Financing Integrated Viral Hepatitis Services

Recommendations for State and Federal Entities

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Financing Integrated Viral Hepatitis Services - *Recommendations for State and Federal Entities*

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EXECUTIVE SUMMARY

The United States remains engaged in a multi-stakeholder comprehensive effort to eliminate viral hepatitis and improve health outcomes for those who have or are at risk for viral hepatitis. The Viral Hepatitis National Strategic Plan: A Roadmap to Elimination 2021-2025 outlines key strategies for elimination that guide a host of federal and non-federal initiatives. Preventing new viral hepatitis infections and improving care and treatment requires a strategic and coordinated approach by federal partners in collaboration with health departments, tribal communities, community-based organizations, and other nonfederal entities.

One critical arm of this coordinated approach requires the implementation of payment and reimbursement practices that support effective and integrated viral hepatitis service provision. The chronic public health underfunding for viral hepatitis; the complexity of payer and reimbursement dynamics; the variety of settings in which viral hepatitis prevention, testing, and care are offered; and access challenges all pose a threat to elimination goals. The Office of Infectious Disease and HIV/AIDS Policy (OIDP), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS) now share recommendations for viral hepatitis financing models that can optimize service provision in clinical and non-clinical settings.

Leveraging Innovative Medicaid Coverage Flexibilities	**Recommendation 1.1** – Integrate viral hepatitis services into new opportunities for health-related social needs (HRSN) services
Incentivizing and Expanding the Viral Hepatitis Workforce	**Recommendation 2.1** – Prioritize reimbursement pathways for providers delivering viral hepatitis services via street medicine **Recommendation 2.2** – Integrate non-clinical staff and people with lived experience into a paid workforce for viral hepatitis service delivery **Recommendation 2.3** – Expand state scope of practice laws and reimbursement policies to increase viral hepatitis service delivery in pharmacy settings
Including Viral Hepatitis Measures in Quality Improvement Activities	**Recommendation 3.1** – Adopt and implement viral hepatitis-related quality measures
Expanding Access to Viral Hepatitis Medications and Testing	**Recommendation 4.1** – Negotiate with viral hepatitis drug manufacturers to reduce prices in exchange for limiting prior authorization **Recommendation 4.2** – Continue Department of Justice enforcement of federal law regarding accessing medically necessary hepatitis C treatment **Recommendation 4.3** – Participate in the 340B Program and Section 318 Program **Recommendation 4.4** – Ensure that updated hepatitis C screening guidelines are implemented across payers and providers
Funding Viral Hepatitis Programming	**Recommendation 5.1** – Include explicit language on viral hepatitis service integration into funding opportunities pertaining to substance use, HIV, and/or STIs **Recommendation 5.2** – Provide guidance on how grantees can braid infectious disease funding streams to better integrate service delivery and create cross-program efficiencies and sustainability **Recommendation 5.3** – Convert the Section 317 Immunization Program into a mandatory funding program through Congressional action

"Our success depends on active participation in a strategic and coordinated response to use the tools we have to prevent, and eventually eliminate viral hepatitis as a public health threat in the United States."

– Admiral Rachel Levine, MD, Assistant Secretary for Health (ASH)

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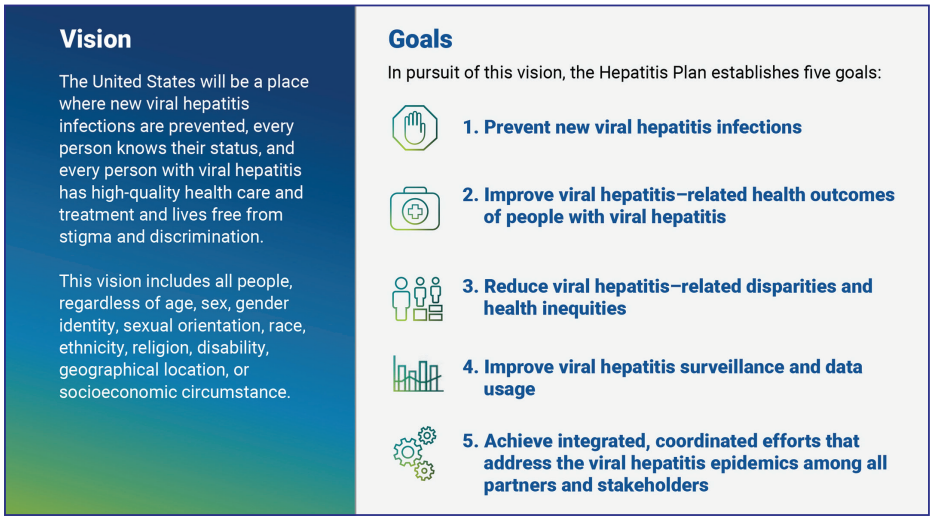
Introduction

Viral hepatitis remains a significant public health concern in the United States. Hepatitis A incidence has declined since the introduction of a vaccine in 1995; however, a series of person-to-person outbreaks between 2016-2023 have led to over 44,900 case reports and over 420 deaths. Approximately 660,000 people have hepatitis B, and there were an estimated 13,800 acute hepatitis B virus infections in 2022.[1] More than 2.4 million people have hepatitis C,[2] with an estimated 67,400 new cases reported in 2022. A concerted effort featuring a variety of strategies – universal screening and periodic risk-based testing, hepatitis A and hepatitis B vaccination, hepatitis B treatment and viral suppression, and hepatitis C treatment and cure – is needed to reverse the alarming trends and make substantial progress towards viral hepatitis elimination.

The Office of Infectious Disease and HIV/AIDS Policy (OIDP) is located in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS). OIDP's mission is to provide strategic leadership and management, while encouraging collaboration, coordination, and innovation among federal agencies and stakeholders to reduce the burden of infectious diseases. OIDP leads multiple initiatives specifically focused on addressing viral hepatitis in the United States, including the Viral Hepatitis National Strategic Plan, the National Vaccine Advisory Committee (NVAC), and the Vaccines National Strategic Plan.

The Viral Hepatitis National Strategic Plan

The Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021-2025) was developed under the leadership of OIDP in collaboration with federal partners and input from external stakeholders and the public. It was released in 2021 to provide a framework to eliminate viral hepatitis as a public health threat in the U.S. by 2030.



Initiative Overview

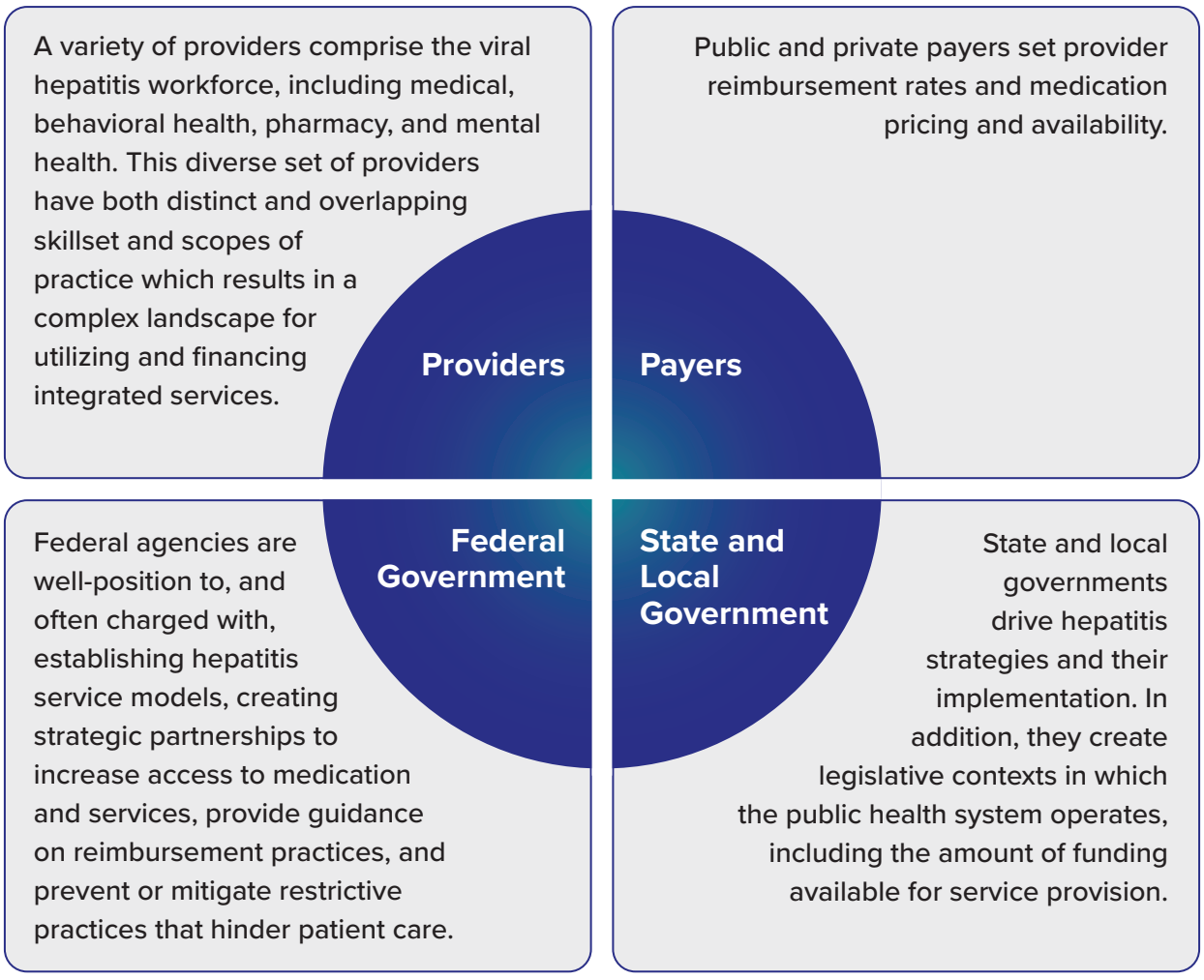
Preventing new viral hepatitis infections and improving care and treatment requires strategic and coordinated approaches by federal partners in collaboration with state and local health departments, tribal communities, community-based organizations, and other nonfederal partners and stakeholders. Many innovations in integrated viral hepatitis service delivery have arisen from urgent need (e.g., restrictive funding landscapes), federally funded pilot/model initiatives, and short-term grant programs with specific activities (e.g., viral hepatitis testing only) and/or setting types (e.g., corrections, substance use disorder programs). In addition to the national-level implementation of viral hepatitis strategies, many states have invested in comprehensive plans to improve viral hepatitis service provision and patient outcomes. However, the number of effective strategies and large-scale assessments of such approaches are limited, posing challenges for identifying and amplifying promising practices.

OIDP launched this initiative to support such an approach to eliminating viral hepatitis by analyzing available findings, identifying emerging practices, and engaging both federal and nonfederal partners. This initiative focuses on identifying payment, reimbursement, and other systemic barriers to integrated viral hepatitis prevention and care and describing models or policies that address these barriers and help to achieve an integrated, coordinated effort amongst stakeholders.

This document reflects OIDP's recommendations for systems-level approaches, to be adopted by a variety of stakeholders, to maximize viral hepatitis service provision in the United States.

Factors/Systems Driving Payment and Delivery Models

Financing of integrated viral hepatitis services reflects a convergence of systems and factors, each of which plays a distinct yet critical role in the larger public health system. Identifying facilitators and barriers to funding efficient and effective service provision within each component can explain strategies to effect systems-level changes.



Barriers to Integrated Viral Hepatitis Service Provision

While there are numerous systems-level financing-related challenges in providing integrated viral hepatitis services, OIDP has identified several key barriers - and their implications - for effectively implementing a comprehensive public health approach to addressing viral hepatitis.

Payers Limit Reimbursement for Community-Based Public Health Interventions and Providers

A care team approach to viral hepatitis screening, prevention, and treatment, with multiple and low-threshold access points for services, has demonstrated success in optimizing patient outcomes.[3] However, state scope of practice restrictions (e.g., state laws limiting pharmacist-administered vaccines and other viral hepatitis services), coupled with reimbursement limitations for certain roles (e.g., case managers), often make innovative delivery models via community-based providers difficult.

Pharmacists are well-positioned to provide viral hepatitis screenings and vaccinations (with the exception of certain restrictions on infant vaccinations), as their training includes performing select diagnostic tests and administering injections; however, scope of practice guidelines vary widely by jurisdiction. In 20 states and the District of Columbia, pharmacists are permitted to independently perform diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[4] The remaining states either prohibit pharmacists performing CLIA-waived tests,[5] which includes hepatitis C antibody testing, or have unclear guidance. There is also wide variation in the extent to which pharmacists can administer viral hepatitis vaccines.[6] Even when scope of practice laws allow pharmacists to provide a viral hepatitis-related service, the reimbursement mechanisms across public and private insurance for any services they provide beyond dispensing drugs are very limited in most states.

Programs that focus on harm reduction (e.g., syringe service programs) or community outreach (e.g., mobile clinics) are a mainstay for many individuals who cannot or choose not to obtain care from traditional clinical sites. This includes, but is not limited to, individuals who are unhoused, use or inject drugs, are undocumented, are justice-involved, or are otherwise in need of destigmatized and tailored service provision. Community-based organizations (CBOs) excel at understanding the complex needs of their service population, as well as establishing trust relationships that can greatly improve patient/client outcomes. However, many organizations lack the infrastructure to bill public and private payers.

Community organizations are often staffed by non-clinical professionals (e.g., case managers, behavioral health specialists, outreach coordinators, peer workers with lived experienced) for whom reimbursement options may be limited, even under state Medicaid programs, due to credentialing requirements. While Medicaid programs allow reimbursement for a range of services provided by non-licensed providers working under the direction of a physician or licensed practitioner, not every community-based organization is able to deliver services in that way. Even when non-clinical services and providers are covered, Medicaid reimbursement rates may not be sufficient to fully reimburse sites for providing the complex care delivery practices needed to serve hard-to-reach individuals who have, or are at high risk for, hepatitis B and hepatitis C infection. Innovative models such as street medicine programs[7] and mobile outreach units require intensive and time-consuming efforts to identify, locate, and engage patients, even prior to providing any reimbursable services.

Siloed Public Health Funding Does Not Incentivize Integration Across Viral Hepatitis Services

Governmental public health funding for infectious disease screening, vaccination, and treatment comes from a variety of sources and is often limited, preventing fully integrated service delivery. Many programs are only able to implement a subset of needed viral hepatitis services, either due to specific funder requirements, or insufficient funds to deliver comprehensive services. Viral hepatitis service provision was once highly siloed due to health professional scope of practice and expertise needed (e.g., clinical credentials for point-of-care testing, requirement for specialty physician management of viral hepatitis treatment). Fortunately, diagnostic and treatment advances have allowed for increased access and more efficient service provision for those with viral hepatitis. However, public health funding streams, particularly those disbursed through state health departments, often fall short of what is needed to maximize these advancements and promote/incentivize integrated services.

The High Price of Hepatitis B and Hepatitis C Treatment Limits Access

The availability of direct-acting antiviral (DAA) therapy for hepatitis C infection that achieves real-world cure rates of over 95% has shifted the goal of hepatitis C elimination from aspirational to truly attainable. Shorter treatment durations, fewer side effects, efficacy against all hepatitis c virus (HCV) genotypes, and suitability even for those with severe liver disease dramatically changed the landscape of hepatitis C management. The price of a full course of DAAs has decreased significantly from their initial entry to the market (from over $100,000 to approximately $30,000),[10] but with more than 2.4 million people with hepatitis C in the United States,[11] the financial burden of a cure for all remains enormous. In a 2015 letter to state Medicaid programs, the Centers for Medicare and Medicaid Services (CMS) provided guidance to states reminding them of the need to ensure access to these treatments and to review restrictions that are inconsistent with clinical guidelines.[12] More recently, HHS and the Department of Justice (DOJ) urged states to review their Medicaid policies surrounding HCV, substance use disorder (SUD), and access to DAAs and to make necessary changes in order to comply with the Americans with Disabilities Act (ADA).[13] Despite these actions, 23 state Medicaid programs and the Medicaid program in Puerto Rico still have pre-authorization requirements and restrictions.[14] Considering that DAAs will remain under patent protection until at least 2029, meeting national elimination targets will require addressing costs for both private and public payers.

Viral Hepatitis Funding in the United States

Many of the challenges identified above would be readily – and rapidly – addressed with sustained increases in public health funding from the federal government. In FY2023, funding for HIV was $7.7 billion in discretionary dollars.[8] Within the Centers for Disease Control and Prevention (CDC), where the majority of federal viral hepatitis funds are administered, over $1 billion dollars were allocated for HIV, compared with $43 million dollar for viral hepatitis.[9] State and local health departments, CBOs, and a host of other viral hepatitis stakeholders have called for substantial increases in federal funding to address long-standing underfunding; however, progress remains slow. If funding levels are likely to remain relatively stable for the foreseeable future, public and private sector innovation is required to maximize existing dollars and implement effective strategies.

Hepatitis B treatment can cost up to $1,600 monthly for brand-name medication.[15] The hepatitis B treatment pipeline is robust and new combination therapies – likely offered at a steep price – may soon become available, adding to current utilization management and coverage restriction challenges. Individuals for whom treatment is indicated often need to take hepatitis B medication for a lifetime, with potentially substantial costs. Preauthorization requirements, inclusion of only a subset of hepatitis B medications on formulary, among other practices can contribute to barriers to patient access to treatment.

An estimated 10% of individuals with chronic hepatitis B or hepatitis C are uninsured and need support in covering medication costs.[16] Public funding opportunities to absorb medication costs for uninsured individuals are limited, thus many programs rely upon manufacturers' patient assistance programs for medication access. Programs also rely on the 340B Drug Pricing Program – a federal program that allows safety net providers (including community health centers, Ryan White HIV/AIDS Program (RWHAP) recipients, and recipients of CDC sexually transmitted disease [STD] funding who qualify as 340B "covered entities" to purchase discounted drugs. But even with discounted prices available through 340B, the cost of viral hepatitis medications can be a barrier.

Community-Based Providers Do Not Have the Capacity to Integrate Services without an Influx of Funding to Build Infrastructure and Expand Staffing

CBOs represent an important component of the viral hepatitis service provision network in the United States. They often have decades of direct community experience, build and maintain trust relationships with individuals often marginalized by the health care system, understand challenges facing their communities (as well as effective solutions), and are leaders in public health innovations that can dramatically improve health outcomes.

While many CBOs have evolved to include integrated viral hepatitis programming based on policy, scientific developments, community need, and funding opportunities, others struggle to fully meet community needs due to funding and capacity challenges. CBOs, particularly non-clinical CBOs, are primarily funded with discretionary grant dollars from state and local governments and charitable entities, which poses significant barriers to sustainability. CBOs regularly struggle to balance maximizing grant-funded programs and planning for the inevitable conclusion of the funding period. In addition, grant-funded programs often have a high reporting and evaluation burden, further reducing resources available for service provision. Clinical programs also struggle with scaling up of innovative delivery interventions. For instance, street medicine programs, which have proven track records at reaching unhoused individuals, have found that expanding the model for viral hepatitis care delivery is difficult without new funding. This funding challenge is exacerbated by the fact that Medicaid reimbursement rates may not fully reimburse the labor needed to implement these types of "boots on the ground" interventions.

Without steady and sufficient levels of funding to build the organizational capacity to provide integrated viral hepatitis services, it remains a challenge to implement robust and continued activities beyond discrete funding periods.

RECOMMENDATIONS

While a more robust financial investment in viral hepatitis prevention, screening, and treatment is needed, the recommendations detailed below are intended to reflect approaches that can be successfully adopted, at least minimally, at current funding levels.

Below are recommendations and existing models where available, that overcome reimbursement and payment barriers. These recommendations were informed by data collected in an environmental scan, insights gleaned from focus groups and in-depth interviews with viral hepatitis stakeholders, and robust discussions with providers and policymakers. The information from these complementary research activities, coupled with OIDP's ongoing strategic focus on pathways to viral hepatitis elimination, yielded a discrete set of multi-sector recommendations. Some recommendations are applicable to multiple hepatitides (e.g., vaccine-related strategies for hepatitis A and B), while others address unique challenges associated with service provision of a given viral hepatitis infection (e.g., addressing cost and access to hepatitis C DAAs). We have identified the entities who are positioned to lead implementation of these recommendations (e.g., federal agencies, health departments, state Medicaid programs), underscoring the importance of collaborative and multi-sector approaches needed to achieve viral hepatitis elimination.

1. Leveraging Innovative Medicaid Coverage Flexibilities

Recommendation 1.1 - Integrate viral hepatitis services into new opportunities for health-related social needs (HRSN) services

Approximately one-third of people with hepatitis B and 60% of those with hepatitis C are covered by public insurance programs.[17,18] Given that Medicaid provides coverage for millions of low-income individuals and those with viral hepatitis, state Medicaid programs are key partners in expanding access to integrated viral hepatitis care and prevention.

Historically, Medicaid programs have been limited in the services it will pay for outside of a traditional clinical model of care. As a result, many social support services – like housing and food access – that may have an outsized impact on health outcomes, particularly for vulnerable communities, were not eligible for coverage. Now, CMS has partnered with a range of states to create groundbreaking opportunities for states to cover clinically appropriate and evidence-based services and supports that address health-related social needs (HRSN), such as food insecurity and housing instability. State Medicaid programs and Medicaid managed care plans have multiple flexibilities and authorities by which they can implement innovative payment and delivery reforms, including Section 1115 Demonstrations and use of managed care in lieu of services and settings (ILOSs) (Table 1). In 2021, CMS issued new guidance supporting state Medicaid programs and managed care plans to increase their role in addressing social determinants of health.[19] The coverage of HRSN services in Medicaid and Children's Health Insurance Program (CHIP) are outlined in guidance published on November 16, 2023.[20]

Section 1115 of the Social Security Act authorizes the HHS Secretary to approve state experimental, pilot, or demonstration projects that are determined by the Secretary to be likely to assist in promoting the objectives of the Medicaid program. The purpose of these projects, which give states additional flexibility to design and improve their programs, is to demonstrate and evaluate state-specific policy approaches to better serve Medicaid populations. Over the years, states have used this flexibility to expand coverage to specific populations, offer new benefits, and, more recently, cover services that better address HRSN.[21]

As mandated in section 5032 of the SUPPORT Act, CMS has also issued guidance to states on utilizing section 1115 demonstrations to support service provision for individuals leaving incarceration.[22] Historically, state Medicaid programs were prohibited from providing Medicaid benefits and services to people in carceral settings. However, recognizing the intense health and social needs of people (e.g., food insecurity, housing instability) as they transition from incarceration back into the community, CMS is now allowing states to use section 1115 demonstration authority to provide a limited number of services to this population for up to 90 days prior to release. The pre-release benefits package is determined by the state during application and may include: 1) case management to assess and address physical and behavioral health needs and HRSN, 2) medication-assisted treatment and associated counseling, and 3) a 30-day supply of all prescription medications at the time of release. While the waiver is not specific to viral hepatitis services, the high prevalence rates among incarcerated people provides clear opportunities to support viral hepatitis medication access and other linkage services to ensure a smooth transition back to the community for beneficiaries with specific clinical conditions.[23]

Medicaid managed care plans also have flexibility to offer innovative services to address HRSN through the use of ILOSs. Under this flexibility, plans can cover services and settings that are determined by States to be medically appropriate and cost-effective substitutes for those covered under the Medicaid State Plan.[24] Recent regulatory changes in the Medicaid and CHIP Managed Care Access, Finance, and Quality final rule[25] and CMS guidance has clarified the use of ILOSs and made it easier for managed care plans to use this authority to cover elements such as housing supports, intensive case management and other supportive services, and nutrition services for clinically defined target populations while also outlining required parameters, including fiscal protections, and monitoring and oversight.[26]

Table 1: Medicaid-specific Flexibilities which Can Support Innovative Viral Hepatitis Payment and Delivery

1115 Demonstrations	In Lieu of Services and Settings (ILOSs)

• States can apply for an 1115 demonstration to support an initial five-year demonstration.
• Requires demonstrations to meet budget neutrality requirements, with spending capped at 3% of state's total Medicaid spend.
• Intended to support innovative responses to health care needs of Medicaid beneficiaries and may go beyond state plan coverage.
• Recent CMS guidance encourages states to use 1115 demonstrations to connect individuals with evidence-based interventions, and partner with housing and social service agencies to provide services, short-term housing assistance and nutrition supports, such as medically tailored meals.
	• An ILOS must be approved by the State as a medically appropriate and cost-effective substitute for a State plan service or setting for clinically defined target populations.
	• An approved ILOS must be authorized and identified in the managed care plan contract and must be offered to enrollees at the option of the managed care plan.[27]
	• Spending on ILOS is capped at 5% of total managed care capitation payments.
	• ILOSs must be services or settings covered in the State plan or section 1915(c) waivers and must comply with general prohibitions on payment for room and board costs under title XIX of the Social Security Act. Examples of ILOSs include:
	  • Enhanced case management
	  • Community Health Workers
	  • Coverage of medically tailored meals (less than 3 meals/day) in lieu of nursing facility care or hospitalizations.

As states start to leverage these authorities and flexibilities, it will be important to assess upcoming opportunities to integrate viral hepatitis services and providers.

States could also ensure that newly developed HRSN screening tools in use by Medicaid programs[30] are effectively reaching people with viral hepatitis so that their specific needs are included in the design of interventions. In addition, states can proactively include viral hepatitis in managed care plan interventions that support HRSN service delivery.[31]

Both Section 1115 demonstrations and ILOSs are intended to promote innovative approaches to support effective service models. As states and other entities increase their utilization of these opportunities, states and federal partners could highlight viral hepatitis delivery models or models that could be adapted for viral hepatitis. This could be accomplished through informational webinars, bulletins, or other guidance to states. This is particularly important for the many state Medicaid 1115 demonstrations and Medicaid managed care ILOSs focusing on people with co-occurring substance use challenges, people who are leaving incarceration, and unhoused communities, all populations who also have greater risk for viral hepatitis.

Model Example: Utilizing an 1115 Demonstration to Expand Access to Social Supports – Arizona

Arizona has an 1115 demonstration that allows Medicaid to provide HRSN services and supports to specific populations. The state has targeted these services to individuals experiencing or at risk of homelessness with a documented health need, including cirrhosis and liver cancer. Arizona's housing support services provide significant housing assistance through Medicaid, including rent/temporary housing and utility costs for up to six months.[27] States could apply for demonstrations that specifically include people with viral hepatitis in eligibility criteria for services.

Model Example: Utilizing 1115 Demonstration to Expand Services to People Leaving Incarceration

Washington has received CMS approval to implement an 1115 demonstration, providing a targeted set of pre-release services for Medicaid-eligible adults and youths in participating carceral facilities. Starting 90 days before release, facilities that meet readiness criteria will offer access to case management, medications for alcohol and opioid treatment disorders, and a 30-day supply of medications upon release. Additional healthcare services offered through this demonstration may include medications during the pre-release period, physical and behavioral health visits, labs and radiology, and care from community health workers with lived experience.[29]

Model Example: Leveraging Community Supports for HRSN - California

Recognizing that Medi-Cal beneficiaries with complex health conditions and unmet HRSN (e.g., housing and food insecurity) often experience worse health outcomes, California has used new federal flexibilities under CalAIM to provide a range of HRSN services. The state now offers 14 Community Supports, which are ILOSs under Medi-Cal, targeting beneficiaries experiencing or at risk of homelessness and/or with complex medical needs. These supports are all aimed at stabilizing housing for individuals with conditions which can include chronic illness or viral hepatitis.[28]

2. Incentivizing and Expanding the Viral Hepatitis Workforce

Recommendation 2.1 – Prioritize reimbursement pathways for providers delivering viral hepatitis services via street medicine

Street medicine is an effective way to deliver a range of public health services to unhoused individuals and other groups facing access barriers. However, identifying sustainable funding for this model is difficult as street medicine programs are largely staffed by individuals with limited opportunities for reimbursement (e.g., case managers, peer workers). Furthermore, street medicine requires intensive and often time-consuming efforts to identify, reach, and engage clients; thus, reimbursement for services rendered will not fully compensate staff for time spent. A major challenge in paying for street medicine has been the lack of a way for street medicine providers to actually bill for services provided on the street as opposed to a brick-and-mortar clinic or mobile unit. In October 2023, CMS addressed this challenge by announcing a new "place of service" code, which will help programs across the country to secure Medicaid reimbursement for covered services provided in the street.[32] Now it is up to state Medicaid agencies to implement this new code and ensure providers are able to use it, particularly for expansion of managed care plans' access to viral hepatitis prevention and treatment. Implementation must also include setting reimbursement rates at levels that recognize the increased investment and time needed to deliver care via street medicine. These investments by Medicaid agencies and managed care plans can increase the access to pathways to care for individuals who may never enter a traditional clinic setting. Systems should be designed and sustained to recognize and pay for labor-intensive efforts in cases where there is tremendous value for both health equity and public health.

Model Example: Supporting Street Medicine through Managed Care Organizations (MCOs) - University of Southern California Keck School of Medicine

The street medicine program that operates out of the University of Southern California Keck School of Medicine is providing a range of hepatitis C services that are paid for by Medi-Cal. Because of the state's decision to carve out medications from Medicaid managed care several years ago, street medicine providers are able to prescribe medicine and order necessary labs on the street (prior to this, Medicaid MCO rules required the primary care provider sign off on prescription and labs). For Medicaid coverage for viral hepatitis services outside of prescriptions, street medicine providers in California rely on contracts with Medicaid MCOs in the state. The state Medicaid agency has encouraged these contracts through its Health and Homelessness Incentive Program. Through this program, Medicaid MCOs can earn incentive payments for putting in place plans to address homelessness and provide support to unhoused individuals. One of the metrics of the program is the extent to which the MCO is contracting with street medicine programs, creating an important incentive for MCO and street medicine partnership.

Model Example: Providing guidance on credentialing, billing and reimbursement practices, and scope of practice considerations for Street Medicine in California

Street medicine providers in California have been successful in working with the state Medicaid program (Medi-Cal) to open up Medicaid reimbursement pathways for street medicine. This has included specific guidance from the state Medicaid agency to all Medicaid managed care plans in the state recommending that they partner with street medicine providers and providing explicit guidance with regard to credentialing, billing and reimbursement practices, and scope of practice considerations.[33]

Recommendation 2.2 – Integrate non-clinical staff and people with lived experience into a paid workforce for viral hepatitis service delivery

Engaging CBOs in Medicaid care delivery in new ways and with innovative financing approaches is essential to reaching individuals who may not be engaged with traditional clinical sites. Despite serving a population of Medicaid beneficiaries, non-clinical CBOs may experience challenges in billing Medicaid for covered services they provide because of a lack of connection with physicians or licensed providers under whose direction they can bill. Medicaid programs and managed care plans should consider innovative ways to fund partnerships with CBOs that support funding of a variety of staff types. The models described below were supported through grants which allows for greater flexibility in supporting multidisciplinary teams.

Model Example: Developing a payment model for care coordination – Project INSPIRE

Project Inspire was funded through Round II Innovation Award from CMS. The project allowed the NYC Health Department to offer comprehensive care coordination to people with hepatitis C who are dually eligible for Medicaid and Medicare. The funding also supported development of a payment model for previously unpaid care coordination services. The services provided to eligible participants included assessment and care planning, clinic-based care coordination and peer navigation, referrals for substance abuse, and services for other medical comorbidities, health promotion and medication adherence support, case conferences, and weekly tele-mentoring sessions. The program has been successful, demonstrating that provision of care coordination services for Medicaid and Medicare beneficiaries resulted in higher cure rates for that population.[34] Economic analyses of the model proposed several ways to pay for these services, including value-based incentive payments to providers who successfully implement the intervention and achieve a certain proportion of sustained virologic suppression.[35]

Model Example: Using CMS Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act grant to support Care Coordination

In 2019, Virginia was one of several states to receive a CMS SUPPORT Act grant.[36] Virginia used a portion of its money to fund a network of community-based harm reduction providers in the state to provide substance use education, peer counseling, case management, and infectious disease screening services, including hepatitis C screening.[37] Prior to the SUPPORT Act funding, there was no way for these nonclinical community-based organizations to get funding from Medicaid because they were not recognized as reimbursable providers. The state structured the financial partnership with the harm reduction providers in the network as per member per month arrangement for the services described above, a partnership which did not require the harm reduction providers to bill Medicaid for specific services and functioned far more like the grant funding with which the harm reduction providers were already familiar.

Though both Project INSPIRE and the Virginia model were supported by finite grant funding, building stronger partnerships between clinical and non-clinical providers in Medicaid has staying power and could fit well with recently announced CMS initiatives that support provision of HRSN services.[38] As more state Medicaid programs and managed care plans explore ways to cover support services, including housing support and case management services, they are simultaneously exploring the provider types needed to deliver these services. Like the Virginia example, this provides opportunities to leverage existing expertise and community touch points, particularly among the vast network of syringe services programs and other harm reduction organizations already providing a range of viral hepatitis services and outreach.

Recommendation 2.3 – Expand state scope of practice laws and reimbursement policies to increase viral hepatitis service delivery in pharmacy settings

Care teams providing a mix of clinical and non-clinical outreach, linkage, prevention, and care and treatment services are essential to efficient and comprehensive viral hepatitis programs. For instance, research shows that pharmacies represent an important health care access point, in part due to the ease of securing appointments, multiple locations, and the frequency with which individuals visit; patients visit community pharmacies approximately 35 times per year, compared with four annual visits to a medical provider office.[39] While pharmacy staff are trained in administering vaccinations, specific scope of practice varies by state, vaccine type, and patient age. Pharmacists in all states can administer CDC-recommended adult vaccines but only 17 states permit pharmacists to prescribe the vaccine themselves.[40] Supporting state law changes to remove the requirement across most of the nation for an outside prescription for pharmacy-administered vaccines can increase the efficiency of vaccine provision and reduce patient barriers to vaccine access.

Model Example: Expanding Pharmacist Scope of Practice & Medicaid Reimbursement

In 2013, California recognized pharmacists as health care providers, recognizing their medication expertise and expanding their authority to provide certain products (e.g., nicotine replacement, travel medication).[43] Since then, California has expanded pharmacist scope of practice laws, as well as Medicaid reimbursement mechanisms for services provided by pharmacists beyond dispensing drugs, including viral hepatitis screening, vaccinations, medication management, and disease management. In 2023, California enacted legislation requiring pharmacist reimbursement for in-scope services provided in a pharmacy setting.[44]

In addition to prescribing and administering viral hepatitis vaccines, pharmacists are well-positioned to provide screening and treatment for viral hepatitis. In an international randomized controlled trial evaluating point-of-care HCV RNA testing and DAA treatment in community pharmacies versus conventional care, pharmacies reported higher treatment initiation (96% versus 83%) and sustained virologic response (SVR) rates (82% versus 40%) compared to conventional care.[41] An analysis across 45 retail pharmacies in nine U.S. states demonstrated success in identifying hepatitis C antibody-positive individuals through point-of-care testing within the pharmacy, as well as linking patients for follow-up testing and care.[42] Among those that were antibody-positive and reached within a 21-28 day follow-up period, 52% reported completing confirmatory testing. Community pharmacies provide an opportunity to complement traditional test and treat settings, especially with the availability of point-of-care HCV RNA testing.

State scope of practice changes that allow pharmacists to provide additional clinical services must also be accompanied by payer changes – particularly state Medicaid reimbursement policy – that create reimbursement mechanisms for providing services not directly related to

dispensing drugs. A major barrier to pharmacist reimbursement for viral hepatitis services is pharmacist statutory exclusion from federal Medicare law's definition of a "health care provider," precluding Medicare billing for most medical services they provide.

Many state Medicaid programs follow Medicare's coverage policy with respect to health care provider definitions. However, Medicaid programs can decide to add pharmacists as a covered provider via state legislative or regulatory changes. Ensuring that pharmacists can both provide vaccination, screening, and treatment services under the scope of their licenses and that they can be reimbursed for the services they provide is critical to expanding access points for viral hepatitis services.

Model Example: Expanding Pharmacist Scope of Practice & Medicaid Reimbursement

Pennsylvania Medicaid has granted "provider-status" to pharmacists, which allows for payment of services on parity with other health care providers. In 2021, pharmacies were permitted to bill for services rendered by pharmacists, and in March 2024, Pennsylvania Medicaid began to enroll pharmacists as Mid-Level Practitioners in the Medical Assistance Program.[45] This recent change allows for reimbursement of services provided within pharmacies, as well as in other settings (e.g., physician offices, medical clinics). Procedure codes reflect pharmacist-delivered "Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided…"[46] Upon enrollment with Medicaid and each MCO in the state, pharmacists can bill Medicaid fee-for-service for services rendered.

The approaches deployed to enable pharmacists to deliver more comprehensive clinical services to patients – expanding scope of practice and reimbursement opportunities – may also be applicable to other health professional types. Successful efforts to facilitate integrated viral hepatitis service provision should examine an array of opportunities for health professionals to provide services and receive appropriate payment or reimbursement.

3. Including Viral Hepatitis Measures in Quality Improvement Activities

Recommendation 3.1 – Adopt and implement viral hepatitis-related quality measures

Quality measures are an important tool for monitoring performance and improving the quality of care. They can hold payers and health systems accountable for providing and covering viral hepatitis services according to current science and clinical guidelines. Public and private payers may incorporate quality measures into their quality management programs on a voluntary basis or because federal and state laws mandate reporting on certain quality measures. However, there are currently very few quality measures used for viral hepatitis, and those that do exist do not uniformly address the different hepatitides (i.e., there are no hepatitis B screening measures, while there is a measure for one-time hepatitis C screening) nor are tested and validated at different levels (i.e., the hepatitis C screening and treatment initiation measure is only tested at the provider level, and not at the plan or state level).[47] This makes it difficult to monitor and measure public and private payer response to viral hepatitis. CMS supports and informs development of quality measures for use in Medicaid and Medicare quality programs. For Medicaid, this includes the Medicaid and CHIP Child and Adult Core Sets (there are currently no viral hepatitis measures in this set). For Medicare, this includes the Merit-based Incentive Payment System (MIPS) and MIPS Value Pathways, which currently do include viral hepatitis measures, but several are outdated. Table 2 includes measures that are currently available or in development and align best with current clinical guidelines and recommendations to allow payers to best monitor viral hepatitis service provision and outcomes.

Table 2: Viral Hepatitis Quality Measures – Adopted and In Development				
One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	Percentage of patients aged >= 18 years who have never been tested for HCV infection who receive an HCV infection test AND who have treatment initiated within three months or who are referred to a clinician who treats HCV infection within one month if they tested positive for HCV.	AGA	Adopted	MIPS Program MIPS Value Pathway
Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	AGA	Adopted	MIPS Value Pathway
Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	AGA	Adopted	MIPS Program
Hepatitis C Virus (HCV) Sustained Virologic Response (SVR)	In patients aged 18 years and older with a diagnosis of chronic HCV and positive HCV RNA, treating providers should confirm and document SVR with an undetectable HCV RNA test at least 20 weeks after last lab with a positive RNA. (20 weeks is intended to capture the minimum duration of therapy with the necessary time to wait to test for SVR).	AGA	In development	
Adult Hepatitis B Vaccination Status[48]	The adult immunization status (AIS-E) measure assesses routine adult vaccination. NCQA proposes adding an indicator that assesses hepatitis B vaccination for adults aged 19–59 years, to drive improvement in vaccination rates.	NCQA	In development	

AGA=American Gastroenterological Association; NCQA=National Committee for Quality Assurance
MIPS=Merit-based Incentive Payment System

Meaningful incorporation of viral hepatitis quality measures into public and private payer practices requires: 1) expert-led development of valid and reliable quality measures that reflect current clinical guidelines and 2) measure adoption and incorporation into public and private payer performance improvement plans.

Development

- Federal agencies and offices within HHS, such as OIDP, CDC, CMS, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Health Resources and Services Administration (HRSA), professional societies, and other relevant organizations can work together to develop a robust set of up-to-date measures for use across federal, state, and private programs and payers that reflect current science and clinical guidelines for viral hepatitis prevention and care in various settings.

Implementation

- Public and private payers can incorporate viral hepatitis quality measures into quality improvement programs to monitor viral hepatitis service provision and outcomes. Increasing quality measure uptake across public and private payers can be supported through collaboration among federal agencies (including HHS, CDC, SAMHSA, and HRSA), state Medicaid programs

and MCOs, and the Core Quality Measures Collaborative (CQMC). The CQMC is a diverse coalition of health care leaders representing over 75 consumer groups, medical associations, health insurance providers, purchasers, and other quality stakeholders. The CQMC is a public-private partnership between AHIP and CMS that comes together to develop and recommend core sets of measures by clinical area.

- Public and private payers can also use quality measures to drive value-based payment and delivery models. Value-based payment or Pay for Performance models could involve including a financial incentive if a payer or provider meets a certain quality metric target. For example, these models could include process measures (e.g., measuring how many patients are screened for hepatitis C) or outcome measures (e.g., measuring the proportion of people diagnosed with hepatitis C who reach sustained virologic response). In July 2021, 38 of 47 state Medicaid programs reported using at least one financial incentive to promote quality of care, most frequently targeting mental health, chronic disease management, and perinatal/birth outcomes.[49] These models offer a promising approach to increase adoption of comprehensive viral hepatitis prevention and care services.

To support development and implementation of viral hepatitis quality measures that can be adopted by CMS quality programs, HHS and other state and federal partners can leverage lessons learned from the development and implementation of the HIV viral suppression measure.

Model Example: Supporting State Medicaid Programs to Adopt HIV Viral Suppression Measure

To support implementation within state Medicaid quality programs and standardized state reporting, CMS added the HIV viral suppression measure to its Medicaid Adult Core Set. The viral suppression measure is an outcome measure that requires linkage of surveillance and administrative claims data. To increase state capacity to collect and report this measure, HRSA funded a cooperative agreement in collaboration with CDC and CMS.[50] Once states and Medicaid managed care plans are consistently reporting on the viral suppression measure, payers can utilize financial incentives or other mechanisms to motivate Medicaid programs or plans to meet certain benchmarks for viral suppression.[51] This type of investment and support across agencies has been helpful to securing state Medicaid buy-in for HIV quality initiatives and while the viral hepatitis measures are at different stages than the HIV measures, the mechanisms CMS and other agencies have used to support partnerships across public health and state Medicaid programs could be replicable.

4. Expanding Access to Viral Hepatitis Services

Recommendation 4.1 – Negotiate with viral hepatitis drug manufacturers to reduce prices in exchange for limiting prior authorization

The President's 2024 and 2025 budget includes an ambitious proposal to eliminate hepatitis C in the United States. The proposed national program – which would include hepatitis C medications, clinical care, and ancillary services for people who are uninsured and on Medicaid – would be funded through mandatory spending authority.[27] The medication access component would likely involve federal negotiation with manufacturers for a subscription program. The federal government would negotiate with at least one manufacturer of a direct acting antiviral for hepatitis C and pay a fixed price for unlimited dispenses for the target population (this could include the uninsured, Medicaid enrollees, and individuals who are incarcerated). In return, the medications would be more widely available without prior authorization.

Model Example: State-Led Negotiations with Drug Manufacturers

A subscription-based payment model (SBPM) (or "Netflix" model) for hepatitis C treatment and drug payment has been adopted by two state Medicaid programs. In this model, states negotiate a fixed payment with pharmaceutical companies to cover an unrestricted supply of medication for beneficiaries. Louisiana implemented a subscription model for hepatitis C medication in 2019 which resulted in a 535% increase in hepatitis C prescription fills compared with pre-SBPM periods.[53] Louisiana's implementation of the subscription model is frequently cited in published literature as a successful model and potential approach for replication in other jurisdictions.

Similar subscription models have been implemented at the state level in Louisiana and Washington, with some success in driving down medication costs in Medicaid and increasing access.[52] There may be an opportunity to build off of this model for hepatitis C and include hepatitis B medications as well.

Recommendation 4.2 – Continue Department of Justice enforcement of federal law regarding accessing medically necessary hepatitis C treatment

Despite the availability of several hepatitis C DAAs on the market and the overall reduction in treatment price since the first product was launched in 2014, some state Medicaid programs and Medicaid managed care plans have prior authorization requirements and other utilization management limitations on access to these curative therapies.[13] CMS issued guidance to state Medicaid programs in 2015 reminding them of their obligations under federal law to provide access to medically necessary care and treatment, clarifying that this obligation required Medicaid programs to lift any limitations or restrictions that were not clinically based.[54] As mentioned above, DOJ also released a letter in 2024 urging states to ensure that their Medicaid policies surrounding HCV, SUD, and access to DAAs complied with the ADA.[55] Despite this guidance and several high profile lawsuits against state Medicaid programs, multiple states have continued to restrict access to HCV DAAs in their Medicaid programs. DOJ and CMS should continue to enforce federal requirements.

Model Example: Leveraging Existing Legislation to Increase Hepatitis C Medication Access

In January 2024, DOJ and HHS issued additional guidance to state Medicaid programs, citing the requirements of states to avoid discriminating against disabilities, such as substance use disorder, as required by the ADA.[55] DOJ entered a settlement agreement with Alabama's Medicaid Agency for denying Medicaid coverage for DAAs to persons with SUD (i.e., those who have consumed alcohol or illicit drugs within the six months prior to DAA treatment). The agreement requires that Alabama Medicaid recipients and providers are notified of these changes and that any denials in DAA coverage due to SUD are promptly remedied.

Recommendation 4.3 – Participate in the 340B Program and Section 318 Program

The 340B Drug Pricing program enables safety net health care providers, known as covered entities, to generate savings on their purchases of prescription drugs – typically by billing insurers for prescription drugs at their standard rates rather than the 340B discounted price – and being able to use the savings between what they pay and what they are reimbursed to support a broader array of services for the individuals and communities they serve. This ensures that the intent of the Program is met – allowing covered entities to stretch scarce resources as far as possible.

Manufacturers participating in Medicare Part B and Medicaid agree to offer a price that will not exceed the statutory 340B ceiling price on their covered outpatient drugs.

Eligible covered entities are outlined in section 340B(a)(4) of the Public Health Service Act (PHSA) and include health centers funded by the HRSA, RWHAP clinics, State AIDS Drug Assistance Programs (ADAPs), STD clinics that receive funding under section 318 of the PHSA, children's hospitals, disproportionate share hospitals, and other safety net providers. To participate in the 340B Program, covered entities must first register, and once approved, the entity is listed on a public database and can begin purchasing drugs to provide to eligible patients of the covered entity, which can only be administered or dispensed on an outpatient basis. There are a number of requirements outlined in the statute that covered entities must adhere to while participating in the Program.

Given the substantial overlap between public health approaches to STI and viral hepatitis, access to the 340B Program to obtain discounted drugs may help confront the urgent need to address hepatitis C in a variety of settings. Because many recipients of CDC 318 funding are 340B eligible, HRSA's 340B Prime Vendor Program offers targeted technical assistance to ensure that grantees (and their subrecipients) understand eligibility for the Program in addition to other statutory programmatic requirements. The 340B Prime Vendor can be reached via phone at 1-888-340-2787 (Monday – Friday, 9 a.m. – 6 p.m. ET) or via email at apexusanswers@340bpvp.com.

Recommendation 4.4 – Ensure that updated hepatitis C screening guidelines are implemented across payers and providers

CDC updated its recommendations for hepatitis C screening in 2020 to include universal screening for adults and periodic screening for those at high risk of hepatitis C.[56] Recognizing the benefits of increasing access to hepatitis C screening and in keeping with the revised CDC recommendations, the U.S. Preventive Services Task Force (USPSTF) updated its recommendation for hepatitis C screening in 2020.[57] In its updated recommendation, USPSTF included hepatitis C screening as a grade B recommendation, indicating that is should be offered or provided, for all asymptomatic adults aged 18-79 years without known liver disease. The USPSTF clarified in its practice considerations that all adults should be offered a one-time screening, and those at increased risk (e.g., people who inject drugs) should be screened more regularly. These guidelines and recommendations ensure that a wider swath of people are screened for hepatitis C and should be widely adopted.

5. Funding Viral Hepatitis Programming

Federal funding and other policies for viral hepatitis are outdated and insufficient to meet the current public health needs and clinical practice guidelines. Policies that restrict comprehensive and efficient service provision may no longer adequately address present-day health care needs. For example, when RWHAP was established in the early 1990s, there was a necessarily precise focus on providing services that explicitly addressed HIV infection (e.g., testing initiatives, treatment pathways). As HIV research and practices evolved, the need for more comprehensive sets of services, such as those addressing social determinants of health or other clinical conditions, became increasingly critical. The federal government has responded to those needs through initiatives such as the RWHAP Special Projects of National Significance which allow for grantees to develop innovative approaches to serving people with HIV.

With the ongoing syndemic of viral hepatitis, HIV, sexually transmitted infections (STI), and SUD, it is critical to avoid addressing these conditions in a siloed fashion and to support integrated funding streams and service delivery. As such, new and/or updated policies that reflect existing and emerging needs and opportunities are needed to ensure progress towards viral hepatitis elimination goals.

Recommendation 5.1 – Include explicit language on viral hepatitis service integration into funding opportunities pertaining to substance use, HIV, and/or STIs

Current federal funding for viral hepatitis – primarily through CDC-funded governmental public health programs – is not enough to meet current need. Viral hepatitis programs depend on close relationships with other infectious disease programs to support integrated infrastructure, staffing, and service delivery models where appropriate and relevant. However, siloed funding mechanisms and grant restrictions prevent this type of collaboration across infectious disease programs. Federal partners have the opportunity to be responsive to the nation's public health needs and include specific reference(s) to how funds could be used to implement a syndemic approach to HIV, viral hepatitis, STI, and SUD service delivery.

Model Example: Promoting Innovation Through Comprehensive Federal and Other Funding Announcements

In June 2023, SAMHSA launched a Notice of Funding Opportunity (NOFO) to support integrated behavioral health and HIV care for unsheltered populations.[58] Funding will support pilot projects that take a syndemic approach to health care delivery through utilization of low-barrier SUD treatment, mental health care, HIV and viral hepatitis testing and treatment, HIV prevention, and harm reduction services. NOFOs that explicitly allow and encourage recipients to use funding across syndemics can drive innovation and promote integrated care models and effective financing strategies.

Model Example: Promoting Innovation Through Comprehensive Federal and Other Funding Announcements

In August 2022, CDC funded a new program, Strengthening Syringe Services Programs, which aims to increase access to harm reduction services for people who use drugs (PWUD) and prevent viral hepatitis, HIV, and other infectious diseases associated with injection drug use.[59] One component of the program supports a partner to expand the reach of syringe services programs (SSPs) and harm reduction services across the United States to prevent infectious consequences of injection drug use and overdose. This will allow SSPs to recruit and retain staff to perform core functions like distribution and disposal of sterile supplies, infectious disease prevention and control, and facilitation of comprehensive social and medical service referrals. It will also provide support for comprehensive SSP services, such as expanded vaccination services, HIV and viral hepatitis testing and linkage to care, naloxone distribution, syringe distribution and disposal, and care coordination within SSPs.

Recommendation 5.2 – Provide guidance on how grantees can braid infectious disease funding streams to better integrate service delivery and create cross-program efficiencies and sustainability

While "braiding" funding streams across different federal grants with distinct grant deliverables and reporting requirements may be a good way to create efficiencies across infectious disease programs, it is a labor-intensive process to operationalize. Federal grant requirements are often stringent with regard to use of funds, leaving little room to integrate specified infectious disease funding into viral hepatitis activities. Though braiding funding – where more than one infectious disease funding source is used to better integrate service delivery – is a favorable approach in concept, it is often difficult for grantees to implement on the ground. Other federal agencies (e.g., CDC, OIDP, Indian Health Service) could similarly contemplate development of a framework that would support sustainable program integration across HIV, STIs, and viral hepatitis, perhaps building off of the "program collaboration and service integration" (PCSI) framework released in 2009.[61]

Model Example: Providing Federal Guidance on Optimizing HIV Funding Streams

The HRSA HIV/AIDS Bureau's (HAB) recent collaboration with the CDC Division of HIV Prevention provides an example of how agencies could better support braided funding across grantees. In January of 2023, HRSA HAB and CDC issued joint guidance describing a "status neutral" framework aimed at better integrating RWHAP HIV care and treatment delivery systems with CDC-funded HIV prevention.[60] The guidance specifically supports grantees to braid funding "to reduce barriers to implementation and to help extend the reach of status neutral services."

Recommendation 5.3 – Convert the Section 317 Immunization Program into a mandatory funding program through Congressional action

The Section 317 Immunization Program is a major funding source for hepatitis A and hepatitis B vaccines distributed by public health programs. However, because the 317 program relies on discretionary congressional funding every year, states are often forced to make difficult vaccine allocation decisions, leaving little resources for viral hepatitis vaccination campaigns outside of outbreak response. The President's 2025 Budget request included a proposal to expand the mandatory Vaccines for Children (VFC) program to include a Vaccines for Adults component in addition to expanding funding for the 317 program. Structuring an adult vaccine program after the successful VFC program would assure a federal funding source for all ACIP-recommended vaccines for uninsured and Medicaid eligible adults. Section 317 grants, which go to state public health programs via the CDC, could be used to invest in and expand provider infrastructure to deliver vaccines.

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