SAMHSA
Substance Abuse and Mental Health Services Administration

Hepatitis C Elimination Initiative Pilot (TI-25-005)
Short Title: Hep C Free
Frequently Asked Questions
https://www.samhsa.gov/grants/grant-announcements/ti-25-005

Eligibility

1. **Can individuals apply for and receive funding through the Hep C Free (TI-25-005) Grant program?**
    a. No, individuals cannot apply to this grant. See page 13 of the NOFO for eligibility information.
    b. Individuals can find resources for treatment or assistance at SAMHSA's Behavioral Health Treatment Services Locator (https://www.findtreatment.gov) or contact SAMHSA's National Helpline at 1-800- 662-HELP (4357).

2. **Can an organization that is currently in the process of securing nonprofit status apply to this program?**
    a. No, an organization must have documentation of their nonprofit status when submitting the application. The documentation must be included in Attachment 8 of the application. See page 13 and page 22 of the NOFO for information about documentation of nonprofit status.

Evidence of Experience and Credentials: Clinical Laboratory Improvement Amendments (CLIA) Waiver

3. **Can an organization apply that does not have a CLIA waiver to perform HCV POC testing?**
    a. Yes. As sated on page 17 of the NOFO "the primary grant applicant must have a CLIA waiver to provide on-site point-of-care HCV testing". Page 21 of the NOFO clarifies that Attachment 1 must include "Documentation of current CLIA waiver or waiver application to implement POC testing for HCV." Failure to submit this documentation will result in your application being screened out and not considered for award.

Evidence of Experience and Credentials: Other

4. **Can you confirm that the two-year licensure and experience requirement is for providers of SUD/SMI services only?**
    a. Yes. Per the NOFO (page 17), "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." [Emphasis added.]

Ryan White HIV/AIDS Program (RWHAP) Partner Questions

5. **Does an organization count as a RWHAP provider if they are not directly receiving funds from RWHAP, but are contracted with a city, state or county that has been awarded RWHAP funds?**
    a. Yes. A RWHAP sub-recipient from a city, county or state would fulfill this requirement.

Funding Tiers

6. **The number of patients cured of HCV determines the amount of funding that an applicant can request. If a patient begins HCV treatment but are lost to follow-up before their course of treatment is complete or before they have achieved Sustained Virologic Response (SVR) can that patient be counted?**
    a. No, for the purposes of funding tier determination, the number of people that are **confirmed as cured of HCV** is the crucial metric. When determining ***realistic and achievable targets***, applicants should take into consideration their organization's expected number of clients that will be lost to follow up and propose ***realistic and achievable targets*** accordingly. See page 26 regarding information setting targets for this grant program. A client must achieve SVR within the reporting period to be counted as cured. See page 14 of the NOFO for information regarding Performance Assessment, which includes information regarding monitoring funding tiers.

Key Personnel

7. **The NOFO states "at least 100 percent level of effort is required" for the two key personnel positions, Nurse Care Manager and Program Coordinator. Can more than one person fill these roles if the combined total is 100% Level Of Effort (LOE)?**
    a. Yes, multiple individuals can fill these roles as long as the combined effort is 100% LOE for each key personnel position. Note that this may create additional reporting burdens.

Required Activities

Outreach and Prevention

8. **In the NOFO, it details that rapid HCV tests should be provided in the Outreach and Prevention section. However, in other places the NOFO says that HCV RNA POC tests must be used. Can we still use rapid HCV antibody tests in outreach settings?**
    a. Yes. HCV rapid/antibody tests may be purchased for use in outreach settings, with the caveat that if a person tests positive during outreach, they must receive an RNA test confirmatory result and either treatment initiation or a prescription for HCV treatment the same day as their outreach positive rapid test. See page 8 for information about rapid HCV/HIV testing in outreach settings.

Same-Day Screening, Testing, and Treatment Initiation

9. **Can we use project funds to buy or lease equipment that provides same day results, GeneXpert HCV test kits (cartridges and transfer tools), sample collection materials, quality controls, etc.?**
    a. Yes, these items can be bought or leased per page 8 of the NOFO, which states: "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**, HIV rapid testing and/or HIV self-test kits." All

equipment and supply costs must be necessary, justified in the budget narrative, and directly aligned with project activities.

Ongoing Treatment: HCV

10. One of the requirements is to conduct same-day screening and HCV treatment initiation. For people with insufficient or no medical coverage, can program funds be used to cover the cost of treatment while medical coverage is obtained?

a. Yes. Program funds can be used to cover the cost of HCV treatment in gap-filling capacity while other coverage is obtained. However, once coverage is obtained through Medicaid, Medicare, the VA, or other funding source, the cost of coverage for this treatment must shift to the new funding source. SAMHSA funds can only be used for HCV treatment as a payer of last resort.

What counts as an HCV Cure?

11. How does SAMHSA define an HCV cure for the purposes of this grant program?

a. Per the NOFO (page 8), screening, testing, and HCV treatment medication should be provided per clinical guidelines. In alignment with recent AASLD/IDSA clinical guideline updates, SAMHSA is defining an HCV cure as sustained virologic response at 4 weeks post-treatment (SVR4). Also following clinical guidelines, treatment completion cannot be used as a proxy to determine HCV cure; a final confirmatory blood test four weeks post-treatment is necessary to confirm cure. See Attachment Y of the NOFO for information regarding the use of motivational incentives to incentivize clients to return for their final confirmatory bloodwork.

Patients for which same-day Direct Acting Antiviral (DAA) is contraindicated

12. The NOFO indicates that "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." How should we implement this requirement for patients for whom DAA for HCV is contraindicated, or for whom we may need to request additional bloodwork before treatment initiation.

a. Per the NOFO (page 8), the provider should provide HCV treatment following HCV Clinical Guidelines. There are some patients for whom same-day test-and-treat HCV treatment may be inappropriate. Per the NOFO (page 9), those patients can still receive the wrap-around services provided by the NOFO, such as SUD and SMI treatment, as well as peer support and care coordination (page 10 – 11). Care coordination can include connecting patients with medical coverage. Once covered by Medicaid, Medicare, the VA, etc, grant staff may work with the patient to coordinate care with specialists as needed.

Program Contact

If you have questions about programmatic implementation, please email the Hep C Free Team:
Substance Abuse and Mental Health Services Administration
HepCFree@samhsa.hhs.gov

Financial and Budget Questions

If you have financial questions, please email the Office of Financial Resources:
Division of Grants Management
240-276-1400
NOFOBudget.CSAT@samhsa.hhs.gov