

Advancing Hepatitis C Elimination

*Hepatitis C Treatment and Elimination Programs in the United States
An Environmental Scan*

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Executive Summary

Hepatitis C is a bloodborne liver infection caused by the hepatitis C virus (HCV). Acute hepatitis C can be a short-term illness with spontaneous clearance. However, over half of acute cases become chronic infections and can result in serious and costly long-term complications including cirrhosis and liver cancer.ⁱ Despite the availability of multiple curative therapies, the hepatitis C incidence rate increased 71 percent from 2014 to 2018, with two-thirds of cases occurring among people most impacted by the opioid crisis.ⁱⁱ

Many populations disproportionately impacted by hepatitis C are underserved by the nation's existing health care infrastructure and may not have access to hepatitis c treatment or care. There have been a number of federal, state, and regional programs designed to reach these patients to provide access to care. Learnings from these programs may inform opportunities for overcoming barriers to testing and care access for impacted populations. Further, characterizing core components and activities of programs that are successful in expanding hepatitis C treatment could inform a national hepatitis C elimination strategy.

The COVID-19 pandemic response implemented “test-to-treat” and vaccination approaches that translated effective biomedical innovation into national impact – an approach that potentially could be applied to other infectious diseases. Any new hepatitis C initiative can leverage not only recent biomedical innovations, but also 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 that can reduce the need for further funding and increase ongoing capabilities to contain hepatitis C among other public health threats.

As part of the ongoing work to support development of a national hepatitis C elimination strategy and corresponding implementation pathway, the Duke-Margolis Center for Health Policy analyzed ongoing programs to treat populations impacted by chronic hepatitis C. The 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.

This environmental scan is intended to be 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. Further work to inform a national strategy includes characterizations of short-term actions, including administrative reforms and pilot opportunities, that can increase the likelihood of success and support feasibility as well as reduce the costs of a national hepatitis C elimination program. Additionally, short term efforts will play an important role in informing what further resources may be necessary to ensure sustainability of national strategic activities and support attaining the ultimate goal of hepatitis C elimination in the U.S.

Introduction

Hepatitis C is a bloodborne liver infection caused by the hepatitis C virus (HCV). Acute hepatitis C can be a short-term illness with spontaneous clearance. However, over half of acute cases become chronic infections and can result in serious and costly long-term complications including cirrhosis and liver cancer.ⁱⁱⁱ The Centers for Disease Control and Prevention (CDC) reports that hepatitis C is associated with 50 percent of liver cancer incidence, for which the rate of death is increasing faster than any other form of cancer.^{iv} Effective treatments for hepatitis C, known as direct acting antiviral (DAA) therapies, inhibit viral protein synthesis and prevent HCV replication. Multiple DAA therapies have become available since 2013 that can clear the virus in 90 percent or more of cases.^v Despite the availability of these curative therapies, the hepatitis C incidence rate increased 71 percent from 2014 to 2018, with two-thirds of cases occurring among people most impacted by the opioid crisis.^{vi}

Following the availability of DAA therapies, drug procurement in the face of large incident populations of presented a significant barrier to access to broad treatment. High unit prices for the curative DAA therapies, which were in the range of \$84,000 per treatment regimen, led public and private payers to limit access to the therapies through prior authorization requirements, patient, provider, and prescriber restrictions. Following the availability multiple competing DAA options net prices have substantially decreased.

While the acquisition costs of DAA treatment are lower, the care cascade – the pathway through which at risk individuals are screened and followed through virus clearance – is complex and presents additional barriers to access for most patients. Hepatitis C requires a two-step diagnostic process, with an HCV antibody screening and polymerase chain reaction (PCR) ribonucleic acid (RNA) confirmatory test. While HCV antibody rapid point-of-care tests are available in addition to standard lab-based testing, RNA confirmatory tests can only be performed in a lab and take several days to process. Following diagnosis, patients undergo initial disease assessment by a provider to determine viral genotype and severity of liver damage. A corresponding DAA therapy is prescribed after the disease assessment and the patient is referred subspecialists based on the severity of any complications. The DAA regimen may last eight to 24-week and a follow-up test is performed to determine whether the patient achieved sustained virologic response (SVR)—viral clearance.

The care cascade presents barriers to access because gaps exist at nearly every stage of the pathway. First, many regions lack the data infrastructure required for surveillance that informs which patients need treatment. Patients may be lost to follow up between screening and diagnosis of hepatitis C due to the two-step diagnostic process in practice today. If a patient receives a positive test, provider shortages, especially within rural areas, can make it difficult to reach a trained provider, and a number of prescribing restrictions further impact access to care. In addition to remaining financial and prior authorization barriers to DAA treatment, substance use disorders (SUD) or other comorbidities as well as stigma or discrimination by providers can make treatment uptake and adherence challenging.^{vii,viii} Finally, absent harm reduction and prevention strategies reinfection in certain underserved populations remain a concern.

Strategic Framework of a National Elimination Program

In order to address the gaps in the hepatitis C care cascade, there have been a number of federal, state, and regional programs designed and implemented to address the burden of hepatitis C among their respective populations.^{ix,x,xi,xii,xiii,xiv,xv} According to U.S. Department of Health and Human Services (HHS) monitoring, there are currently eight federal or multi-state initiatives, as well as 22 state and regional

programs.^{xvi} These programs have several overlapping features that have helped them engage the public and successfully test and treat members of underserved communities. These features include comprehensive surveillance efforts to track patient and community progress, targeted educational and public awareness efforts, expanded screening sites, linkage to care between diagnosis and treatment, and provider training to allow non-specialist health care providers to offer hepatitis C care. These elements appear to be key to identify patients, initiate treatment, and provide locally accessible support throughout the entire care cascade. While each program is tailored for a specific region and/or population, the existence of a number of overlapping programmatic features suggest that there are core activities that can serve as the foundation for a national approach to hepatitis C.

Common core programmatic activities for hepatitis C elimination programs, which together serve as a framework for a national hepatitis C elimination strategy, include the following:

- 1) Diagnostic development: Accelerating the development of point-of-care diagnostics and expanded use of reflex testing to facilitate single-visit test to treat care models
- 2) Surveillance: Develop networks that enable data sharing across healthcare, labs, and public health entities to support patient identification and track elimination metrics
- 3) DAA and diagnostic procurement: Expand population-level procurement models for both DAAs and diagnostics
- 4) Care Integration: Coordinated care at the primary care provider level linking diagnosis, disease assessment, and treatment
- 5) Education: Provider training and public outreach about testing and treatment

Many populations disproportionately impacted by hepatitis C are served by Medicare, Medicaid, HRSA, or state Departments of Corrections (DOCs). Even with insurance, many of these patients have been underserved by the nation's existing healthcare infrastructure and may not have access to basic care. As such, it is important that a national strategy and implementation pathway address purchaser-/payer-specific considerations and other structural barriers in order to both reach patients and ensure access to treatment and care.

The Duke-Margolis Center for Health Policy assessed the landscape of hepatitis C treatment and elimination programs in order to analyze how strategic components described are implemented across different populations served by different payers or purchasers. This document compiles information gathered through peer-reviewed and gray literature as well as stakeholder interviews. Stakeholders interviewed included discussions with experts who work at the programmatic level as well as those working at a higher level on hepatitis C elimination efforts and include those with current or former roles in regional, state, and federal level entities as well as non-governmental organizations actively engaging with or on behalf of populations impacted by hepatitis C. The objective of this analysis is to inform a comprehensive implementation pathway for a national hepatitis C elimination program.

Population Specific Considerations of Existing Programs to Address Hepatitis C

Hepatitis C affects diverse patient populations with distinctive clinical and socioeconomic features, and differences in the purchasers financing care have an important impact on activities carried out under different programs. Key patient populations impacted by hepatitis C include: Medicaid beneficiaries, Medicare beneficiaries, incarcerated populations, the uninsured, private health insurance recipients,

American Indians and Alaska Natives (AI/AN) who receive care through the Indian Health Service (IHS), and military veterans who may receive care through the VHA health system.^{1,2}

Barriers to care across these patient populations differ based on are differences in provider networks and prescription drug coverage across payers or healthcare purchasers. Thus, considerations related to Medicare, Medicaid, systems reaching the uninsured, and state Departments of Corrections will be key to inform implementation for a national hepatitis elimination program.

Barriers to Care for Medicaid, Uninsured, Incarcerated, and Medicare Populations

Medicaid eligible population

Medicaid eligible populations, including existing beneficiaries and individuals who are un-or underinsured who may qualify for Medicaid coverage, are among those most heavily impacted by hepatitis C. Approximately three percent of Medicaid beneficiaries 18 and older have a chronic infection.^{xvii}

A large disease burden in Medicaid eligible populations mean that states face a considerable cost burden despite the decrease in the cost of DAAs. Coupled with budget cycles linked to legislative sessions and state spending constraints, it is difficult for states to accommodate large up-front spending increases on DAAs. Consequently, states have historically rationed treatment through prescribing restrictions. While some states have removed or reduced prescribing restrictions for DAAs, policies that limit patient access remain prevalent. Current restrictions include prior authorization requirements, fibrosis restrictions, substance use restrictions prior to or during treatment, counseling on substance use, specialist prescriber requirements, and restricted access to retreatment.^{xviii} Beyond financial limitations, Medicaid programs may also face barriers in identifying patients due to insufficient data infrastructure and limited sharing capabilities between state and local health agencies.

This population may require treatment for multiple conditions and integrate social support services. To further complicate care delivery, many Medicaid eligible populations live in rural areas without Rural Health Clinics (RHC) or Federal Qualified Health Centers (FQHCs) nearby to help ensure access hepatitis C screening.^{xix} If a patient is screened, barriers to reaching care include finding local providers who accept Medicaid patients, transportation, long wait times for appointments, inconvenient office hours, and occupations that don't allow for flexible schedules.^{xx}

Uninsured population

Among the uninsured, the hepatitis C prevalence is approximately two and a half percent. Community based care delivery programs and safety net clinics provide services to the un- or underinsured. However, funding and capacity for these regional programs and care sites may fluctuate over time, and such conditions may impact the ability to implement sustainable infrastructure and integrated systems. In addition, like Medicaid patients, uninsured patients in rural areas may not live close to RHCs and FQHCs with specialty care. Even if enrolled in treatment, the cost of DAA may be a major barrier to adhering to hepatitis C treatment, as many live below 200 percent of the Federal poverty level but may not be eligible for Medicaid and other public assistance or may not be aware of their eligibility. Barriers

¹ Please note that populations served by the IHS are also served by a number of other payers including Medicare and Medicaid and therefore will be impacted by related payer-specific considerations with hepatitis C care and treatment access.

² People who inject drugs (PWID) are disproportionately represented in some of the key coverage groups and may be particularly vulnerable to hepatitis C infection and re-infection.

to care for the uninsured population are numerous and are typically tied to low socio-economic status. This population has low awareness of and uptake of hepatitis C treatment, and many may be uneducated about hepatitis C or their personal status. Patients may have difficulty navigating screening and treatment, or may have a mistrust of the medical system, which can stem from language barriers, cultural context, and citizenship status among other factors.

Incarcerated population

Hepatitis C prevalence ranges significantly across states and prison systems, but approximately 20 percent of incarcerated people have hepatitis C, making up nearly 30 percent of the total U.S. cases.^{xxi} Screening practices vary across prison systems and given the cost of treatment and limited health staff, states may not have the resources to implement universal testing and subsequent treatment. Prisons systems often lack capacity to provide education and counseling, and many patients remain unaware of their status and risk of infection.

For patients who are screened, the dearth of providers remains a barrier to accessing medical care and DAA therapy. Individuals incarcerated in state and federal systems face significant challenges in accessing timely, appropriate care and hepatitis C drugs. Prisons have significant leeway in determining treatment access due to low standards for healthcare based on what classifies as “reasonably adequate” care. In most cases, only patients in advanced stages of disease who are in incarcerated settings are eligible for DAA therapy.^{xxii}

Medicare population

The hepatitis C prevalence rate in the Medicare population is approximately one and a half percent.^{xxiii} In recent years, the incidence rate of hepatitis C among the Medicare population has increased and is projected to increase further in the near future—an estimated 75% of hepatitis C patients may be enrolled in Medicare within the next 15 years.^{xxiv} Of note, Medicare is also the payer likely to absorb costs from complications of untreated hepatitis C given eligibility for individuals age 65 and up.

There are several barriers to accessing hepatitis C care and treatment for Medicare beneficiaries. Lack of a rigorous surveillance system may hinder providers’ ability to identify Medicare beneficiaries in need of testing as well as those with positive tests in need of follow up care to initiate treatment. Patients themselves may have limited awareness of testing recommendations for their age group, or may have limited access to screening. Even with a positive diagnosis, some Medicare beneficiaries may face challenges accessing care due to a lack of transportation, high costs of care, and scheduling appointments with appropriate specialists, all of which are worse for Medicare beneficiaries in rural areas.^{xxv}

Cost of hepatitis C treatment is also a barrier to accessing hepatitis C treatment for Medicare beneficiaries. Because hepatitis C drugs are self-administered prescriptions, they fall under Medicare Part D coverage. 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.^{xxvi} Additionally, the structure of Medicare, with separate plans for prescription drug coverage, presents some challenges to implementing population-oriented strategies that integrate drug procurement and care models.

Opportunities for states to address DAA and diagnostic procurement, care integration, and education among the Medicaid, uninsured and incarcerated populations through administrative levers and federal supports

State Medicaid agencies have several administrative levers that can be used in combination with existing federal programs and funding streams to expand access to care for Medicaid, incarcerated and uninsured populations. States can use a combination of these approaches to improve procurement of DAAs and diagnostics, build capacity and infrastructure, increase provider uptake of screening and treatment, integrate social support services and expand coverage for certain services among populations currently ineligible for Medicaid. Many of these state-level approaches are drawn from state experiences with HIV containment. As there is significant overlap in the patient populations affected with HIV and hepatitis C and there are opportunities to build on existing HIV infrastructure and capacity to expand access to hepatitis C treatment. However, while there are lessons to gain from care delivery and surveillance of HIV, many these structures were implemented in a siloed fashion and are not always applicable to other disease areas. There is an opportunity to better integrate hepatitis C care delivery and surveillance into existing systems, to facilitate a more person-centered approach, and better treat hepatitis C alongside other conditions including HIV, hepatitis A and B, SUD, and behavioral health. Doing so may allow stakeholders to leverage fewer resources to greater effect in advancing hepatitis C elimination for impacted populations where there is significant overlap with other population health challenges.

Procurement of DAAs and Diagnostics

Population-level procurement models for DAAs and testing can ensure adequate availability of affordable treatment and innovative one-step diagnostics for impacted populations. Payment approaches through negotiated manufacturer and payer/purchaser agreements, coupled with expanded coverage policies will facilitate broader access to testing and treatment to advance hepatitis C elimination efforts. While a number of examples for DAA procurement exist within the hepatitis C space, relevant payment approaches for novel hepatitis C diagnostic procurement can likely be best informed by examples from outside of the hepatitis C space, notably from the COVID-19 experience.

States can implement an expenditure-cap model or enter into pooled purchasing arrangements to improve DAA access among Medicaid beneficiaries

Several states, including Louisiana, Washington, and Michigan, have piloted novel payment contracts with manufacturers to improve access to DAA therapies for Medicaid beneficiaries and incarcerated populations. These population-focused procurement models establish annual expenditures caps on DAA treatment followed with nominal net price per unit for additional courses through supplemental drug rebates. This approach ensuring budget predictability and controlled DAA procurement expenditure. This approach depends on capacity building, expanded outreach, and test to treat capabilities for Medicaid providers, as states will need to administer enough doses to surpass the agreed upon annual cap in order to benefit from the nominal price per unit. Additional Federal supports and provider performance incentives through state plan amendment templates may be needed to assure expanded access. For states who do not have the resources to implement such models directly with manufacturers, multi-state purchasing pools with common formularies, such as the National Medicaid Pooling Initiative and Sovereign States Drug Consortium, can facilitate state negotiations with manufacturers for higher supplemental rebates. These purchasing pools can also include the 340B drug discount program in negotiations and financing.

States can leverage the 340B Drug Discount Program to expand DAA access for the uninsured population

The 340B Drug Discount Program, overseen by the HRSA Office of Pharmacy Affairs (OPA), is the primary means for access to specialty drugs to un-or underinsured and underserved populations. It is also a major source of savings for safety net clinics, which can support additional clinical and social services. States can use administrative levers to increase the number of specialist providers affiliated with 340B covered entities. This extends access to 340B discounted drugs among un-or underinsured patients without requiring patients to change providers or site of care. ^{xxvii}

Despite the significant benefits of the 340B discount program, there are many administrative complexities. The duplicate discount prohibition prevents manufacturers from offering a 340B discount and Medicaid rebate on the same drug. CEs have different approaches for preventing duplicative discounts among Medicaid patients (carve-in vs carve-out) and have administrative processes for tracking prescriptions. 340B also poses challenges for states implementing expenditure cap models. If Medicaid establishes a contract for an expenditure cap and nominal price per unit with a manufacturer but isn't able to receive the negotiated rebates for treatment of Medicaid patients administered 340B discounted drugs, then the Medicaid program may be unable to attain the anticipated level of savings through the expenditure cap arrangement.

State can directly negotiate lower prices or utilize the 340B program for DAA access among incarcerated populations

States can acquire discounted prices for DAAs for incarcerated persons through direct negotiation with manufacturers. For instance, Washington state negotiated a contract separate from the expenditure-cap model for Medicaid beneficiaries, to also increase DAA access among non-Medicaid populations under the state's jurisdiction. This contract included persons within the Department of Corrections, Public Employees Benefits Board Program, the Department of Labor & Industries, and the Department of Social & Health Services. ^{xxviii} The DAA under contract was placed on the preferred drug list across these agencies and they received an upfront discount through their wholesaler. State DOCs can also leverage the 340B discount program and obtain these discounts by contracting with 340B entities including FQHCs and other community safety-clinics, 340B eligible hospitals, and public universities. This is exemplified through the University of Texas Medical Branch (UTMB), which has a disproportionate share hospital and specialized clinic that provides nearly all of the healthcare services for the state's incarcerated population. In receiving care through this covered entity, a nearly all persons incarcerated in state correctional facilities have access to 340B discounted drugs. An approach among states where incarcerated persons cannot receive care directly from a 340B covered entity, is to utilize organizations receiving Section 318 funding. Entities receiving Section 318 funding to treat sexually transmitted infections (STIs) are eligible for 340B discounts if certified by the Secretary. The DOC can leverage these clinics to provide STI treatment including for hepatitis C and HIV or work with states to itself become a subgrantee of the state DOH for STI funding. In Florida, the DOC and DOH entered into an agreement where incarcerated persons receive STI treatment by county health department physicians and can thus receive medication through the health department's pharmacy at the 340B discounted price. This model can also be applied on a more local level for county jails. County jails can acquire Section 318 sub-grantee status through partnerships with local health departments and with approval by the Secretary can directly dispense 340B discounted drugs to the incarcerated. ^{xxix}

Care Integration

There are several administrative levers states may be able to leverage to build capacity and enhance delivery of hepatitis C services in the primary care setting. Through state Medicaid mechanisms including managed care organizations, Section 1115 demonstration waivers or state plan amendments (SPAs), states can expand coverage, direct funding to providers, augment reimbursable services, improve care coordination and develop infrastructure and capacity.

Contract adjustments with Managed Care Organizations (MCOs) for provider and patient education and provider financial incentives to increase hepatitis C screening and treatment among the Medicaid population

Financial incentives, such as per-case “hepatitis C case management payments” linked to reporting on screening, treatment initiation, and completion rates, may be used in order to increase screening and treatment. These incentives can be implemented for relevant primary care providers in traditional fee-for-service Medicaid as well as MCOs.^{xxx} States have flexibility under managed care contracts to enhance provider reimbursement through plan rate increases for hepatitis C services or to direct plans to implement value-based payment arrangements or performance initiatives that link additional payments to performance metrics, and a growing number of states are implementing payment reforms for advanced primary care with accountability. As done in Louisiana, states can include hepatitis C in quality improvement goals and require managed care plans to report on quality outcomes related to case management outreach, provider education, screening, and DAA treatment initiation through Performance Improvement Projects (PIPs). This will not only incentivize providers to increase 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. MCOs are also an avenue for increased awareness and education of hepatitis C testing and treatment options among providers and patients. States can utilize MCO communication channels to reach beneficiaries and provider and patient education measures can be incorporated in managed care PIPs, directing MCO case management teams to conduct outreach and education. There are also opportunities for states to directly or indirectly incorporate development of telecommunication capabilities into managed care contracts. Finally, there are mechanisms for states to develop plans that are catered to needs of a defined population. New York, for instance, has developed a managed care HIV Special Needs Plan or Health and Recovery Plan through which MCOs are able to meet the health care and social needs of beneficiaries with mental illness and/or SUD, experiencing homelessness, are transgender and/or living with HIV/AIDS.

State plan amendments to expand coverage eligibility and coordinated care services

State Medicaid programs can leverage different authorities, such as enacting SPAs, to expand coverage or improve case management services for hepatitis C. One example of this approach is the use of Health Homes (HH) for the management of HIV. The Affordable Care Act in 2010 created the optional benefit for Medicaid programs to establish Health Homes that coordinate care for Medicaid beneficiaries with two or more chronic conditions. Health Homes provide case management to help address barriers to care, meet social service needs, adhere to treatment and stabilize health through contracts with managed care plans. To incentivize states to take up this benefit, the federal government temporarily increased the Federal Medical Assistance Percentage (FMAP), offering a 90% federal match for certain Health Home services. CMS issued guidance to states for developing state plan amendments to support the implementation of Health Homes.^{xxxii} New York and Rhode Island are piloting Health Home models to include the care coordination needs of incarcerated persons re-entering the community. States have flexibility in designing health homes to include a broader range of eligible chronic conditions, payment methods for core services, and whether to target the services to a particular regional or offer them

statewide. While Health Homes cannot be specific to justice involved populations, eligible chronic conditions can include those heavily affecting this population. Pilot programs for the justice involved populations can be centered around developing the infrastructure, including data sharing capabilities, and network building, to support coordination and a smooth transition to Health Home services post-release.^{xxxii}

1115 demonstration waivers to expand services among Medicaid beneficiaries, uninsured and incarcerated

Section 1115 Demonstration Waivers are a mechanism for states to pilot programs or develop infrastructure and capacity for hepatitis C treatment. It may be used to compensate providers in safety net clinics for providing services for both Medicaid eligible and uninsured populations. One instance of this is the Texas Public Health Provider – Charity Care Program, which provides supplemental payments to publicly-owned and operated community mental health clinics, local behavioral health authorities, local mental health authorities, local health departments, and public health districts. These payments are intended to mitigate uncompensated care costs incurred by qualifying providers associated with caring for low-income populations.^{xxxiii} States also have some authorities for targeted coverage expansion for certain populations through these waivers. For example, Maine received approval for a demonstration to offer a set of HIV services, including access to anti-retroviral therapies, for the treatment of HIV among low-income persons. This not only includes persons who qualified for MaineCare (State Medicaid program) but also those who were at or below 250 percent of the federal poverty line that did not qualify for Medicaid.^{xxxiv}

Section 1115 waivers can also be used to develop infrastructure, specifically for telecommunication and virtual education. New Mexico, received approval for an 1115 demonstration waiver that allowed MCOs to access virtual educational modules as a means of increasing the primary care provider network. New Mexico used Project ECHO as its a virtual education platform to support capacity building in local health care systems by training and tele-mentoring primary care providers in hepatitis C screening and treatment. Hundreds of providers have been trained through these means, increasing access to hepatitis C care among hardly-reached communities. The success of telecommunications platforms has increased its recognition as a viable tool for capacity building activities and states have several options for financing these models, including through 1115 waivers.

Section 1115 waivers are also being used for targeted coverage expansion for incarcerated populations by implementing a partial waiver of the statutory Medicaid exclusion policy (which prohibits Medicaid dollars to be spent on incarcerated persons). California receive CMS approval to extend select Medicaid services to all Medicaid-eligible adults and youth in correctional facilities who meet certain health criteria (this includes adults diagnosed with mental health disorder, SUD, chronic condition, intellectual or developmental disability, traumatic brain injury or who are pregnant) 90 days prior to release and support with continuation of care after-release. Covered services are intended to leverage community-based partnerships and improve care coordination by connecting those transitioning with a Community Health Worker (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.^{xxxv} Concurrent with these services is the PATH initiative, a five-year program with funding to build capacity and infrastructure among community partners to improve their ability to provide treatment and services for justice-involved persons. The Biden administration is encouraging state Medicaid programs to adopt similar measures to provide SUD treatment to the incarcerated and other health-related social needs. CMS recently released guidance for states to help increase care for

individuals who are incarcerated in the period immediately prior to their release. Eleven states have already submitted waivers for approval.^{xxxvi}

Additional considerations for local and regional programs

State-level mechanisms have been used to further the efforts of local and regional programs aimed at improving testing and treatment for hepatitis C. As previously described, states have several mechanisms to direct payments to safety net providers, expand reimbursable services, and build capacity in order to increase treatment access. These supports can advance test-to-treat care models and reach many populations including Medicaid eligible persons, the uninsured, eligible American Indian/Alaska Natives, veterans, persons with mental illness or SUD, persons experiencing homelessness, and the justice involved.

Co-location of services for opioid use disorder, behavioral health, HIV and hepatitis C, is an effective approach in reaching these underserved communities, streamlining treatment and retaining patients along the care cascade. It is increasingly utilized in regional hepatitis C elimination efforts. Administering hepatitis C treatment alongside medication assisted treatment for SUD, such as in a methadone clinic, may address barriers to access such as linkage to specialists, education, and stigma. The convenience for patients of receiving care at one location, the familiar and supportive environment, can support treatment adherence and continuity.^{xxxvii} There are notable regulatory, administrative, and capacity challenges to facilitate the co-location of hepatitis C and opioid use treatment services. For instance, harm reduction sites may not have the spatial arrangement to meet CMS regulations or the administrative capacity to report cases or file for reimbursement for hepatitis C related services. Further, specific to hepatitis C screening, POC tests require CLIA waivers to be used in community-based organizations such as SSPs with limited staff.

Another care delivery approach utilized for HIV to better integrate preventative services that could be useful for hepatitis C is the “status neutral approach.” This is a holistic approach that seeks to embed prevention and HIV care into traditional care delivery and keep patients engaged in care even once viral load is suppressed. Persons at high risk of HIV are engaged in preventive measures and social support services whether or not they receive a positive test. This helps mitigate stigma, increase access to care, prevent new infections, maintain viral suppression for those who receive treatment. New York introduced a status neutral approach for HIV and has seen a 22% decrease in HIV diagnoses between 2016 and 2019. After receiving community input through engagement effort, Chicago implemented a status neutral program that integrated services like STI screening, SUD treatment, mental health, housing, financial assistance, and psychosocial support in addition to HIV treatment and prevention, regardless of status. Similar status-neutral approaches have been implemented in Puerto Rico, Texas, and DC.^{xxxviii} Given the significant rates of HIV and hepatitis C coinfection (21% of individuals in the US with HIV also have hepatitis C), similar modes of disease acquisition, and similar issues with stigma around the two diseases, a status neutral approach may also lead to positive outcomes for people with hepatitis C.^{xxxix}

Local care delivery approaches are reliant on community involvement and partnerships with community-based organizations. Coalition building with community organizations will help build capacity for social needs services and advocate for supportive policies and funding.

Opportunities to Expand Access through Additional Funding

While these state mechanisms can help develop treatment and care coordination capacity at the primary care level, there are limitations to the reach of these mechanisms, especially in regard to coverage and access to care among individuals who are only able to access care in non-traditional care settings, if 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. Providing hepatitis C care alongside social services and other wraparound services will help reach and treat these patients. 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. Below are examples that illustrate the role of additional allocated funds in advancing efforts to test and treat certain populations impacted by hepatitis C.

State Level

At the state level, there are further activities that may be pursued to support hepatitis C elimination programs, notably around supporting care for incarcerated populations and for expanded hepatitis C surveillance, which may warrant additional funding.

Building on state-level mechanisms for Departments of Corrections (DOCs)

Access to hepatitis C services is very challenging for incarcerated populations. Section 1115 initiatives previously described that expand Medicaid coverage are limited to incarcerated persons re-entering communities. Some states have secured dedicated funding and cross-agency collaboration to expand services within correctional facilities. For example, a coalition formed in Alaska between state agencies and community organizations successfully advocated for additional funding from the state legislature for the Alaska DOC. This additional funding supported expansion of hepatitis C services including universal opt-out screening.^{xl}

Some states have been required to increase funding for health services among the incarcerated as a result of lawsuits filed by incarcerated persons due to repeated denial of access to hepatitis C treatment. Court's ruling in favor of patients in incarcerated settings have required a number of state DOCs to provide hepatitis C screening, treatment and monitoring in correctional facilities. States have needed to allocate additional funds to provide required screening for individuals upon entry into DOC custody, as well as treatment and DAA access. Following a class-action lawsuit brought against the Pennsylvania DOC, Pennsylvania is now allocating \$14 million to screen and treat hepatitis C within the prison system. Pennsylvania has also been the first state to extend screening and treatment on a large scale to jails.^{xli} Jails partnered with community health organization Philadelphia FIGHT in order to provide care management services to help patients continue their care upon release from jail.^{xlii} As the initial touchpoint for persons entering the criminal justice system, jails may be best suited for implementation of universal, opt-out, point-of-care testing and hepatitis C education among justice-impacted populations. While universal screening and treatment efforts in jails can face barriers due to the transient nature of these facilities, jails can partner with local organizations and health care centers to support linkage to care and treatment continuation, as is now done in Pennsylvania.^{xliii} Although lawsuits have facilitated much needed changes in access to hepatitis C treatment among some segments of the incarcerated population, the resulting hepatitis C initiatives exemplify what can be accomplished through additional state funding. Additionally, non-traditional care delivery models such as use of telehealth and pharmacist-led treatment model in Virginia DOC, can provide approaches to extend state

resources.^{xliv} Despite some efforts to increase hepatitis C services in correctional facilities, treatment remains highly variable from state to state and funding and expansion of health services for incarcerated populations is still often politically unfavorable.

Expanding state-level surveillance

A significant barrier to developing state-level surveillance is limited federal funding. Currently states only receive \$200,000 from the CDC to support surveillance infrastructure development that supports more complete data reporting, and the capacity to identify and respond to outbreaks. Consequently, many states may not have the resources to ensure complete reporting, or have the personnel to aggregate and analyze data. In contrast, many resources have been allocated to support HIV data reporting, case investigation and data analysis, contributing to a robust surveillance infrastructure across states. For instance, the HIV Data-to-Care approach involves case investigation to link people to care who previously received positive antibody screens or RNA tests but showed no indication of treatment and viral suppression. While, approaches such as Data-to-Care for HIV can be applied to hepatitis C, HIV surveillance systems are discrete and cannot be leveraged or integrated with surveillance systems for other communicable diseases. Local health departments often do not receive risk factor information which includes signs and symptoms, race and ethnicity, pregnancy status, and do not have the capacity to follow-up and extract this data from providers.

Despite limited resources, states can automate processes in local health departments to mitigate reporting burden, pass legislation requiring reporting of rapid antibody tests and negative case reporting, use lab data to determine which labs are not conducting reflex testing.

Federal Procurement of DAAs and Diagnostics

At the federal level, there are a number of mechanisms that can support hepatitis C elimination programs, most notably for the Medicare, underinsured, and uninsured populations. Some of these strategies can utilize existing programs and funding, while others may require additional federal funding to support infrastructure and capacity building.

Procurement for Medicare populations

Many Medicare part D plans require prior authorization or high coinsurance for DAAs. Branded DAAs are often placed in high tiers of drug formularies which may result in higher patient cost high. There is also evidence that, due to sponsor rebates to part D plan sponsors for higher cost DAAs, Medicare patients have been less likely to receive the generic versions of the DAAs available than Medicaid patients, leading to higher out-of-pocket (OOP) costs and higher costs for the Medicare program.^{xlv} As a result, the average OOP costs for a full treatment course for Medicare beneficiaries with low-income subsidies is between \$10-\$1,100, and without subsidies the OOP costs can range between \$6,200-\$10,900.^{xlvi} In a recent report on the costs of DAAs in Medicare part D plans, the Office of Inspector General in DHHS recommended that Part D plans increase access to and use of generic DAAs to lower both Medicare and patient OOP costs by both reconsidering formularies and providing provider education on lower-cost DAAs. This strategy to lower costs, combined with eliminating prior authorization requirements, may help increase Medicare patient uptake of hepatitis C treatments.

CMS has also worked on a number of CMS Innovation Center (CMMI) models to help increase beneficiary access to certain drugs which could be applied to DAAs. CMMI tests new systems and payment models designed to lower costs while increasing quality of care and improving health outcomes for Medicare and Medicaid beneficiaries.^{xlvii} Although most models test different ways to pay

for care, some models include elements of drug pricing. Notably, a new proposed CMMI model will allow for CMS to negotiate directly with manufacturers for procurement of cell and gene therapies, which tend to be very specialized and expensive. Medicaid agencies will allow CMS to negotiate these contracts on a multi-state level, allowing for a more streamlined negotiation process for both CMS and manufacturers.^{xlviii} Additionally, before the Inflation Reduction Act capped insulin prices, CMS invited Part D plan sponsors through the CMMI model “Part D Senior Savings” to offer supplemental benefits for insulins through a benefit design with predictable copays, capped at \$35 per month, in the deductible, coverage, and coverage gap phases.^{xlix}

Procurement for other populations

Outside of CMS, there are other examples of the federal government procuring medical products, particularly to ensure more equitable distribution of vaccines and antivirals. For example, the Vaccines for Children (VFC) program is a federally-funded entitlement program, originally established in the Omnibus Budget Reconciliation Act (OBRA) in 1993.ⁱ This program provides vaccines to children aged 18 years and younger who are un-or underinsured and have limited ability to pay. The CDC purchases vaccines at a discounted price and distributes them to VFC-enrolled providers. Pharmacies are also eligible to enroll in the VFC program to expand access to vaccines, however, only a small number of pharmacies are enrolled, as most state Medicaid programs do not cover the administration fee in pharmacy settings.ⁱⁱ The President’s proposed budget for fiscal year 2024 included a Vaccines for Adults program, which would expand access to ACIP-recommended vaccines for approximately 30 million uninsured adults.ⁱⁱⁱ There may be similar avenues to having the CDC or other federal entities purchase DAAs at a discounted price to distribute to health departments or FQHCs that may be more likely to reach un-or underinsured populations.

The federal U.S. COVID-19 Test-to-Treat Initiative also provides insights into what might be needed to make a federally-funded and administered procurement and care model for hepatitis C successful. The initiative is part of a broad federal strategy to efficiently connect eligible and high-risk individuals to COVID-19 treatment.^{liii} Test-to-Treat combines large-scale, population-focused procurement of tests and treatments with a one-stop healthcare setting where patients can receive a rapid COVID-19 test (or bring in a positive test), counseling and assessment from a healthcare provider, and a prescription for a COVID-19 oral antiviral, if eligible. Sites of care include pharmacies, community health centers, HRSA-supported FQHCs, long-term care facilities, and VA clinics.^{liv} Forty percent of these sites are in communities with high social vulnerability, and all sites are asked to collect demographic data on individuals receiving prescriptions in order to assess gaps in access to care sites. The barriers to care for hepatitis C and COVID-19 are similar, which may allow stakeholders to utilize strategies from the COVID-19 Test-to-Treat Initiative for a potential hepatitis C model.

Education and Awareness

There are ongoing efforts to strengthen delivery of vaccines through education and community outreach that may be applicable to hepatitis C elimination. For example, the Strengthening the Vaccines for Children Program Act of 2021 seeks to expand the VFC program by including children enrolled in CHIP, expanding coverage under Medicaid to include vaccine counseling and educational services for children, and adding a temporary FMAP increase for states that conduct culturally appropriate outreach regarding the benefits of vaccinations for children.^{lv} Although the legislation has not moved past the introduction stage, similar payment incentives to state Medicaid agencies for hepatitis C counseling, education, and culturally appropriate community outreach may help reach underserved populations.

Additionally, national level awareness campaigns can support general knowledge of hepatitis C risk factors, symptoms, and screenings. The US Department of Health and Human Services has experience with nationwide educational campaigns, such as the *We Can Do This* Campaign, which is designed to increase general confidence in COVID-19 vaccines and treatments, as well as reinforce COVID-19 prevention measures. The program offers different guidance documents for reaching out to different populations, guides about how to discuss and post about different topics, and works with community partners to spread messaging.^{lvi} During the COVID-19 pandemic, testing and vaccination strategies designed to reach underserved communities and communities with low uptake had greater successes materials and communications were ADA and linguistically accessible, culturally responsive, and communicated by local community partners and leaders.^{lvii} Hepatitis C educational and awareness campaigns could employ similar strategies to ensure reach to underserved populations.

Care Integration

Barriers to testing and treatment access compound throughout the hepatitis C care cascade. Strengthening care integration may prove key for increasing the number of people screened and treated for hepatitis C. Learnings from past and ongoing efforts to streamline the diagnosis, linkage to care, disease assessment, and treatment process may be applicable to a number of populations impacted by hepatitis C.

Medicare

CMS and the American Gastroenterological Association (AGA) are currently in the process of testing a change to existing Medicare Incentives Payment System (MIPS) performance measure #400, which currently requires physicians to report on one-time hepatitis C screenings.^{lviii} This new measure would require reporting not only on first time hepatitis C antibody tests, but also on the percentage of patients that have never been tested for hepatitis C, receive an infection test, and initiate treatment within three months or are referred to another clinician for treatment within one month of the positive test.^{lix} AGA is also working on an additional quality measure for future consideration into the quality payment program, which would record cases of sustained virologic response. 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 surveillance efforts.^{lx} Since half of all eligible Medicare beneficiaries are now enrolled in Medicare Advantage plans, these private plans could include similar performance measures and other quality improvement measures to have a standard set of reportable metrics to inform surveillance and elimination program metrics.^{lxi}

CMS has also been increasing its efforts to integrate and coordinate primary and specialty care for Medicare and Medicaid beneficiaries through capacity building and innovative payment models. This may help increase the number of beneficiaries successfully cured. For example, CMS has recently announced a “Making Care Primary” model, which aims to build out care management, integration, and community connections to streamline care for beneficiaries.^{lxii} CMS is prioritizing organizations with no prior experience with value-based care, is involving FQHCs, and is working with both Medicaid agencies and private payers in eligible states to ensure there is alignment in goals for primary care. The three program tracks involve different levels of CMS investments to improve infrastructure at participating sites, with payment structures varying from fully FFS with some incentives for improving patient outcomes to fully prospective, population-based payments with greater financial rewards for improving patient outcomes. The goals of the 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. This model will help support greater care coordination from diagnosis to treatment for hepatitis C.

Notable Hepatitis C and Other Disease Treatment Programs

A number of regional and local programs as well as supportive efforts by states have demonstrated improvements in the care cascade can be made both within and outside of the primary care setting. Detailing notable programs in the hepatitis C space as well as programs with parallels to the hepatitis C care cascade or populations of interest can shed further light on challenges and opportunities with implementation of elimination programs in these settings.

Regional and Local Programs

There have been a few regional hepatitis programs that can serve as examples of both how to use existing resources and how to capitalize on additional funding to increase successes and identify continuing gaps in hepatitis C elimination. Baltimore, Seattle, and Chicago all implemented community-based care models for people with hepatitis C with grant funding from the CDC.^{lxiii, lxiv, lxv} All three programs utilized existing care delivery sites, ranging from FQHCs and free and charitable clinics (FCCs) to academic centers and multi-clinic health systems, but focused on increasing the capacities of the staff and infrastructures at the sites to improve screening, care linkage, and treatment rates. The programs primarily targeted screening and treating the Baby Boomer population and the Chicago program also targeted other high-risk individuals, such as people who inject drugs. All three programs ran from 2014-2018 or 2019. Key elements of each program included training primary care providers on how to appropriately test and offer treatments for hepatitis C and some form of data linkage across electronic health records and lab data to create better hepatitis C surveillance within the community. Two of the three programs (Seattle and Chicago) also included public education and awareness campaigns to increase screening rates.

Evaluations of the programs showed increases in screenings, reflex testing rates, and treatment across target populations. Having a greater number of primary care providers that were able to successfully treat hepatitis C helped to effectively expand treatment access in areas where specialty care is limited, particularly in the Baltimore program. In tandem with removing prescribing restrictions, education and training for PCPs can be an effective and scalable program element for increasing the number of patients screened and treated. Data linkage and presentation was also an effective element of all three programs. 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.

Programs Implemented through Indian Health Services

The Cherokee Nation (CN) Hepatitis C Elimination Program included a comprehensive range of elements in order to support improved patient identification and streamlining of care delivery among individuals living in a 14-county CN reservation in Oklahoma.^{lxvi} 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. Through this effort, hepatitis C screening rates increased from 21 to 38 percent, and substantial improvements were made across the care cascade especially in hepatitis C linkage to care and curative therapies. The didgʷálic Wellness Center in WA on Swinomish Tribal lands demonstrated success in co-locating care with a single point of treatment and integrating ancillary

services such as transportation and childcare to remove barriers to access. This program began as a center to treat alcohol dependence then expanded to include opioid use disorder. The center continued to grow to meet the needs of the community and included services such as mental health care, primary health care, SUD treatment, medication assisted treatment (MAT), on-site social workers, and a hepatitis C treatment program.^{lxvii} This program provides a replicable model for how to deliver tailored, culturally relevant care and social services to a historically hardy reached population.

The Veterans Administration Hepatitis C Elimination Program

The VA hepatitis C elimination program was successful in identifying and treating the majority of impacted individuals served by the VHA.^{lxviii} The VHA is able to negotiate substantial discounts for drug prices to support large-scale DAA treatment for veterans under care of the VHA. In conjunction with drug procurement, the VHA established a national hepatitis C clinical dashboard and registry along with clinic-based interventions such as automated EHR prompts for providers. The VHA additionally established the Hepatitis C Innovation Team (HIT) Collaborative, which included use of multi-disciplinary field-based care teams trained in clinical systems redesign and innovation to improve care pathways for hepatitis C.^{lxix} Since 2014, the VHA has treated over 100,000 veterans. An estimated 25,000 veterans remain untreated.^{lxx} This program is an example of combining a population-focused drug procurement component, surveillance system, and targeted and coordinated care pathway. However, this strategy may not be widely applicable for a national strategy because of the nature of the VA as a single-payer, service-sharing system, and its ownership and access to all VA patient data.^{lxxi}

The Ryan White HIV/AIDS Program

The Ryan White HIV/AIDS Program (RWHAP) is administered by the Health Resources & Services Administration (HRSA) and provides care, medication, and essential support services to un- and underinsured people living with HIV/AIDS.^{lxxii} The program does not specifically procure medical services, but instead provides grants to cities, states, counties, and community-based groups for different health and social services required to support impacted populations. RWHAP is split into five parts with different beneficiary and eligibility requirements. Through this structure, the program is able to fund a wide range of care and support services, provide educational services to providers and patients, and develop innovative care models.^{lxxiii} There may be opportunities to expand care delivery services to accommodate testing and treatment for hepatitis C at participating sites given the significant overlap in the populations served here and those in need of greater access to testing and treatment for hepatitis C.

A similar approach of federal level grants for regional or local support services may be suitable for reaching certain populations with hepatitis C, especially those already receiving care through RWHAP-supported activities, given that there is some overlap between the HIV and hepatitis C populations. However, the frequently asymptomatic nature of hepatitis C poses an additional awareness and education barrier beyond that currently experienced by patients with HIV/AIDS. Additionally, the RWHAP has received federal appropriations to support its programming, ranging from \$220.6 million at program inception in 1991 to \$2.5 billion in 2023.^{lxxiv}

Conclusion

In order to address existing challenges in treating all impacted populations in a comprehensive and coordinated manner, the elements of a national strategic framework and corresponding implementation pathway should reflect the lessons learned and opportunities from ongoing efforts to treat populations impacted by hepatitis C. 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, the

uninsured, incarcerated, the Medicaid eligible, and Medicare-populations. Leveraging existing programs with community ties and trusted community workers to engage and expand awareness for at-risk and hardly reached 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 while leveraging existing programs for populations most at risk, as this may help limit additional resource needs to carry out a large-scale elimination effort. However, it is critical that stakeholders use such activities as a way to bolster long term activities needed to reach the goal of hepatitis C elimination.

Hepatitis C treatment programs have traditionally been implemented through public health organizations including the CDC, state, and local health departments. Albeit with limited funding, these organizations have piloted programs that informed successful models with the goal of hepatitis C elimination in certain states, tribal programs, and the Veterans Administration. The COVID-19 pandemic response implemented “test-to-treat” and vaccination approaches that translated effective biomedical innovation into national impact – an approach that potentially could be applied to other infectious diseases. Any new hepatitis C initiative can leverage not only recent biomedical innovations, but also 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 that can reduce the need for new appropriations and increase ongoing capabilities to contain hepatitis C and other public health threats.

Findings from this environmental landscape as well as stakeholder interactions conducted to date will inform a refined focus for the center’s hepatitis C work moving forward. The refined focus includes creating supports and incentives for large-scale procurement models for DAAs and diagnostics; implementing feasible community-based models for expanded treatment access, harm reduction, and co-location; implementing accountable payment mechanisms to support care capabilities; and strengthening surveillance infrastructure to track elimination metrics.

Further work will also need to include characterizations of short-term actions, including administrative reforms and pilot opportunities, that can increase the likelihood of success and support feasibility of larger-scale implementation a national hepatitis C elimination program. Additionally, short term efforts will play an important role in informing what additional resources may be necessary to ensure sustainability of national strategic activities and support attaining the ultimate goal of hepatitis C elimination in the U.S.

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