U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Bureau of Primary Health Care Health Center Program

Fiscal Year 2021 Ending the HIV Epidemic – Primary Care HIV Prevention

Funding Opportunity Number: HRSA-21-092 Funding Opportunity Types: New Assistance Listings (CFDA) Number: 93.527

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date in Grants.gov: February 2, 2021 Supplemental Information Due Date in EHBs: March 1, 2021

Ensure your SAM and Grants.gov registrations and passwords are current immediately!

HRSA will not approve deadline extensions for lack of registration.

Registration in all systems, including SAM.gov, Grants.gov, and EHBs

may take up to one month to complete.

Issuance Date: December 4, 2020

Rebecca Levine

Public Health Analyst, Bureau of Primary Health Care

Office of Policy and Program Development

Contact: https://bphccommunications.secure.force.com/ContactBPHC/BPHC Contact Form

Telephone: (301) 594-4300

PCHP Technical Assistance webpage: https://bphc.hrsa.gov/program-opportunities/primary-care-

hiv-prevention

Authority: Section 330(e), (g), (h), and/or (i) of the Public Health Service Act (42 U.S.C. § 254b(e), (g), (h), and/or (i)), as appropriate.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 Ending the HIV Epidemic – Primary Care HIV Prevention (PCHP) funding opportunity under the Health Center Program. The purpose of PCHP is to expand HIV prevention services that decrease the risk of HIV transmission in geographic locations identified by Ending the HIV Epidemic: A Plan for America. This FY 2021 funding will make available HIV prevention investments to Health Center Program operational (H80) grant award recipients located in Ending the HIV Epidemic: A Plan for America geographic locations that did not receive FY 2020 PCHP funding.

This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds efficiently.

Funding Opportunity Title:	Fiscal Year (FY) 2021 Ending the HIV Epidemic - Primary Care HIV Prevention (PCHP)
Funding Opportunity Number:	HRSA-21-092
Due Date for Applications – Grants.gov :	February 2, 2021 (11:59 p.m. ET)
Due Date for Supplemental Information – HRSA Electronic Handbooks (EHBs):	March 1, 2021 (5 p.m. ET)
Anticipated Total Annual Available Funding:	Approximately \$83 million
Estimated Number and Type of Awards:	Up to 300 awards
Estimated Award Amount:	\$275,000, subject to availability of funds
Cost Sharing/Match Required:	No
Period of Performance:	2 years, beginning August 1, 2021
Eligible Applicants:	 Organizations that: Are receiving Health Center Program operational (H80) grant funding, Are located in the 57 geographic locations identified by Ending the HIV Epidemic: A Plan for America, and Did not receive an FY 2020 PCHP award.
	See Section III.1 of this notice of funding opportunity (NOFO) for details.

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Two-Tier Application Guide*, available online at https://www.hrsa.gov/sites/default/files/hrsa/grants/apply/applicationguide/sf-424-program-specific-app-guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

Application resources, including example forms and documents, as well as a frequently asked questions document, are available at the PCHP technical assistance webpage (https://bphc.hrsa.gov/program-opportunities/primary-care-hiv-prevention). HRSA will hold a pre-application Technical Assistance (TA) webinar that will include an overview of these instructions and address questions on the application process and PCHP objectives.

The HRSA <u>Primary Health Care Digest</u> is a weekly email newsletter containing information and updates pertaining to the Health Center Program, including competitive funding opportunities. Organizations interested in seeking funding under the Health Center Program are encouraged to have several staff subscribe.

Health center strategic partners are available to assist you in preparing a competitive application, including National Training and Technical Assistance Partners (NTTAPs), Primary Care Associations (PCAs), and Health Center Controlled Networks (HCCNs). The Lesbian, Gay, Bisexual, and Transgender People and Health Information Technology NTTAPs have materials that may advance your work plan and support its successful implementation. The HRSA-supported Telehealth Resource Centers offer technical assistance and coaching to advance the use of telehealth. For a list of HRSA-supported PCAs, NTTAPs, and HCCNs, refer to HRSA's Strategic Partnerships webpage.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for FY 2021 Ending the HIV Epidemic – Primary Care HIV Prevention (PCHP) funding. PCHP funding will expand HIV prevention services¹ that decrease the risk of HIV transmission in geographic locations identified by Ending the HIV Epidemic: A Plan for America. This FY 2021 funding opportunity will make available HIV prevention investments to Health Center Program operational (H80) award recipients located in Ending the HIV Epidemic: A Plan for America geographic locations that did not receive FY 2020 PCHP funding.

Announced in 2019, Ending the HIV Epidemic: A Plan for America is a Department of Health and Human Services (HHS) initiative to reduce the number of new HIV infections by 75 percent within 5 years, and by at least 90 percent within 10 years. Initiative activities currently focus on identified HIV hot spots (targeted geographic locations²), which are: 48 counties; Washington, D.C.; San Juan, Puerto Rico; and seven states that have a substantial rural HIV burden.³

The initiative includes four strategies:

- **Diagnose** all people with HIV as early as possible after transmission.
- **Treat** people with HIV rapidly and effectively to reach sustained viral suppression.
- Prevent new HIV transmission by using proven interventions, including preexposure prophylaxis (PrEP) and syringe services programs (SSPs).⁴
- **Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

2. Background

The Health Center Program is authorized by section 330 of the Public Health Service Act (PHSA) (42 U.S.C. § 254b). Awards under this NOFO are authorized under Section 330(e), (g), (h), and/or (i) of the Public Health Service Act (42 U.S.C. § 254b(e), (g), (h),

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¹ The Centers for Disease Control and Prevention (CDC) describes HIV prevention to include multiple strategies, such as pre- and post-exposure prophylaxis, and taking antiretroviral therapy as prescribed. See Appendix A for example activities that support HIV prevention, and CDC HIV prevention resources available at https://www.cdc.gov/hiv/basics/prevention.html.

² Targeted geographic locations may be referred to in other resources as "geographic areas," "Phase I jurisdictions," or "Priority Jurisdictions."

³ Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2017; vol. 29. Published

³ Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2017; vol. 29. Published November 2018. Accessed February 11, 2020. Available at https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdf.

⁴ Under federal law and policy, Federal funds may not be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug. For SSP information see, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Summary of Information on The Safety and Effectiveness of Syringe Services Programs (SSPs). Published May 2019. Accessed February 12, 2020. Available at https://www.cdc.gov/ssp/syringe-services-programs-summary.html.

and/or (i)), as appropriate. For the purpose of this NOFO, existing health centers are defined as those receive funding, as appropriate, under sections 330(e), (g), (h) and/or (i) of the PHSA (42 U.S.C. § 254b(e), (g), (h), and/or (i)). PCHP funding will be awarded to existing health centers under the same subsection(s) of section 330 as their Health Center Program operational grant, or H80, award.

An estimated 1.2 million people in the United States currently live with HIV.⁵ Annual HIV infections in the United States have decreased by more than two-thirds since the mid-1980s. However, the number of new infections has remained relatively stable in recent years (36,400 estimated in 2018), indicating that effective HIV prevention and treatment strategies are not adequately reaching individuals in need. New HIV infections are preventable through testing, treatment, and PrEP when clinically indicated.⁶

Health centers are a key point of entry to HIV prevention and treatment services. In 2019, 2.2 million (2,233,156) health center patients received an HIV test. Of those who tested positive for HIV for the first time (7,164), over 87 percent were successfully linked to treatment within 90 days. More than 196,000 patients living with HIV receive medical care services at health centers, and many sites are co-funded by the Ryan White HIV/AIDS Program (RWHAP).⁷

Health centers are well-positioned to advance the Ending the HIV Epidemic initiative by leveraging their integrated service delivery model. The model integrates comprehensive primary care services, which includes HIV prevention, with behavioral health and enabling services. Integrated care can reduce transmission of HIV infection; improve health outcomes for people with HIV infection; and prevent, identify, and treat co-infections and co-morbidities, such as sexually transmitted infections and substance use disorders.⁸ Furthermore, the health centers' use of inter-professional teams, patient-centric approaches, care management, and coordinated care have demonstrated success in overcoming common barriers to patients initiating and continuing services for HIV prevention and treatment.⁹

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⁵ Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2014–2018. *HIV Surveillance Supplemental Report* 2020;25(No. 1). Published May 2020. Accessed May 19, 2020. Available at http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. ⁶ Clinical indication for PrEP is described by the U.S. Preventive Services Task Force Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis recommendations released June 2019 and the Centers for Disease Control and Prevention U.S. Public Health Service "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States- 2017 Update."

⁷U.S. Department of Health and Human Services, Health Resources and Services Administration, Health Center Data and Reporting, available at https://data.hrsa.gov/tools/data-reporting.

⁸ Remien RH. Berkman A. Mver L. Bastos FI. Kagee A. El-Sadr WM. Integrating HIV care and HIV prevention: legal, policy and programmatic recommendations. *AIDS*. 2008;22 Suppl 2(Suppl 2):S57–S65. ⁹ U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care. Integrating HIV Care, Treatment & Prevention Services into Primary Care – A Toolkit for Health Centers. Rockville, Maryland: U.S. Department of Health and Human Services, 2017.

FY 2021 PCHP awards will build upon FY 2020 PCHP awards ¹⁰ to <u>195 health centers</u> by funding additional health centers with permanent service delivery sites (i.e., sites that operate at a fixed address and are open year round) in the targeted geographic locations at the time of the NOFO release.

For information on HRSA-supported HIV and primary care resources, technical assistance, and training, visit the HRSA webpages on Ending the HIV Epidemic: A Plan for America and HIV and Health Centers.

http://bphc.hrsa.gov/programopportunities/fundingopportunities/SAC/index.html

Funding Requirements

Your application must demonstrate how you will use PCHP funds to achieve three objectives:

- 1. Increase the number of patients counseled and tested for HIV.¹¹
- 2. Increase the number of patients prescribed PrEP.¹²
- 3. Increase the number of patients linked to HIV care and treatment. 13

You will advance progress on the PCHP objectives by implementing activities within four focus areas:

- PrEP prescribing;
- Outreach;
- Testing; and
- Workforce development.

PCHP funds may support HIV prevention activities throughout your service area with a focus on the Ending the HIV Epidemic targeted geographic location. To maximize PrEP access, your proposed project should incorporate the use of available medication assistance and donation programs, including Ready, Set, PrEP, 14 before using PCHP funds to support access to PrEP for health center patients. 15

¹⁰ HRSA-20-091, awarded February 26, 2020.

¹¹ Branson BM et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep 2006 Sep 22; 55:1-17.

¹² Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. Published March 2018. Accessed on March 25, 2020 at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

<u>quidelines-2017.pdf.</u>

13 For more information, see Understanding the HIV Care Continuum available at https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf.

¹⁴ HHS launched <u>Ready</u>. <u>Set</u>. <u>PrEP</u> as part of the Ending the HIV Epidemic initiative. This national program makes PrEP medications available at no cost to people without prescription drug insurance coverage.

¹⁵ Medication assistance and donation programs have their own application and/or data tracking requirements. PCHP funding can be used to support staffing and/or systems to satisfy those requirements.

HRSA encourages you to consider your team's cultural and clinical competence, and patients' barriers to seeking HIV prevention care, such as trauma, stigma, and social determinants of health (SDOH), as you develop your project. SDOH include factors like socioeconomic status, neighborhood and physical environment, social support networks, community violence, and intimate partner violence. SDOH affect a wide range of health, functioning, and quality-of-life outcomes and risks. Addressing SDOH, such as intimate partner violence, is a HRSA objective to improve the health and well-being of individuals and the communities in which they reside.

HRSA strongly encourages you to consider how telehealth ¹⁶ and mobile units can support your proposed service delivery plan. Specifically, tele-PrEP (i.e., PrEP-related clinical services delivered virtually in alignment with your scope of project) can increase medication access and adherence for patients at risk for HIV who face barriers to accessing care. ¹⁷

HRSA also encourages you to establish or enhance partnerships with RWHAP-funded organizations, health departments, and other community and faith-based organizations. These partnerships may facilitate referrals of individuals in need of HIV prevention services to health centers for testing and PrEP and, as appropriate, to link individuals testing positive for HIV to these organizations for care and treatment.

II. Award Information

1. Type of Application and Award

Type of applications sought: New.

HRSA will provide funding in the form of a grant.

2. Summary of Funding

HRSA estimates approximately \$83 million to be available annually to fund 300 recipients. You may apply for a ceiling amount of \$275,000 total cost (includes both direct and indirect costs) per year. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation. 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, HRSA can process applications and award funds in a timely manner.

¹⁶ Telehealth is the use of electronic information and telecommunications technologies to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

¹⁷ For information about tele-PrEP delivery, see PrEP Telehealth, available at https://www.ncsddc.org/wp-content/uploads/2018/04/PrEP-Telehealth-IB.pdf.

The funding start date is August 1, 2021. You will apply for 2 years of funding. Funding beyond the first year is subject to the availability of appropriated funds for the Health Center Program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

HRSA may adjust the final award amounts based on the number of fundable applications and final FY 2021 appropriations.

PCHP funding will have a separate grant number than your H80 award. You must document use of PCHP funds separately and distinctly from other Health Center Program funds.

While PCHP funding will be issued as a new award, all uses of PCHP funds must align with your current Health Center Program scope of project. Your scope of project includes the approved service sites, services, providers, service area, and target population, which are supported (wholly or in part) under your total approved health center budget. As a condition of this grant, you must comply with all Health Center Program requirements as described in the Health Center Program Compliance Manual, and applicable law.¹⁸

Funding to support the Ending the HIV Epidemic initiative may be made available beyond the 2 years of initial funding under this NOFO. If further funding is made available, HRSA will assess your performance on the PCHP objectives through various means, including triannual reports and annual Uniform Data System (UDS) data. Performance assessments may result in increased, level, reduced, or no additional funding. If further funding is awarded, this award may be supplemented and/or further funding may be made available under your H80 award.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 C.F.R. part 75. See Section IV.2.iii for instructions on the development of the application budget.

III. Eligibility Information

1. Eligible Applicants

PCHP funding is available to organizations that:

- Are receiving Health Center Program operational (H80) grant funding under sections 330(e), (g), (h), and/or (i),
- Have at least one permanent operational service delivery site (i.e., sites that operate at a fixed address and are open year round) in one of the targeted geographic locations, and

¹⁸ Requirements are stated in 42 U.S.C. § 254b (section 330 of the PHSA), and in applicable program regulations (42 C.F.R. parts 51c and 56, as appropriate) and grants regulations (HHS Grants Policy Statement and 45 C.F.R. part 75).

Did not receive an FY 2020 PCHP award.

See the <u>PCHP technical assistance webpage</u> for a list of eligible health centers.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

HRSA will consider non-responsive any application that exceeds the ceiling amount on the SF-424A and Budget Narrative and will not consider it for funding under this notice.

HRSA will consider any application that does not include the <u>Project Narrative</u> described in <u>Section IV.2.ii</u> non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

HRSA will only accept one validated electronic submission under this funding opportunity number in Grants.gov.¹⁹ Applications submitted after the first submission will be marked as duplicates and considered ineligible for review. If you wish to change information submitted in a Grants.gov application, you may do so in the HRSA Electronic Handbooks (EHBs) application phase.

If you wish to change information submitted in EHBs, you may reopen and revise your application. You must ensure that the application is resubmitted to HRSA before the EHBs deadline or HRSA will not consider it for funding under this notice.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA **requires** you to apply electronically through Grants.gov and EHBs. You must use a two-phase submission process associated with this NOFO and follow the directions provided at http://www.grants.gov/applicants/apply-for-grants.html and in EHBs.

- Phase 1 Grants.gov Required information must be submitted and validated via Grants.gov with a due date of February 2, 2021 at 11:59 p.m. ET; and
- **Phase 2 EHBs** Supplemental information must be submitted via EHBs with a due date of *March 1, 2021* at 5 p.m. *ET*.

¹⁹ Grants.gov has compatibility issues with Adobe Reader DC. Direct questions pertaining to software compatibility to Grants.gov. See <u>Section VII</u> for contact information.

Note: The EHBs application module will be available December 18, 2020.

Only applicants who successfully submit the workspace application package associated with this NOFO in Grants.gov (Phase 1) by the due date may submit the additional required information in EHBs (Phase 2).

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-21-092 to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.

2. Content and Form of Application Submission

Application Format Requirements

Section 5 of HRSA's <u>SF-424 Two-Tier Application Guide</u> provides instructions for the budget, budget narrative, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Two-Tier Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in English and U.S. dollars (45 C.F.R. § 75.111(a)).

The following application components must be submitted in Grants.gov:

- Application for Federal Assistance (SF-424)
- Project Abstract (attached under box 15 of the SF-424)
- Project/Performance Site Locations
- Grants.gov Lobbying Form
- Key Contacts

The following application components must be submitted in EHBs:

- Project Narrative
- Budget Information Non-Construction Programs (SF-424A)
- Budget Narrative and Table of Personnel Paid with Federal Funds
- Program-Specific Forms
- Attachments

See Section 9.5 of the <u>SF-424 Two-Tier Application Guide</u> for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of 60 pages when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of support. Standard OMB-approved forms do not count in the page limit. The indirect cost rate agreement does not count in the page limit. **We**

strongly urge you to take appropriate measures to ensure that your application does not exceed the specified page limit.

Applications must be complete, within the specified page limit, validated by Grants.gov, and submitted under HRSA-21-092 before the Grants.gov and EHBs deadlines.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 C.F.R. § 75.371, including suspension or debarment. (See also 2 C.F.R. parts 180 and 376, and 31 U.S.C. § 3321.)
- 3) If you are unable to attest to the statements in this certification, you must include an explanation in ATTACHMENT 2: Other Relevant Documents.

See Section 5.1.viii of HRSA's <u>SF-424 Two-Tier Application Guide</u> for additional information on all certifications.

Program-Specific Instructions

In addition to application requirements and instructions in Sections 4 and 5 of HRSA's <u>SF-424 Two-Tier Application Guide</u> (including the budget, budget narrative, certifications, and abstract), include the following:

i. Project Abstract (Submit in Grants.gov)

See Section 5.1.ix of HRSA's <u>SF-424 Two-Tier Application Guide</u>. In addition, provide your Health Center Program grant number (H80CSXXXXX – **reminder: this is an eligibility factor**), a brief summary of how your proposed project will increase the number of patients counseled and tested for HIV, the number of patients prescribed PrEP, and the number of patients linked to HIV care and treatment; and a brief description of how the proposed project will focus on the targeted geographic locations.

ii. Project Narrative (Submit in EHBs – required for completeness)

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, **consistent with forms and attachments**, and organized in alignment with the sections and numbering format below so that reviewers can understand the proposed project.

Successful applications will contain the information below. Use the following section headers for the narrative: Need, Response, Collaboration, Resources/Capabilities, Evaluative Measures, and Support Requested.

NEED – Corresponds to Section V.1 Review Criterion 1: NEED

1) Describe the HIV testing needs of the service area. Specifically:

- a) Provide the estimated number of people in need of HIV testing in your service area and how you determined that number. Sources of information may include, but are not limited to, your current needs assessment, 20 Centers for Disease Control and Prevention's HIV surveillance reports (https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html), CDC National HIV Behavioral Surveillance (NHBS) reports (https://www.cdc.gov/hiv/statistics/systems/nhbs/index.html), and community health needs assessments (such as those conducted by a hospital, health department, or other organization that serves the service area).
- b) Describe factors in your service area that affect access to or use of HIV testing (e.g., transportation, income level, employment, insurance, education, stigma/bias, perceived HIV risk). Include any unique population-specific health care needs or characteristics that affect health status (e.g., food or housing insecurity, financial strain, intimate partner violence (including human trafficking), language or cultural barriers).
- 2) Describe the PrEP needs of the service area. Specifically:
 - a) Provide the estimated number of people in need of PrEP in your service area and how you determined that number. Sources of information may include, but are not limited to, your current needs assessment, persons with PrEP indications estimation tool (https://prepind.shinyapps.io/prepind2/),CDC HIV surveillance reports (https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html), CDC NHBS reports (https://www.cdc.gov/hiv/statistics/systems/nhbs/index.html), and community health needs assessments.
 - b) Describe factors in your service area that affect access to or use of PrEP (e.g., transportation, income level, employment, insurance, education, stigma/bias, perceived HIV risk). Include any unique population-specific health care needs or characteristics that affect health status (e.g., food or housing insecurity, financial strain, intimate partner violence (including human trafficking), language or cultural barriers).
- 3) Describe the linkage to HIV care and treatment needs of the service area. Specifically:
 - a) Provide the estimated number of people in need of HIV care and treatment in your service area and how you determined that number. Sources of information may include, but are not limited to, your current needs assessment,²¹ Centers for Disease Control and Prevention's HIV surveillance reports (https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html), CDC National HIV Behavioral Surveillance (NHBS) reports (https://www.cdc.gov/hiv/statistics/systems/nhbs/index.html), and community

²⁰ See Chapter 3: Needs Assessment of the Compliance Manual.

²¹ See Chapter 3: Needs Assessment of the Compliance Manual.

health needs assessments (such as those conducted by a hospital, health department, or other organization that serves the service area).

b) Describe factors in your service area that affect linkage to HIV care and treatment (e.g., transportation, income level, employment, insurance, education, stigma/bias, perceived HIV risk). Include any unique population-specific health care needs or characteristics that affect health status (e.g., food or housing insecurity, financial strain, intimate partner violence (including human trafficking), language or cultural barriers).

RESPONSE - Corresponds to Section V.1 Review Criterion 2: RESPONSE

- Complete the structured work plan on the Project Overview Form in EHBs by selecting or describing activities that you will conduct to achieve the <u>PCHP</u> <u>objectives</u>:
 - 1. Increase the number of patients counseled and tested for HIV.
 - 2. Increase the number of patients prescribed PrEP.
 - 3. Increase the number of patients linked to HIV care and treatment.

In the structured work plan, describe how each activity proposed addresses an unmet need or barrier to achieving increases in HIV testing, PrEP prescribing, and/or linkage to HIV care and treatment. Refer to Section IV.2.v. Program-Specific Forms for detailed guidance. In your narrative response, describe mitigation strategies that will be utilized to avoid or lessen the impact of COVID-19 or other public health emergency disruptions on your planned activities.

Appendix A: Example Uses of Funding lists example activities that may help your health center to expand HIV prevention services.

- 2) Describe how the proposed personnel (direct hire and contracted) listed in the Budget Narrative are essential and sufficient to successfully implement the proposed project, including clearly describing each individual's role in the PCHP project.
- 3) Describe how the HIV prevention services supported with PCHP funding will be delivered in an integrated manner with other comprehensive primary care services to ensure optimal health results and advance health equity within your service area (e.g., patient navigation, team-based care, testing for and treating co-occurring health conditions).
- 4) Describe how you will incorporate medication assistance/donation programs, including Ready, Set, PrEP, to help patients afford PrEP.
- 5) Describe how you will use heath IT, including electronic health record (EHR) systems and telehealth, to improve the quality of HIV prevention services. Specifically address plans for use of mobile technologies (e.g., text reminders) and tele-PrEP, including integration with home testing (see the BPHC Bulletin on HIV

self-testing, for more information:

https://content.govdelivery.com/accounts/USHHSHRSA/bulletins/28da1bchttps://www.cdc.gov/hiv/testing/self-

<u>testing.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhiv%2Ftesting%2Fhome-specimen-collection.html</u>).

COLLABORATION – Corresponds to <u>Section V.1 Review Criterion 3:</u> COLLABORATION

- Describe how you will establish or enhance partnerships with other providers/organizations delivering HIV testing, PrEP prescribing, and HIV care and treatment, including health departments, RWHAP-funded organizations, and other health centers.
 - a. Describe how you will work together to build upon existing and forthcoming Ending the HIV Epidemic activities.
 - b. Describe how you will leverage these relationships to facilitate referrals of patients to your health center for PrEP.
- 2) In <u>ATTACHMENT 1</u>, include letters of support.
 - a) Required: Providers/organizations that will provide HIV testing, PrEP prescribing, HIV care and treatment, and/or other related services on behalf of your health center (through an agreement/arrangement) in support of your PCHP project.
 - b) Optional: Other health centers (Health Center Program award recipients and look-alikes) and/or other HIV prevention service providers/organizations in the service area (health department, community-based organization) to demonstrate support for the proposed project.

Letters of support must be current and must include a signature. If you are not able to obtain a required support letter, include documentation of efforts made to obtain the letter.

RESOURCES/CAPABILITIES – Corresponds to <u>Section V.1 Review Criterion 4:</u> RESOURCES/CAPABILITIES

- 1) Describe the capabilities and expertise that qualify your health center to carry out the proposed project, including the skills and experience of proposed project personnel, including specific operational and/or clinical experience, and also cultural competence in the area of HIV prevention or associated services (i.e., HIV testing, treatment, and linkage to care and treatment).
- Describe resources that you will leverage to support project implementation, such as technical assistance providers and peer support programs (e.g., hotlines, peer virtual groups, PrEP SMS support).

EVALUATIVE MEASURES – Corresponds to <u>Section V.1 Review Criterion 5:</u> **EVALUATIVE MEASURES**

- 1) Describe how you will measure progress on the following metrics for reporting annually in the UDS as well as in triannual reports:²²
 - a) Patients tested for HIV.
 - b) Patients prescribed PrEP.
 - c) Percentage of patients newly diagnosed with HIV who were seen for follow-up treatment within 30 days of diagnosis.
- 2) Describe how your quality improvement/quality assurance (QI/QA) program will support the proposed project, including:
 - a) How you include or will incorporate HIV prevention activities and patient data into your QI/QA program.
 - b) How you will use QI/QA reports for PCHP project improvement.

SUPPORT REQUESTED – Corresponds to <u>Section V.1 Review Criterion 6: SUPPORT</u> REQUESTED

 Provide a consistent budget presentation (i.e. SF-424A, Federal Object Class Categories (FOCC) Form, Budget Narrative) that aligns with the proposed plan to expand HIV prevention services (as outlined in the RESPONSE section and the work plan) and projected measures improvement (as outlined in the Evaluative Measures section).

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any forms or attachments referenced in a narrative section may be considered during the objective review.

Narrative Section, Forms, and Attachments	Review Criteria
Need section of the Project Narrative	(1) Need
Response section of the Project	
Narrative	(2) Response
Project Overview Form: Work Plan	` '

²² For more information about these measures, see the 2020 UDS Manual, available at https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/pdf/2020-uds-manual.pdf.

Narrative Section, Forms, and Attachments	Review Criteria
Collaboration section of the Project Narrative Attachment 1: Letters of Support	(3) Collaboration
Evaluative Measures section of the Project Narrative	(4) Evaluative Measures
Resources/Capabilities section of the Project Narrative	(5) Resources/Capabilities
Support Requested section of the Project Narrative SF-424A Budget Narrative FOCC	(7) Support Requested

iii. Budget (Submit in EHBs)

Follow the instructions included in Section 5.1.iv of HRSA's <u>SF-424 Two-Tier</u> <u>Application Guide</u> and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects your application for funding, you will have a well-organized plan and, by carefully following the approved plan, may be able to avoid audit issues during the implementation phase.

Reminder: The Total Project or Program Costs are the total allowable costs²³ (inclusive of direct **and** indirect costs) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you.

In addition, PCHP requires the following.

You must present the total budget for the project, which includes PCHP funds (up to \$275,000 annually) and all non-federal funds that will support the proposed project. You have discretion about how you propose to allocate the total budget between PCHP federal funds and other funding that supports the project, provided that the projected budget complies with all applicable HHS policies and other federal requirements.²⁴

PCHP funding may support eligible costs associated with <u>SSPs</u>, which are an effective public health approach to reduce the spread of infectious diseases such as HIV.²⁵ All activities must be carried out consistent with Health Center Program requirements as described in the <u>Health Center Program Compliance Manual</u>, including those associated with <u>Chapter 9: Sliding Fee Discount Program</u>.

²³ For details on allowable costs, see 45 C.F.R. part 75, available at http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75.

²⁴ See Chapter 17: Budget of the Compliance Manual.

²⁵ For guidance on using federal funding to support SSPs, see <u>Department of Health and Human</u>
<u>Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016</u>
and the <u>HRSA-Specific Implementation Guidance to Support Certain Components of Syringe Services</u>
<u>Programs, 2016</u>.

Budget Information Form (SF-424A):

- In Section A, enter the PCHP funding requested in the Federal column for year 1
 (12 months) of funding. The maximum amount you may request cannot exceed
 \$275,000.
- In Section A Budget Summary, under New or Revised Budget, in the Federal column, enter the federal funding requested for year 1 for each type of section 330 funding under subsections (e), (g), (h) and/or (i) of the PHSA (Community Health Center, Migrant Health Center, Health Care for the Homeless, and/or Public Housing Primary Care, collectively "population types") that you currently receive. Funding must be requested and will be awarded proportionately for all population types for which you currently receive Health Center Program funding. No new population types may be added for this purpose. Enter all other project costs in the Non-Federal column. Estimated Unobligated Funds are not applicable for this funding opportunity.
- In Section B Budget Categories, enter an object class category (line item) budget for year 1, broken out by federal and nonfederal funding. The amounts for each category in the Federal and Non-Federal columns, as well as the totals, should align with the Budget Narrative.
- In Section C Non-Federal Resources, enter the amount of all other sources of funding for the proposal for year 1, not including the federal funding request. The total in Section C must be consistent with the Non-Federal Total in Section A.
 When providing Non-Federal Resources by funding source, include other federal funds supporting the proposed project in the "other" category.
- In Section E Federal Funds Needed for Balance of the Project, enter your federal PCHP funding request for year 2 in the first column for each type of section 330 funding that you currently receive (similar to Section A). The maximum amount you may request cannot exceed \$275,000.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 5.1.iv Budget – Salary Limitation of HRSA's <u>SF-424</u> <u>Two-Tier Application Guide</u> for additional information. Note that these or other salary limitations will apply in the following fiscal years, as required by law.

iv. Budget Narrative (Submit in EHBs)

PCHP requires a detailed budget narrative that outlines federal and non-federal costs for year 1 and year 2 by object class category. The sum of line item costs for each category must align with those presented on the SF-424A Budget Information Form. See Section 5.1.v of HRSA's <u>SF-424 Two-Tier Application Guide</u>. In addition, provide a table of personnel to be paid with federal funds, as shown in the example provided in HRSA's <u>SF-424 Two-Tier Application Guide</u>. For year 2, the narrative should highlight the changes from year 1 or clearly indicate that there are no substantive changes. See the <u>PCHP Technical Assistance webpage</u> for an example Budget Narrative.

Your budget narrative must:

- Demonstrate that you will use PCHP funds for costs that will advance progress on the PCHP objectives.
- Clearly detail proposed costs for each line item on the SF-424A Budget Information Form, with calculations for how you derive each cost.
- Not include ineligible costs.
- Provide HRSA with sufficient information to determine if you will use PCHP funds separately and distinctly from other Health Center Program support (e.g., H80 awards).

All contractual arrangements must be appropriate for health center oversight of the proposed project, and include any contractors and sub-recipients.

Format the budget narrative to have all columns fit on an 8.5 x 11 page when printed.

v. Program-Specific Forms (Submit in EHBs)

You have already submitted the required SF-424 information through Grants.gov. This refers to Phase 2 of your application, supplemental information to be submitted through EHBs. To preview the forms to be completed in EHBs, visit the PCHP technical assistance webpage.

Federal Object Class Categories Form (Required)

Enter federal and non-federal expenses by object class category for all proposed PCHP activities and purchases for year 2, similar to the way you did this in Section B of the SF-424A for year 1. Federal costs should only reflect PCHP funds; do not include other federal awards. The total federal request may not exceed \$275,000. Costs listed on this form must align with your Budget Narrative, SF-424A Budget Information Form (Section E), and Equipment List Forms, if applicable.

Project Overview Form (Required)

Work Plan

You must complete two fields in the work plan table: activity and activity selection rationale. For the activity field, select from the list of activity options for each focus area, or write in your own after selecting "other." You must select or write in at least two activities—and no more than five—per focus area. You may access the activity lists outside of EHBs in Appendix A: Example Uses of Funding.

In the activity selection rationale field, you will describe how each selected activity addresses an unmet need or barrier to achieving the <u>PCHP objectives</u> that is specific to your service area and/or health center. This rationale will provide critical information for reviewers as they assess your proposed project. Using a generic rationale throughout the work plan may negatively affect your review score. Information included in your work plan should be consistent with the information in other application components (e.g., Budget Narrative).

Scope of Project

Evaluate your current scope of project in light of your proposed project.²⁶ If your scope requires changes based on your proposed project, indicate if changes will be required to your Form 5A: Services Provided, Form 5B: Service Sites, and/or Form 5C: Other Activities/Locations, and provide an overview of the change along with a timeline for making the necessary request(s). Access the technical assistance materials on the Scope of Project resource webpage and contact your H80 project officer for guidance in determining if a scope adjustment or change in scope will be necessary.

You must submit scope adjustment and change in scope requests outside of the PCHP application, and obtain approval before implementing a new service, service delivery method, or site. You should allow 60 days for HRSA to review your request. You may use PCHP funds to support a new service, site, or activity once it is added to your approved scope of project.

- Review your Form 5A: Services Provided. When reviewing this form, consider the following:
 - Your PCHP work plan may require a change in service delivery methods (e.g., to move screening or diagnostic laboratory services from Column III to Column I).
 - HIV prevention is a component of comprehensive primary care services.
 Therefore, it is not a separate major service category on Form 5A.
- Review your Form 5B: Service Sites. When reviewing this form, consider the following:
 - If you propose to use PCHP funds to purchase a mobile unit and the mobile unit will not replace a current mobile site, you will need to request a change in scope to add a mobile site to Form 5B.
- Review your Form 5C: Other Activities/Locations. A change may be needed if you propose to use PCHP funds to provide services at locations that do not meet the definition of a service site or have irregular or limited timeframes (e.g., home visits, health fairs, portable clinical care).²⁷

Technical Assistance

Indicate up to three technical assistance topics that would most support the successful implementation of your work plan. If you select "other" and/or "my health center could provide peer support to others," you must provide additional information in the comment box. You may also use the comment box to describe your needs specific to the selected

²⁶ You can view your scope of project in the Approved Scope section of your H80 grant folder in EHBs.

²⁷ See section III.B.1.g: Other Activities of Policy Information Notice 2008-01 for additional information, available at https://bphc.hrsa.gov/sites/default/files/bphc/programrequirements/pdf/pin2008-01.pdf.

topic area(s). This information may inform HRSA's HIV prevention technical assistance strategy.

Equipment List Forms (if applicable)

This application includes two Equipment List Forms. If you request to use PCHP funds for equipment in year 1 on your <u>SF-424A</u>, provide the required details in the Year 1 Equipment List Form. If you request to use PCHP funds for equipment in year 2 on your <u>FOCC</u> (row d), provide the required details in the Year 2 Equipment List Form.

Each proposed equipment purchase must be listed separately and align with the <u>FOCC</u> and the <u>Budget Narrative</u>. Annual equipment costs may not exceed \$150,000. Any equipment purchased with PCHP funds must support your PCHP work plan, be procured through a competitive process, and be maintained, tracked, and disposed of in accordance with <u>45 C.F.R. part 75</u>.

Equipment includes moveable items that are non-expendable, tangible personal property (including information technology systems) having a useful life of more than 1 year and a per-unit acquisition cost that equals or exceeds the lesser of the capitalization level established by the applicant for its financial statement purposes, or \$5,000. Moveable equipment can be readily shifted from place to place without requiring a change in the utilities or structural characteristics of the space. Permanently affixed equipment (e.g., heating, ventilation, and air conditioning (HVAC), generators, lighting) is categorized as minor alteration or renovation (A/R), and is not allowed.

You should report yearly license renewals for existing EHRs or health information technology in "Other Costs" in your budget, not as equipment. You should report licenses for EHRs or health information technology, as part of an EHRs or health information technology system purchase, as part of the overall equipment purchase.

For each item on the Equipment List Form, complete the following fields:

- Type Select clinical or non-clinical.
- **Item Description** Provide a description of each item.
- **Unit Price** Enter the price of each item.
- Quantity Enter of the number of each item to be purchased.
- **Total Price** The system will calculate the total price by multiplying the unit price by the quantity entered.

The selection of all equipment should be based on a preference for recycled content, non-hazardous substances, non-ozone depleting substances, energy and water efficiency, and consideration of final disposal (disposed in a manner that is safe, protective of the environment, and compliant with all applicable regulations), unless there are conflicting health, safety, and performance considerations. You are strongly encouraged to employ the standards established by either the Electronic Product Environmental Assessment Tool (EPEAT) or Energy Star, where practicable, in the procurement of equipment. Following these standards will mitigate the negative effects

on human health and the environment. Additional information for these standards can be found at http://www.epeat.net and http://www.energystar.gov.

vi. Attachments (Submit in EHBs)

Provide the following items in the order specified below.

Unless otherwise noted, attachments count toward the application page limit. Indirect cost rate agreements (provided in Attachment 2: Other Relevant Documents) will not count toward the page limit. **You must clearly label each attachment** according to the number and title below (e.g., Attachment 1: Letters of Support). Merge similar documents (e.g., letters of support) into a single file.

Attachment 1: Letters of Support (Required)

Upload current dated letters of support to provide evidence of commitment to the project. See the COLLABORATION section of the Project Narrative for details on required documentation. Letters of support should be addressed to the organization's board, CEO, or other appropriate key management staff member.

You are encouraged to consider the effect on your application's page length when providing optional letters of support.

Attachment 2: Other Relevant Documents (as applicable)

Upload an indirect cost rate agreement, if applicable. Include other relevant documents to support the proposed project, as desired. If you propose to use PCHP funds to support participation in an SSP, you are **required** to submit supporting documentation. For information on required documentation, see the <u>Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016 and the HRSA-Specific Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016. Maximum of 5 uploads.</u>

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must provide your DUNS number, also known as the Unique Entity Identifier, in the Grants.gov portion of your application. The DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update page.

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless you are exempted from those requirements under 2 C.F.R. § 25.110(b) or (c), or have an exception approved by the agency under 2 C.F.R. § 25.110(d)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements. If you have not fully

complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award, and HRSA may use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

Currently the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://www.sam.gov/portal/SAM##11)
- Grants.gov (http://www.grants.gov/)

For further details, see Section 3.1 of HRSA's SF-424 Two-Tier Application Guide.

<u>SAM.GOV</u> ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at SAM.gov.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date

The due date for applications under this NOFO in Grants.gov (Phase 1) is *February 2, 2021 at 11:59 p.m. ET*. The due date to complete all other required information in EHBs (Phase 2) is *March 1, 2021 at 5 p.m. ET* (with access in EHBs starting December 18, 2020). HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadlines** to allow for any unforeseen circumstances. See Section 9.2.5 – Summary of emails from Grants.gov in HRSA's <u>SF-424 Two-Tier Application Guide</u> for additional information.

5. Intergovernmental Review

The Health Center Program is a program subject to the provisions of Executive Order 12372, as implemented by 45 C.F.R. part 100. See Section 5.1.ii of HRSA's <u>SF-424</u> Two-Tier Application Guide for additional information.

6. Funding Restrictions

You may request funding for up to 2 years, at no more than \$275,000 per year (including direct and indirect costs). Awards to support projects beyond the first budget year will be contingent upon congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. See Section 5.1 of HRSA's <u>SF-424 Two-Tier Application Guide</u> for additional information. Note that these or other restrictions will apply in the following fiscal year, as required by law.

<u>45 C.F.R. part 75</u> and the <u>HHS Grants Policy Statement</u> (HHS GPS) include information about allowable expenses. Funds under this notice may not be used for the following costs:

- Costs already paid for by other Health Center Program funds;
- Purchase or upgrade of an EHR that is not certified by the Office of the National Coordinator for Health Information Technology;²⁸
- New construction activities, including additions or expansions;
- Minor A/R projects;²⁹
- Installation of trailers and pre-fabricated modular units:
- Facility or land purchases;
- Purchase of vehicles to transport patients or health center personnel;
- Needles and syringes for illegal drug injection; 30 or
- Devices solely used for illegal drug injection (e.g., cookers).³¹

Under existing law and consistent with Executive Order 13535 (75 FR 15599), health centers are prohibited from using federal funds to provide abortion services (except in

²⁸ The Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology have established standards and other criteria for structured data. For additional information, refer to https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html

²⁹ Minor A/R projects include work to repair, improve, and/or reconfigure the interior arrangements or other physical characteristics of a location.

³⁰ See the Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016, available at https://www.cdc.gov/hiv/pdf/risk/hhs-ssp-guidance.pdf.

³¹ See the Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016, available at https://www.cdc.gov/hiv/pdf/risk/hhs-ssp-guidance.pdf.

cases of rape or incest, or when the life of the woman would be endangered). This includes all funds awarded under this notice and is consistent with past practice and long-standing requirements applicable to awards to health centers.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding, including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. You can find post-award requirements for program income at 45 C.F.R. § 75.307. In accordance with Sections 330(e)(5)(D) and 330(k)(3)(D) the health center must use any non-grant funds as permitted under section 330, and may use such funds for such other purposes as are not specifically prohibited under section 330, if such use furthers the objectives of the health center project.

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate the merit of the application. The entire proposal will be considered during objective review. Project Period Length Criteria

Six review criteria are used to review and rank PCHP applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1: NEED (15 Points) – Corresponds to Section IV.2.ii NEED

- 1. The strength of the demonstrated need for increased access to HIV testing within the service area. The extent to which the applicant describes how the estimated unmet testing and treatment needs of the service area were determined and the factors that went into that determination.
- The extent to which the applicant demonstrates an understanding of factors in the service area that affect access to and use of HIV testing, including for any special populations.

- 3. The strength of the demonstrated need for increased access to PrEP within the service area. The extent to which the applicant describes how the estimated unmet PrEP needs of the service area were determined and the factors that went into that determination.
- 4. The extent to which the applicant demonstrates an understanding of factors in the service area that affect access to and use of PrEP, including for any special populations.
- 5. The strength of the demonstrated need for increased linkage to HIV care and treatment within the service area, focusing on the targeted geographic location. The extent to which the applicant describes how the estimated unmet linkage to HIV care and treatment needs of the service area were determined and the factors that went into that determination.
- 6. The extent to which the applicant demonstrates an understanding of factors in the service area that affect linkage to HIV care and treatment, including for any special populations.

Criterion 2: RESPONSE (30 Points) - Corresponds to Section IV.2.ii RESPONSE

- 1. The strength of the work plan to achieve the <u>PCHP objectives</u>, specifically the appropriateness and strength of the rationale for how each activity proposed addresses an unmet need or barrier to achieving increases in HIV testing, PrEP prescribing, and/or linkage to HIV care and treatment. Additionally, the likelihood that described mitigation strategies will successfully avoid or lessen the impact of COVID-19 or other public health emergency disruptions on your planned activities.
- 2. The extent to which the applicant describes how proposed personnel (direct hire and contracted) listed in the <u>Budget Narrative</u> will be essential and sufficient to successfully implement the proposed project, including a clear description of their role(s) in the PCHP project.
- 3. The strength of the applicant's strategies to deliver care in an integrated manner with other comprehensive primary care services to ensure optimal health results and advance health equity.
- 4. The extent to which the applicant describes how medication assistance/donation programs, including Ready, Set, PrEP, will be maximized to help patients afford PrEP.
- 5. The extent to which health IT, including EHR and telehealth will drive improvement in the quality of HIV prevention services and incorporate mobile technologies and tele-PrEP, including integration with home testing.

Criterion 3: COLLABORATION (10 points) – Corresponds to Section IV.2.ii COLLABORATION

- 1. The extent to which the applicant describes how partnerships will be established or enhanced with other providers/organizations delivering HIV testing, PrEP prescribing, HIV care and treatment, and other related services, as well as:
 - Plans to leverage these partnerships to build upon existing and forthcoming Ending the HIV Epidemic activities.
 - Plans to leverage these partnerships to facilitate referrals of patients to the health center for PrEP.
- 2. The extent to which the letters of support provided in <u>ATTACHMENT 1</u> document support for the PCHP project.

Criterion 4: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV.2.ii RESOURCES/CAPABILITIES

- The capabilities, expertise, and commitment of project staff, including specific operational and/or clinical experience and cultural competence in the area of HIV prevention or associated services, to successfully implement the proposed project.
- The extent to which the applicant describes how technical assistance resources, such as technical assistance providers and peer support programs (e.g., hotlines, peer virtual groups, PrEP SMS support) will be leveraged to support project implementation.

Criterion 5: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV.2.ii EVALUATIVE MEASURES

- 1. The strength of the applicant's plan to measure and provide triannual reports and annual progress data on the number of patients tested for HIV, the number of patients prescribed PrEP, and the percentage of patients newly diagnosed with HIV who were seen for follow-up treatment within 30 days of diagnosis.
- 2. The strength of the applicant's current inclusion or plan to incorporate HIV prevention activities and patient data into the QI/QA program, and use QI/QA reports to improve the proposed project over time.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV.2.ii SUPPORT REQUESTED

1. The extent to which the applicant provides a detailed budget presentation (e.g., SF-424A, FOCC, Budget Narrative) that aligns with the proposed plan to expand HIV prevention services, and projected measures improvements described in the EVALUATIVE MEASURES section.

2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

See Section 6.3 of HRSA's SF-424 Two-Tier Application Guide for more details.

Compliance Status³²

You will not receive PCHP funding if you meet any of the following exclusion criteria at the time HRSA makes funding decisions:

- You are no longer an active H80 award recipient under sections 330(e), (g), (h), and/or (i), or
- You have an active 30-day condition on your H80 award related to Health Center Program requirement area(s).

3. Assessment of Risk

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory, or other requirements (45 C.F.R. § 75.205).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine if HRSA can make an award, if special conditions are required, and what level of funding is appropriate. HRSA may conduct site visits and/or use the current compliance status to inform final funding decisions.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to

³² See Chapter 2: Health Center Program Oversight of the Compliance Manual.

other information in <u>FAPIIS</u> in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in <u>45 C.F.R. § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants</u>.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 C.F.R. § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will issue the NoA on or around the start date of August 1, 2021. See Section 6.4 of HRSA's <u>SF-424 Two-Tier Application Guide</u> for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Two-Tier Application Guide.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Requirements of Subawards

The terms and conditions in the NoA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NoA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 C.F.R. § 75.101 Applicability for more details.

3. Reporting

Award recipients must comply with Section 7 of HRSA's <u>SF-424 Two-Tier Application</u> <u>Guide</u>, continue other required Health Center Program reporting, and complete the following reporting:

- Triannual Reports You will complete triannual reports to describe accomplishments and barriers toward implementing the proposed project. These reports will be informed by your PCHP work plan.
- Progress Report A streamlined non-competing continuation progress report must be submitted and approved by HRSA to trigger the release of year 2 funding (dependent upon congressional appropriation, satisfactory recipient

performance, and a determination that continued funding would be in the best interest of the Federal Government). You will receive an email message via HRSA EHBs when it is time to begin working on the progress report.

 Integrity and Performance Reporting – The NoA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>2 C.F.R. part 200</u> <u>Appendix XII</u>.

Funding to support the Ending the HIV Epidemic initiative may be made available beyond the 2 years of initial funding under this NOFO. If further funding is made available, HRSA will assess performance on PCHP objectives using triannual reports and the calendar years 2021 and 2022 UDS data. Performance assessments will inform decisions on PCHP funding after this award's initial funding period. Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020.

VII. AGENCY CONTACTS

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Francesca Mack and Doris Layne-Sheffield Grants Management Specialists Division of Grants Management Operations Office of Financial Assistance Management (OFAM) Health Resources and Services Administration 5600 Fishers Lane, Room 10W61A Rockville, MD 20857

Telephone: (301) 443-6363 and (301) 945-9881

Email: FMack@hrsa.gov and DLayne-Sheffield@hrsa.gov

You may request additional information and/or technical assistance related to this NOFO's programmatic requirements by contacting:

Rebecca Levine
Public Health Analyst
Office of Policy and Program Development
Bureau of Primary Health Care (BPHC)
Health Resources and Services Administration
5600 Fishers Lane, Room 16N46C
Rockville, MD 20857

Telephone: (301) 594-4300 Contact: BPHC Contact Form

Web: PCHP Technical Assistance webpage

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726, (International Callers, dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base: https://cscnpsprod.service-now.com/hhs grants

You may need assistance when working online to submit the remainder of your information electronically through EHBs. Always obtain a case number when calling for support. For assistance with submitting the remaining information in EHBs, contact the support team, Monday-Friday, 7:00 a.m. to 8:00 p.m. ET:

Health Center Program Support Telephone: 1-877-464-4772 Web: BPHC Contact Form

VIII. Other Information

Technical Assistance

HRSA will hold a pre-application TA webinar for applicants seeking funding through this opportunity. Visit the <u>PCHP Technical Assistance webpage</u> for webinar details, instructions for, and copies of forms, frequently asked questions, and other resources that will help you submit a competitive application.

HRSA Primary Health Care Digest

The HRSA <u>Primary Health Care Digest</u> is a weekly email newsletter containing information and updates pertaining to the Health Center Program, including release of all competitive funding opportunities. You are encouraged to subscribe several staff.

Federal Tort Claims Act (FTCA) Coverage

FTCA coverage for new services and sites is dependent, in part and where applicable, on HRSA approval of a post-award change in the scope of the project. For more information, review the FTCA Health Center Policy Manual, available at https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahcpolicymanualpdf.pdf.

Tips for Writing a Strong Application

See Section 5.7 of HRSA's SF-424 Two-Tier Application Guide.

APPENDIX A: EXAMPLE USES OF PCHP FUNDING

The following list of example uses of funding is organized by focus area and is the same as the list of activity options presented in the work plan. All PCHP-supported activities must be conducted in alignment with your scope of project.

PrEP Prescribing

- Support PrEP access through care coordination that will help patients obtain PrEP medication through <u>patient assistance programs</u>, <u>donation programs</u>, including Ready, Set, PrEP, and the 340B Drug Discount Program.
- Purchase Food and Drug Administration (FDA)-approved PrEP medications for patient use to facilitate same-day PrEP initiation.³³
- Enhance workflows and use of technology, including EHR enhancements and tele-PrEP, to improve PrEP access and adherence, support for the appropriate transition from PEP to PrEP, evaluation for co-occurring conditions, and necessary monitoring and follow up.
- Support PrEP adherence through care integration and coordination support that address co-existent behavioral health conditions and social determinants of health.
- Revise policies and procedures to better ensure a culturally competent, welcoming environment to engage all patients, including at-risk populations.
- Support PrEP access and adherence through such strategies as using a PrEP navigator to provide care coordination to patients at risk for acquiring HIV, providing patient education and counseling, and collaborating with community-based organizations working with at-risk populations.
- Leverage partnerships with Health Center Controlled Networks and the Health
 Information Technology NTTAP to support data-driven quality improvement of
 PrEP and other prevention services through such strategies as strengthening
 information exchange with health departments regarding referrals and re engaging patients in care, and using pharmacy data on PrEP prescriptions filled
 to promote adherence.
- <u>Purchase systems and/or contract for services to provide virtual care</u>, such as those that increase patient engagement and self-management, home monitoring of symptoms and medication adherence, 24-hour access, and synchronous and asynchronous patient visits.
- <u>Purchase home laboratory kits for patient use</u> to support adherence to PrEP follow-up test recommendations.
- <u>Update health center emergency operation plans</u> to ensure continuity of PrEP access during emergencies (e.g., natural disasters, public health emergencies).
- Enhance the use of telehealth to deliver HIV prevention services, such as tele-PrEP, including by establishing contracts to provide peer coaching, receiving

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³³ Kamis K, Scott K, Gardner E, et al. 859. Same-Day HIV Pre-exposure Prophylaxis (PrEP) Initiation During Drop-in STD Clinic Appointments Is a Safe, Feasible, and Effective Method to Engage Patients at Risk for HIV in PrEP Care. *Open Forum Infect Dis*. 2018;5(Suppl 1):S20. Published 2018 Nov 26.

- referred patients from HIV-testing sites, integrating with HIV home testing, embedding live streaming consulting into the EHR, and leveraging the technical assistance available through HRSA-funded <u>Telehealth Resource Centers</u> and the <u>Health Information Technology NTTAP</u>.
- Enhance the EHR to facilitate reporting, including to UDS, of PrEP prescription, follow-up testing, and adherence.
- Enhance the EHR to support or improve health information exchange with clinical and community-based partners, such as health departments and pharmacies for prescription fill information (i.e., RxFill).

Outreach

- Organize and participate in community health fair events to attract and enroll community members and raise awareness of HIV, PrEP, post-exposure prophylaxis (PEP), and how to reduce HIV infection risk.
- Engage new patients by providing outreach and HIV prevention education and <u>services</u> at community locations throughout the service area, accurately reflecting such activities on current scope of project Form 5C: Other Activities/Locations.
- <u>Leverage partnerships with health departments</u>, <u>RWHAP-funding organizations</u>, <u>and other community and faith-based organizations</u> (e.g., emergency departments, emergency medical services, police departments, corrections departments, opioid treatment programs, housing programs) to increase referrals received for HIV prevention services.
- Coordinate with health departments and other community and faith-based organizations to develop and enhance joint social media campaigns to reach individuals at risk for HIV infection.
- <u>Provide training and education to patients, families, and communities</u> on the availability of evidence-based resources and strategies to prevent HIV and related conditions, including mental health conditions, substance use disorders, viral hepatitis, endocarditis, and sexually transmitted infections.
- Strengthen partnerships to ensure use of culturally-appropriate approaches to
 engage communities at risk for HIV, including people experiencing
 homelessness, people who inject drugs, migrant communities, gay and bisexual
 cis-gender men, and people identifying as transgender (e.g., opioid treatment
 programs, medication-assisted treatment providers, organizations providing
 counseling and behavioral therapy, SSPs (consistent with applicable federal and
 state law, including but not limited to federal restrictions on use of grant funds),
 housing programs, faith-based organizations, and community centers).
- <u>Participate in SSPs</u> (consistent with applicable federal and state law, including but not limited to federal restrictions on use of grant funds) and <u>condom</u> <u>distribution programs</u> to increase access to interventions to reduce HIV transmission, to the extent legally permissible.
- To develop data collection and reporting processes that foster real-time use of clinical data, leverage strategic partnerships with Health Center Controlled Networks and the Health Information Technology NTTAP to reduce risk of co-

- occurring conditions such as substance use disorders and mental health conditions, sexually transmitted infections, viral hepatitis, and other infectious diseases, among patients living with HIV.
- To support data driven quality improvement, leverage strategic partnerships with Health Center Controlled Networks and the Health Information Technology NTTAP through activities such as enhancing electronic patient engagement and achieving cost efficiencies through care integration.
- Update health center website and social media feeds to disseminate resources
 that will increase community knowledge of the impact of COVID-19 on patients
 living with HIV.

Testing

- Enhance workflows to support universal HIV testing (i.e., an opt-out screening protocol) by enhancing clinical decision support, EHR forms and reports, and data extraction from health information exchanges.
- Establish workflows to support rapid access to HIV testing, including those that
 facilitate access through any service, such as behavioral health, oral health, and
 women's health.
- Enhance the EHR to support HIV testing by including domains to record HIV risk factors, post-hospitalization or emergency department follow up, and history of related co-occurring conditions, including infectious diseases and substance use disorders.
- Enhance test result reporting workflows, care coordination, and supporting enabling services to link individuals newly diagnosed with HIV to appropriate care and treatment.
- Increase use of clinical decision support and enhanced workflows to facilitate
 risk-based HIV testing and to provide appropriate follow-up HIV testing and other
 recommended laboratory tests for patients using PrEP and patients who
 previously tested negative for HIV who are at risk for acquiring HIV.
- <u>Increase use of clinical decision support to screen for common co-occurring conditions</u> including sexually transmitted infections, viral hepatitis, endocarditis, mental health conditions, and substance use disorders, and provide appropriate care as indicated, such as education and counseling, vaccination, and treatment.
- <u>Purchase HIV tests and other tests for commonly co-occurring sexually transmitted infections, and tests for serum creatinine for patient use</u> to ensure safe use of PrEP.
- Purchase and provide to health center patients HIV home-tests or home specimen collection kits used to test for HIV and related conditions, and integrate HIV home testing with PrEP services, where feasible (see the BPHC Bulletin on HIV self-testing, for more information: https://content.govdelivery.com/accounts/USHHSHRSA/bulletins/28da1bc).
- Enhance the EHR with clinical decision support to facilitate the consistent use of clinical guidelines on HIV testing, prevention, referral, and treatment, as well as appropriate management of PrEP.

Workforce Development

- Support training for providers and staff in accessing available resources to help patients access PrEP.
- Provide professional development about PrEP prescribing practices and addressing barriers to PrEP, such as follow up for required testing and stigma, to increase PrEP initiation, patient engagement, and self-management.
- Support the preparation of licensed and pre-license professionals and paraprofessionals to provide HIV prevention services through such activities as peer mentorship; learning collaboratives; targeted recruiting; developing, implementing, and evaluating experiential training; coordinating student and postgraduate rotations, residencies, and/or fellowships; and building academic partnerships.
- Enhance strategic partnerships, including those with AIDS Education and
 <u>Training Centers, RWHAP-funded organizations, PCAs, and NTTAPs</u>, to support
 provider and staff professional development through such activities as education,
 clinical consultation, peer coaching, learning collaboratives, and other technical
 assistance.
- Support providers to serve as on-hand consultants at the point of care for other health center providers and staff in topics essential to HIV prevention services (e.g., diagnosing and treating common co-occurring conditions such as substance use disorders and mental health conditions, sexually transmitted infections, and viral hepatitis; risk reduction counseling; patient engagement; and care coordination).
- Support training and accredited continuing education for providers and staff in taking sexual health histories; supporting patients' behavior changes to reduce risk; maximizing the success of PrEP; and implementing effective <u>high-impact</u> <u>HIV prevention interventions</u>, including testing, PrEP, PEP, diagnosis, and linkage to treatment.
- Support SSPs by supporting training and accredited continuing education for leadership, providers, and staff on the allowed activities, such as providing comprehensive primary care services including testing for HIV, sexually transmitted infections, and vital hepatitis; provision of PrEP and PEP; substance use disorder and mental health services; immunizations including hepatitis A and B; and increasing access to these services through peer counseling, care management, and transportation.
- <u>Create a welcoming environment by supporting training and accredited continuing education for leadership, providers, and staff</u> that addresses stigma, trauma, cultural competence, patient health literacy, and financial and other barriers that may impede access to needed HIV prevention services.
- Support training and accredited continuing education for health center personnel, including physicians, nurses, assistants, pharmacy staff, community health workers, patient advocates, and other personnel on guidelines for HIV testing and delivering test results to patients.

- <u>Hire primary care providers and clinical pharmacists who can deliver HIV prevention services</u>, including follow-up HIV testing, prescribing PrEP and PEP, co-occurring condition management, and HIV treatment.
- <u>Hire primary care and/or enabling service providers</u> to support the delivery of integrated primary and HIV care services, linkage to treatment, and care coordination necessary for persons who test positive for HIV, including internal and external referrals for appropriate treatment.
- Support culturally appropriate and trauma-informed HIV prevention services by hiring and/or contracting with enabling services providers such as outreach and enrollment specialists, care coordinators, patient educators, and translators.
- Contract with a practice transformation facilitator to implement evidence-based prevention and treatment strategies within an integrated HIV-primary care model by redefining roles, creating new roles, and modifying workflows.
- Build new and enhance existing care coordination infrastructures, including
 infrastructure to support the delivery of virtual care, to help address barriers to
 HIV prevention and treatment services, and the identification and management of
 co-occurring conditions, including viral hepatitis, sexually transmitted infections,
 bacterial and fungal infections associated with injection drug use (e.g.,
 endocarditis, cellulitis), and mental health and substance use disorder services.
- Follow and educate staff on the principles and standards in the Data Security and
 Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease,
 and Tuberculosis Programs: Standards to Facilitate Sharing and Use of
 Surveillance Data for Public Health Action to strengthen participation in
 cybersecurity information sharing and analysis systems that protect patients'
 clinical information, and provide necessary training to personnel to ensure robust
 and consistent security of patients' health information.