Funding Opportunity Number:	CDC-RFA-PS20-2009
Funding Opportunity Title:	Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments
Program Office:	National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention
Drafter:	Ruth Jiles
FOA Analyst:	Constance Jarvis

Special Instructions:

Gray shaded text denotes standardized language that is required content in every announcement.

Gray shaded underlined text denotes optional standard language where users can opt to include certain text when appropriate.

Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-PS20-2009. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Notice of Funding Opportunity (NOFO) Title:

Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments

C. Announcement Type: New - Type 1

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

New – Type 1

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS20-2009

E. Assistance Listings (CFDA) Number:

93.270

F. Dates:

1. Due Date for Letter of Intent (LOI):	**03/25/2020**
2. Due Date for Applications:	**05/11/2020**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

Applications due 60 days after publication date.

3. Date for Informational Conference Call:
Call # 1: March 18, 2020 at 1:00 PM (Eastern Standard Time)

Call # 2: April 1, 2020 at 1:00 PM (Eastern Standard Time)

For conference line/bridge information, please reference link below:

https://www.cdc.gov/hepatitis/policy/FO-IntegratedHepSurvPrevFundingForHealthDepts.htm

G. Executive Summary:

1. Summary Paragraph:
This NOFO supports integrated viral hepatitis surveillance and prevention programs in states and large cities in the United States. Key strategies include viral hepatitis outbreak planning and response; and surveillance for acute hepatitis A, B and C, and chronic hepatitis C. Recipients should develop a jurisdictional viral hepatitis elimination plan, increase comprehensive hepatitis B and C reporting, improve HBV and HCV testing and increase healthcare providers trained to treat hepatitis B and C. Contingent on funding, the following activities can be supported: surveillance for chronic hepatitis B and perinatal hepatitis C; increased hepatitis B and C testing and referral to care in high-impact settings (syringe services programs (SSPs), substance use disorder (SUD) treatment centers, correctional facilities, emergency departments and sexually transmitted disease clinics; and increased access to services preventing viral hepatitis and other infections among persons who inject drugs (PWID). Contingent on funding, an optional component will support improved access to prevention, diagnosis, and treatment of viral, bacterial and fungal infections related to drug use in settings disproportionately affected by drug use. Expected outcomes include improved surveillance for viral hepatitis, increased stakeholder engagement in viral hepatitis elimination planning, and improved access to viral hepatitis prevention, diagnosis, and treatment among populations most at risk.

a. Eligible Applicants: Open Competition
b. NOFO Type: Cooperative Agreement
c. Approximate Number of Awards: 58
Component 1: 58 awards

Component 2: 58 awards

Component 3: 10 awards

d. Total Period of Performance Funding: $341,020,000
Total period of performance funding: Up to $341,020,000

Component 1 (Surveillance): up to $131,600,000 (Component 1 estimated at $11,600,000 in Year One)

Component 2 (Prevention): up to $126,670,000 (Component 2 estimated at $6,670,000 in Year One)

Component 3 (Special Projects): up to $82,750,000 (Component 3 estimated at $2,750,000 in

Year One)

This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

e. Average One Year Award Amount: $315,000

Component 1 (Surveillance): $200,000

Component 2 (Prevention): $115,000

Component 3 (Special Projects): $275,000

These amounts are subject to availability of funds.

f. Total Period of Performance Length: 5

g. Estimated Award Date: 09/01/2020

h. Cost Sharing and / or Matching Requirements: N

Cost sharing or matching funds are not required for this program.

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

An estimated 2.4 million people are infected with hepatitis C virus in the United States [1], and an estimated 44,000 people are newly infected every year [2]. Hepatitis C is curable, yet only about 56% of adults living with hepatitis C know they are infected [3], and about 1 out of every 14 new cases is reported to public health [4]. An estimated 862,000 people are living with hepatitis B virus in the United States [5], and an estimated 22,000 people are newly infected every year [2]. Hepatitis B is vaccine preventable and treatable, yet only about 32% of adults living with HBV know they are infected [3], and about 1 out of every 7 new cases are reported to public health [4]. The most common risk factor for acute hepatitis B and C is injection drug use [2]. Further, the United States continues to experience an unprecedented multi-state outbreak of acute hepatitis A, with over 30,000 reported cases since 2016 as of January 25, 2020, primarily affecting people who use drugs and people experiencing homelessness [6].

Priorities for this cooperative agreement are: Component 1, improve surveillance for viral hepatitis A, B and C in states and large cities, including outbreak detection, investigation and control; Component 2, facilitate state and large city viral hepatitis elimination planning, and increase access to hepatitis B and C testing and prevention, including hepatitis A and B vaccination, SSPs and medication assisted treatment (MAT) and treatment services. An additional optional Component 3 funds comprehensive, outcome-focused approaches to preventing

infections associated with injection drug use, reducing overdose deaths, and linking people to SUD treatment.

National surveillance data has been critical for identifying injection drug use as the primary risk factor for ongoing transmission of hepatitis B and C [2]. For PWID with opioid use disorder (OUD), MAT reduces the risk of hepatitis C acquisition by 50% and the combination of high coverage needle and syringe exchange and MAT reduces hepatitis C acquisition by 74% [7]. PWID can be treated for hepatitis C with sustained viral response about 90% [8]. Despite evidence of effectiveness, state policies may limit access to direct acting antiviral treatment and SSPs [9], and access to MAT remains suboptimal [10]. In addition, hepatitis A and B are vaccine preventable, yet vaccination rates among adults (hepatitis A, 9%, hepatitis B, 24.5%) [11], including adults at increased risk (hepatitis B estimated 17 – 41%) [12, 13], are low. Comprehensive SSPs (https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf) provide syringe exchange and access to other needed services for PWID.

National surveillance data can be leveraged for rapidly detecting outbreaks [6, 14], accurately assessing burden of disease, and monitoring elimination efforts for hepatitis B and C at the jurisdictional level [15, 16]. This cooperative agreement enables states to collect data to evaluate disease burden and trends and analyze and disseminate that data to develop or refine recommendations, policies, and practices that will ultimately reduce the burden of viral hepatitis in the jurisdiction.

This NOFO builds on CDC-RFA PS17-1703 which funded 14 states to build registries of hepatitis B and hepatitis C cases and improve completeness of case reports; and CDC-RFA-PS17-1702 which funded 50 jurisdictions to identify high burden areas for hepatitis B and/or hepatitis C and improve prevention and treatment in those areas. Both awards have been in place since fiscal year 2017.

b. Statutory Authorities

This program is authorized under Section 318 of the Public Health Service Act (42 U.S.C Section 247(c), as amended.

c. Healthy People 2030

This NOFO addresses the following "Healthy People 2020" focus area(s) of Immunization and Infectious Diseases:

- IID-1.3 Reduce, eliminate, or maintain elimination of new hepatitis B cases among persons 2 to 18 years;
- IID-15 Increase hepatitis B vaccine coverage among high-risk populations;
- IID-25 Reduce hepatitis B;
- IID-26 Reduce new hepatitis C infections; and,
- IID-27 Increase the percentage of persons aware they have hepatitis C infection

(http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=23).

d. Other National Public Health Priorities and Strategies

This NOFO supports the goals of the 2017-2020 HHS National Viral Hepatitis Action Plan, https

://www.hhs.gov/hepatitis/viral-hepatitis-action-plan/index.html.

This NOFO also supports the Division of Viral Hepatitis (DVH) Strategic plan, https://www.cdc.gov/hepatitis/pdfs/dvh-strategicplan2016-2020.pdf, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention strategic plan, https://www.cdc.gov/nchhstp/strategicpriorities/.

Finally, this NOFO supports the goals of enhancing community-based SSPs, as outlined in "Policies & Issues: Syringe Services Programs" at HIV.gov, https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs.

e. Relevant Work

This NOFO builds upon previous or current hepatitis B and hepatitis C prevention or surveillance projects, including:

CDC-RFA-PS17-1702 - Improving Hepatitis B and C Care Cascades; Focus on Increased Testing and Diagnosis

CDC-RFA-PS17-1703 - Strengthening Surveillance in Jurisdictions with High Incidence of Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) Infections

CDC-RFA-PS19-1909 National Harm Reduction Technical Assistance and Syringe Services Program (SSP) Monitoring and Evaluation Funding Opportunity

CDC-RFA-PS19-1904: Capacity Building Assistance (CBA) for High Impact HIV Prevention Program Integration

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	**Short-term (Yrs 1-3) and Intermediate (Yrs 4-5) Outcomes**	**Long-term Outcomes**
1. Core Viral Hepatitis Outbreak Response and Surveillance Activities		1. Establishment of comprehensive national viral hepatitis surveillance 2. Reduced new viral hepatitis infections 3. Increased access to care for
1.1 Develop, implement, and maintain plan to rapidly detect and respond to outbreaks of: Hepatitis A Hepatitis B Hepatitis C	**Short-term Outcomes:** **Established jurisdictional framework for outbreak detection and response** Earlier detection and response to viral hepatitis outbreaks **Intermediate Outcomes:** Reduced new cases of viral hepatitis	
1.2 Systematically collect, analyze, interpret, and	**Short-term Outcomes:** **Increased public health reporting of chronic**	

disseminate data to characterize trends and implement public health interventions for: Hepatitis A Acute hepatitis B Acute and chronic hepatitis C	**and perinatal HCV and chronic HBV infection, and undetectable HCV RNA and HBV DNA laboratory results** **Improved monitoring of burden of disease and trends in hepatitis A, acute hepatitis B, and acute hepatitis C** **Improved monitoring of burden of disease and outcomes in chronic hepatitis C** **<u>Intermediate Outcomes</u>:** **Improved monitoring of hepatitis C continuum of cure (CoC)** **Improved development and utilization of viral hepatitis surveillance data reports**	persons with viral hepatitis 4. Improved health outcomes for people with viral hepatitis 5. Reduced deaths among people with viral hepatitis
1.3 Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for: Chronic hepatitis B Perinatal hepatitis C	**<u>Short-term Outcomes</u>:** **Improved monitoring of burden of disease and trends in perinatal hepatitis C** **<u>Intermediate Outcomes</u>:** **Improved monitoring of burden of disease and outcomes in chronic hepatitis B** **Improved monitoring of hepatitis B CoC**	6. Reduced viral hepatitis-related health disparities 7. Decreased overdose deaths among PWID
2. Core Viral Hepatitis Prevention Activities		8. Decreased infections from drug use
2.1 Support viral hepatitis elimination planning and surveillance, and maximize access to testing, treatment, and prevention Increase routine HCV and HBV testing in high volume laboratories and health systems Expand provider capacity to treat hepatitis C and/or hepatitis B Disseminate materials regarding evidence-based best practices for access to HCV treatment and viral	**<u>Short-term Outcomes</u>:** **Increased state engagement with key stakeholders in viral hepatitis elimination planning** **Increased commercial and hospital-based laboratories conducting HCV RNA reflex testing** **Increased HCV and/or HBV testing in health care systems** **<u>Intermediate Outcomes</u>:** **Increased healthcare providers trained in prescribing hepatitis C and/or hepatitis B treatment** Increased access to HCV treatment Increased access to SSPs for PWID	

hepatitis prevention		
2.2 Increase access to HCV and HBV testing and referral to care in high-impact settings Increase routine HCV and HBV testing in high-impact settings Provide post-test counseling and referral to treatment or prevention	**Short-term Outcomes:** Increased access to HCV RNA reflex and/or HBV testing among persons receiving services in high-impact settings **Increased awareness of infection status among people diagnosed with chronic hepatitis C and/or hepatitis B** **Increased referral to treatment for people living with hepatitis C and/or hepatitis B** Increased referral to treatment and prevention services for persons who inject drugs (PWID) **Intermediate Outcomes:** Increased cure of hepatitis C	
2.3 Improve access to services preventing viral hepatitis and other bloodborne infections among PWID Support SSPs Establish hepatitis A and B vaccine delivery teams	**Short-term Outcomes:** **Increased utilization of SSPs among PWID** **Increased referral of PWID to SUD treatment** **Increased receipt of hepatitis A and hepatitis B vaccination among clients in high-impact settings**	
3. Special Projects: Prevention, Diagnosis, and Treatment related to the infectious disease consequences of drug use		
3.1 Improve access to services for PWID in settings disproportionately affected by drug use: Develop and implement PWID service bundle in settings that serve PWID (e.g., SSPs, MAT providers, hospital settings, correctional facilities) **3.2 Implement prevention services and interventions to address emerging issues**	**Short-term Outcomes:** **Increased access to high-coverage needle-syringe exchange among PWID** **Increased linkage to SUD treatment (including MAT among PWID with OUD)** **Increased HCV, HIV, and HBV testing among PWID** **Increased linkage to treatment services among people with infectious complications (viral hepatitis, HIV, bacterial, fungal) of SUD** **Increased receipt of hepatitis B and A vaccination among PWID**	

related to drug use Education and training to address emerging issues	Increased dissemination of evidence-based interventions and guidance to reduce bacterial and fungal complications among PWID **<u>Intermediate Outcomes</u>:** **Decreased new viral hepatitis, HIV and other infections (e.g., bacterial, fungal) among PWID** **Increased hepatitis C cures among PWID with hepatitis C** Decreased unsafe injection practices	

i. Purpose

The purpose of this NOFO is to establish integrated viral hepatitis programs in health departments to: 1) expand jurisdictional surveillance for acute hepatitis A, B, and C; perinatal hepatitis C; and chronic hepatitis B and C, and 2) facilitate the development and implementation of viral hepatitis elimination plans. An optional component funds increased access to the prevention, diagnosis, and treatment of viral hepatitis B and C, HIV, bacterial and fungal infectious disease consequences of drug use among PWID in settings disproportionately affected by drug use.

ii. Outcomes

The recipient is expected to make measurable progress towards addressing the short-term and intermediate outcomes that appear **in bold** in the NOFO logic model. Indicators that quantify these outcomes are described in the section entitled CDC Evaluation and Performance Measurement Strategy.

Expected short-term and intermediate outcomes include the following:

<u>Component 1 Core Viral Hepatitis Outbreak Response and Surveillance</u>

(Three required sections including one section contingent on funding)

1.1 Develop, implement, and maintain plan to rapidly detect and respond to outbreaks for: hepatitis A, hepatitis B, and hepatitis C

- Outcome 1.1.1 Established jurisdictional framework for outbreak detection and response

1.2 Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C

Short-term outcomes:

- Outcome 1.2.1 Increased public health reporting of chronic and perinatal HCV and chronic HBV infection, and undetectable HCV RNA and HBV DNA laboratory results
- Outcome 1.2.2 Improved monitoring of burden of disease and trends in hepatitis A, acute hepatitis B, and acute hepatitis C
- Outcome 1.2.3 Improved monitoring of burden of disease and outcomes in chronic hepatitis C

Intermediate outcomes:

- Outcome 1.2.4 Improved monitoring of hepatitis C continuum of cure (CoC)
- Outcome 1.2.5 Improved development and utilization of viral hepatitis surveillance data reports

1.3 Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B, and perinatal hepatitis C (Contingent on available funding)

Short-term outcomes:

- Outcome 1.3.1 Improved monitoring of burden of disease and trends in perinatal hepatitis C

Intermediate outcomes:

- Outcome 1.3.2 Improved monitoring of burden of disease and outcomes in chronic hepatitis B
- Outcome 1.3.3 Improved monitoring of hepatitis B CoC

<u>Component 2 Core Viral Hepatitis Prevention</u>

(Three required sections including two sections contingent on funding)

2.1 Support viral hepatitis elimination planning and surveillance, and maximize access to testing, treatment, and prevention

Short-term outcomes:

- Outcome 2.1.1 Increased state engagement with key stakeholders in viral hepatitis elimination planning
- Outcome 2.1.2 Increased commercial and hospital-based laboratories conducting HCV RNA reflex testing
- Outcome 2.1.3 Increased HCV and/or HBV testing in health care systems

Intermediate outcomes:

- Outcome 2.1.4 Increased healthcare providers trained in prescribing hepatitis C and/or hepatitis B treatment

2.2 Increased access to hepatitis C and hepatitis B testing and referral to care in high-impact settings (Contingent on available funding)

Short-term outcomes:

- Outcome 2.2.2 Increased awareness of infection status among people living with chronic hepatitis C and/or hepatitis B
- Outcome 2.2.3 Increased referral to treatment for people living with hepatitis C and/or hepatitis B

2.3 Improve access to services preventing viral hepatitis and other bloodborne infections among PWID (Contingent on available funding)

Short-term outcomes:

- Outcome 2.3.1 Increased utilization of SSPs among PWID
- Outcome 2.3.1 Increased referral of PWID to SUD treatment
- Outcome 2.3.3 Increased receipt of hepatitis A and hepatitis B vaccination among clients in high-impact settings

Component 3 (Optional). Special Projects: Prevention, Diagnosis, and Treatment related to the infectious disease consequences of drug use

(Two optional sections contingent on available funding)

3.1 Improve access to services for PWID in settings disproportionately affected by drug use

Short-term outcomes:

- Outcome 3.1.1 Increased access to high coverage needle-syringe exchange among PWID
- Outcome 3.1.2 Increased linkage to substance use disorder treatment (including MAT among PWID with OUD)

- Outcome 3.1.3 Increased HCV, HIV, and HBV testing among PWID
- Outcome 3.1.4 Increased linkage to treatment services among people with infectious complications (viral hepatitis, HIV, bacterial, fungal) of SUD
- Outcome 3.1.5 Increased receipt of hepatitis B and A vaccination among PWID

Intermediate outcomes:

- Outcome 3.1.7 Decreased new viral hepatitis, HIV and other infections (e.g., bacterial, fungal) among PWID
- Outcome 3.1.8 Increased hepatitis C cures among PWID with hepatitis C

3.2 Prevention services and interventions to address emerging issues related to drug use

(No outcomes specified; based on availability of funding, this sub-component will be considered for funding in years 2-5)

iii. Strategies and Activities

Recipients are required to provide an integrated viral hepatitis surveillance and prevention program in the public health jurisdiction. The program consists of six required strategies (three funded and three contingent on funding) and two optional strategies contingent on funding with related activities. Recipients can request to opt out of selected required activities by providing a strong justification, which must be based on program need, resources and/or policies. Approval will be made after review of the application.

Required activities include those related to six strategies: 1.1, develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for: hepatitis A, hepatitis B, and hepatitis C; 1.2, systematically collect, analyze, interpret, and disseminate data to characterize trends, and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C; 1.3, systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C; 2.1, support viral hepatitis elimination planning and surveillance, and maximize access to testing, treatment, and prevention; 2.2, increase access to HCV and HBV testing and referral to care in high-impact settings; and 2.3, improve access to services preventing viral hepatitis and other bloodborne infections among PWID.

Component 1: Core Viral Hepatitis Outbreak Response and Surveillance

Required Component 1 Strategies and Activities:

1.1. Develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for: hepatitis A, hepatitis B, hepatitis C virus.

- Engage surveillance stakeholders at the state and local levels and collaborate with CDC DVH epidemiologists to develop (a) plan(s) to rapidly detect and respond to outbreaks.
- Develop (a) plan(s) to respond to outbreaks of viral hepatitis. It is anticipated that hepatitis

outbreak plans may be integrated with other jurisdictional outbreak and emergency response plans. Elements of the plans may vary based on the type of outbreak (e.g., viral hepatitis among PWID and/or persons with other risk factors, healthcare-associated outbreaks of hepatitis B or C, foodborne outbreak of hepatitis A, etc.), and may include, where relevant:

- Routine review of surveillance data (and other data sources) to detect outbreaks
- Key departments / personnel to include on the outbreak investigation team
- Outbreak response management structure
- Laboratory testing
- Contact tracing and partner services, as applicable
- Prevention and control measures
- Linkage to case management and clinical care
- Communication plan with key stakeholders, media, and health department leadership
- Role of community-based organizations and partners
- Debrief, evaluations, and after-action report
- Case investigations forms, flowcharts, and other tools to expedite outbreak investigation

1.2. Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C.

- Collaborate with jurisdictional public health staff and leaders, as appropriate to:
  - Identify and clarify gaps in jurisdiction ability to include chronic hepatitis B and C, perinatal hepatitis C, undetectable HCV RNA and HBV DNA laboratory results as reportable conditions and under public health surveillance.
  - Explore and identify options, activities, and stakeholders required to establish surveillance of chronic hepatitis B and C and perinatal hepatitis C, undetectable HCV RNA and HBV DNA laboratory results.
  - As appropriate, educate stakeholders about options and proposed surveillance plans. Consult with stakeholders on the best course of action to establish public health reporting of chronic and perinatal hepatitis B and C.
  - During years two to five, implement plans to address gaps in establishing public health reporting of chronic and perinatal hepatitis B and C, and reporting of undetectable HCV RNA and HBV DNA.
- Inform laboratories that conduct hepatitis testing of reporting requirements and establish a mechanism for reporting to the appropriate health department (local or state).
- Develop and implement a plan to improve completeness of case reports for hepatitis A, acute hepatitis B and acute and chronic hepatitis C.
- Follow-up with health care providers and/or case patients to improve completeness of risk factor information for all cases of hepatitis A, acute hepatitis B and acute hepatitis C.
- Follow-up with health care providers and/or case patients to improve completeness of demographic information for all cases of hepatitis A, acute hepatitis B and acute and chronic hepatitis C.
- Jurisdictions without existing registries should create a hepatitis C registry to avoid

duplication of cases and to monitor continuum of cure.
- Notify CDC of all cases of hepatitis A, acute hepatitis B and acute and chronic hepatitis C that meet the CSTE case definition.
- Beginning in year three, produce an annual surveillance report that includes hepatitis A, acute hepatitis B and acute and chronic hepatitis C surveillance data.
- Beginning in year three, use jurisdiction-specific data, including undetectable HCV RNA, mortality data, and other data as available to monitor the continuum of care for hepatitis C.

Required Component 1 Strategies and Activities Contingent on Funding:

1.3. Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C.

- Develop and implement a plan to improve completeness of case reports for chronic hepatitis B and perinatal hepatitis C.
- Follow-up with health care providers and/or case patients to improve completeness of demographic information for all cases for chronic hepatitis B and perinatal hepatitis C.
- Jurisdictions without existing registries should create a hepatitis B registry to avoid duplication of cases and to monitor continuum of care.
- Notify CDC of all cases of chronic hepatitis B and perinatal hepatitis C that meet the CSTE case definition.
- Beginning in year three, produce an annual surveillance report that includes chronic hepatitis B, and perinatal hepatitis C surveillance data.
- Beginning in year three, use jurisdiction specific data including undetectable HBV DNA, mortality data, and other data as available to monitor the continuum of care for hepatitis B.

CDC federal funds may be used to support CDC's ability to monitor, control, and prevent viral hepatitis by standardizing the reporting of surveillance data, including:

- Implementing new National Notifiable Disease Surveillance System (NNDSS) case notification messages (e.g. hepatitis HL7 Message Mapping Guide, see https://wwwn.cdc.gov/nndss/case-notification/) using the new HL7 case notification structure and onboarding process (https://www.cdc.gov/nmi/ta-trc/index.html); and
- Enhance existing information systems(s) y adding or improving functionality.

Component 2 Core Viral Hepatitis Prevention Activities

Required Component 2 Strategies and Activities

2.1 Support viral hepatitis elimination planning and surveillance, and maximize access to treatment, and prevention.

The World Health Organization has set worldwide goals for elimination of Hepatitis B and C by 2030 (www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/)

In the United States, the National Academies of Sciences, Engineering and Medicine has developed a strategy for elimination of hepatitis B and C by 2030. (http://www.nationalacademies.org/hmd/reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx) and the Department of Health and Human Services has put forward a National Viral Hepatitis Action Plan addressing similar goals. (www.hhs.gov/sites/default/files/National%20Viral%20Hepatitis%20Action%20Plan%202017-2020.pdf)

- Identify and engage partners as members of a jurisdictional "Viral Hepatitis Elimination Technical Advisory Committee" or create a coalition of appropriate partners and key stakeholders. Document committee membership, governance, meetings, and member roles and responsibilities. See "Collaborations," in this NOFO.)
- Develop or expand upon an evidence based viral hepatitis B and C elimination plan. Include strategies to eliminate hepatitis B and C among risk groups (e.g., PWIDs, persons who are incarcerated, persons who are foreign born for hepatitis B) and other target populations with higher prevalence of hepatitis B and hepatitis C. See "Target Populations," in this NOFO.
- Engage with key partners and stakeholders to set goals and objectives, identify target populations, develop a logic model and an action plan.
- Understand the program focus and priority areas. Develop program goals and measurable objectives (e.g., SMART objectives).

2.1.a Increase routine HCV and HBV testing in high volume laboratories and health systems.

CDC encourages recipients to build partnerships to encourage adherence to evidence-based guidelines for prevention and treatment of viral hepatitis. Collaborating organizations should be encouraged to provide hepatitis B and hepatitis C testing and care services consistent with CDC, U.S. Preventive Services Task Force (USPSTF), and American Association for the Study of Liver Diseases (AASLD) testing and clinical management recommendations (https://www.hcvguidelines.org/).

2.1.a.i Increase routine HCV and HBV testing in high volume laboratories.

Testing and reporting practices must be improved in order to accurately detect all persons with current hepatitis B and C infection so that they can be linked to appropriate care and treatment. For hepatitis C, all persons recommended for HCV screening should initially be tested for HCV

antibody. A positive test result for HCV antibody indicates either current (active) HCV infection (acute or chronic), past infection that has resolved, or a false-positive result. Therefore, an HCV nucleic acid test (NAT) to detect viremia is necessary to confirm active hepatitis C infection and guide clinical management, including initiation of hepatitis C treatment. (www.hcvguidelines.org/evaluate/testing-and-linkage).

To ensure complete testing and an efficient patient-centered approach, automatic reflex confirmatory HCV RNA testing is recommended with the same laboratory sample for all patients with a positive antibody test result. If the reflex confirmatory HCV RNA test is positive, a diagnosis of active hepatitis C infection is confirmed, and the individual should be directly referred for hepatitis C care and treatment.

- In year one, collaborate with the viral hepatitis surveillance coordinator to identify the highest volume Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified laboratories that report 80% or more hepatitis C antibody tests and tests for hepatitis B in the jurisdiction.
- In collaboration with the viral hepatitis surveillance coordinator, conduct a needs assessment by the end of year one for these laboratories, to describe their current hepatitis B and C testing practices, determine if they are conducting reflex HCV RNA confirmation and identify the key barriers/challenges and solutions needed to increase reflex HCV RNA testing. Alternatively, in collaboration with the viral hepatitis surveillance coordinator, jurisdictions may conduct a survey of all CLIA-certified laboratories in the jurisdiction to collect the same information.
- In collaboration with jurisdictional leadership and stakeholders, summarize assessment (survey) information with recommendations to improve access to reflex HCV RNA testing beginning in year two.
- Improve partnerships with the health care and community-based organizations to educate providers, patients, stakeholders and others to implement routine HBV and HCV testing, including reflex HCV RNA confirmation. Assure that routine HBV and HCV testing is addressed in the viral hepatitis elimination plan.

2.1.a.ii Increase routine HCV and HBV testing in health systems.

- In collaboration with the jurisdictional viral hepatitis surveillance coordinator and/or stakeholders, identify the five highest volume health systems in the jurisdiction in year one.
- By the end of year one, conduct a needs assessment for the identified high-volume health systems to describe their current hepatitis B and C testing practices, prevalence, barriers/challenges, and solutions needed to increase routine HBV and HCV testing; and provide feedback with recommendations to improve access to routine HCV and HBV testing.

- Improve partnerships with the health care systems to educate providers, patients, stakeholders, and others to implement routine HBV and HCV testing, beginning in year two.
- Assure that routine HCV and HBV testing is addressed in the viral hepatitis elimination plan.

2.1.b Expand provider capacity to treat hepatitis C and/or hepatitis B.

The 2010 Institute of Medicine (IOM) reported that the U.S. health-care system has insufficient capacity to provide the recommended preventive and clinical-care services for the 2.7-3.9 million persons living with hepatitis C (http://www.cdc.gov/hepatitis/PDFs/IOM-HepatitisAndLiverCancerReport.pdf). Routine hepatitis C antiviral treatment can be safely and effectively delivered in primary-care settings by primary care providers with appropriate training, while persons with advanced liver disease should be referred to specialists for management. (http://www.ncbi.nlm.nih.gov/pubmed?term=(Brew%20IF)%20AND%20Primary%20Care).

The Extension for Community Healthcare Outcomes (Project ECHO) model was developed to enhance primary-care capacity to treat patients with hepatitis C infection and improve access to hepatitis C care in rural settings through case-based learning facilitated by regular video-conferencing with hepatitis C specialists (https://echo.unm.edu/). The program demonstrated the quality of hepatitis C care and treatment provided by primary-care physicians participating in ECHO as being comparable with specialty care in a hepatitis C clinic. Other strategies that might improve rates of initiation and completion of treatment include comprehensive case management (e.g., peer navigation, bridge counseling) and multidisciplinary, integrated care programs.

Close cooperation among public health and clinical care professionals (e.g., specialists in hepatitis C care and primary-care providers) involved in the testing, diagnosis, care, and treatment of HCV-infected persons can optimize cure of HCV infection (http://www.ncbi.nlm.nih.gov/pubmed/23811030

https://link.springer.com/content/pdf/10.1007%2Fs40506-018-0177-5.pdf

https://www.sciencedirect.com/science/article/pii/S2213076417301045?via%3Dihub).

- Collaborate with the Viral Hepatitis Elimination Technical Advisory Committee, or other coalition of appropriate partners and stakeholders to address provider capacity for treatment of hepatitis B and C. Stakeholders might include state and/or local health departments, specialists in hepatitis B and hepatitis C management and/or continuing medical education, public and private health insurance payors, professional organizations, primary-care providers (e.g., hospital-based, care networks, and community health centers), persons with lived experience (injection drug use and viral hepatitis) and other

stakeholders and partners serving the jurisdiction. See "Collaborations" in this NOFO.

- In collaboration with the key partners and stakeholders in the workgroup:
    - A process for primary-care provider training and consultation with hepatitis C specialists on an ongoing basis in various settings (e.g., based on Project ECHO or other evaluated models of hepatitis C care using telemedicine, e-consultation or video conferencing).
    - A repository of existing hepatitis B and hepatitis C training resources, with links to this information on the health department website.
    - Guidance to implement appropriate HCV testing among primary-care providers. Appropriate HCV testing means following current CDC and USPSTF recommendations for testing (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm, https://www.uspreventiveservicestaskforce.org/Page/Document/ClinicalSummaryFinal/hepatitis-c-screening, or updated recommendations as available) and in accordance with CDC's guidance for laboratory diagnosis of current hepatitis C (http://www.cdc.gov/hepatitis/HCV/LabTesting.htm), which requires HCV-RNA confirmation to diagnose current HCV infection.
    - Training on strategies to reduce or assist with the administrative burden of hepatitis C treatment (e.g., prior authorization, patient assistant programs).
    - Training on strategies for case management and patient navigation to facilitate treatment initiation and completion and retention of patients in care.
    - Training to support implementation of EMR prompts and reminders in health care settings
    - Training to expand and improve linkage to care and treatment for persons with chronic hepatitis B and hepatitis C infection,
    - Recruit and train providers on the viral hepatitis clinical and preventive services guidelines, risk factors and treatment options and provide continuing education credits.
    - Ongoing updates and support for providers who have completed basic training.
    - A provider resource directory, identifying both private and public provider resources for treatment of hepatitis B and C.
    - Protocols for primary-care provider training and consultation for various audiences in culturally sensitive, language appropriate formats. Partner with professional, medical, and other organizations (e.g.: SAMSHA-ATTC, Medicaid) to build a provider workforce skillful at providing viral hepatitis prevention, care, and treatmentDevelopment of worksheets, job aids, and other tools to support implementation.
    - Development of worksheets, job aids, and other tools to support implementation.
    - Address provider training in the jurisdictional viral hepatitis elimination plan (year one); plans to address provider training might include:
    - Address implementation of the plan (year three to five); implementation plans may include:

2.1.c. Disseminate materials regarding evidence-based practices for access to hepatitis C treatment and viral hepatitis prevention.

Evidence-based prevention services for persons at-risk for viral hepatitis include MAT for persons with moderate or severe OUD, SSPs providing sufficient sterile injection materials for all injections, and vaccination against hepatitis A and B. In addition, for persons with hepatitis B and C infection, treatment should be offered in accordance with standard guidelines (https://www.hcvguidelines.org/, https://aasld.org/publications/practice-guidelines). See "Background," in this NOFO.

- Collaborate with stakeholders and partners, e.g., viral hepatitis elimination technical advisory committee, to develop a plan to disseminate materials regarding evidence-based practices for access to hepatitis C treatment and harm reduction (year one); elements of the plan might include:
    - Information on hepatitis C treatment recommendations for public and private insurance payors
    - Information on harm reduction for law enforcement and other emergency responders
    - Information on recommended viral hepatitis prevention and treatment services for PWID, their family and friends
    - Information on recommended viral hepatitis prevention and treatment services for high-impact settings.
    - Prioritized materials matched to target audiences; for example:
    - Plans for developing, adapting or identifying materials regarding evidence-based practices
    - Plans for dissemination of materials.
- During years two to five:
    - Disseminate materials regarding evidence-based practices for access to hepatitis C treatment and harm reduction programs; update as needed
    - Evaluate impact.

Required Component 2 Strategies and Activities Contingent on Funding

2.2. Increase access to HCV and HBV testing and referral to care in high-impact settings.

For the purpose of this section of the NOFO the following apply:

"High-impact" settings are venues serving persons with a high prevalence of injection drug use or hepatitis B, hepatitis C or HIV (e.g. SSPs, SUD treatment centers, correctional facilities, emergency departments and sexually transmitted disease clinics). Recipients must focus activities in one or more high-impact settings working in collaboration with relevant organizations to provide viral hepatitis testing and referral to care.

Recognizing the importance of tailoring local approaches, this award supports local partnerships to implement the activities in high-impact settings in the jurisdiction through the collaboration of organizations that, together, demonstrate:

- Specialized experience and capacity for reaching PWID
- Ability to perform screening and diagnostic testing for hepatitis B and hepatitis C infections
- Established partnerships to refer PWID diagnosed with hepatitis B and hepatitis C infection to appropriate care
- Established partnerships to refer PWID to appropriate prevention services
- Use of data systems to track testing, test results, and referrals, and to report cases of hepatitis B and hepatitis C infection to the appropriate health department in accordance with applicable requirements

Example program partnerships for increasing access to HCV and HBV testing and referral to care in high-impact settings:

1. SSPs. Viral hepatitis testing and referral services are incorporated into an existing SSP in this example. The SSP conducts outreach/education for their PWID clientele about viral hepatitis infections and offers testing for hepatitis B and hepatitis C to all SSP clients. For those who test positive for current infection, SSP staff make referrals and patient or peer navigators link clients to an identified partner primary care clinic or hospital system for HCV RNA testing (if needed) and evaluation, treatment, and care for hepatitis B or hepatitis C infection.
2. SUD Treatment Facilities and MAT providers. In this example, a SUD treatment facility or MAT provider conducts hepatitis B and hepatitis C testing on all clients. Patient or peer navigators link those who test positive for current infection, facility staff make referrals to an identified partner primary care clinic or hospital system for evaluation, treatment, and care.
3. Emergency Department/Hospital Systems. In this example, an emergency department of a local hospital conducts hepatitis B testing and hepatitis C testing for patients presenting with an illness associated with injection drug use (e.g., invasive bacterial or fungal infections, wound infections), an illicit drug overdose, or who have injection drug use history documented in the medical chart. For those who test positive for current infection, ED staff make referrals to appropriate primary care clinic or specialty care clinic affiliated with the hospital. ED staff also connect the patient to a patient or peer navigator who helps ensure the patient makes the first visit (e.g., helps with transportation assistance, appointment reminders)
4. Correctional facilities. In this example, correctional facilities (e.g., local jail, state prison) test new inmates on arrival for hepatitis B and hepatitis C. Those who test positive for current infection are referred for medical care within the correctional facility.

Applicants may propose to build state laboratory capacity for hepatitis C and hepatitis B testing. This may include purchase of necessary equipment and performance of validation testing and quality assurance. The applicant must describe the need for the additional laboratory capacity and how it will facilitate this project and enhance overall capacity at the state lab. Recipients may

purchase hepatitis B and C test kits (including HCV RNA tests) for this component.

Patient navigators (or peer navigators) may be clinic- or hospital-based and work in partnership with one or more high-impact settings in the community (e.g., SSP, SUD treatment facility, MAT provider). Alternatively, patient or peer navigators may be community-based and affiliated with the organization that has a high-impact setting (e.g., SSP, SUD treatment facility, MAT provider) and link patients to one or more clinics or hospitals in the community for evaluation and care.

Patient navigator and referral services can include scheduling hepatitis B or hepatitis C-related medical appointments, preparing clients for medical appointments, and coordinating efforts with the client's care team to ensure the first visit is scheduled and occurs. Patient navigation services can also include linkage or referral to treatment for those diagnosed with hepatitis B or hepatitis C, and prevention services for PWID (e.g., patient navigators (or other staff for the project) may provide to all clients educational materials and referrals for viral hepatitis prevention services recommended for PWID such as SSPs, SUD treatment, hepatitis A and hepatitis B vaccination, and family planning).

2.2.a Increase routine HCV and HBV testing in high-impact settings.

- Collaborate with key stakeholders and partners to establish partnerships, to select one or more high priority high-impact settings, and develop a plan to increase HBV and HCV testing.
- Conduct a needs assessment with clients and staff in high-impact settings on HBV and HCV screening and testing practices and referral or linkage to treatment.
- Support high-impact settings to:
    - Opt-out initial and annual HCV antibody test (anti-HCV) with reflex or immediate HCV-RNA test to confirm positive anti-HCV (current HCV infection)
    - HCV RNA testing where reflex or immediate HCV-RNA testing is not possible.
    - Hepatitis B surface antigen, antibody to hepatitis B core antigen, and antibody to hepatitis B surface antigen test
    - Strengthen efforts to conduct hepatitis B and hepatitis C screening and testing in the high-impact settings
    - Offer testing to all persons in the high-impact settings as follows:
    - Track the number of persons tested and test results, including follow-up diagnostic test results
    - Ensure that cases of hepatitis B and hepatitis C are reported to the appropriate local or state health department in accordance with applicable notifiable infectious disease reporting requirements.
    - Conduct outreach to increase the number of persons provided testing services in the high-impact settings.
    - Provide education (counseling or materials) on potential interventions that could increase testing and diagnosis of hepatitis B and C

- Systematically compile, summarize and disseminate evaluation data.

2.2.b. Provide post-test counseling and referral to treatment or prevention.

- Support high-impact settings to:
    - Collaborate with key stakeholders and partners to develop a plan for referring and linking persons diagnosed with hepatitis B and hepatitis C to appropriate medical care.
    - Ensure all persons diagnosed with hepatitis B and/or hepatitis C infection are referred to appropriate medical care.
    - Track the number of persons testing positive for hepatitis B and C who received post-test counseling and were referred to treatment. Refer all PWID in the high-impact setting to SUD treatment facilities and SSPs (where available)
    - Track the number of persons identified as PWID who were referred to SSPs and SUD treatment
- Systematically compile, summarize and disseminate evaluation data.

2.3.a Support SSPs.

CDC supports the implementation of comprehensive SSPs as an effective public health approach to reduce the spread of infectious diseases associated with injection drug use. SSPs have been associated with reduced risk of infection with bloodborne pathogens such as HIV and viral hepatitis. In addition to improving access to sterile injection equipment, SSPs often provide other services important in supporting PWID. SSPs offer risk reduction counseling and are an important venue for HIV, viral hepatitis, STD, and TB testing; hepatitis A and hepatitis B vaccination; linkage to care and treatment; the provision of naloxone; and referrals to substance use treatment. More information for applicants is provided at the following link: https://www.cdc.gov/ssp/index.html.

Refer to the HHS Syringe Services Programs (SSP) Implementation Guidance at https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs.

The CDC Program Guidance for Implementing Certain Components of Syringe Services Programs, 2016, provides specific procedures for CDC-funded grantees: https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf. Further information on SSPs can be found at: https://www.cdc.gov/ssp/index.html

Determination of Need

Resources awarded as part of this NOFO may be used to support viral hepatitis prevention, diagnosis and linkage to care activities in SSPs, but only when certain conditions are met. In consultation with CDC, state and local health departments must first demonstrate that the jurisdiction or area they are serving is at risk for or experiencing a significant increase in hepatitis infections or an HIV outbreak due to injection drug use through the Determination of Need (DON) process. Applicants can initiate the DON request at any time during the application

process. If concurrence with the DON has not been received at the time the application for funding is submitted, applicants should include documentation that DON request has been submitted. Funds cannot be allocated to support SSPs until concurrence with the DON has been received. To see if your jurisdiction has a DON, or to learn more, see: https://www.cdc.gov/ssp/determination-of-need-for-ssp.html.

CDC federal funds may be used to support certain components of SSPs, including—

- Staff
- Supplies (e.g., alcohol pads, sterile water, cotton)
- Testing kits for viral hepatitis and HIV
- Syringe disposal services
- Navigation services to ensure linkage to services
- Provision of naloxone to reverse drug overdoses (CDC funds may not be used to purchase naloxone)
- Communication, outreach and educational materials
- Condoms
- Planning and evaluation activities; specifically: needs assessment and/or special studies to identify:
- Resource needs (staffing, supplies, other needs to facilitate service delivery consistent with this NOFO)
- Staff training and development needs
- Client needs, such as hours of service availability, types of services needed, perception of services offered, perception of stigma and compassion during service delivery
- Other assessment needs to design services consistent with this NOFO
- Evaluation studies to document impact of grant-funded interventions

CDC federal funds may **not** be used for –

- Needles and syringes for illegal drug injection
- Other devices solely used for illegal drug injection (e.g., cookers)

2.3.b Establish hepatitis A and B vaccine delivery teams

- Vaccination teams can be located in a single site or they can travel to multiple high-impact settings to deliver vaccine. Staffing for teams can be part-time (e.g., 20% of a nurse assigned full-time to an SSP) or full time (e.g., travelling full-time vaccination team that serves multiple high-impact settings). Jurisdictions should use funding to develop the most efficient and effective plan to deliver vaccine to the target populations.
- Support vaccine delivery teams and staff in high-impact settings to identify, adapt or develop written hepatitis A and B vaccination protocols and standing orders, including assessment of immune status, as feasible, and maintenance of up to date vaccination records.
- Support vaccine delivery teams to train and collaborate with staff in high-impact settings to implement protocols.

- Support vaccine delivery teams and staff in high-impact settings to assess client immune status, as feasible, to hepatitis A and B and to assure that client's vaccination series for hepatitis A and B is completed.
- Systematically compile, summarize and disseminate evaluation data.

Component 3 (Optional) Special Projects: Prevention, Diagnosis, and Treatment related to the infectious disease consequences of drug use

Component 3 activities are optional and contingent on allocation of funding.

People who inject drugs are at high risk for infectious consequences including viral hepatitis, HIV, and bacterial or fungal infections which require costly and prolonged medical care. In 2017, there were over 45,000 new cases of hepatitis C, and rates of endocarditis have more than doubled since 2010. Ongoing outbreaks of hepatitis A among PWID since 2016 have resulted in over 30,000 cases, and HIV outbreaks among PWID are now threatening progress in IDU-associated cases nationally. Common among these patients is an underlying OUD. However, patients with OUD seen in community settings or hospital-based systems often are not provided comprehensive care to address multiple co-morbidities. At SSPs and other community health settings, PWID are rarely provided or linked to comprehensive preventive and treatment services, and lack access to social services. In hospitals settings, PWID are infrequently started on medication-assisted treatment (MAT) and are often not provided with diagnostic and preventive services during their medical care or linked to these services upon discharge.

3.1 Improve access to services for PWID in settings disproportionately affected by drug use.

Component 3.1 activities should be focused on a comprehensive, outcome-focused approach to preventing infections associated with injection drug use, reducing overdose deaths, and linking people to substance use treatment. Programs that incorporate multiple interventions, focus on full coverage of the populations most at risk, and ensure increased access to services at the local and/or state level are encouraged. Components should include improving access to preventive, diagnostic and treatment services for PWIDs in settings serving PWID.

3.1.a Develop and implement "PWID service bundle" in settings that serve PWID (e.g., SSPs, MAT providers, hospital settings, correctional facilities).

Jurisdictions should choose one or more "settings serving PWID" for implementation of a "PWID service bundle" either across the jurisdiction, or in an area of the jurisdiction highly impacted by drug use.

"Settings that serve PWID." For the purposes of this section of the NOFO, "settings serving PWID" are venues serving persons with a high prevalence of injection drug use and include:

1. SSPs

2. SUD treatment programs
3. Hospital-based programs (emergency department visits or hospital admissions among PWID)
4. Correctional settings
5. Other settings with demonstrably high prevalence of people with a history of current or past injection drug use.

Recognizing the importance of tailoring local approaches, this funding supports local or jurisdiction-wide partnerships to deliver the PWID service bundle in settings serving PWID according to the needs of the jurisdiction. Participating settings should have:

1. Specialized experience and capacity for reaching PWID,
2. Ability to deliver the "PWID service bundle", and
3. Systems to track baseline data on access to services and improvement in service delivery during the intervention.

"PWID service bundle." For the purpose of this section of the NOFO, a "PWID service bundle" is defined as a list of services designed to prevent, mitigate or treat infectious complications of injection drug use.

PWID service bundle should include access (directly or through referral) to the following components:

1. Sterile injection paraphernalia sufficient for all injections. High coverage needle-syringe exchange, or provision of sterile injection paraphernalia sufficient for all injections, coupled with needle and syringe disposal services. High coverage needle-syringe exchange is associated with reductions in transmission of hepatitis C and HIV and can be offered in SSPs and multiple other settings. Needle and syringe disposal programs are associated with reduced syringe litter in the community. For further information, see: https://www.cdc.gov/ssp/index.html.
2. Assessment for OUD and MAT for those with known OUD. SUD is a brain disease that affects behavior and leads to an inability to control the use of a legal or illegal drug or medication even in the face of significant harmful effects. Treatment varies depending on the substance. Medication for OUD, also called MAT, is effective in reducing death from overdose and transmission of infectious diseases such as HCV and HIV. For information, see: https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview.
3. Naloxone and naloxone training. Naloxone is prescribed for persons with OUD, their friends, family and companions for use in the event of an opioid overdose, typically through a low-threshold standing order. For information on naloxone and naloxone training, see: https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone
4. Testing for HCV, HBV and HIV.
   For guidelines:

   HCV guidelines: https://www.hcvguidelines.org/. Briefly, "Annual HCV testing is recommended for PWID with no prior testing, or past negative testing and subsequent

injection drug use. Depending on the level of risk, more frequent testing may be indicated."

HBV guidelines: https://www.aasld.org/sites/default/files/2019-06/HBVGuidance_Terrault_et_al-2018-Hepatology.pdf and https://www.cdc.gov/hepatitis/hbv/HBV-RoutineTesting-Followup.htm . Briefly, PWID with unknown HBV status should be tested for anti-HBs, anti-HBc and HBsAg and simultaneously receive the first dose of hepatitis B vaccine. They should complete the vaccination series if susceptible.

HIV testing: https://www.cdc.gov/HIV/Basics/index.html and https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm. Briefly, PWID not known to be HIV positive should have HIV testing on an annual basis.

5. Vaccination for hepatitis A and B
   For guidelines:

   Hepatitis A vaccine: https://www.cdc.gov/hepatitis/hav/havfaq.htm#vaccine. Briefly, all PWID should be offered hepatitis A vaccine.

   Hepatitis B vaccine: https://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#vaccFAQ . Briefly, all susceptible PWID should be offered hepatitis B vaccine.

6. Treatment for infectious diseases (viral, bacterial and fungal)

   For guidlines:

   HCV: https://www.hcvguidelines.org/. Briefly, hepatitis C treatment is recommended for all persons with acute or chronic HCV infection and "active or recent drug use or a concern for reinfection is not a contraindication to HCV treatment."

   HBV: https://www.aasld.org/sites/default/files/2019-06/HBVGuidance_Terrault_et_al-2018-Hepatology.pdf. Briefly, all persons with chronic HBV infection should be followed indefinitely by a knowledgeable physician.

   HIV: https://aidsinfo.nih.gov/guidelines. Briefly, antiretroviral therapy (ART) is recommended for all persons with HIV to reduce morbidity and mortality and to prevent the transmission of HIV to others.

7. HIV pre-exposure prophylaxis (PrEP) for PWID testing negative for HIVFor guidelines: (https://aidsinfo.nih.gov/guidelines

Implementation of "PWID service bundle" in settings serving PWID include:

- Formation of a project management team or coalition with representation from settings that serve PWID, including front-line staff, persons with lived experience, experts/consultants/champions, if applicable, and other relevant stakeholders to oversee the project and offer stakeholder input through the life of the project.
- In collaboration with project management team or coalition, rapid assessment of:
  - Numbers of visits per year from PWID in each participating setting that serves PWID,
  - Baseline data, if available, on access of PWID clients to service bundle,
  - Existing data on health outcomes (morbidity and mortality) associated with injection drug use in the service area for the project, and

    - Collective resources and expertise.
- Development of a service delivery model. Service delivery models should be selected based on the needs of the PWID clients, the staff in collaborating settings serving PWID and the surrounding community. Two of the more effective models are presented here:
    - Service integration or "one stop shop." In this patient-centered model, all needed services are available in the same location, preferably delivered by the same patient care team. See:
        - doi 10.1007/s11904-018-0396-x or
        - https://www.thenationalcouncil.org/integrated-health-coe/ or
        - https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-hcv-pwid-guide.pdf, chapter 17.
    - Patient navigator or peer navigator – patient navigators are trained community health workers who serve as patient advocates and help PWID clients make and attend appointments, maintain adherence to treatment plans, interface with healthcare staff to better understand treatment recommendations and communicate needs, etc. Peer navigators are patient navigators with lived experience. See https://www.aidsunited.org/data/files/Site_18/PeerNav_v8.pdf

- Based on rapid assessment, prioritization of initial element(s) of the PWID bundle for implementation, with supporting development of:
    - Plans for staff training and/or requests for technical assistance
    - Standing orders, nurse-driven protocols, etc.
    - Patient and staff educational materials
    - Evaluation plan to track implementation
    - Plans to report cases of reportable infections to the jurisdictional health authority
- Establishment of ongoing process to continually:
    - Evaluate needs and progress and health outcomes in the target population
    - Present status to project management team or coalition to determine next steps and adapt strategies according to data
    - Develop and implement plans to add service bundle components, as appropriate to deliver a complete PWID service bundle to target population.

Example Program Models

1. Example models of jurisdiction-wide partnerships in settings that serve PWID

1.a Jurisdiction-wide in SSPs. In this example, the jurisdiction forms a project management team with representatives of SSP leaders, front-line SSP staff, persons with lived experience and a coordinator affiliated with an integrated specialty clinic. The management team rapidly collects baseline data, develops a service delivery model and staged implementation plan with standardized protocols to add PWID bundle services in SSPs jurisdiction-wide. The management team meets to review progress and evaluation data and adjust the implementation plan accordingly.

1.b Jurisdiction-wide in SUD treatment facilities. In this example, the SUD treatment facilities deliver MAT for OUD and naloxone and naloxone training, but other elements of the PWID bundle are lacking. Jurisdictional leaders and SUD treatment facility leaders form a management team with representation from persons with lived experience. They review baseline data and develop an implementation plan focusing initially on infectious disease screening (HCV, HBV and HIV). The SUD treatment facilities develop capacity through their own staff or in collaboration with local medical providers to provide access to clinical hepatitis A and B vaccination and treatment for infectious diseases (viral, bacterial and fungal) either on-site or through referral. Because some clients are continuing to use injection drugs, the management team determines how to provide their clients with access to high coverage needle and syringe exchange, either directly through SUD treatment facilities or by referral. The management team meets regularly to evaluate progress and review options and needs for progressively adding additional bundle services.

2. Example model of community-specific partnerships of settings that serve PWID

2.a Community-specific, multi-agency. Based on epidemiologic data, the health department focuses efforts on a single community disproportionately impacted by high-risk drug use. Partners within the identified community include a large hospital, a correctional facility, an SSP, and several MAT providers. Health department and facility leaders form a management team with representation from persons with lived experience. They review baseline data, identify facility-specific gaps in the PWID services bundle, and work collaboratively to develop facility-specific implementation plans. The health department continues to convene partners to review data and resources, and to problem-solve to assure the success of the intervention.

3.2 Implement prevention services and interventions to address emerging issues related to drug use.

(3.2 Activities not funded in Y1)

- Maintain awareness of emerging issues related to drug use by monitoring Epi-X, MMWR, and scientific literature; and responding to reports and consultations from astute clinicians and other front-line staff within the jurisdiction.
- When an emerging issue is identified, identify, adapt or develop evidence-based educational materials for providers and patients to raise awareness and improve response about diagnosis, prevention and control.
- Disseminate materials and evaluate response.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

In order to achieve the goals of the project, recipients are required to collaboratively partner with CDC and other CDC-funded state and local health department surveillance and prevention programs such as, but not limited to, HIV, STD, immunization, public health emergency preparedness and response, healthcare associated infections, comprehensive cancer prevention programs, and injury prevention. Collaboration is also required between other state and local viral hepatitis grantees. Applicants should also describe collaborations with CDC's Center for Surveillance, Epidemiology, and Laboratory Services to implement hepatitis message mapping guide (MMG) and transition to HL7 based case reporting through NNDSS.

The goal of all collaborations should be to deliver integrated surveillance and prevention services to the jurisdiction, through good communication, collaboration and coordination with programs that have a similar mission and similar target populations. Security and confidentiality agreements may be required to share data between CDC-funded programs.

To document intended collaborations, including the purpose and nature of the collaboration, applicants are encouraged to file MOUs/MOAs, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov

Local health department applicants are required to submit a letter of agreement / MOU between the appropriate state and local health department delegating authority for surveillance to the local health department and detailing how surveillance data will be reported to CDC.

b. With organizations not funded by CDC:

Recipients are required to establish, build, and/or maintain other collaborative relationships consistent with the goals of the project. These collaborations include, but are not limited to, jurisdictional public health agency leadership; Governor-led commissions/initiatives for statewide action on the opioid crisis; state Medicaid and mental health or behavioral health agencies; state, regional and/or local correctional agencies; state/local harm reduction coordinators and harm reduction coalitions; professional associations representing provider and healthcare and mental health and substance use treatment organizations; tribal communities and tribal health providers; health advocates and persons with lived experience (viral hepatitis, SUD); academic medical centers, laboratories, provider champions, health systems and mental health and SUD treatment providers serving target populations; and state and local health departments and state and local public health associations. The purpose of the collaborations should include improved efficiency of surveillance and improved recommendations for the jurisdiction; improved surveillance and access to data and information; and improved engagement, communication and cross-collaboration among disparate agencies and providers who care for PWIDs and members of other focus populations identified by the jurisdiction.

Applicants are encouraged to file letters of support, as appropriate, name the file "Letters of support", and upload it as a PDF file at www.grants.gov .

If applying for Component 3 funding, relevant MOU(s), MOA(s), or letters of support are encouraged from proposed collaborating settings that serve PWID (such as SSPs, SUD treatment programs, hospitals, emergency departments and correctional settings) that will be providing

PWID bundle services and testing and reporting hepatitis C, HIV and hepatitis B cases to the applicant and from programs that will link PWID to care and treatment, as described in the logic model. Letter(s) of support from state or local harm reduction coalitions and other key stakeholders are also recommended.

2. Target Populations

While Components 1 and 2 are designed to be implemented jurisdiction-wide, recipients are nonetheless encouraged to target services to those populations most in need as defined by analysis of viral hepatitis surveillance data, or other appropriate sources of data including HIV surveillance data and data on morbidity and mortality related to SUD. Applicants may also use national or jurisdictional vulnerability analysis to identify geographic areas most at risk of hepatitis C and HIV outbreaks. Populations of focus for surveillance and prevention, diagnosis, and referral activities include: PWIDs, persons living with HIV, and persons served in high-impact settings (e.g. SSPs, SUD treatment facilities, correctional facilities, emergency departments, sexually transmitted disease clinics, and other settings that serve PWID). Applicants are encouraged to evaluate jurisdictional data to identify disparities by race, ethnicity, gender, risk behavior, geography, socioeconomic status, membership in tribal communities, birth country, birth cohort, and other factors.

Target populations for surveillance of hepatitis B also include: Asian and Pacific Islanders; and non-Hispanic Blacks. Target populations for hepatitis A surveillance include persons using drugs and persons experiencing homelessness.

For Component 3, applicants may focus jurisdiction-wide or in a smaller community. Applicants should evaluate HIV, hepatitis B and hepatitis C surveillance data and data on morbidity and mortality due to SUD to document the jurisdiction or a geographic area within the jurisdiction is disproportionately at risk for infectious disease consequences of drug use. Applicants may also use data on fungal and bacterial infections related to injection drug use, if available. Applicants should characterize size and other characteristics for the population(s) who are expected to receive services funded in Component 3. To the extent possible, the applicant should also characterize the target population currently receiving services in those settings serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.) that will collaborate with the grantee to expand services under Component 3.

a. Health Disparities

Health disparities in viral hepatitis are inextricably linked to a complex blend of social determinants that influence populations most severely affected by this disease. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic disadvantage. Social determinants of health affect disparities in viral hepatitis, HIV, STD and TB. Environmental factors such as housing conditions, social networks, and social support are also key drivers for acquisition and transmission of viral hepatitis, HIV, STDs, and TB. This NOFO supports efforts to improve the health of populations disproportionately affected by viral hepatitis by maximizing the health impact of public health services, reducing disease prevalence, and promoting health equity. See “Healthy People 2020” in this NOFO.

Applicants should use epidemiologic data to identify communities within their jurisdictions

disproportionately affected by viral hepatitis and other related diseases and plan activities to reduce health disparities and promote health equity.

Details of the health equity strategy and approach are outlined in the NCHHSTP Social Determinants of Health White Paper (https://www.cdc.gov/nchhstp/socialdeterminants/docs/SDH-White-Paper-2010.pdf) and updates on the approach are described in Public Health Reports special supplement (Dean HD, Williams KM, Fenton KA. From Theory to Action: Applying Social Determinants of Health to Public Health Practice. Public Health Reports. 2013;128(Suppl 3):1-4.).

iv. Funding Strategy

Total period of performance funding: Up to $341,020,000

Component 1 (Surveillance): up to $131,600,000 (Component 1 estimated at $11,600,000 in Year One)

Component 2 (Prevention): up to $126,670,000 (Component 2 estimated at $6,670,000 in Year One)

Component 3 (Special Projects): up to $82,750,000 (Component 3 estimated at $2,750,000 in Year One)

This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC's approach to evaluation and performance measurement strategy involves assessing the performance of the overall project (i.e., all grantees combined) and each individual grantee (jurisdiction), including quality of data, effective program implementation, and accountability of funds. This approach includes:

- Jurisdictions' contribution to overall project performance,
- How NOFO funds are being allocated and spent, and
- Progress towards achieving the intended performance objectives of the NOFO.

Program evaluation includes collection and analysis of program performance data submitted by grantees, tracking of key performance indicators and process indicators, review of required

reports, conference calls with grantees, and site visits. During the period of performance, CDC may partner with grantees on evaluation activities.

Data collection is used for program accountability, monitoring, evaluation and performance improvement. Data will include, but are not limited to, national viral hepatitis surveillance data submitted to CDC, and annual performance reports. Grantees will collect required quantitative and qualitative data in a CDC-approved format and submit to CDC, according to an established schedule and via CDC approved systems, subject to approval by Office of Management and Budget (OMB).

Applicants should include a data management plan (DMP) that is as complete as possible. The DMP may be submitted as a checklist, paragraph, or other format that addresses:

- A description of the data to be collected or generated in the proposed project;
- The standards to be used for the collected or generated data;
- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions for the protection of privacy, confidentiality, security, and intellectual property, or other rights;
- Statement of the use of data standards that ensure all documentation that describes the method of collection, what the data represent, and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified; and,
- Other additional requirements based on the program.

CDC does not have a standard format for DMP; applicants can review examples of DMP at:

- University of California: http://dmp.cdlib.org/
- USGS: http://www.usgs.gov/datamanagement/plan/dmplans.php
- ICPSR: http://www.icpsr.umich.edu/icpsrweb/content/datamanagement/dmp/plan.html

Findings will be systematically reviewed by CDC to identify challenges encountered by grantees, identify capacity-building assistance needs and actions needed to improve overall project performance, compare methods and outcomes across awardees to identify promising practices for dissemination during the period of performance, demonstrate the value of the NOFO (e.g., improved public health outcomes, effectiveness of key prevention strategies and activities), and contribute to the evidence base for NOFO strategies and activities. Data will also be used to produce surveillance reports, reports on project accomplishments, project feedback reports, fact sheets, and other monitoring and evaluation reports. Approximately three months after the grantee has submitted data to CDC, CDC will provide all grantees with a report that summarizes each grantee's performance. This report will be reviewed and discussed with the grantee by the project officer. Findings may also be reported at national conferences, online, in peer-reviewed journals and in other public forums.

Grantees will be expected to demonstrate progress toward achieving the intended short-term and intermediate outcomes that are bolded in the logic model. For each of the NOFO's eight program strategies (six required, including three contingent on funding; and two optional and contingent on funding), a list of outputs i.e., program activities, outcomes, and indicators is presented below.

Component 1 Core Viral Hepatitis Outbreak Response and Surveillance Activities

Required Measures

1.1 Develop, implement, and maintain plan to rapidly detect and respond to outbreaks for: hepatitis A, acute hepatitis B, acute hepatitis C

1.1.1 Established jurisdictional framework for outbreak detection and response

Measures

- 1.1.1.a A documented plan for responding to outbreaks of hepatitis A, hepatitis B, and hepatitis C infections.
- 1.1.1.b CDC is notified of outbreaks within 5 business days of identifying the outbreak.
- 1.1.1.c CDC is notified of all cases associated with an outbreak within 30 days of case investigation start date.

1.2 Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for hepatitis A, acute hepatitis B, acute and chronic hepatitis C.

1.2.1. Increased public health reporting of chronic and perinatal HCV and chronic HBV infection, and undetectable HCV RNA and HBV DNA laboratory results

Measure

- **1.2.1.a Jurisdiction receives reporting of all (positive/detectable, negative/undetectable) HCV RNA and HBV DNA results at the state or local health department.**

1.2.2 Improved monitoring of burden of disease and trends in hepatitis A, acute hepatitis B, and

acute hepatitis C infections

Measures

- 1.2.2.a Laboratories that perform viral hepatitis-related testing for the jurisdiction report a minimum of 95% of viral hepatitis-related test results to the state or local health department.
- 1.2.2.b A minimum of 85% of viral hepatitis lab results are entered into the jurisdiction's viral hepatitis surveillance database within 60 days of specimen collection date.
- 1.2.2.c A minimum of 90% of case reports of hepatitis A, acute hepatitis B, and acute hepatitis C are submitted to CDC by the health department within 90 days of case investigation start date.
- 1.2.2.d Case reports of hepatitis A, acute hepatitis B, and acute hepatitis C submitted to CDC by health departments are at least 90% complete for age, gender, race/ethnicity, county of residence, and outbreak status.
- 1.2.2.e Case reports of hepatitis A, acute hepatitis B, and acute hepatitis C submitted to CDC by health departments are at least 70% complete for risk factors.

1.2.3 Improved monitoring of burden of disease and outcomes in chronic hepatitis C infections

Measures

- 1.2.3.a A minimum of 90% of case reports of chronic hepatitis C are submitted to CDC by the health department within 90 days of case investigation start date.
- 1.2.3.b A minimum of 90% of case reports of chronic hepatitis C submitted to CDC are complete for age, gender, race/ethnicity, and county of residence.
- 1.2.3.c A minimum of 90% of case reports of chronic hepatitis C are included in a longitudinal surveillance registry, including longitudinal detectable and undetectable HCV-RNA test results.

1.2.4 Improved monitoring of hepatitis C continuum of cure (CoC) (Intermediate outcome)

Measures

- 1.2.4.a Jurisdiction reports data on hepatitis C continuum of care, consistent with CDC guidance (TBD 2020).

1.2.5 Improved development and utilization of viral hepatitis surveillance data reports (Intermediate outcome)

Measures

- 1.2.5.a Prepare and disseminate an annual viral hepatitis surveillance data report, including data on hepatitis C CoC, to support prevention programs and policies.

Component 1 Measures, Contingent on Funding

1.3 Systematically collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C

1.3.1 Improved monitoring of burden of disease and trends in perinatal hepatitis C

Measures

- 1.3.1.a By December 31st of each year, mother and child matches are ascertained from local/state health department vital records through the end of the prior year by linking all known births to mothers found in viral hepatitis surveillance data base.
- 1.3.1.b A minimum of 90% of case reports of perinatal hepatitis C submitted to CDC within 90 days of case investigation start date.
- 1.3.1.c A minimum of 90% of case reports of perinatal hepatitis C submitted to CDC are complete for age, gender, race/ethnicity, county of residence.
- 1.3.1.c A minimum of 90% of perinatal infant) hepatitis C case reports are linked with a maternal report.

1.3.2 Improved monitoring of burden of disease and outcomes in chronic hepatitis B (Intermediate outcome)

Measures

- 1.3.2.a A minimum of 90% of case reports of chronic hepatitis B submitted to CDC within 90 days of case investigation start date.
- 1.3.2.b A minimum of 90% of case reports of chronic hepatitis B submitted to CDC are complete for age, gender, race/ethnicity, county of residence.

1.3.3 Improved monitoring of hepatitis B CoC (Intermediate outcome)

Measures

- 1.3.3.a A minimum of 90% of case reports of chronic hepatitis B are included in a longitudinal surveillance registry, including longitudinal detectable and undetectable HBV DNA test results.
- 1.3.3.b Jurisdiction reports data on hepatitis B CoC, consistent with CDC guidance (TBD).
- 1.3.3.c Chronic hepatitis B data and hepatitis B CoC data are included in the annual summary of surveillance data.

Component 2 Core Viral Hepatitis Prevention Activities

Required Measures

2.1 Support viral hepatitis elimination planning and surveillance, and maximize access to testing, treatment and prevention

2.1.1. Increased state engagement with key stakeholders in viral hepatitis elimination planning

Measures

- 2.1.1.a Establishment and maintenance of a viral hepatitis elimination technical advisory committee (or coalition) with membership to support jurisdictional viral hepatitis elimination planning, with membership including representatives from public health, corrections, Medicaid, injury prevention services, substance use and mental health services, people with viral hepatitis lived experience, and healthcare provider and community-based organizations.
- 2.1.1.b Conduct at least two meetings per year of the viral hepatitis elimination technical advisory committee (or coalition).
- 2.1.1.c Development and maintenance of a viral hepatitis elimination plan with support from the technical advisory committee (coalition).

2.1.2 Increased commercial and hospital-based laboratories conducting HCV RNA reflex testing

Measures

- 2.1.2.a CLIA-certified laboratories that conduct testing for at least 80% of all anti-HCV results identified in the jurisdiction
- 2.1.2.b The proportion conducting HCV RNA reflex testing was assessed; feedback with

recommendations conducted.
- 2.1.2.c The jurisdictional viral hepatitis elimination plan addresses recommendations for increasing HCV RNA reflex testing.

2.1.3 Increased HCV and/or HBV testing in health care systems

Measures

- 2.1.3.a The top 5 highest volume health systems in the jurisdiction identified
- 2.1.3.b The proportion of health systems promoting routine HCV and HBV testing assessed; feedback with recommendations was conducted.

2.1.4 Increased healthcare providers trained in prescribing hepatitis C or hepatitis B treatment (Intermediate outcome)

Measures

- 2.1.4.a The jurisdictional viral hepatitis elimination plan addresses provider training in prescribing hepatitis C and hepatitis B treatment.

Required Component 2 Measures, Contingent on Funding

2.2 Increased access to hepatitis C and hepatitis B testing and referral to care in high-impact settings [sexually transmitted diseases clinics, corrections, SSPs, SUD treatment facilities, emergency departments; and homeless services for vaccination]

2.2.2 Increased awareness of infection status among people diagnosed with chronic HCV or HBV

Measures

- 2.2.2.a Jurisdiction established relationship with partners in high-impact settings to identify high priority facility/ies for expansion of testing for HCV and HBV in high-impact settings, stratified by setting type.
- 2.2.2.b Number of clients seen, stratified by setting type
- 2.2.2.c Number of clients screened for hepatitis C (anti-HCV), by setting type
- 2.2.2.d Number of clients positive for anti-HCV, by setting type
- 2.2.2.e Number of clients tested for HCV RNA, by setting type.
- 2.2.2.f Number of clients positive for HCV RNA, by setting type.
- 2.2.2.g Number of clients screened for hepatitis B, by setting type

- 2.2.2.h Number of clients positive for HBsAg, by setting type

2.2.3 Increased referral to treatment for people living with hepatitis C or hepatitis B

Measures

- 2.2.3.a Number of clients positive for HCV RNA referred to treatment, by setting type
- 2.2.3.b Number of clients positive for HBsAg referred to evaluation, by setting type

2.3 Improve access to services preventing viral hepatitis and other bloodborne infections among PWID

2.3.1 Increased utilization of SSPs among PWID

Measures

- 2.3.1.a Number of SSPs in the jurisdiction
- 2.3.1.b Number of SSP visits in the jurisdiction, stratified by SSP
- 2.3.1.c Number of unduplicated SSP clients in the jurisdiction, by SSP
- 2.3.1.d Mean (median) syringe coverage rates, by SSP

2.3.2 Increased referral of PWID to SUD treatment

Measures

- 2.3.2.1 Number of PWID referred to SUD treatment by SSPs in the jurisdiction, stratified by SSP

2.3.3 Increased receipt of hepatitis A and hepatitis B vaccination in high-impact settings

Measures

- 2.3.3.a Number of hepatitis A vaccination doses administered to clients in the high-impact settings, by setting
- 2.3.3.b Number of SSP clients in the high-impact settings who completed hepatitis A vaccination series, by setting
- 2.3.3.c Number of hepatitis B vaccination doses administered to SSP clients in the high-

impact settings, by setting
- 2.3.3.d Number of SSP clients in the high-impact settings who completed hepatitis B vaccination series, by setting

Component 3 (Optional) Special Projects: Prevention, Diagnosis, and Treatment related to the infectious disease consequences of drug use

(Contingent on funding)

3.1 Improve access to services for PWID in settings disproportionately affected by drug use:

3.1.1 Increased access to high coverage needle-syringe exchange by PWID

Measures

- 3.1.1.a Number of PWID served, stratified by setting serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.)
- 3.1.1.b Syringes distributed, by setting

3.1.2 Increased linkage to SUD treatment (including MAT among PWID with OUD)

Measures

- 3.1.2.a Number of PWID in settings serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.) who are linked to SUD treatment, by setting
- 3.1.2.b Number of PWID assessed for OUD, by setting
- 3.1.2.c Number of PWID with OUD, by setting
- 3.1.2.d Number of PWID with OUD who are linked to MAT, by setting

3.1.3 Increased HCV, HIV, and HBV testing among PWID

Measures

- 3.1.3.a Number of clients tested for anti-HCV in settings serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.), stratified by setting
- 3.1.3.b Number of clients screened (anti-HBc, HBsAg, anti-HBs) for HBV, by setting serving PWID

- 3.1.3.c Number of clients screened for HIV, by setting serving PWID

3.1.4 Increased linkage to treatment services among people with infectious complications (viral hepatitis, HIV, bacterial, fungal) of SUD

Measures

- 3.1.4.a Number of clients testing positive for anti-HCV, by setting serving PWID
- 3.1.4.b Number of clients positive for anti-HCV tested for HCV RNA, by setting serving PWID
- 3.1.4.c Number of clients testing positive for HCV RNA, by setting serving PWID
- 3.1.4.d Number of HCV RNA (+) clients linked to hepatitis C treatment, by setting serving PWID
- 3.1.4.e Number of clients testing positive for HBsAg, by setting serving PWID
- 3.1.4.f Number of HBV (+) clients linked to hepatitis B care, by setting serving PWID
- 3.1.4.g Number of SSP clients testing positive for HIV, by setting serving PWID
- 3.1.4.h Number of HIV (+) SSP clients linked to HIV treatment, by setting serving PWID
- 3.1.4.g Number of clients referred for treatment for bacterial or fungal infections, by setting serving PWID

3.1.5 Increased receipt of hepatitis B and A vaccination among PWID

Measures

- 3.1.5.a Number of hepatitis A vaccination doses administered to clients, by setting serving PWID
- 3.1.5.b Number of clients who completed hepatitis A vaccination series, by setting serving PWID
- 3.1.5.c Number of hepatitis B vaccination doses administered to clients, by setting serving PWID
- 3.1.5.d Number of clients who completed hepatitis B vaccination series, by setting serving PWID

3.1.7 Decreased new viral hepatitis, HIV and other infections (e.g., bacterial, fungal) among PWID (Intermediate outcome)

Measures

- 3.1.7.a Number of new confirmed acute hepatitis B cases reported among PWID in the jurisdiction
- 3.1.7.b Number of new confirmed acute hepatitis C cases reported among PWID in the jurisdiction

- 3.1.7.c Number of new confirmed HIV cases reported among PWID in the jurisdiction

3.1.8 Increased hepatitis C cure rates among PWID with hepatitis C infection (Intermediate outcome)

Measures

- 3.1.8.a Jurisdiction reports data on hepatitis C continuum of care for PWID in the jurisdiction, consistent with CDC guidance (TBD).

3.2 Implement prevention services and interventions to address emerging issues related to drug use

Measures may be developed as emerging issues identified.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP), if applicable, for accuracy throughout the lifecycle of the project. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the

Reporting Section of this NOFO.

CDC will offer supplemental program guidance at the time of funding and work with states during the first six months of funding to facilitate writing the Evaluation and Performance Management Plan.

The basic evaluation plan for each component must include:

- How key program partners will be engaged in the evaluation and performance measurement planning process,
- The type of evaluation(s) to be conducted, i.e. process and/or outcome measures,
- Key evaluation questions to be answered,
- Potential data sources, internal and external, for collecting appropriate evaluation and performance data,
- Specific performance measures which are identified for impact and effectiveness and timeline for completion,
- Performance measures which reflect activities proposed in the work plan,
- How evaluation findings will be used for continuous program and quality improvement, and
- How evaluation findings will be disseminated to stakeholders.

CDC will develop guidance for laboratory-based hepatitis C and B CoC in collaboration with a workgroup to include representation from jurisdictional health departments in the United States.

c. Organizational Capacity of Recipients to Implement the Approach

All applicants must demonstrate existing or forthcoming capacity to successfully execute all strategies and activities to meet program requirements. Ability to collaborate with partners and stakeholders is critical to achieving programmatic objectives for viral hepatitis surveillance and prevention. Applicants should describe health department infrastructure, mission, organizational structure, commitment to working effectively with technical advisory groups and stakeholders, and progress towards health department accreditation. Applicants should describe organizational technical capacity, including authority and ability to systematically collect viral hepatitis surveillance data from all reporting entities across the jurisdiction and from other jurisdictions as appropriate, access NNDSS and/or SAMS reporting systems, electronic laboratory reporting, surveillance, outbreak and emergency response, public health laboratory capacity, access to information technology services, and ability to assure data confidentiality.

Applicants should also describe fiscal, administrative, support and personnel services that will be responsible for supporting hepatitis program activities and personnel. Finally, applicants should describe physical space, computer, internet and phone access planned to be available to viral hepatitis staff.

Workforce Capacity

Applicants should describe health department strategies to recruit and retain a competent workforce and assure that workforce has access to continuing education and attendance at national conferences in order to grow and maintain expertise. Applicants should have strategies for ongoing assessment and monitoring of program activities to assure that they are meeting program performance standards and the needs of the population and external stakeholders.

Staffing and management

Applicants should describe key staff including program manager, principal investigator, surveillance and prevention coordinators, data manager/analyst, etc.; supply curriculum vitae and job descriptions for key positions, documenting any experience with viral hepatitis surveillance and prevention. It is anticipated that salaries and duties of staff will be shared across other programs within the health department. Applicants should describe how staff will communicate and collaborate within the hepatitis program, and with other health department programs such as immunization, HIV, STD, and injury prevention. Applicant organizations are required to submit an organizational chart for the agency and the hepatitis program staff showing relations with other CDC-funded programs within the health department.

Component 3

For optional component 3, applicants should clearly document capacity and commitment for ongoing long-term collaboration with settings serving PWID (SSPs, SUD treatment programs, hospitals, and/or correctional settings) in the jurisdiction to improve viral hepatitis diagnosis, treatment and prevention (hepatitis A and B vaccination and linkage to SUD treatment) services for PWID. Applicants should also describe current or proposed capacity to work with settings serving PWID to support collaborating settings that serve PWID to do rapid assessment and develop a plan for stepwise implementation of the PWID service bundle in targeted settings serving PWID. The applicant should consider documenting how other stakeholders, champions and partners in the jurisdiction will be able to support collaborating settings

d. Work Plan

Applicants are required to provide a workplan that provides both a high-level overview of the entire five-year period of performance and a detailed description of the first year of the award. The work plan should incorporate all NOFO-related program strategies and activities, and explain how all activities clearly align with logic model, outcomes and indicators from Evaluation and Performance Measurement section. A separate workplan is required for each component; each required strategy and activity should be clearly labelled. Failure to clearly label workplans may affect funding award.

Note: Post-award, proposed work plan activities may be adjusted in collaboration with CDC to better address the overarching goals of the project. If funding for Strategies 1.3, 2.2 and 2.3 is

awarded, CDC with work with recipients to finalize workplans for those strategies.

The applicant should address:

1. Five-Year Overview of Project (include narrative) (Applies to Components 1, 2 and (optional) 3)
    - Intended outcomes for the entire five-year period of performance

1. Year 1 Overview (include narrative) (Applies to Component 1, 2 and (optional) 3)
    - Intended outcomes for year one.

1. Year 1 Detailed Work Plan (include narrative) (Applies to Component 1, strategies 1.1, and 1.2; Component 2, strategy 2.1; and Optional Component 3, strategies 3.1 and 3.2)
    - Outcomes aligned with program strategies and activities
    - SMART objectives aligned with performance targets
    - Responsible party and timeline for implementation

An example of a workplan template follows; the jurisdiction may use any template that clearly links program activities to expected outcomes.

Number, Outcome	Strategies and Activities	Objectives	Performance target	Responsible person	Timeline

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

Monitoring may also include other activities deemed necessary to monitor the award, if applicable. After review of the first annual performance report, if the awardee is not conducting required recipient activities or not meeting process or outcome standards, CDC will provide or facilitate technical/capacity building assistance for program improvement. Recipients performing at a less than sufficient level to achieve program objectives within stated timeframes will be placed on a time-phased Programmatic Improvement Plan (PIP) developed by the CDC Project Officer/Project Consultant/Epidemiologist in collaboration with the awardee. The PIP is a comprehensive tool used to assist recipients to improve program performance through identifying factors contributing to less than sufficient performance and developing specific action steps to address areas in need of improvement. If placed on a PIP, the awardee will have an opportunity to document a plan of action to improve the performance of program activities. In subsequent budget periods, funding may be affected based on performance.

Monitoring and reporting activities are outlined in Chapter 2.01.101 of the HHS Grants Policy Administration Manual (GPAM) that assists grants management staff (e.g., grants management officers [GMOs] and specialists [GMS], and project officers) in the identification, notification, and management of high-risk recipients.

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

- Collaborate to ensure coordination and implementation of strategies to support the implementation of comprehensive viral hepatitis surveillance and prevention activities.
- Provide guidance and coordination to funded organizations to improve the quality and effectiveness of work plans, evaluation strategies, products and services, and collaborative activities with other organizations.
- Collaborate to ensure coordination and provide policy and program information for rapid dissemination and implementation.
- Work with recipients to identify and address capacity building assistance (CBA) and TA

needs that are essential to the success of the project.

- Provide access to training and TA that will strengthen staff capacity relevant to all required strategies and activities of the program.
- Provide guidance to the recipient and set standards on data collection, use, and submission requirements.
- Provide guidance and technical assistance in implementing the Hepatitis Message Mapping Guide (MMG) and facilitate collaborations with CSELS to transition to HL7 based case reporting to CDC through the NNDSS
- Provide technical advice in the development of systems to implement and advance CDC policies, initiatives and programs.
- Collaborate to ensure coordination and implementation of technical assistance services to state and local health department viral hepatitis program staff.
- Collaborate in assessing progress toward meeting goals/outcomes and in establishing measurement and accountability systems for documenting outcomes, such as increased performance improvements and best or promising practices.
- Provide guidance and coordinate with the recipient to improve the quality and effectiveness of the proposed program. This may include revision of the work plan, evaluation strategy, products and services, among others.
- Foster and support ongoing opportunities for networking, communication, coordination, and collaboration.
- Provide consultation in planning, operating, analyzing and evaluating viral hepatitis programs, including viral hepatitis elimination planning, CDC special initiatives, (e.g., program integration, viral hepatitis elimination, and program evaluation activities.)
- Monitor recipient program performance using multiple approaches, such as standardized review of performance, recipient feedback and other data reports, to support program development, implementation, evaluation, and improvement.
- Provide support and facilitate program collaboration with other CDC programs and HHS offices to enhance and improve integration of services.
- Assist in assessing program operations and in evaluating overall effectiveness of programs.
- Provide capacity building assistance where identified or as needed to the recipient.
- Collect and disseminate information, best practices, lessons learned, and evaluation results (e.g., through conferences, guidance, material development, webinars, data sharing publications, other social media, participation in meetings, committees, and working groups related to the cooperative agreement).
- Provide requirements and expectations for standardized and other data reporting and support monitoring and evaluation activities.

B. Award Information

1. Funding Instrument Type:	Cooperative Agreement CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.
2. Award Mechanism:	U51

U51. Health Planning Strategies/National Academy of Sciences Activities

3. Fiscal Year: 2020
4. Approximate Total Fiscal Year Funding: $21,020,000
5. Approximate Period of Performance Funding: $341,020,000

This amount is subject to the availability of funds.

Total period of performance funding: Up to $341,020,000

Component 1 (Surveillance): up to $131,600,000 (Component 1 estimated at $11,600,000 in Year One)

Component 2 (Prevention): up to $126,670,000 (Component 2 estimated at $6,670,000 in Year One)

Component 3 (Special Projects): up to $82,750,000 (Component 3 estimated at $2,750,000 in Year One)

This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

Estimated Total Funding: $341,020,000
6. Approximate Period of Performance Length: 5 year(s)
7. Expected Number of Awards: 58
Component 1: 58 awards

Component 2: 58 awards

Component 3: 10 awards

8. Approximate Average Award: $315,000 Per Budget Period
Component 1 (Surveillance): $200,000

Component 2 (Prevention): $115,000

Component 3 (Special Projects): $275,000

These amounts are subject to availability of funds.

9. Award Ceiling: $0 Per Budget Period

This amount is subject to the availability of funds.

1. Additional funds may become available during the five-year period of performance.

2. The funding amount of awards made in subsequent years will be based on the availability of funding.

For Component 3 (Special Projects):

3. Approximate Number of Awards: 10 (first year).

4. Additional funds may become available during the five-year period of performance.

5. The funding amount and number of awards for special projects (Component 3) in subsequent years will be based on the availability of funding.

6. Applications for special projects funding may be submitted annually during each year of the period of performance of this announcement.

10. Award Floor: $0 Per Budget Period

11. Estimated Award Date: 09/01/2020

12. Budget Period Length: 12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments

Additional Eligibility Category:

2. Additional Information on Eligibility

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

3. Justification for Less than Maximum Competition

This funding opportunity limits competition to state, county and city or township governments and their bona fide agents. These entities have the statutory authority to conduct viral hepatitis surveillance activities and to design, implement, and evaluate prevention programs and policies that impact communities. Also, the state health departments are the only entities required to receive reports of acute hepatitis B, acute hepatitis C, chronic hepatitis B, and perinatal and chronic hepatitis C from local health departments/jurisdictions and to notify (submit reported cases) CDC of reported cases. Eligible applicants are those who have the responsibility, authority, and ability to enforce laws, rules, or regulations pertaining to collecting and reporting of viral hepatitis surveillance data and those that have coordinated jurisdictional wide authority for viral hepatitis strategic planning for prevention and control activities at the state and local levels.

The statutory language under Section 318 of the PHS Act (42 U.S.C. Sections 247c) provides CDC with the opportunity to provide project grants to the States and, in consultation with the State Health Authority, political subdivisions for,

1. Sexually transmitted diseases surveillance activities, including the reporting, screening, and

follow-up of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

2. Case finding and case follow-up activities regarding sexually transmitted diseases, including

contact tracing of infectious case of sexually transmitted diseases and routine testing, including laboratory tests and follow-up systems;

3. Interstate epidemiologic referral and follow-up activities regarding sexually transmitted

diseases; and

4. Special studies or demonstrations to evaluate or test sexually transmitted disease prevention and

control strategies and activities as may be prescribed by the Secretary.

As such this statutory language applies to viral hepatitis given the hepatitis B virus is transmitted when blood, semen, or another body fluid from a person infected with the virus enters the body of someone who is not infected. Although infrequent, hepatitis C can also be spread through sex with an HCV infected person.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

Cost sharing or matching funds are not required for this program.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at https://www.sam.gov/SAM/.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number	1. Click on http:// fedgov.dnb.com/ webform 2. Select Begin DUNS	1-2 Business Days	To confirm that you have been issued a new

	System (DUNS)	search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number		DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter of Intent: **03/25/2020**

b. Application Deadline

Due Date for Applications: **05/11/2020** , 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.
Applications due 60 days after publication date.

Date for Information Conference Call

Call # 1: March 18, 2020 at 1:00 PM (Eastern Standard Time)

Call # 2: April 1, 2020 at 1:00 PM (Eastern Standard Time)

For conference line/bridge information, please reference link below:

https://www.cdc.gov/hepatitis/policy/FO-IntegratedHepSurvPrevFundingForHealthDepts.htm

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa)) /Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS. When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications. A letter of intent is requested, however, it's not required.

LOIs may be sent via U.S. express mail or email to:

Kimberly Calhoun, MBA

Division of Viral Hepatitis (DVH)

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road NE, Mailstop US 12-3, Atlanta, GA 30333

Telephone number: 404.639.3878

Email address: gyy8@cdc.gov

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package.
Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)
A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)
Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include **all** of the following headings (including subheadings): Background, Approach,

Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see https://www.cdc.gov/od/science/integrity/reducePublicBurden/.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)
Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to

carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data. Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.
Vital records data, including births and deaths, are used to inform public health program and

policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.
Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

Submit one budget, with funding details listed by component. Within components, specify the amount of funding for each strategy. Failure to clearly label budget narrative may affect funding award.

Keep in mind that funding is organized as follows:

- Component 1, Strategies 1.1 and 1.2 (Required)
- Component 1, Strategy 1.3 (Required, contingent on funding)
- Component 2, Strategy 2.1 (Required)
- Component 2, Strategies 2.2 and 2.3 (Required, contingent on funding)
- Component 3, Strategies 3.1 and 3.2 (Optional, contingent on funding)

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.

- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Intergovernmental Review

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372, which established a system for state and local intergovernmental review of proposed federal assistance applications. Applicants should inform their state single point of contact (SPOC) as early as possible that they are applying prospectively for federal assistance and request instructions on the state's process. The current SPOC list is available at: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

16. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed

Central identification number (PMCID) thereafter.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

Funds cannot be used to purchase drugs and/or vaccine. Awardees may not use funds to purchase sterile needles or syringes for drug injection.

Funds can be used to purchase hepatitis testing kits, laboratory equipment, and /or contracts in accordance with NOFO. Funds can be used to support SSPs consistent with guidance in this

NOFO if a Determination of Need is in place for the jurisdiction. See: https://www.cdc.gov/ssp/determination-of-need-for-ssp.html

Note that all activities funded under this NOFO must be in compliance with applicable anti-lobbying provisions. See Section 17, Funding Restrictions for further detail and links to applicable guidance.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:
https://www.cdc.gov/grants/additionalrequirements/ar-25.html

19. Other Submission Requirements

a. Electronic Submission:
Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.
https:// www.grants.gov/help/html/help/index.htm? callingApp=custom#t=
Get_Started%2FGet_Started. htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.
An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

   If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review
All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.
i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach
Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Approach Maximum Points:40

Component 1- **Core Viral hepatitis Outbreak Response and Surveillance Activities**

Evaluate the extent to which the applicant:

- Outlines the process for developing and implementing a jurisdictional framework for outbreaks; describes how stakeholders will be included in the process and how data will be used to document that a cluster or outbreak exists. **(5 points)**
- Describes how hepatitis A, acute hepatitis B, and acute and chronic hepatitis C case data will be systematically collected, analyzed, interpreted, and disseminated to characterize trends in disease, identify and describe affected and at-risk populations, support prevention programs and policies and public health interventions. **(10 points)**
- Describes process for developing hepatitis C continuum of cure (HCV CoC) using case surveillance data, mortality data and data on negative HCV RNA, how data will be obtained, analyzed, reported and shared with partners and stakeholders. **(5 points)**
- Describe plans for engaging staff and leaders in discussions about improved public health reporting of chronic hepatitis B and C, and perinatal C infections, detectable and undetectable HCV RNA and HBV DNA. **(5 points)**
- Describes how perinatal hepatitis C and chronic hepatitis B case data will be systematically collected, analyzed, interpreted, and disseminated to characterize trends in disease, identify and describe affected and at-risk populations, support prevention programs and practices and public health interventions. **(10 points)**
- Describes the process for developing hepatitis B continuum of care (HBV CoC) using case surveillance data, mortality data and negative HBV DNA, how the data will be obtained, analyzed reported and shared with partners and stakeholders. **(5 points)**

Component 2 – **Core Viral Hepatitis Prevention Activities**

- Demonstrates plans to increase stakeholder engagement and improved local partnerships, working towards developing a new or an enhanced viral hepatitis elimination plan **(5 points)**
- Presents outcomes that are consistent with the period of performance outcomes

described in the CDC Project Description and logic model **(5 points)**

- Demonstrates data-driven selection of high-impact settings including selection of at least one high-impact setting **(5 points)**
- Demonstrates that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the period of performance outcomes (20 points)
    - Demonstrates coordination and collaboration with key partners at state/local and federal level for guidance and technical assistance on ways to effectively communicate and educate policymakers about jurisdictions hepatitis B and hepatitis C prevention, surveillance, care, and treatment programs **(5 points)**.
    - Describes plans to increase laboratory capacity for reflex HCV testing and improve partnerships and education at health care organizations and community health centers to increase routine HBV and HCV testing **(3 points)**.
    - Demonstrates coordination and collaboration with other agencies and programs particularly HIV testing, opioid overdose prevention, immunization programs, SSP's, correctional agencies, hospitals, emergency department and viral hepatitis prevention programs-within their jurisdictions that are targeting the same population (PWID at risk for viral hepatitis) to meet goals of this project **(3 points)**
    - Describes plans to improve provider capacity, recruit and train additional primary care providers, throughout the period of performance, caring for the target population. **(3 points)**
    - Describes credible, achievable and evidence-based strategies and activities to increase: utilization of SSPs, testing for HBV, HCV and HIV, and linkage to prevention (SUD treatment and hepatitis B and A vaccination) and hepatitis B, hepatitis C and HIV treatment services and reduce health disparities and improve access to care among PWIDs **(3 points)**.
    - Clearly documents existing and intended collaborations. Include complete and signed MOA, letter of support and worksheet for health-center, SSP's partnership etc., if available **(3 points)**
- Presents a work plan that is aligned with the strategies. Activities, outcomes and performance measures in the approach and is consistent with the content and format proposed by CDC **(5 points)**

Component 3 Special Projects: **Prevention, Diagnosis, and Treatment Related to the Infectious Disease Consequences of Drug Use**

- Clearly outlines evidence the target population for Component 3 activities (i.e., the community for projects that will focus on multiple settings within a community or the jurisdiction for projects that will focus on specified setting(s) jurisdiction-wide) is disproportionately affected by drug use, including: data such as hepatitis B, hepatitis C, and/or HIV incidence and risk factors; data on morbidity and mortality related to SUD; trends in morbidity and/or mortality due to hepatitis B, hepatitis C, HIV, or related to

SUD ; and demographic and other descriptive data for affected persons. Optional data on bacterial and fungal infections among PWID may also be included **(5 points)**

- Clearly documents existing or intended collaborations with management team or coalition representing setting(s) serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.), including representation from leadership, front-line staff, persons with lived experience and other critical partners **(5 points)**
- For collaborating settings serving PWID, describes baseline service area; baseline services offered; and data on persons currently served. **(5 points)**
- Describes plans for rapid assessment to include number of persons served in participating settings, baseline data on access to PWID service bundle and review of outcome data (morbidity/mortality related to injection drug use and SUD) in the target population (**5 points**)
- Describes credible, achievable and evidence-based strategies and activities to increase: access toPWIDs. **(10 points)**
- Demonstrates that the proposed use of funds is an efficient and effective way to implement proposed strategies and activities **(5 points)**
- Presents a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach. **(5 points)**

ii. Evaluation and Performance Measurement Maximum Points:35

Evaluate the extent to which the applicant describes:

Component 1- **Core Viral Hepatitis Outbreak Response and Surveillance Activities**

- How key program partners will be engaged in the evaluation and performance measurement processes. **(3 points)**
- The type of evaluation to be conducted, expected monitoring and evaluation (M & E) activities, and key evaluation questions to be answered. **(10 points)**
- Available data sources and feasibility of collecting appropriate evaluation and performance measurement data, and specific details on data utilization and data sharing with participating providers. **(5 points)**
- Data management and analysis capacity for local use and for submission to CDC. **(5 points)**
- How evaluation findings will be used for continuous program and quality improvement. **(5 points)**
- How evaluation and performance measurement will contribute to development of the evidence base, where program strategies that lack a strong evidence base of effectiveness are being employed. **(4 points)**
- Willingness to collaborate with the evaluation team identified by CDC and tasked with additional evaluation of awardees' overall programmatic implementation of their project. **(3 points)**
-

Component 2- **Core Viral Hepatitis Prevention Activities**

- Shows/affirms the ability of jurisdiction to collect data on the indicators specified by CDC in the project description and presented by the applicant in their approach. **(10 points)**
- Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities. **(10 points)**
- Describes how performance measurement and evaluation findings will be reported and shared with stakeholders, including but not limited to SSPs, and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement. **(10 points)**
- Describe how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base. **(5 points)**

Component 3- **Special Projects: Prevention, Diagnosis, and Treatment Related to the Infectious Disease Consequences of Drug Use**

- Shows/affirms the ability of jurisdiction and collaborating settings serving PWID (SSPs, SUD treatment programs, hospitals, correctional settings, etc.) to collect data on indicators specified by CDC in the project description and presented by the applicant in their approach. **(10 points)**
- Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities. (**10 points)**
- Describes how performance measurement and evaluation findings will be reported, shared with stakeholders, including but not limited to settings serving PWID, providers and clients, and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement. **(10 points)**
- Includes a preliminary Data Management Plan (DMP). **(5 points)**

iii. Applicant's Organizational Capacity to Implement the Approach — Maximum Points:25

Evaluate the extent to which applicant:

Component 1- **Core Viral Hepatitis Outbreak Response and Surveillance Activities**

- Describes capacity to conduct activities funded by this announcement **(3 points)**.
- Describes viral hepatitis surveillance infrastructure at the state and local levels, including ability to collect and use electronic laboratory data and electronic medical/health records, capacity for performing laboratory tests, ability to manage case reports, and interpret and disseminate surveillance data; and reporting practices of local health departments that ensure completeness of case reporting. **(5 points)**
- Describes existing laws and/or regulations that mandate reporting for hepatitis A, acute and chronic hepatitis B, acute and chronic hepatitis C, perinatal hepatitis B, and where

applicable perinatal hepatitis C. Provide URL link(s) to the appropriate laws/regulations. **(2 points)**

- Describes experience and capacity to implement the evaluation plan **(5 points)**. If the evaluation plan has been previously implemented, describe implementation, barriers and facilitators to the success of the plan, and lessons learned.
- Describes the plan for staffing to support Component 1 to provide appropriate management and staff to achieve the project outcomes. **(10 points)**
    - Clearly define and describe staff roles and relevant experiences that will potentially contribute to the success of the overall project. An organizational chart that include positions and names of staff in the relevant positions should be included. Curriculum vitas should be provided for each staff person who is involved in the project

Component 2- **Core Viral Hepatitis Prevention Activities**

- Provides a staffing plan and project management structure that will be sufficient to achieve the project outcomes, and which clearly defines staff roles. Provides an organizational chart. **(5 points)**
    - Applicant must have staffing capacity to coordinate and /or conduct the activities and achieve the objectives of this NOFO
- Provide evidence of adequate partnership building and community engagement experience **(5 points)**
    - Demonstrates the ability to collaborate with partner organizations in high-impact settings to provide hepatitis B and C testing, targeting PWIDs (e.g., SSP's, correctional facilities, etc.)
    - Demonstrates the ability to collaborate with health care providers to deliver appropriate medical care for hepatitis B and hepatitis C infections.
- Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and to achieve the project outcomes. (**5 points)**
- Demonstrates current and planned collaboration between viral hepatitis surveillance and prevention to define target populations and high-impact settings and plan and evaluate the interventions **(5 points)**
- Demonstrates experience and capacity to implement the evaluation plan. **(5 points)**

Component 3- **Special Projects: Prevention, Diagnosis, and Treatment Related to the Infectious Disease Consequences of Drug Use**

- Demonstrates collaboration with settings serving PWID and other jurisdictional stakeholders who can support the project and provide technical assistance **(5 points)**
- Demonstrates relevant experience and capacity (management, administrative, and technical) to implement the activities and achieve the project outcomes. **(5 points)**
- Demonstrates current and planned collaboration between jurisdictional health department staff with responsibility to conduct surveillance and prevention programs for substance use disorder and viral, bacterial and fungal infectious disease complications of injection drug use to define the target population, support the rapid

assessment and planning process and evaluate the interventions **(5 points)**
- Demonstrates experience and capacity to implement the evaluation plan. **(5 points)**
- Provides a staffing plan and project management structure that will be sufficient to achieve the project outcomes and which clearly defines staff roles. Provides an organizational chart. **(5 points)**

Budget

A separate budget is required for each component in this NOFO. Provide a detailed budget and line-item justification for all operating expenses.

Within the budget for component 1, clearly mark expenses for required strategies (1.1 and 1.2) and required strategies that are contingent on funding (1.3).

Within the budget for component 2, clearly mark expenses for required strategy (2.1) and required strategies that are contingent on funding, (2.2 and 2.3).

All strategies for Component 3 are contingent upon funding and the budget should clearly reflect this.

Failure to provide budgets that reflect strategies that are to be funded with current funds and those that are contingent upon funding may jeopardize funding.

The budget should be consistent with the activities, objectives and outcomes of the project. The budget should address funds requested, as well as the applicant's in-kind or direct support. The budget and budget justification will be included as a separate attachment, not to be counted in the narrative page limit.

Although the budget is not scored, applicants should consider the following in development of their budget.

- The extent to which the budget is itemized for conducting the project and the justification is reasonable and consistent with stated objectives and planned program activities.
- If the applicant requests indirect costs in the budget, a copy of the indirect cost rate agreement is required.
- If the indirect cost rate is a provisional rate, the agreement must reflect a rate obtained

within the previous 12 months.
- The indirect cost rate agreement should be uploaded as a PDF file with "Other Attachment Forms" when submitting via Grants.gov.

c. Phase III Review

All three components will be reviewed and scored separately for a possible 100 points per component. Scores for Components 1 and 2 will be combined for an overall score of 200 points. This combined score will be used to determine funding levels for components 1 and 2.

As indicated, Component 3 will be reviewed and scored separately and that overall score will be used to determine funding levels, contingent upon funding.

For Components 1 and 2, CDC may fund out of rank order based on any of the following criteria, using the best data available at the time:

- Jurisdictions with the highest incidence and number of acute hepatitis B or hepatitis C;
- To maintain geographic diversity;
- To maintain racial/ethnic diversity;
- Jurisdictions with the highest prevalence of current hepatitis C infections among adults as reported by Rosenberg, et. al. 2018 (https://www.ncbi.nlm.nih.gov/pubmed/3064639); and/or
- Other published supporting evidence that is indicative of increases in hepatitis B or hepatitis C transmission, such as:
    - mortality data showing increasing deaths with hepatitis C and/or hepatitis B listed as an underlying or contributing cause of death,
    - mortality data showing increasing deaths due to drug overdose,
    - data from the Substance Abuse and Mental Health Services Administration showing high and/or increasing rates of injection drug use within the jurisdiction or etc.).

The most recent state-specific incidence data for highest hepatitis B and hepatitis C may be found at https://www.cdc.gov/hepatitis/statistics/2017surveillance/index.htm

For Component 3, CDC may fund out of rank order based on any of the following criteria, using the best data available at the time:

- Incidence of or risk factors for hepatitis B, hepatitis C or HIV;
- Morbidity or mortality related to SUD;
- Geographic diversity; and/or
- Racial and ethnic diversity

CDC will provide justification for any decision to fund out of rank order.

Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

09/01/2020

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.
Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.
The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2020

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access

AR-29: Compliance with EO13513 , & ldquo, ?Federal Leadership on Reducing Text Messaging while Driving?, October 1, 2009

AR-32: Appropriations Act, General Provisions

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report	No later than 120 days before	Yes

(APR)	end of budget period. Serves as yearly continuation application.	
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

• Performance measures and targets
• The frequency that performance data are to be collected.
• How performance data will be reported.
• How quality of performance data will be assured.
• How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
• Dissemination channels and audiences.
• Other information requested as determined by the CDC program.

Evaluation

• The types of evaluations to be conducted (e.g. process or outcome evaluations).

• The frequency that evaluations will be conducted.
• How evaluation reports will be published on a publically available website.
• How evaluation findings will be used to ensure continuous quality and program improvement.
• How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
• Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.
This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
    - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.

- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

For year two and beyond of the award, recipients may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The recipients must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

This report is due 90 days after the end of the period of performance. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov. Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.
For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www. fsrs.gov/documents /ffata_legislation_ 110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:
"Commodity" means any material, article, supplies, goods, or equipment;
"Foreign government" includes any foreign government entity;
"Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:
a. recipient name;
b. contact name with phone, fax, and e-mail;
c. agreement number(s) if reporting by agreement(s);
d. reporting period;
e. amount of foreign taxes assessed by each foreign government;
f. amount of any foreign taxes reimbursed by each foreign government;
g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

G. Agency Contacts

CDC encourages inquiries concerning this notice of funding opportunity.

Program Office Contact

For programmatic technical assistance, contact:

Kimberly Calhoun, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention

Component 1 - Surveillance

Ruth Jiles, PhD

Division of Viral Hepatitis (DVH)

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road NE, Mailstop US 12-3, Atlanta, GA 30333

Telephone number: 404-718-8557

Email address rxg0@cdc.gov

Or

Component 2- Prevention

Kimberly Calhoun, MBA

Division of Viral Hepatitis (DVH)

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road NE, Mailstop US 12-3, Atlanta, GA 30333

Telephone number: 404-639-3878

|Email address gyy8@cdc.gov

Or

Component 3

Hope King, PhD, MSPH

Division of Viral Hepatitis

1600 Clifton Road NE, Mailstop US 12-3, Atlanta, GA 30333

Telephone number: 404-718-8528

Email: hking@cdc.gov

Telephone: (404) 639-3878
Email: gyy8@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance,** contact:

Constance Jarvis, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
Constance Jarvis, Grants Management Officer

CDC Procurement and Grants Office

2920 Brandywine Road

Mail Stop K-14

Atlanta, GA 30341

Telephone: (770) 488-5859

Email: abq3@cdc.gov

Telephone: (770) 488-5859
Email: abq3@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.
Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

- Letters of Support
- Organization Charts
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

Required Attachments:

Organizational charts

Indirect Cost Rate, if applicable

Local health department applicants are required to submit a letter of agreement / MOU between the appropriate state and local health department delegating authority for surveillance to the local health department and detailing how surveillance data will be reported to CDC.

Optional Attachments / Strongly Encouraged:

Letters of support

MOUs / MOAs

Applicants may submit up to 10 pages for the "base" (subsections of the project description that the components share with each other, which may include background, target population, collaboration, health disparities, organizational capacity (include organizational capacity for each component)) and up to 10 pages for project narrative subsections that are specific to each component (Approach, Evaluation and Performance Plan, and Work Plan). Submissions must be single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.
Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see http:// www.cdc.gov/ grants/ additional requirements/ index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).
Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.
Assistance Listings (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.
Assistance Listings (CFDA) Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency
Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.
Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.
CDC Assurances and Certifications: Standard government-wide grant application forms.
Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).
Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.
Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.
Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.
Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.
Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http:// www.cdc.gov /grants /additionalrequirements /index.html.
DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.
Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.
Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented

appropriately and outcomes are achieved.
Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.
Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.
Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.
Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.
Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.
Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.
Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.
Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.
Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.
Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.
Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.
Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered

indirect costs.
Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf.
Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.
Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.
Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.
Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.
Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.
Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).
Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.
Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.
Outcome: The results of program operations or activities; the effects triggered by the program.

For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the

approved budget.

NOFO-specific Glossary and Acronyms

Activity -- actions mounted by the program and its staff to achieve the desired outcomes in the target groups. Typical program activities may include, among others, outreach, training, funding, service delivery, collaborations and partnerships, and health communication. Source: https://www.cdc.gov/eval/guide/step2/index.htm#matching

CLIA or Clinical Laboratory Improvement Amendments of 1988 -- regulations that include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. For more information, please refer to CLIA at 42 CFR 493.3. Demographic information about CLIA-certified laboratories is available here: https://www.cdc.gov/clia/LabSearch.html

Comprehensive SSP – Syringe services program (SSP) that provides sterile injection equipment, injection equipment disposal, naloxone and naloxone training, infectious disease screening and linkage to treatment, screening for OUD and linkage to MAT, and numerous other screening, prevention and treatment services for PWIDs. For information on SSPs, see: https://www.cdc.gov/ssp/index.html

ED – emergency department

Elimination – Hepatitis B and C elimination as a public health threat is defined as 90% reduction in new chronic infections and 65% reduction in mortality. Source: https://www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/

Harm Reduction Program – any program that serves PWID to reduce the harms associated with injection drug use; often used to refer to SSPs and MAT. See comprehensive SSPs and MAT.

HBV – hepatitis B virus

HCV – hepatitis C virus

Health systems -- organizations of people, institutions, and resources that deliver health care services to meet the health needs of target populations. The specific definition of a health care system evolves over time; example definitions are available on the Agency for Healthcare and Research Quality (AHRQ) website. https://www.ahrq.gov/chsp/chsp-reports/resources-for-understanding-health-systems/defining-health-systems.html

High coverage needle-syringe exchange – provision of sufficient sterile injection paraphernalia to cover all injections. High coverage needle-syringe exchange is effective in reducing transmission of HCV and HIV.

High-Impact Setting – setting such as SSPs) SUD treatment centers, correctional facilities, emergency departments, hospitals and sexually transmitted disease clinics serving persons with a high prevalence of injection drug use or hepatitis B, hepatitis C or HIV

HIV – human immunodeficiency virus

Indicator -- measurable information used to determine if a program is implementing their program as expected and achieving their outcomes. Source: https://www.cdc.gov/eval/indicators/index.htm

Integration of services --mechanism for organizing and blending interrelated health issues, activities, and services in order to maximize public health impact through new and established linkages across programs to facilitate the delivery of services. Integration delivers seamless services to clients in public health, medical and other settings. Source: https://www.cdc.gov/nchhstp/programintegration/about.htm

MAT – Medication-assisted treatment (such as buprenorphine, methadone, or naltrexone) or medications used to treat OUD. See: https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview

Naloxone – an injected or inhaled medication that rapidly reverses opioid overdose. See: https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone

NNDSS – a multifaceted program that includes an electronic surveillance system for collection, analysis, and sharing of health data. It also includes policies, laws, electronic messaging standards, people, partners, information systems, processes, and resources at the local, state, territorial, and national levels. Source: https://wwwn.cdc.gov/nndss/

Objectives -- Statements describing the results to be achieved, and the manner in which they will be achieved. Source: https://www.cdc.gov/std/Program/pupestd/Developing%20Program%20Goals%20and%20Objectives.pdf

Example of an objective: By {date}, {specify %} of syringe services programs in {target area} will offer opt-out testing for anti-HCV with reflex testing to HCV RNA.

OUD – opioid use disorder. A type of substance use disorder (SUD) related to dependence on opioid medication.

Outbreak – an increase, often sudden, in the number of cases of a disease above what is normally expected in a specified population, timeframe and geographic area. Source: https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html

Outcome -changes in someone or something (other than the program and its staff) that you hope will result from your program's activities. For programs dealing with large and complex public health problems, the ultimate outcome is often an ambitious and long-term one, such as eliminating the problem or condition altogether or improving the quality of life of people already affected. Source: https://www.cdc.gov/eval/guide/step2/index.htm#matching

Output -- direct products of activities, usually some sort of tangible deliverable. Outputs can be viewed as activities redefined in tangible or countable terms. For example, the affordable housing program's activities of engaging volunteers, recruiting sponsors, and selecting families have the corresponding outputs: number of volunteers engaged, number of sponsors recruited and committed, and number and types of families selected. Source: https://www.cdc.gov/eval/guide/step2/index.htm#matching

Patient Navigator - a person employed by an organization to facilitate access from one community-based organization to another, help clients address barriers to care and track referral outcomes. Patient navigators may be peers, social workers, outreach workers, or anyone who is familiar with the local landscape of community-based organizations and can support clients in accessing needed care.

Peer Navigator – a type of patient navigator who is also "a role model" with lived experience "and a shared community membership as the populations with which they work. Peers are

trained, often paid, professional staff members rather than volunteers. Their work includes case finding and community outreach; routine appointment reminder phone calls; accompaniment to appointments; transportation assistance; referrals and associated follow-up; and adherence education and support." Adapted from: AIDS United. Best Practices for Integrating Peer Navigators into HIV Models of Care.

Washington, DC. 2015. https://www.aidsunited.org/data/files/Site_18/PeerNav_v8.pdf

Policy surveillance -- ongoing, systematic collection, analysis, interpretation and dissemination of information about a given body of public health law and policy. Source: https://read.dukeupress.edu/jhppl/article/41/6/1151/40084/Policy-Surveillance-A-Vital-Public-Health-Practice

PWID – Persons who Inject Drugs

PWID Bundle – a group of services needed by PWIDs to prevent or mitigate health effects from injection drug use. Includes provision of sufficient sterile injection equipment to cover all injections, disposal of used injection paraphernalia, naloxone provision and training, assessment for OUD and linkage to MAT, screening and linkage to treatment for infectious diseases such as HCV, HBV, HIV, sexually transmitted infections, condoms, vaccination for hepatitis B and C, PrEP for HIV. The bundle can also include patient-centered reproductive care including access to long-acting reversible contraceptives.

SAMS – Secure Access Management System, a CDC-managed secure portal for exchange of public health information.

Services for persons who inject drugs – programs designed to treat, prevent and manage health outcomes associated with injection drug use and /or SUD, such as SSPs, SUD treatment programs, etc.

Settings serving PWID—settings serving PWIDS include SSPs, substance use disorder (SUD) treatment centers, correctional facilities, emergency departments and hospitals. Any venue with a demonstrably high prevalence of PWID clients is defined as a "setting serving PWID."

SMART Objectives – Objectives that are Specific (concrete, detailed, and well defined so that you know where you are going and what to expect when you arrive); Measurable (numbers and quantities provide means of measurement and comparison); Achievable (feasible and easy to put into action); Realistic (considers constraints such as resources, personnel, cost, and time frame); and Time-Bound (A time frame helps to set boundaries around the objective) Source: https://www.cdc.gov/phcommunities/resourcekit/evaluate/smart_objectives.html

SSP – Syringe Services Program. See also "Comprehensive SSP."

SUD -- Substance use disorder. Substance use disorders occur when the recurrent use of alcohol and/or drugs causes clinically significant impairment, including health problems, disability, and failure to meet major responsibilities at work, school, or home. https://www.samhsa.gov/find-help/disorders Also see: https://www.mayoclinic.org/diseases-conditions/drug-addiction/symptoms-causes/syc-20365112

Target population -- group(s) of persons disproportionately affected by hepatitis B and/or C (e.g. racial/ethnic minorities, persons with low socio-economic status, PWID). For Component 3, target populations can also be defined as populations disproportionately affected by injection drug use. See "Target Populations" in this NOFO.

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