Hepatitis C Elimination Initiative Pilot

Pre-Application Webinar

Kristin Roha, MS, MPH
Senior Advisor
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Kristin.Roha@samhsa.hhs.gov
HepCFree@samhsa.hhs.gov

7/17/2025, 2:30 – 3:30 pm EDT

SAMHSA
Substance Abuse and Mental Health Services Administration

WELCOME! …and Logistics

This presentation is being recorded.

We will have a brief Q&A at the end of this webinar.
Please enter your questions into the Q&A box in Teams.
You will also be able to raise your hand to ask a question directly.

SAMHSA
Substance Abuse and Mental Health Services Administration

Presentation Outline

- Purpose of the Hepatitis C Elimination Initiative Pilot (Hep C Free)
- Funding Details
  - Funding tiers explained
- Eligible Applicants
  - Considerations for Successful Applicants
- Required and Allowable Activities
- Key Personnel
- Data Collection
- Performance Assessment
- Funding Restrictions and Limitations
- Evidence of Experience and Credentials
- Application Details
- Q&A

Purpose of the Hep C Free Grant Program

- The purpose of this proof-of-concept program is to **leverage existing health care institutions' capacity to prevent, test for, treat, and cure Hepatitis C (HCV)** in individuals with substance use disorder (SUD) and/or severe mental illness (SMI), particularly in communities severely affected by homelessness and to gain insights on effective ways to identify patients, complete treatment and reduce reinfection.
- Through this initiative, SAMHSA aims to **increase the number of individuals who are cured of HCV**, reduce the incidence of HCV and HIV in grant funded communities, and help to address the intersection of SUD, SMI, infectious disease, and homelessness in high-need populations across the nation.
- A key aim of this program is to **pilot an integrated care approach** that cures HCV among the population of focus while also addressing key risk factors for HCV, including SUD, SMI, and homelessness.
- By addressing these risk factors, SAMHSA aims to…**[create a] scalable model that can be applied more broadly** to ensure long-term reduction or elimination of HCV among communities starting with those that have the greatest burden.

Funding Details

- **Funding Type**: Grant
- **Estimated Total Available Funding**: $100,000,000 for the first 2 years (total of $50,000,000 per year) NOTE: Recipients will receive funding for year 1 and year 2 of the project period at the initial award.
- **Length of Project Period**: Up to 3 years.
- **Estimated Number of Awards**: Up to 13-40 awards based on final mix of award sizes. At least one, and up to five, award(s) will be made to American Indian/Alaska Native (AI/AN) tribes, or tribal organizations, pending sufficient application volume and final mix of award sizes.
- **Estimated Award Amount**: Up to $2,500,000 – $7,500,000 total per award for the first 2 years ($1,250,000 - $3,750,000 per year for the first two years). Funding is based on **three funding tiers**.

Funding Tiers Explained

This award has three funding tiers. Applicants must **self-select into a funding tier** based on the needs of their population of focus as well as their implementation capacity. SAMHSA expects applicants to propose ***realistic and achievable targets*** for your population of focus. Your targets must be supported by the burden of HCV among your population of focus, which you will describe in detail in your application project narrative.

The funding tiers are:

1. Recipients treating and curing 25 – 50 patients per year for hepatitis C, up to **$2,500,000 per award** ($1,250,000 per year) for the first 2 years.

2. Recipients treating and curing 51-100 patients per year for hepatitis C, up to **$5,000,000 per award** ($2,500,000 per year) for the first 2 years.

3. Recipients treating and curing >100 patients per year for hepatitis C, up to **$7,500,000 per award** ($3,750,000 per year) for the first 2 years.

If you treat and cure **fewer** patients than the number in the tier identified in your application, your year 3 award will be consistent with the number of patients you treated and cured. If you treat and cure **more** patients than the number in the tier identified in your application, your year 3 award will remain unchanged.

Eligible Applicants

Eligible applicants are States and Territories, including the District of Columbia, political subdivisions of States, Indian tribes or tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or award with the Indian Health Service, or other public or private non-profit entities, including faith-based organizations.

- **At least one, and up to five award(s)** will be made to American Indian/Alaska Native (AI/AN) tribes, or tribal organizations, pending sufficient application volume.
  - Applications from Tribal Nations or recognizable tribal organizations will be reviewed separately by peer reviewers with expert experience working with HCV-related programs within American Indian/Alaska Native (AI/AN) tribes, or tribal organizations.

Considerations for Successful Applicants

- This grant program specifically seeks applications from existing health care institutions that **demonstrate strong infrastructure and established networks** capable of reaching individuals with the greatest needs and most limited resources across geographic boundaries.
- Applicants should have the **proven ability to rapidly implement** integrated HCV, SUD, and serious mental illness treatment, **leveraging their existing resources** and community relationships to achieve meaningful impact at scale.
- Recipients of this program are expected to **implement a holistic approach** that integrates HCV and HIV testing and comprehensive prevention treatment, and recovery support services for SUD, SMI, HCV, and HIV as needed.

Considerations for Successful Applicants

- SAMHSA encourages you to address the behavioral health needs of all people including populations with higher prevalence of behavioral health conditions in your service area.
- **All activities proposed in your application and budget narrative must be in alignment with the current Executive Orders (EOs). For the latest guidance please visit: Presidential Actions – The White House. If an application does not align with EOs, the application will not receive funding.**

Required Activities

Your organization is required to implement all the required activities. Recipients are required to carry out activities within **five broad categories:**

1. **Outreach and Prevention**: Use community health prevention navigation to identify and connect individuals and social networks at risk for substance use, SUD, HCV, and homelessness to prevention and treatment services. This includes providing case management, facilitated referral to care and system navigation for SUD, HCV, HIV, SMI, and social services.

This **presentation provides an overview** of required and allowable activities. Applicants are encouraged to **review the NOFO in full** for an in-depth description of all required and allowable activities.

Required Activities

Your organization is required to implement all the required activities. Recipients are required to carry out activities within **five broad categories:**

2. **Same-Day Screening, Testing, and Treatment Initiation**: Integrated same-day HCV and HIV testing, confirmatory testing, provision of results, initial medication prescription or initiation of HCV treatment, and linkage to care coordination and ongoing treatment. This same-day testing should be integrated with concurrent screening for SUD and SMI and initiation of treatment and active linkage to ongoing care as needed.
    - Conduct integrated same-day on-site screening and testing for HCV and HIV. This testing must be conducted using tests that provide same-day results, such as **HCV RNA point-of-care testing**.
    - The provider must provide the patient with test results, a medication prescription or initiation of medication for Hepatitis C as per HCV Clinical Guidelines **for screening, diagnosis**, and linkage to care coordination and **ongoing treatment** that day.

This **presentation provides an overview** of required and allowable activities. Applicants are encouraged to **review the NOFO in full** for an in-depth description of all required and allowable activities.

Required Activities

3. **Ongoing Treatment**: Provide integrated low-barrier HCV, HIV, SUD and SMI treatment in communities that are at increased risk of HCV. **The goal is to cure people that have HCV.** Using a treatment-as-prevention approach, will help prevent recurrence of HCV, transmission of HCV to others, thus reducing new cases of HCV. Treatment of SUD and SMI is expected for those who need these services.
   - For people who test positive for HCV RNA, provide on-site direct-acting antiviral-based treatment, peer support, and care coordination.
4. **Peer Support and Care Coordination**: Support patients with HCV, HIV, SUD, and/or SMI by providing comprehensive peer support services and care coordination across treatment, recovery, and social services based on the participant's individual needs. This will help foster trust, reduce stigma as a barrier to care, and empower participants through shared experience and comprehensive coordinated care.
5. **Evaluation**: Identify outcomes, track progress, and publicly report data on the impact of this HCV pilot program.

This **presentation provides an overview** of required and allowable activities. Applicants are encouraged to **review the NOFO in full** for an in-depth description of all required and allowable activities.

Allowable Activities

Allowable activities are **not** required. However, your organization may propose to use funds for activities listed as allowable in **four broad categories**:

1. Outreach and Prevention
2. Same-Day Screening, Testing, and Treatment Initiation
3. Ongoing Treatment
4. Peer Support and Care Coordination

This **presentation provides an overview** of required and allowable activities. Applicants are encouraged to **review the NOFO in full** for an in-depth description of all required and allowable activities.

Key Personnel

- Key Personnel are staff members who **make significant contributions to the project**, even if they do not receive a salary from the project. They are expected to regularly participate in program monitoring activities. This program's Key Personnel includes the Project Director (PD), Program Coordinator, and Nurse Care Manager.
  - **The Project Director** (PD) is responsible for oversight of the project, including overseeing, monitoring, and managing the award. At least **20% level of effort is required**.
  - **The Program Coordinator** (PC) is responsible for overseeing the day-to-day management and operations of the award, including supervising staff; **100% level of effort is required**.
  - **The Nurse Care Manager** (NCM) is responsible for coordinating the physical and behavioral health needs of individuals with HCV and other health conditions, ensures a client-centered, low barrier approach to HCV treatment, and problem solves any issues participants may have in accessing HCV treatment medications. This individual must be a Registered Nurse or Advanced Practice Registered Nurse; **100% level of effort is required**.
- **If awarded funding, you will be notified if your proposed Key Personnel have been approved.** If your organization needs to replace a Key Personnel during your project period, SAMHSA needs to review their resume and job description to determine whether the replacement can be approved.

Data Collection and Reporting

- You must report program-specific data in SAMHSA's Performance Accountability and Reporting System (SPARS) using SAMHSA's uniform data collection tool. The specific measures to be gathered and reported on will be provided post-award. A cascade of care approach will be used for infectious disease data collection and reporting, including HCV cure rates.
- Program-specific data on cascade of care measures, linkage to social services including housing support and changing housing status, and administrative data about the services provided will be reported on a quarterly basis. You will receive training and technical assistance on SPARS after award.
- The data you collect allows SAMHSA to report on key outcome measures. Performance data will be reported to the public as part of SAMHSA's Congressional Budget Justification as well as other methods.
- **The data collection tools reflect the Presidential Executive Orders.**

Performance Measurement and Assessment

- Recipients are required to submit programmatic progress reports that discuss if you are meeting the objectives you selected for this project, achieving the outcomes you anticipated, and if any changes need to be made. You must review your performance data to find out if you are making progress and improving project management.

This **presentation provides an overview** of required and allowable activities. Applicants are encouraged to **review the NOFO in full** for more information regarding performance measurement and assessment. In particular, refer to the **Reporting Requirements**, **Developing Goals and Measurable Objectives**, and **Developing the Plan for Data Collection and Performance Measurement** sections as you prepare your application.

Performance Assessment: Funding Tiers

This award has three funding tiers. Applicants must self-select into a funding tier based on the needs of their population of focus as well as their implementation capacity. SAMHSA expects applicants to propose ***realistic and achievable targets*** for your population of focus. Your targets must be supported by the burden of HCV among your population of focus, which you will describe in detail in your application project narrative.

The funding tiers are:

1. Recipients treating and curing 25 – 50 patients per year for hepatitis C, up to **$2,500,000 per award** ($1,250,000 per year) for the first 2 years.

2. Recipients treating and curing 51-100 patients per year for hepatitis C, up to **$5,000,000 per award** ($2,500,000 per year) for the first 2 years.

3. Recipients treating and curing >100 patients per year for hepatitis C, up to **$7,500,000 per award** ($3,750,000 per year) for the first 2 years.

If you treat and cure **fewer** patients than the number in the tier identified in your application, your year 3 award will be consistent with the number of patients you treated and cured. If you treat and cure **more** patients than the number in the tier identified in your application, your year 3 award will remain unchanged.

Funding Restrictions and Limitations

- **Recovery housing is an allowable cost**. However, funds **cannot** be used to pay for non-recovery housing application fees, or housing deposits.
- Funds from this grant program **cannot** be used to purchase:
  - Maintenance psychiatric medications;
  - Medications to treat HBV, HIV, STIs, or TB;
  - PrEP or PEP for HIV; and
  - Pipes/pipets, syringes, needles or other drug paraphernalia.
- Funds **cannot** be used to make direct payments to individuals to enter treatment or continue to participate in prevention or treatment services (See 42 U.S.C. § 1320a-7b).

This **presentation provides an overview** of funding restrictions and limitations. Applicants are encouraged to **review the NOFO in full** for more information about funding restrictions and limitations.

SAMHSA
Substance Abuse and Mental Health Services Administration

Funding Restrictions and Limitations

- Funds from this grant program **can** be used to purchase the following as a payer of last resort. (Note: These purchases may only be made after the grant recipient has budgeted for and/or implemented all required activities listed in the Required and Allowable activities section.)
  - Direct-acting antiviral (DAA) treatment for HCV
    - *Grant funds should be used to purchase the most cost-effective HCV DAA available*
  - FDA-approved medications to treat SUD
  - Psychiatric medication to be used in a gap-filling capacity while clients in need receive Medicaid or other ongoing coverage
  - HAV and HBV vaccinations
  - Naloxone
  - Substance test kits, including test strips for xylazine, fentanyl and other synthetic drugs

This **presentation provides an overview** of funding restrictions and limitations. Applicants are encouraged to **review the NOFO in full** for more information about funding restrictions and limitations.

Funding Restrictions and Limitations

- Funds under this NOFO are permitted to offer **motivational incentives** of up to $25 per incentive to patients to encourage engagement in treatment activities, clinical appointments, or adherence to treatment regimens. These incentives should be directly linked to enhancing patient well-being, promoting recovery, or encouraging consistent participation in treatment programs. Incentives are limited to four times per patient through the course of HCV treatment and the final bloodwork to confirm HCV cure. Permissible forms of incentives include tangible items, vouchers, or gift cards redeemable for specific items and services that support patient health, recovery, or treatment engagement.
- **Cash or unrestricted cash-equivalent incentives are strictly prohibited.**

Refer to **Appendix Y** of the NOFO for additional information on motivational incentive safeguards adherence.

Evidence of Experience and Credentials

- SAMHSA believes that only existing, experienced, and appropriately credentialed organizations with an established record of service delivery and expertise will be able to provide the required services **quickly and effectively**. You are encouraged to include appropriately credentialed organizations that provide services to populations and communities with higher prevalence of behavioral health conditions.
- In **Attachment 1,** you must submit Letter(s) of Commitment to show that you can meet the following **three service provision requirements**:
  - The **primary grant applicant must have a CLIA waiver** to provide on-site point of care HCV testing and HCV treatment that is integrated with behavioral healthcare. **Failure to submit CLIA waiver documentation will result in your application being screened out.**
  - The provider(s) of the other required activities may be your organization, or another organization committed to the project as demonstrated by a Letter of Commitment (LOC).
  - Each mental health/substance use disorder prevention, treatment, or recovery support provider organization (which may include the applicant and any partners) **must have at least 2 years of experience** (as of the due date of the application) providing relevant services.
- Each service provider must be in compliance with all applicable local (city, county) and state licensing, accreditation, and certification requirements, as well as all federal requirements, **as of the due date of the application**.

Other than the CLIA waiver requirement, this is not a screen-out criteria. Following the review of your application, you may be requested to submit additional documentation or verify that the documentation submitted is complete. **Your application will not be considered for an award if the requested information is not received by the due date.**

SAMHSA
Substance Abuse and Mental Health Services Administration

Application Evaluation Criteria and Merit Review

Project Narrative Section	Points	Approximate Pages
Section A: Population of focus	20	3
Section B: Proposed implementation Approach	30	9
Section C: Proposed evidence-based practice (EBP), evidence-informed practices (EIP), and/or community-defined practice (CDP)	15	2
Section D: Organizational experience and staffing	25	5
Section E: Data collection and performance measurement	10	1
TOTAL	**100**	**20**

SAMHSA
Substance Abuse and Mental Health Services Administration

Section A: Population of Focus (20 points, approx. 3 pages)

- Given the crisis of homelessness in the U.S., this program looks to especially reach communities that have been heavily impacted by the intersection of homelessness, substance use/substance use disorder and mental illness, and infectious diseases, specifically HCV.
- Describe the specific geographic catchment area where you will deliver services, including which state(s) and/or county your organization will serve. Describe the burden of homelessness, HCV, substance use/substance use disorder and mental illness in your geographic catchment area, using quantifiable data to the extent available. **Your data regarding the burden of HCV among your population of focus must support the target tier you select in Section B: Implementation Approach.**
- Provide a demographic profile of the individuals you will serve that includes race, ethnicity, federally recognized tribe (if applicable), language, sex, age, housing status, insurance status, and socioeconomic status. Include a description of the risk factor profile for hepatitis C in your population of focus.
- Describe why there is a need for this project, including any service gaps experienced by populations affected by the intersection of homelessness, substance use, substance use disorder, mental illness, and HCV.

Funding Tiers

This award has three funding tiers. Applicants must self-select into a funding tier based on the needs of their population of focus as well as their implementation capacity. SAMHSA expects applicants to propose ***realistic and achievable targets*** for your population of focus. Your targets must be supported by the burden of HCV among your population of focus, which you will describe in detail in your application project narrative.

The funding tiers are:

1. Recipients treating and curing 25 – 50 patients per year for hepatitis C, up to **$2,500,000 per award** ($1,250,000 per year) for the first 2 years.

2. Recipients treating and curing 51-100 patients per year for hepatitis C, up to **$5,000,000 per award** ($2,500,000 per year) for the first 2 years.

3. Recipients treating and curing >100 patients per year for hepatitis C, up to **$7,500,000 per award** ($3,750,000 per year) for the first 2 years.

If you treat and cure **fewer** patients than the number in the tier identified in your application, your year 3 award will be consistent with the number of patients you treated and cured. If you treat and cure **more** patients than the number in the tier identified in your application, your year 3 award will remain unchanged.

Section B: Proposed Implementation Approach (30 points, approx. 9 pages)

- Describe the goals and measurable objectives of your proposed project. (See Developing Goals and Measurable Objectives section.) **They must align them with the Statement of Need in Section A.**
- Describe how you will implement all the required activities. **Include any anticipated other sources of funding**, including Medicaid, Medicare, commercial insurance, etc., and how these funding sources will be leveraged to implement the required and allowable activities.
- In **Attachment 4**, provide no more than a two-page chart or graph depicting a **realistic timeline** for the entire 3 years of the program. It must include dates, key activities (i.e., Step I required activities), and responsible staff. Indicate when service delivery will begin. The timeline does not count towards the page limit for the Program Narrative.

Section C: Proposed EBP, EIP, and/or CDP (15 points, approx. 2 pages)

1. Identify the evidence-based practice(s), evidence-informed practice(s), and/or community-defined practice(s) that you will use. Discuss how each intervention chosen is appropriate for the individuals you will serve.
2. Describe any modifications you will make to the EBP(s), EIP(s), and/or CDP(s) and the reasons the modifications are necessary. If you are not proposing to make any modifications, indicate so in your response.
3. Describe how you will ensure the fidelity of the selected practice(s) that will be implemented. (For more information about monitoring fidelity, see Fidelity Monitoring Tip Sheet).

Section D: Organizational Experience and Staffing (25 points, approx. 5 pages)

- Describe the experience your organization has with similar projects and/or providing services to the population(s) of focus, including serving populations affected by the intersection of homelessness, substance use, substance use disorder, mental illness, and HCV. Include a description of your organization's existing infrastructure and capacity for testing and treating HCV integrated within behavioral healthcare settings.
  - By the time of award, your organization must have a CLIA waiver to provide HCV POC testing, so indicate that your organization will have a CLIA waiver here and submit your waiver or your application for such a waiver in Attachment 1.
- Identify any organization(s) you will partner with, including those who will comprise your required coalition and any Ryan White HIV/AIDS Program providers if your organization is not already one.
- Provide a complete list of all significant staff positions for the project, including the Key Personnel (Project Director, Program Coordinator, and Nurse Care Manager). For each, describe their:
  - Role;
  - Level of effort (LOE), stated as a percentage of employment (e.g., 1.0 FTE = full-time)
  - Qualifications, including their experience providing services to the individuals to be served

Section E: Data collection and performance measurement (10 points, approx. 1 page)

- Describe how you will monitor and report on key outcome measures and measurable objectives data for this project.
- Describe how you will identify outcomes, track progress, and publicly report data on this HCV elimination program, including collecting client-level data as part of a cross-site evaluation.
- Describe how you will use the data to manage, monitor, and enhance the program (See **Developing the Plan for Data Collection and Performance Measurement**).

Q&A

Please enter your questions into the Q&A box or raise your hand.

SAMHSA
Substance Abuse and Mental Health Services Administration

Q&A

- Question: Though this grant places an emphasis on curing patients with HCV, can the wrap-around services be provided to clients that are at risk for HCV but do not have HCV?
- Answer: Yes, though this grant places an emphasis on curing patients with HCV, the required activities of this grant includes providing services to individuals and social networks that are at risk for SUD, SMI, HCV, HIV, and homelessness. Thus, SAMHSA expects that many of the individuals that receive the wrap-around services provided by the grant program will not have HCV, but may be at risk for or living with SUD, SMI, HIV, and/or be experiencing homelessness. SAMHSA expects that people at risk for or living with these conditions should receive the comprehensive wrap-around services for which they quality, and that individuals with HCV will receive the comprehensive wrap-around services as well as HCV treatment services until they are cured.

Q&A

- Question: If a grant in the lowest or middle funding tier achieve greater than their tier's HCV cure target, can they be moved to a higher funding tier for Year 3?
- Answer: No, grants may be moved to a lower funding tier in Year 3 if they do not achieve the HCV cure target required by their funding tier, but no grant will be moved to a higher funding tier for Year 3.

Q&A

- Question: Regarding funding tiers, is decreasing from one tier to the next lower funding tier if HCV treatment targets are not met the only punitive measure that grants may receive?
- Answer: No. Per the NOFO, “annual continuation awards are contingent on the availability of funds, **progress in meeting project goals and objectives**, timely submission of required data and reports, and compliance with all terms and conditions of award.” Thus, grants that are generally successful in providing clients with all required activities but fail to achieve their HCV cured target will be decreased to a lower funding tier for Year 3. However, grants that are generally unsuccessful in providing all required activities as well as failing to achieve their HCV cure target may face more severe punitive action.

Q&A

- Question: Can grant funds be used for rapid HCV tests?
- Answer: No, per the NOFO, HCV tests "must be conducted using tests that provide same-day results, such as **HCV RNA point-of-care testing**."

Q&A

- Question: Given the importance of reaching the required number of patients that achieve sustained virologic response (SVR) within the reporting period to maintain the same funding level for Year 3, how are clients treated for HCV counted? If a client starts HCV treatment but has not finished it before the end of the reporting period, can they be counted as one of the patients required to maintain the grant's funding tier?
- Answer: No, a client must achieve SVR within the reporting period. A client that begins HCV treatment within the reporting period but has not achieved SVR before the end of the reporting period may not be counted as cured during that reporting period. However, they can be counted as cured in the reporting period in which they have achieved SVR.

Thank you

SAMHSA's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes.

If you have questions about this NOFO, please contact:

HepCFree@samhsa.hhs.gov

www.samhsa.gov

1-877-SAMHSA-7 (1-877-726-4727) ● 1-800-487-4889 (TDD)

SAMHSA
Substance Abuse and Mental Health Services Administration