February 19, 2020

Dear Colleagues,

APHL would like to provide some brief guidance to assist you as you engage with your eligible state, local and/or territorial health departments (or their Bona Fide Agents) that are eligible for Phase I of the Ending the HIV Epidemic Initiative as they submit their applications for the recently released CDC-RFA-PS20-2010: Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States. The application is due March 25, 2020 and the estimated award date is June 1, 2020.

If you are not familiar with the HHS Ending the HIV Epidemic: A Plan for America (EHE), this initiative focuses on reducing new HIV infections in the US by 90% by 2030. In the 2020 federal appropriations, CDC received $140 million dollars to support the EHE efforts, of which $109 million is being disbursed through the above mentioned Notice of Funding Opportunity (NOFO) to enable jurisdictions to implement comprehensive HIV programs targeting the populations most impacted by HIV. The EHE initiative has 4 pillars, with the first being “Diagnose” followed by Treat, Prevent and Respond. These pillars rely on effective testing and reporting of results, something our members are well equipped to provide and/or support. Whether the testing is performed in the public health laboratory (PHL), commercial laboratories, or through rapid testing or other mechanisms, the PHL can and should play an instrumental role in helping health departments and jurisdictions meet their larger goals of reducing new HIV infections. We encourage all PHLs to review the information enclosed and the NOFO on which this is based, and to initiate or further conversations with your health department’s HIV program about how you can either directly support (testing in your PHL) or indirectly support their efforts (helping to ensure quality testing is being performed elsewhere).

If you have any questions please feel free to reach out via phone or email.

Sincerely,

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Summary of PS20-2010 Components

Component A: Ending the HIV Epidemic Initiative (Core Component) – 5 year Performance

- **32 Awards**: a minimum of $1.8 million per funded jurisdiction; funding will be determined by formulas reflecting a base funding amount based on HIV disease prevalence, number of counties within the health department jurisdiction (if applicable), and program performance (in subsequent years). Funding will vary by jurisdiction.

- **Eligible applicants**: Eligible applicants include state, local, and territorial health departments or their Bona Fide Agents identified in Phase 1 of the Ending the HIV Epidemic (EHE) Initiative and that have a current direct funding relationship with CDC. Eligibility for funding to implement the above described program is contingent upon the existence of a comprehensive EHE plan, which are currently under development in each of the eligible jurisdictions. The plans, which are due this summer, will inform the strategies deployed for each of the pillars. (Note: If the PHL is not already engaged in or aware of the planning process this would be a good time to engage with your partners)

- **Goal**: This component is intended to build on the on-going activities funded through PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments to strategically advance (i.e., initiate or expand) HIV prevention efforts. The included strategies and activities were selected to maximize the ability of Phase 1 jurisdictions to achieve the EHE initiative goal of reducing all new infections by 75% in 5 years; focus efforts around the EHE four pillars; and facilitate transfer of knowledge and best practices from the Phase 1 jurisdictions to other jurisdictions so that the EHE goal of reducing all new infections by 90% can be achieved by 2030.

Component B: HIV Incidence Surveillance- 4 years (beginning in Year 2)

- 8 Awards (Starting Year 2); with an average yearly award of $450,000-$725,000-funding begins in Year 2 (tentative, actual funding and plans are dependent on actual funding allocations received by CDC for Year 2)

- **Eligible applicants**: Eligibility is based on a number of factors including EHE geographic focus area with >300 new HIV diagnoses annually, reliable incidence estimates from the CD4-based model and previous success in implementing recency assay-based HIV Incidence Surveillance. The eligible jurisdictions based on those criteria are: Alabama, Florida, Michigan, South Carolina, District of Columbia, Houston, New York City and Texas

- **Goal**: This component will assess HIV incidence using a recent infection testing algorithm (RITA) and testing, clinical and other data collected by surveillance from persons newly diagnosed with HIV.

Component C: Scaling Up HIV Prevention Services in STD Clinics- 5 years

- 5-8 Awards ; with an average yearly award of $400,000-$800,000

- **Eligible applicants**: Only jurisdictions eligible for Component A of this NOFO, PS20-2010, can apply for Component C. Applicants must demonstrate that the proposed STD specialty clinic has the following services available onsite: STAT syphilis test, microscope for STAT
• **Goal:** The focus of this component is to: strengthen infrastructure and enhance and scale up quality HIV prevention services in STD specialty clinics; increase the number and percentage of STD clinic visits in which patients who are diagnosed with an acute STD and are not known to be HIV-infected are tested for HIV; increase uptake of PrEP/nPEP for those with acute STDs and are vulnerable for acquiring HIV infection; establish cost effective models for PrEP/nPEP services; and optimize linkage to, retention in, and re-engagement in HIV care and prevention services for patients who are HIV-positive and not in care or not virally suppressed.

**Potential Role of PHLs by PS20-2010 Component**

*Items in italic font below are taken directly from the NOFO and serve as support for the bulleted points provided by APHL above them.*

**Component A: Ending the HIV Epidemic Initiative (Core Component)**

**General Items**

• Reach out to your health department HIV program to determine how the PHL can coordinate, contribute, or otherwise participate in implementing their comprehensive elimination plans.
  - Applicants are strongly encouraged to coordinate with partners including… “STD, viral hepatitis, and TB programs… laboratory units… STD and TB clinics…” to implement their comprehensive HIV programs. (pg. 8)

• Advocate to participate in EHE planning or coordinating activities, such as an EHE Advisory Group/Committee in your jurisdiction
  - Funding recipients are required to establish a new or expand an existing EHE advisory group or ad-hoc committee (pg. 8)

• Discuss with your health department’s HIV program how the PHL can support integrated screening activities and diagnosis for STDs in uninsured and underinsured persons (pg. 8)
  - Note: Applicants are eligible to use up to **10%** of the approved total funding amount to: 1. enhance and expand integrated screening activities (e.g., screening for STDs, viral hepatitis, and/or TB), conducted in conjunction with HIV testing, with accompanying referral for prevention and care services; and/or 2. diagnose and treat STDs for uninsured or underinsured people receiving care in not-for-profit or governmental clinics, when conducted in conjunction with HIV testing and provided that these facilities document their ability to provide safety-net STD clinical preventive services as per CDC guidance. At a minimum, clinics receiving assistance should have the capacity to rapidly diagnose and treat bacterial STDs. (pg. 8-9)

• Discuss how funding from this opportunity could support improved ordering and reporting systems in the PHL to benefit submitters and surveillance programs.
  - Moreover, HIV surveillance provides data critical to monitoring the success of efforts to end the HIV epidemic. In accordance with existing surveillance standards, recipients should strengthen HIV surveillance systems, **including developing secure means for**
timely and accurate reporting of HIV diagnoses and other HIV-related laboratory test results (within two months of the specimen collection date) for assessment of patient needs to maximize real-time linkage to partner services, care, and essential support services. This is a mandatory program requirement and jurisdictions cannot opt out of this program requirement. Failure to implement and maintain comprehensive collection and reporting of HIV laboratory data will result in the restriction of funds.

Strategy 1: Diagnose all people with HIV as early as possible (pg 11-12)

- Discuss with the health department the role of the PHL in performing HIV testing and/or how the PHL can support agencies providing testing services in assuring appropriate and quality testing methods, such as through providing training, tools, or technical assistance.

Strategy 1A: Expand or implement routine opt-out HIV screening in healthcare and other institutional settings located in high prevalence communities

- Discuss with the health department the role of the PHL in performing HIV testing and/or how the PHL can support screening in healthcare and other institutional settings, including selection and use of appropriate test strategies and implementation of methods to assure high quality testing. This could take the form of providing confirmatory testing for point of care testing performed in clinical settings or for clinical facilities, such as STD clinics, which are performing testing in a STAT laboratory, proficiency testing, education of testing or laboratory staff, and technical assistance as needed.

Strategy 1B: Develop locally tailored HIV testing programs to reach persons in non-healthcare settings

- Discuss how the PHL can partner with the health department HIV program and providers of testing in non-healthcare settings to determine appropriate tests and assure and/or improve the quality of testing. This could take the form of offering information and consultation on test selection, or providing confirmatory testing, proficiency testing, training, education, and technical assistance as needed.
  - Collaborate with laboratories to determine appropriate tests and improve the quality of testing in non-healthcare settings. (pg. 12)

Strategy 1C: Increase at least yearly re-screening of persons at elevated risk for HIV per CDC testing guidelines, in healthcare and non-healthcare settings

- Assist the health department HIV program with an evaluation of the currently available testing infrastructure (PHL, clinical laboratories, or non-clinical facilities) to determine whether there are currently systems in place, or whether with infrastructure or workflow/system upgrades, there could be improvements to annual re-screening efforts.
  - Establish systems whereby patients with elevated risk are routinely identified and HIV tests are ordered at least yearly. In some settings, annual screening of all patients could be considered. (pg. 12)
- Discuss with the health department HIV program how the PHL can support or expand a rapid self-test program including ensuring that the method used meets regulatory requirements for
laboratory testing, and identifying how confirmatory or follow-up testing will be performed to maximize the efficiency of this approach.

Strategy 2: Treat people with HIV rapidly and effectively to reach viral suppression

Strategy 2A: Ensure rapid linkage to HIV medical care and antiretroviral therapy (ART) initiation for all persons with newly diagnosed HIV

Strategy 2B: Support re-engagement and retention in HIV medical care and treatment adherence, especially for persons who are not recipients of Ryan White HIV/AIDS Programs

- Evaluate and determine what services or support your PHL could offer, such as viral load testing and or genotyping that could help support rapid linkage to clinical care, and timely reporting of HIV diagnoses to the health department. If appropriate, discuss further with your health department HIV program.

Strategy 3: Prevent new HIV transmission by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs)

Public Health Laboratories should review testing that is recommended for persons prior to PrEP enrollment as well as monitoring (every 3 months) while on PrEP to determine the extent to which it may be feasible and value added if performed in the PHL to support this strategy. Further details can be found in the Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update Clinical Practice Guideline, but a shortened summary is provided below:

1. HIV Testing (documented negative test result and no signs/symptoms of acute HIV infection), prior to prescribing PrEP and every 3 months while taking PrEP
   a. Ideally an HIV Ag/Ab test conducted in a laboratory
2. Hepatitis B Virus: documented HBV infection status and vaccination status
3. Hepatitis C Virus (risk group dependent): testing is recommended for persons who have ever injected drugs and as a baseline laboratory test for MSM prior to initiating PrEP, further recommendations on frequency of testing while on PrEP are not included in the CDC Guidance
4. Renal Function (estimated creatinine clearance): documented renal function, prior to starting PrEP, after 3 months and every 6 months after
5. Bacterial STIs (syphilis, gonorrhea and chlamydia): assess for STI symptoms and test for bacterial STIs at initiation for PrEP and every 3-6 months including testing extra genital sites (oral and pharyngeal) if applicable.

Strategy 3A: Accelerate efforts to increase PrEP use, particularly for populations with the highest rates of new HIV diagnoses and low PrEP use among those with indications for PrEP.

- Discuss with the health department HIV program how the PHL can play a role in supporting scale up and/or expansion of PrEP by performing testing needed to initiate and/or monitor PrEP and/or how the PHL can help ensure appropriate and quality testing methods are being utilized by agencies delivering PrEP services
- **CDC funds may be used for laboratory costs for screening or monitoring PrEP per CDC Guidelines for uninsured or underinsured people receiving PrEP in not-for-profit or governmental clinics (pg. 15)**

**Strategy 3B: Increase availability, use, and access to and quality of comprehensive Syringe Services Programs (SSPs)**

- Discuss with the health department HIV program the role of the PHL in scaling up/or expanding SSP services by performing testing for SSP clients, and/or how the PHL can help ensure appropriate and quality testing methods are being utilized in this setting as persons seeking services at SSPs should be offered/have access to infectious disease testing including: HIV, HAV, HBV, and HCV, syphilis, gonorrhea, and chlamydia as well as testing for PrEP onboarding.
  - **Ensure that SSPs provide clients with the following standard services: needs-based access to sterile needles and syringes and other injection equipment (e.g., sterile water, cookers), condoms, syringe disposal, HIV and HCV testing, linkage to HIV and HCV care, linkage to PrEP, naloxone distribution, and linkage to medication-assisted treatment (pg. 16).**
  - **Ensure that SSPs have the following additional services provided directly to clients or available through formal, active referral arrangements facilitated by patient navigators: Infectious disease prevention, detection, care, and treatment; including HIV, viral hepatitis (HAV, HBV, and HCV), sexually transmitted infections (syphilis, gonorrhea, and chlamydia) and wound care (pg. 16).**

**Strategy 4: Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them**

**Strategy 4A: Develop partnerships, processes, data systems, and policies to facilitate robust, real-time cluster detection and response**

- Advocate to participate in EHE planning or coordinating activities, such as an in your jurisdiction to guide cluster/outbreak response. The PHL can serve as an important ally and partner in helping to educate stakeholders internally and externally and could potentially assist with analyzing molecular surveillance/cluster investigations and/or offer bioinformatics support. If your laboratory is contributing data to cluster investigations (diagnostic testing, genotyping etc.) the role of the PHL is that much clearer in this role.
  - **Establish new or expand an existing standing committee that meets routinely to guide cluster response (pg. 17).**

**Strategy 4B: Investigate and intervene in networks with active transmission**

- PHLs serve a critical role in outbreak responses through already established relationships with the HD HIV program, and can provide timely and potentially prioritized testing for persons that are linked to a cluster/outbreak investigation. This testing could include HIV, HCV, HBV, and other STDs to support linkage of cases, and/or for rapid start ART and/or PrEP.
Provide linkage to critical services to network members. Prioritize network members for enhanced linkage to services including: testing and future re-testing for HIV, HCV, HBV, and STDs; PrEP; SSPs; HIV medical care; including rapid start of ART and PrEP; and other essential support services (e.g., housing, social services) (pg. 17).

Strategy 4C: Identify and address gaps in programs and services revealed by cluster detection and response

- Assess whether the PHL can provide any additional support: directly through testing, or consultation, education, or technical support to address any gaps in programs or services for cluster detection and response, and share that information with the health department HIV program.

Component B: HIV Incidence Surveillance (Optional)- Begins in Year 2

The focus of this component is on surveillance and recency. PHLs can consult with the health department HIV program if there are approaches that they can partner on, but the testing will take place in a centralized laboratory that has not yet been identified. One of the items that the PHL might be asked to assist with is providing remnant specimens for further testing. Further details on this component can be found in the NOFO.

Component C: Scaling Up HIV Prevention Services in STD Clinics (Optional)

If a jurisdiction applies for component C they must address all strategies and activities described in the NOFO.

Strategy C1: Conduct assessment of the clinic infrastructure to document HIV and STD prevention services, identify gaps, and assess service quality

- Discuss with HD how the PHL could offer technical and operational expertise, including consultation, education, and treating, to achieve the goals of strategy C1.
- There are several specific items mentioned in the NOFO (below) that involve assessing laboratory capacity, identify new testing strategies, and improving capacity for certain testing approaches the PHL could support and/or assist the HD HIV program with evaluating.
- PHLs can provide expertise, and technical or training assistance necessary for establishing, expanding, or improving point-of-care testing, specimen self-collection and other approaches by ensuring that the method(s) and approaches meet regulatory requirements for laboratory testing, identifying how confirmatory or follow-up testing could be performed, how to implement appropriate and sufficient QA/QC, and to maximize the efficiency of any of these approaches.
  - Clinic and laboratory components may include management, physical structure, supply systems, technical equipment, information technology (including electronic health records), clinical services, staffing and organizational structure, and data (pg. 22)
Identify new testing and prevention strategies (e.g. STD specimen self-collection, express STD testing services, viral load testing comprehensive sexual health services including HCV screening and HBV, HAV and HPV vaccination) and wrap around follow-up services for PrEP patients, if applicable to the clinic (pg. 22).

Assess existing ancillary and laboratory service capacity including specimen self-collection, POC testing, and rapid turnaround time for results, and, if necessary, establish agreements for laboratory services (pg. 22).

Strategy C2: Implement evidence-based approaches to scale up capacity, sexual risk assessments, self-collected STD testing and treatment, and HIV testing and viral load assessment.

- PHLs could help the health department and/or STD clinic setup appropriate protocols for self-collection, ensuring that the samples collected would be able to be tested by the laboratory (i.e. self-collected specimens have been validated for the method being used) as well as identifying workflows for HIV testing and viral load assessment as needed.

Strategy C3: Expand the capacity of STD clinics to offer PrEP, nPEP, and strengthen clinic and laboratory capacity for recommended follow-up visits for individuals.

- Discuss with the health department HIV program the role of the PHL in helping strengthen clinic and laboratory capacity for PrEP onboarding and/or how the PHL can help ensure appropriate and quality testing methods are being utilized. See Strategy 3 for more information on testing for PrEP implementation and expansion.

Strategy C4: Optimize linkage to, retention in, and re-engagement with HIV medical care

- Evaluate and determine what services or support your laboratory could offer that would support rapid linkage to clinical care, and timely reporting of HIV diagnoses to the health department, such as providing or expanding viral load or genotype testing; or providing training or technical consultation to clinical laboratories, or testing providers to improve efficiency of testing/shorten-time to results delivery. If appropriate, discuss further with your health department HIV program.

Strategy C5: Facilitate the development of partnerships with other community HIV clinical providers and health department and community-based organizations providing HIV prevention services and collaborating in the implementation of the EHE

- Advocate to be an active member of the HD efforts for EHE Implementation.