population-based procurement models, there needs to be consideration of new funding opportunities for safety-net clinics to supplement the loss of 340B revenue, potentially supported by expected savings from this purchasing reform and the other complementary steps to support safety-net clinics. More research is needed to understand the impact of alternative procurement strategies on sites that rely on the 340b program on both drug purchasing and programmatic development.

Finally, building on our preceding analysis, there are opportunities to better align public health grant funding opportunities to deliver the full range of hepatitis C services along the care cascade for populations most in need. For instance, the primary purpose for SAMHSA grant funds is the treatment of substance use disorder. However, with broader shifts towards a whole-person centered approach to care, grants have included funds for hepatitis C screening, vaccination for hepatitis A and B and linkage to care support. Some clinics receive both SAMHSA and HRSA funding to support co-location of SUD, mental health and hepatitis C treatment all in a single site

of care. Expanded capacity for SAMHSA grants to cover hepatitis C treatment in addition to screening would enable co-location of services, including among mobile opioid treatment programs. Peer support specialists are a critical piece in building trust within the community, drawing in patients to treatment and helping them navigate the treatment pathway. Whereas HRSA can fund FQHCs where some patients may receive treatment for hepatitis C, SAMSHA grants can help fund referral or linkage of patients to community social services. There is an opportunity to build capacity and workforce of peer support specialists specifically with lived experience with hepatitis C and use funding from different agencies to create a cohesive care pathway for patients.

Additional Supportive Actions at the State, Local, and Regional Level

Collaboration and Coalition Building

There are also local and regional strategies that should be facilitated by new federal steps toward hepatitis C elimination. Partnerships between local and state health departments, community-based organizations, academic health centers, community health clinics, and other key stakeholders, are critical for a community-driven and unified regional approach to hepatitis C elimination. Local and regional partnerships allow for more community-specific solutions to address social determinants of health and provide whole-person care. Strong regional networks that rely on community referrals, linkages to local resources and social services, and allow for co-location of services at non-traditional sites would support keeping patients in the care cascade from diagnosis to treatment. Existing infrastructure from HIV/AIDS, SUD, and harm reduction programs can be leveraged by building on established relationships.

Inclusion of the community voice and providing resources into local communities can also help establish community trust, engagement, and support for an elimination program. Through building community and health care relationships, regional and local leaders may emerge to champion hepatitis C elimination efforts in different settings. These champions are especially effective for supporting dissemination of resources and funding, amplifying advocacy efforts, and informing the public about educational campaigns.

Education and Awareness

Another way to build capacity at the local level is to elevate provider education strategies, as demonstrated in Seattle, Baltimore, and Chicago. Educating primary care providers about how and when to prescribe DAAs led to an increase in the hepatitis C screenings and treatments in those sites.[65, 66, 67] Having more primary care providers that were able to successfully treat hepatitis C helped expand treatment access in areas where specialty care was limited, particularly in the Baltimore program.

Patient education about hepatitis C programs will also be important for patient uptake. Public awareness programs around risk factors for hepatitis C, and dissemination of information about the elimination program, will be most effective when tailored to specific community circumstances. HHS can provide initial starting materials for a public awareness campaign, similar to the *We Can Do This* COVID-19 vaccination campaign.[68] However, public education campaigns must then be localized, population specific, and community-driven in order to effectively communicate messaging to priority populations. For example, testing and vaccination strategies designed to reach underserved communities and communities with low uptake saw greater successes once materials and communications were were made linguistically accessible and compliant with the Americans with Disabilities Act and linguistically accessible, culturally responsive, and communicated by local community partners and leaders.[69] Hepatitis C educational and awareness campaigns could employ similar strategies to ensure reach to underserved populations and promote a test to treat strategy.

Technical Assistance to Support Site Level Capacity Building

Eliminating hepatitis C in the US necessitates a strong health care safety-net infrastructure with capacity to deliver hepatitis C screening and treatment to reach vulnerable and high-risk patients, especially in areas with

severe provider shortages. Safety-net clinics will need technical assistance to support improved hepatitis C treatment programs. Clinics will have different needs and may require additional staff for care coordination, nursing, pharmacy, social services or data management services to support comprehensive hepatitis C care delivery. Technical assistance teams can evaluate and guide clinics in integrating hepatitis C treatment into existing workflows. Interventions can include clinical decision support tools, lab orders for reflex testing, telehealth capabilities, patient outreach and care coordination, and scripted language for providers and front-line staff to effectively communicate hepatitis C messaging with patients. Building hepatitis C services into routine workflow structures establishes sustainable systems across the care cascade. Harm reduction and other non-traditional care sites will have their own barriers to implementing hepatitis C services, including billing and reimbursement capabilities and data sharing limitations, which will require targeted capacity building efforts.

As noted above, there is a need for improved alignment and reduced burden of data collection and sharing to support effective containment and elimination. This includes unified measures across CMS, HRSA and SAMHSA. Data linkage and presentation was also an effective element of all three program examples in Seattle, Baltimore, and Chicago. Merging hepatitis C relevant data from EHRs, lab testing, and prescribing data, especially when coupled with EHR screening alert processes (such as in the Seattle program), were effective methods for identifying patients in different touchpoints in the care pathway and the types of engagement they might need. Federal technical support for consistent data use agreements to enable key data sharing and the creation of a unified federal data platform could improve transparency on progress towards hepatitis C elimination targets.

Disease Detection and Monitoring

States have a number of strategies to boost disease detection and monitoring for infectious diseases, including hepatitis C. For example, many states are advancing data linkage across different data systems such as vaccine registries, homeless management information systems, and others to help inform future initiatives and target resources. In Louisiana, the Office of Public Health (OPH) partnered with hospital systems to establish the Louisiana Public Health Information Exchange (LaPHIE). LaPHIE is an EHR integrated system, that allows for the bi-directional flow of OPH HIV, tuberculosis or syphilis disease detection and monitoring data to patient identification at the point of care.[70] Clinics and academic centers can also partner with local health departments to create regional registries that track hepatitis C testing and treatment progress through aggregated lab, EHR, and prescription fill data.

Community health clinics can support their own care cascades by utilizing data extracted from EHRs to develop dashboards at the site-level. This can inform target response by helping providers track their progress in screening and treatment, identify patients never screened, or find and engage patients who received a positive diagnosis but never engaged in care. CMS and CDC are undertaking further steps with ONC to support these state and local efforts by creating aligned payment incentives, interoperability requirements, and infrastructure supports for more standardized, automated processes in sharing data and constructing measures of access and performance, to mitigate reporting burden and to enhance the ability of EHRs and state and local public health data infrastructures to use data that meet consistent standards.

Conclusion

In order to address existing challenges in providing effective, longitudinal treatment for all populations impacted by hepatitis C, the implementation pathway should reflect the lessons learned and opportunities for synergies with existing health care and public health initiatives. There are many programs in place that have demonstrated notable successes in engaging the patient populations with the greatest proportions of hepatitis C prevalence, namely, uninsured, incarcerated, the Medicaid eligible, and Medicare populations. Leveraging existing programs with community ties and trusted community workers to engage and expand awareness for underserved populations will be critical to advance hepatitis C elimination.

A national strategy can build on these ongoing activities aiming to reduce the burden of hepatitis C, helping to leverage any new resources to carry out a large-scale elimination effort. These steps can also create more support for investments that build up long term capabilities to sustain the goal of hepatitis C elimination, as well as complement needed steps toward strengthening primary care capabilities for other infectious and chronic diseases that disproportionately affect similar traditionally underserved populations. By building hepatitis C activities into routine primary care services at a range of traditional and nontraditional sites, stakeholders can make the most of time-limited resources dedicated to a national elimination effort and support a sustainable approach to hepatitis C containment and elimination.

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Appendix

Methods

In order to leverage the expertise and incorporate perspectives from individuals whose work has bearing on a national hepatitis C program, the Duke-Margolis Institute collaborated with a range of stakeholders, including government and public health agencies, clinicians, manufacturers, researchers, representatives from state and local public health, among others through interviews, convenings, and other touch points. Research activities were iterative and ensured recommendations were tested and refined through multiple interactions with key stakeholders and experts.

Researchers conducted a literature scan on the burden of disease of hepatitis C in the US, followed by a review of public health programs addressing hepatitis C, HIV, and SUD. This analysis includes review of common core components across as well as purchaser and population-specific considerations organized to illustrate policies that can be used in a national elimination program.

Duke-Margolis prepared an environmental scan report, which includes a compilation of published and gray literature, survey of relevant organization webpages and key stakeholder information, and further programmatic details gathered through key stakeholder informational interviews conducted by the Duke-Margolis team.

We then identified individuals with experience related to each of the strategic framework components - diagnostic development, disease detection, education, DAA procurement, and care integration – within the context of hepatitis C, as well as those with expertise related to the different payers and key populations impacted by hepatitis C. We conducted a total of 18 semi-structured group and individual interviews with providers; representatives from government agencies; health organizations; people with experience running local or regional hepatitis elimination programs; and academic researchers. Two private roundtables were additionally conducted in order to discuss findings from interviews and literature reviews and identify gaps that may require further research.

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