U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Bureau of Primary Health Care Health Center Program

Look-Alike Renewal of Designation Fiscal Year 2022

Issuance Date: July 2, 2021

All applications started in the HRSA Electronic Handbooks (EHBs) on or after the issuance date must adhere to the instructions contained therein.

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Look-Alike Renewal of Designation Technical Assistance webpage: https://bphc.hrsa.gov/programopportunities/lookalike/RD/index.html

EXECUTIVE SUMMARY

Look-Alikes (LALs) were established to maximize health care access for medically underserved populations and communities by allowing entities that do not receive Health Center Program funding to become Federally Qualified Health Centers (FQHCs). LALs operate and provide services consistent with health centers funded under the Health Center Program.

The Health Resources and Services Administration (HRSA) is accepting applications from existing LALs for LAL Renewal of Designation (RD). Submission and approval of the LAL RD application assures continued access to comprehensive, culturally competent, high-quality primary health care services for communities and populations currently served by LAL organizations.

Application Availability:	HRSA Electronic Handbooks (EHBs) access granted 180 calendar days prior to the end of the current designation period (approximately 2.5 years into a 3-year designation period or approximately 6 months into a 1-year designation period).	
Application Due Date:	90 calendar days after EHBs access is granted (90 calendar days before the end of the current designation period).*	
Eligible Applicants:	Eligible applicants are LAL organizations in the last year of their current designation period.	
	At the time of RD submission, an applicant must:	
	Provide comprehensive primary medical care as its main purpose at one or more permanent service delivery sites.	
	 b. Ensure access to services in the service area/target population, for all individuals, without regard to ability to pay. 	
	c. Serve a designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP).	
	See the Eligibility section for complete eligibility information, including exclusions.	

Submission Schedule

Designation Period Start Date	EHBs Access*	EHBs Deadline*
January 1, 2022	7/4/2021	10/2/2021
February 1, 2022	8/4/2021	11/2/2021
March 1, 2022	9/1/2021	11/30/2021
April 1, 2022	10/2/2021	12/31/2021
May 1, 2022	11/1/2021	1/30/2022
June 1, 2022	12/2/2021	3/1/2022

^{*}EHBs access and deadline dates are auto-generated by EHBs. Please work within these dates and, if needed, request technical assistance prior to the deadline if the deadline falls on a weekend or holiday.

Technical Assistance

Application resources, as well as forms instructions and samples are available at the RD Technical Assistance webpage.

The HRSA Primary Health Care Digest 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 at https://public.govdelivery.com/accounts/USHHSHRSA/subscriber/new?topic_id=USHHSHRSA 118.

HRSA-supported Primary Care Associations (PCAs) and/or National Health Center Training and Technical Assistance Partners (NTTAPs) are available to assist you in preparing a competitive application. For a listing of HRSA-supported PCAs and NTTAPs, refer to HRSA's Strategic Partnerships webpage.

Other Federal Benefits

Receipt of LAL renewal of designation, while a basis for eligibility, does not, of itself, confer such benefits as FQHC reimbursement or 340B Drug Pricing Program participation. Such benefits depend upon compliance with applicable requirements in addition to renewal of designation, including the completion of separate applications, as appropriate. The Centers for Medicare and Medicaid Services (CMS) manages FQHC reimbursement (see https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html). More information about the 340B Drug Pricing

Program is available in the <u>Other Information</u> section. Renewal of designation does not confer Federal Tort Claims Act (FTCA) coverage.

Summary of Changes

- Last year, HRSA extended designation periods for LALs in a 3-year designation period by 1 year to enable them to focus on COVID-19 public health emergency response efforts.
- Similarly, for LALs in a 3-year designation period, HRSA extended designation periods scheduled to end in FY 2022 by one year. These service areas will be included in the FY 2023 Renewal of Designation. HRSA plans a similar process for LALs whose 3-year designation periods are scheduled to end in FY 2023.
- A new item about the impact of the COVID-19 public health emergency is included in the NEED section of the Project Narrative.
- The Clinical and Financial Performance Measure forms will not be used in the RD and question 3 in the <u>EVALUATIVE MEASURES</u> section of the <u>Project</u> <u>Narrative</u> has been expanded.
- Nonprofit/public center documentation was added to <u>Form 1C: Documents on File</u>.
- You must attest on the Scope Certification form that you have reviewed the Uniform Data System (UDS) Manual and that you will report the required data annually in UDS.

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I. Renewal of Designation Description

1. Purpose

These RD instructions will be used by current LAL organizations to apply to renew their LAL designation. For the purpose of this document, the term "health center" encompasses Health Center Program LALs designated under the following statutory subsections of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b):

- i. Community Health Center (CHC section 330(e))
- ii. Migrant Health Center (MHC section 330(g))
- iii. Health Care for the Homeless (HCH section 330(h))
- iv. Public Housing Primary Care (PHPC section 330(i))

2. Background

LALs were established to maximize health center access for medically underserved populations and communities by allowing entities that do not receive Health Center Program funding to becoming FQHCs. While LALs do not receive Health Center Program funding, they are eligible to apply to Center's for Medicare and Medicaid Services (CMS) for FQHC reimbursement. LALs are also eligible to apply to participate in the 340B Federal Drug Pricing Program, receive automatic Health Professional Shortage Area designation, and may access National Health Service Corp providers.

Through the HRSA Health Center Program, health centers improve the health of the nation's high need geographic areas and populations by ensuring access to comprehensive, culturally competent, high-quality primary health care services. Individually, each health center plays an important role in ensuring access to services. Combined, health centers have a critical impact on improving the health care status of millions of medically underserved and vulnerable individuals throughout the United States and its territories.

An amendment to the Omnibus Budget Reconciliation Acts¹ created and defined a category of facilities under Medicare and Medicaid known as FQHCs. One type of FQHC is an entity that meets the requirements of the Health Center Program, as determined by HRSA, but does not receive Health Center Program funding. HRSA refers to these health centers as Health Center Program LALs. The Balanced Budget Act (BBA) of 1997 added the requirement that a LAL "entity may not be owned, controlled or operated by another entity."

Look-Alike designation allows entities that do not receive Health Center Program funding to provide services and obtain federal benefits consistent with those health centers funded under the Health Center Program. Both Health Center Program award recipients and LALs provide a comprehensive system of care that is responsive to

¹ Omnibus Budget Reconciliation Acts (OBRA) of 1989, 1990, and 1993, amended section 1905 of the Social Security Act (SSA).

primary health care needs, provides services to all persons regardless of ability to pay and meets all Health Center Program requirements. For the purposes of this document, the term "health center" refers to both Health Center Program LALs and award recipients.

Designation Application Requirements

Your application must document an understanding of the need for primary health care services in the service area and propose a comprehensive plan that demonstrates compliance with the Health Center Program requirements.² The plan must ensure the availability and accessibility of primary health care services to all individuals in the service area and target population, regardless of ability to pay. Your plan must include collaborative and coordinated delivery systems for the provision of health care to the underserved.

HRSA assesses health centers for Health Center Program compliance on a regular basis, including via the RD application review process. Failure to fulfill applicable Health Center Program requirements may jeopardize LAL designation per Uniform Guidance 2 CFR Part 200, as codified by the United States Department of Health and Human Services (HHS) at 45 CFR Part 75. If you fail to resolve conditions through the completed progressive action process outlined in Chapter 2: Health Center Program Oversight of the Compliance Manual, HRSA will terminate the designation.

If your RD application is approved for continued designation, HRSA may issue a Notice of LAL Designation (NLD) for a 3-year or 1-year designation period (see details in the <u>Designation Period Length Criteria</u> section). If you receive a 1-year designation period, you must submit a Compliance Achievement Plan for HRSA approval. If you do not submit the required Compliance Achievement Plan within 120 days of receipt of the NLD, HRSA will withdraw support through termination of the designation unless the LAL has made a demonstration of good cause as to why it has not submitted its Compliance Achievement Plan.³

HRSA will not designate a LAL applicant for a third consecutive 1-year designation period in the presence of continued noncompliance with the Health Center Program requirements under these RD instructions (see the <u>Designation Period Length Criteria</u> section for details).

In addition to the Health Center Program requirements, specific requirements for applicants requesting LAL renewal of designation under each population type are outlined below.

COMMUNITY HEALTH CENTER (CHC) APPLICANTS:

• Ensure compliance with PHS Act section 330(e) and program regulations, requirements, and policies.

² Requirements as stated in section 330 of the PHS Act and corresponding regulations, and as detailed in the Health Center Program Compliance Manual (<u>Compliance Manual</u>).

³ Refer to Section 330(e)(1)(B) of the PHS Act.

• Provide a plan that ensures the availability and accessibility of required primary health care services to underserved populations in the service area.

MIGRANT HEALTH CENTER (MHC) APPLICANTS:

- Ensure compliance with PHS Act section 330(g); and, as applicable, section 330(e), program regulations, requirements, and policies.
- Provide a plan that ensures the availability and accessibility of required primary health care services to migratory and seasonal agricultural workers and their families in the service area, which includes:
 - Migratory agricultural workers who are individuals whose principal employment is in agriculture, who have been so employed within the last 24 months, and who establish for the purposes of such employment a temporary abode;
 - Seasonal agricultural workers who are individuals whose principal employment is in agriculture on a seasonal basis and who do not meet the definition of a migratory agricultural worker;
 - o Individuals who are no longer employed in migratory or seasonal agriculture because of age or disability who are within such catchment area; and/or
 - o Family members of the individuals described above.

NOTE: Agriculture refers to farming in all its branches, as defined by the North American Industry Classification System under codes 111, 112, 1151, and 1152 (48 CFR § 219.303).

HEALTH CARE FOR THE HOMELESS (HCH) APPLICANTS:

- Ensure compliance with PHS Act section 330(h); and, as applicable, section 330(e), program regulations, requirements, and policies.
- Provide a plan that ensures the availability and accessibility of required primary health care services to individuals:
 - Who lack housing (without regard to whether the individual is a member of a family):
 - Whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations;
 - Who reside in transitional housing;
 - Who reside in permanent supportive housing or other housing programs that are targeted to homeless populations; and/or
 - Who are children and youth at risk of homelessness, homeless veterans, and veterans at risk of homelessness.
- Provide substance use disorder services.

PUBLIC HOUSING PRIMARY CARE (PHPC) APPLICANTS:

- Ensure compliance with PHS Act section 330(i); and, as applicable, section 330(e), program regulations, requirements, and policies.
- Provide a plan that ensures the availability and accessibility of required primary health care services to residents of public housing and individuals living in areas immediately accessible to public housing. Public housing includes public housing agency-developed, owned, or assisted low-income housing, including mixed

- finance projects, but excludes housing units with no public housing agency support other than Section 8 housing vouchers.⁴
- Consult with residents of the proposed public housing sites regarding the planning and administration of the program.

NOTE: The RD application must request designation for the same health center type(s) included in the current designation (i.e., CHC, MHC, HCH, and/or PHPC). Changes to the designation types can only be proposed via a Change in Scope request in the EHBs.

II. Designation Information

Designation will be granted for a period of up to three years. Continued designation is contingent upon satisfactory LAL performance, including the timely submission of all required LAL submissions, and a decision that continued designation is in the best interest of the Federal Government. Required submissions include, but are not limited to, the RD and Annual Certification (AC) applications, as well as annual Uniform Data System (UDS) submissions.

III. Eligibility Information

1. Eligible Applicants

Applicants must meet all of the following eligibility requirements. If your application does not demonstrate compliance with all eligibility requirements, it may be considered ineligible or will have conditions placed on the NLD. You must address these conditions to ensure ongoing designation.

- 1) You must be a currently designated LAL organization.⁵ Section 1905(I)(2)(B)(iii) of the Social Security Act, as amended. Current LAL organizations include domestic public or nonprofit private entities, including domestic faith-based and community-based organizations, tribes, and tribal organizations.⁶
- 2) You must not be owned, controlled, or operated by another entity. Organizational structures such as parent-subsidiary arrangements or network corporations may not be eligible for designation.
- 3) You must perform a substantive role in the project and meet the program requirements. LAL organizations that do not propose to perform a substantive role in

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⁴ For the purpose of funding under section 330(i) of the PHS Act, and as presented in the <u>Glossary</u> of the <u>Compliance Manual</u>, "public housing" is defined in 42 U.S.C. § 1437a(b)(1).

⁵ For more information about becoming a LAL refer to the LAL Initial Designation Technical Assistance webpage located at

https://bphc.hrsa.gov/programopportunities/lookalike/initialdesignationinstructions.html.

⁶ Refer to Chapter 1: Health Center Program Eligibility of the Compliance Manual.

⁷ Section 1905(I)(2)(B)(iii) of the Social Security Act, as amended.

- the project will be considered non-responsive and will not be considered for designation.
- 4) You must indicate on <u>Form 1A: General Information Worksheet</u>, comprehensive, primary medical care as your organization's main purpose by documenting that the number of projected medical patients is greater than the number of projected patients within each of the other service types.
- 5) You must continue operating a health center that makes all required primary health care services, including preventive and enabling services, available and accessible in the service area, either directly or through established arrangements, without regard to ability to pay.⁸ You may not propose to provide only a single type of service, such as dental, behavioral, or prenatal services.
- 6) You must propose on <u>Form 5A: Services Provided</u> to make General Primary Medical Care (see footnote 8) available directly (Column I) and/or through formal written contractual agreements in which the health center pays for the service (Column II).
- 7) You must continue to provide access to services for all individuals in the service area and target population, as described in the <u>RESPONSE</u> section of the Project Narrative. In circumstances where a sub-population is targeted (e.g., homeless youth), you must ensure that health center services are available and accessible to others who seek services at the LAL site(s).
- 8) Your organization (with the exception of applicants with designation for only serving special populations (i.e., MHC, HCH, and/or PHPC)) must continue to serve a defined geographic area that is currently federally designated, in whole or in part, as an MUA or an MUP.
- 9) You must meet the application deadline (90 days prior to the end of your current designation period). See <u>Submitting the Application</u> for detailed information about the application timeline and due date.

IV. APPLICATION AND SUBMISSION INFORMATION

HRSA *requires* you to apply electronically through the EHBs. In addition to following these instructions, review the <u>EHBs RD User Guide</u>. Applications must be submitted in the English language.

⁸ Refer to the Service Descriptors for Form 5A: Services Provided, available at https://bphc.hrsa.gov/about/requirements/scope/form5aservicedescriptors.pdf, for details regarding required primary health care services.

1. Content and Form of Submission

Application Requirements

The following application components must be submitted in the EHBs:

- Project Abstract
- Project Narrative
- Budget Narrative
- Program-Specific Forms (samples are available on the <u>LAL RD Technical</u> Assistance webpage)
- Attachments

Application Page Limit

The total size of all uploaded files included in the page limit may not exceed the equivalent of **160 pages** when printed by HRSA. The page limit includes the project and budget narratives, attachments and collaboration documentation. Standard OMB-approved forms that are included in the application package do not count in the page limit. It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit.

Applications must be complete, within the specified page limit, and submitted prior to 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 CFR § 75.371, including suspension or debarment. (See also 2 CFR 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 <u>Attachment 11: Other Relevant Documents</u>.

Submitting the Application

You must submit your application electronically through the EHBs. Refer to the EHBs RD User Guide available on the <u>LAL RD Technical Assistance webpage</u> for submission instructions.

Your application is due 90 days prior to the end of your organization's current designation period. The EHBs system will send an email notice regarding the availability of the application to your organization's contacts, as you've identified in the EHBs, 180 days prior to the end of the current designation period. This means you will have 90 calendar days to complete and have your Authorizing Official (AO) submit the RD application in the EHBs.

You are urged to submit in advance of the 90-day deadline. Failure to submit your RD application by the due date (90 days prior to the end of your current designation period) may result in termination of the LAL designation and all corresponding benefits.

Application Components

Include the following in your RD application:

i. Cover Page

An EHBs form that provides a summary of project-related information.

ii. Project Abstract

An attachment that provides a summary of the project. Include the following at the top of the Project Abstract:

- Project Title: Look-Alike Renewal of Designation
- Congressional District (s) for your organization and Service Area
- Types(s) of Health Center Program Designation (i.e., CHC, MHC, HCH and/or PHPC)

The abstract should be a brief description of your project. Include the following in the body of the abstract:

- A brief history of your organization, the community you serve, and your target population.
- A brief summary of the major health care needs and barriers to care you address through the project. This summary should include the needs of any targeted special populations (migratory and seasonal agricultural workers, people experiencing homelessness, and/or residents of public housing).
- How your project addresses the need for comprehensive primary health care services in your community.
- Number of current and proposed patients, providers and service delivery sites and locations.

iii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, **consistent with forms and attachments**, and well-organized in alignment with the sections and numbering format below to facilitate reviewer understanding of the proposed project and, where applicable, HRSA assessment of compliance with Health Center Program requirements, consistent with the Compliance Manual.

The application content that HRSA will utilize, in whole or in part, in the RD-based assessment of compliance is noted with a bolded, underlined asterisk (_*_). Refer to the RD Compliance Assessment Guide at the RD Technical Assistance webpage for the specific Compliance Manual chapters and elements that relate to items with a bolded, underlined asterisk.

Use the following section headers for the Project Narrative: Need, Response, Collaboration, Evaluative Measures, Resources/Capabilities, and Governance.

Your Project Narrative must:

- Address the specific Project Narrative items below, with the requested information appearing under the appropriate Project Narrative section header or in the designated forms and attachments.
- Reference attachments and forms as needed. Referenced items must be part of the EHBs submission.
- Where applicable, demonstrate compliance with Health Center Program requirements, as detailed in the Compliance Manual.
- Reflect your currently approved scope of project. You must request any changes in scope separately through EHBs.

NEED

Information provided in the NEED section must:

- Serve as the basis for, and align with, the activities and goals described throughout the application.
- Be utilized to inform and improve the delivery of health center services.
- 1) Describe the proposed service area (consistent with <u>Attachment 1: Service Area Map and Table</u>), including:
 - a) The service area boundaries.
 - b) If it is located in an Opportunity Zone (if applicable).9
 - c) How you annually review and, if necessary, update your service area based on where patients reside. Such updates should be consistent with data reported in the uniform Data System (UDS).
- Describe your process for assessing proposed service area/target population need, including:
 - a) How often you conduct or update the needs assessment.
 - b) How you use the results to inform and improve service delivery.
 - Using and citing current data (including data for each special population (MHC, HCH, PHPC)), address the following:
 - Factors associated with access to care and health care utilization (e.g., geography, transportation, occupation, transience, unemployment, income level, educational attainment).
 - Any unique health care needs or characteristics that impact health status (e.g., language barriers, food insecurity, housing insecurity, financial strain,

⁹ The list of Qualified Opportunity Zones is available at https://www.cdfifund.gov/Pages/Opportunity-Zones.aspx.

lack of transportation, the physical environment, intimate partner violence, human trafficking).¹⁰

3) Describe how the COVID-19 public health emergency impacted service area/target population need.

RESPONSE

1) Describe how you provide access to all required and any proposed additional services (consistent with <u>Form 5A</u>: <u>Services Provided</u>), including how you will address health care access and utilization barriers (e.g., geography, transportation, occupation, transience, unemployment, income level, educational attainment) and other factors that impact health status (e.g., language barriers, food insecurity, housing insecurity, financial strain, lack of transportation, the physical environment, intimate partner violence, human trafficking).

Note: If you are requesting HCH designation, you must provide substance use disorder services (documented on <u>Form 5A: Services Provided</u>) to this population directly (Column I) and/or through contractual agreement (Column II).

- 2) Describe how the proposed service delivery sites on <u>Form 5B</u>: <u>Service Sites</u> assure the availability and accessibility of services (consistent with <u>Form 5A</u>: <u>Services Provided</u>) within the proposed service area, relative to where the target population lives and works (e.g., areas immediately accessible to public housing for health centers targeting residents of public housing). Specifically address:
 - a) Access barriers (e.g., distance or travel time for patients, physical geographic barriers, residential patterns, economic and social groupings).
 - b) How the following service delivery site factors facilitate access: total number and type (e.g., fixed, mobile, school-based), hours of operation, and overall location (e.g., proximity to public housing).

Note: Ensure information aligns with Form 5B: Service Sites.

- 3) Describe how you educate patients on insurance, inform them of third-party coverage options available to them, and provide enrollment assistance.
- 4) Describe how you address continuity of care, including:
 - a) Hospital admitting privileges.
 - b) Receipt, follow-up, and recording of medical information from referral sources.
 - c) Follow-up for patients who are hospitalized or visit a hospital's emergency department.

¹⁰ Social determinants of health (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 health and well-being of individuals and the communities in which they reside.

- 5) _*_ Describe the following aspects of the sliding fee discount program (SFDP) policies:
 - a) How they apply uniformly to all patients.
 - b) Definitions of income and family.
 - c) Methods for assessing all patients for sliding fee discount eligibility based only on income and family size.
 - d) How the structure of each sliding fee discount schedule (SFDS) ensures that patient charges are adjusted based on ability to pay (consistent with Attachment 9: Sliding Fee Discount Schedule).
 - e) If you have a nominal charge¹¹ for patients with incomes at or below 100 percent of the Federal Poverty Guidelines (FPG),¹² whether the nominal charge: (1) is flat, (2) is set at a level that is nominal from the perspective of the patient, and (3) does not reflect the actual cost of the service being provided. State if you do not have a nominal charge for patients with incomes at or below 100 percent of FPG.
- 6) Describe how you determined the number of unduplicated patients that you project to serve by the end of the designation period, as documented on <u>Form 1A: General Information Worksheet</u>. Include how that determination took into consideration recent or potential changes in the local health care landscape (e.g., after-effects of the COVID-19 public health emergency, potential changes in insurance coverage), organizational structure, and/or workforce.

COLLABORATION

- _*_ Describe efforts to collaborate with other providers or programs in the service area (consistent with <u>Attachment 1: Service Area Map and Table</u>), including local hospitals, specialty providers, and social service organizations (including those that serve special populations), to provide access to services not available through the health center, to support:
 - a) Continuity of care across community providers.
 - b) Access to other health or community services that impact the patient population.
 - c) A reduction in the use of hospital emergency departments for non-urgent health care.
- 2) _*_ Describe and document in <u>Attachment 8: Collaboration Documentation</u> efforts to coordinate and integrate your activities with federally-funded entities, as well as state and local health services delivery projects and programs serving similar patient populations in the service area (consistent with <u>Attachment 1: Service Area Map and Table</u>). At a minimum, this includes establishing and maintaining relationships with other health centers¹³ ¹⁴ in the service area. If you do not provide documentation of collaboration with one or more health centers in the service area in <u>Attachment 8</u>:

¹¹ Nominal charges are not minimum fees, minimum charges, or co-pays. See <u>Chapter 9: Sliding Fee</u> <u>Discount Program</u> of the Compliance Manual.

¹² FPG are available at https://aspe.hhs.gov/poverty-guidelines.

¹³ Inclusive of Health Center Program award recipients and look-alikes.

¹⁴ You are encouraged to consider the impact on your application's page length when providing non-required documentation of collaboration.

<u>Collaboration Documentation</u>, explain why and provide documentation of your outreach.

- 3) Describe your efforts to collaborate and ensure that health center services are coordinated with, and complement, services provided by each of the following entities in the area (if not present in the proposed service area, state this):
 - a) Social service agencies that address social determinants of health (e.g., language barriers, food insecurity, housing insecurity, financial strain, lack of transportation, the physical environment, intimate partner violence, human trafficking).
 - b) Local hospitals, including critical access hospitals.
 - c) Rural health clinics.
 - d) Health departments.
 - e) Home visiting programs.
 - f) State and local tuberculosis programs.
 - g) Clinics supported by the Indian Health Service.
 - h) Community-based organizations (e.g., organizations funded under the Ryan White HIV/AIDS Program).

EVALUATIVE MEASURES

- 1) Describe how the health center's Quality Improvement/Quality Assurance (QI/QA) program addresses:
 - a) Adherence to current clinical guidelines and standards of care in the provision of services.
 - b) Identification and analysis of patient safety and adverse events, including implementation of follow-up actions, as necessary.
 - c) Assessment of patient satisfaction.
 - d) Use of patient records data to inform modifications to the provision of services.
 - e) Oversight of and decision-making regarding the provision of services by key management staff and the governing board.
- 2) Describe how your electronic health record (EHR) system will:
 - a) Protect the confidentiality of patient information and safeguard it, consistent with federal and state requirements.
 - b) Facilitate performance monitoring and improvement of patient outcomes.
 - c) Track social risk factors that impact patient and population health.
- 3) Describe how you will focus efforts to improve clinical quality and/or health outcomes, and reduce health disparities within your patient population, including within the following specified areas:
 - a) Hypertension (e.g., controlling high blood pressure)
 - b) Diabetes (e.g., hemoglobin A1c (HbA1c) poor control (>9%))
 - c) Mental health (e.g., screening for depression and follow-up plan, depression remission at 12 months).
 - d) Substance use disorder (e.g., access to medication-assisted treatment (MAT)).

- e) Improving maternal and child health (e.g., early entry into prenatal care, low birth weight, childhood immunization status).
- f) Ending the HIV epidemic (e.g., HIV screening, HIV linkage to care, pre-exposure prophylaxis (PrEP)).

RESOURCES/CAPABILITIES

- 1) Describe your organizational structure, including:
 - a) How any contractors will assist in carrying out the proposed project (consistent with Attachments <u>2: Bylaws</u> and <u>3: Project Organizational Chart</u>, and, as applicable, Attachments <u>6: Co-Applicant Agreement</u> and <u>7: Summary of Contracts and Agreements</u>).
 - b) Whether your organization is part of a parent, affiliate, or subsidiary organization (consistent with Form 8: Health Center Agreements).
- 2) Describe the following related to the staffing plan (consistent with <u>Form 2: Staffing Profile</u>):
 - a) How it ensures that clinical staff, contracted providers, and/or referral providers/provider organizations will carry out all required and any proposed additional services (consistent with Form 5A: Services Provided).
 - b) How the size, demographics, and health care needs of the service area/patient population were considered when determining the number and mix of clinical staff.
 - How you maintain documentation of licensure, credentialing verification, and applicable privileges for clinical staff (e.g., employees, individual contractors, volunteers).
- 3) Describe the key management team (e.g., project director (PD)/chief executive officer (CEO), clinical director (CD), chief financial officer (CFO), chief information officer (CIO), chief operating officer (COO)), including:
 - a) How the makeup and distribution of functions among key management staff, and their qualifications (consistent with Attachments <u>4: Position Descriptions for Key Management Staff</u> and <u>5: Biographical Sketches for Key Management Staff</u>), support the operation and oversight of the proposed project, consistent with scope and complexity.¹⁵
 - b) _*_ Responsibilities of the PD/CEO for reporting to the health center governing board and overseeing other key management staff in carrying out the day-to-day activities of the proposed project (consistent with Attachment 4: Position
 Descriptions for Key Management Staff).
- 4) _*_ Describe how you conduct billing and collections, including:
 - a) How board-approved policies, as well as operating procedures, ensure that fees
 or payments will be waived or reduced based on specific circumstances due to
 any patient's inability to pay.

¹⁵ The PD/CEO must be a direct employee of the health center.

- b) Participating in Medicare, Medicaid, Children's Health Insurance Program (CHIP), and, as appropriate, other public or private assistance programs or health insurance, as applicable (consistent with Form 3: Income Analysis).
- 5) Describe how you use or plan to use telehealth¹⁶ to:
 - a) Provide in-scope services¹⁷ (list all services that are or will be provided via telehealth).
 - b) Communicate with providers and staff at other clinical locations.
 - c) Receive or perform clinical consultations.
 - d) Send and receive health care information from mobile devices to remotely monitor patients.¹⁸
- 6) Describe your current ability and/or plans for maintaining continuity of services and responding to urgent primary health care needs during disasters and emergencies, ^{19, 20} including:
 - a) Response and recovery plans.
 - b) Backup systems to facilitate communications.
 - c) Patient records access.
 - d) Integration into state and local preparedness plans.
 - e) Provision of status updates to HRSA-supported <u>Primary Care Associations</u> (PCAs).

GOVERNANCE

Health centers operated by Native American tribes or tribal, Native American, or Urban Indian groups are ONLY required to respond to Item 4 below.

- 1) <u>*</u> Describe where in <u>Attachment 2: Bylaws</u> (and, if applicable, <u>Attachment 6: Co-Applicant Agreement</u>) you document the following board composition requirements:
 - a) Board size is at least 9 and no more than 25 members, with either a prescribed number or range of board members.²¹

¹⁶ Telehealth can be an important tool for delivering services and resources to HRSA's target populations. Telehealth is defined as the use of electronic information and telecommunication technologies to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health. You are strongly encouraged to use telehealth in your proposed service delivery plan when feasible or appropriate. Additional information on telehealth can be found at https://telehealth.hhs.gov. In addition, if you use broadband or telecommunications services for the provision of health care, HRSA strongly encourages you to seek discounts through the Federal Communication Commission's Universal Service Program. For information about such discounts, see https://www.usac.org/rural-health-care. Patients may also be eligible for free or low cost mobile or broadband services through the Universal Service Lifeline program at https://www.lifelinesupport.org.

¹⁷ For information about telehealth and the health center scope of project, see Program Assistance Letter (PAL) 2020-01.

¹⁸ For more information, see http://www.telehealthtechnology.org/toolkits/mhealth.

¹⁹ Including natural or manmade disasters, as well as emergent or established public health emergencies.

²⁰ Consistent with the Center for Medicare & Medicaid Services (CMS) national emergency preparedness requirements. See details at https://www.cms.gov/Medicare/Provider-Enrollment-and-centification/SurveyCertEmergPrep/Emergency-Prep-Rule.

²¹ List board members on Form 6A: Current Board Member Characteristics.

- b) At least 51 percent of board members are patients served by the health center.^{22,} 23, 24
- c) Patient members of the board, as a group, represent the individuals served by the health center in terms of demographic factors (e.g., gender, race, ethnicity).²⁵
- d) Non-patient members are representative of the community served by the health center or the health center's service area.
- e) Non-patient members are selected to provide relevant expertise and skills (e.g., community affairs, local government, finance and banking, legal affairs, trade unions and other commercial and industrial concerns, social services).
- f) No more than one-half of non-patient board members may earn more than 10 percent of their annual income from the health care industry.
- g) Health center employees and immediate family members (i.e., spouses, children, parents, or siblings through blood, adoption, or marriage) of employees may not be health center board members.^{26, 27}
- 2) <u>*</u> Describe where in Attachment <u>2: Bylaws</u> (and, if applicable, <u>Attachment 6: Co-Applicant Agreement</u>) you document the following board authority requirements:
 - a) Holding monthly meetings.
 - b) Approving the selection (and dismissal or termination, as appropriate) of the PD/CEO.
 - c) Approving the annual Health Center Program project budget and applications.
 - d) Approving proposed health center services and the locations and hours of operation of health center sites.
 - e) Evaluating the performance of the health center.
 - f) Establishing or adopting policies related to the operations of the health center.
 - g) Assuring the health center operates in compliance with applicable federal, state, and local laws and regulations.
- 3) <u>*</u> Referencing specific sections in Attachments <u>2: Bylaws</u>, <u>6: Co-Applicant Agreement</u>, and <u>Form 8: Health Center Agreements</u>, describe how your governing board maintains the authority for oversight of the proposed Health Center Program project. Specifically address the following:
 - a) No other individual, entity, or committee (including, but not limited to, an executive committee authorized by the board, and consistent with Attachment 3: Project

²² For the purposes of board composition, a patient is an individual who has received at least one service in the past 24 months that generated a health center visit, where both the service and the site where the service was received are within the proposed scope of project.

²³ You will include representative(s) from or for each of the target <u>special population(s)</u> on <u>Form 6A:</u> <u>Current Board Member Characteristics</u>.

²⁴ You may request a waiver of this requirement on Form 6B: Request for Waiver of Board Member Requirements if you are requesting designation to serve only special populations (i.e., HCH, MHC, and/or PHCP). If this request is granted, it will be valid for the designation period.

²⁵ Board representation is demonstrated on Form 6A: Current Board Member Characteristics.

²⁶ Refer to Chapter 20: Board Composition of the Compliance Manual.

²⁷ In the case of public agencies with co-applicant boards, this includes employees or immediate family members of either the co-applicant organization or of the public agency component in which the health center project is located (e.g., employees within the same department, division, or agency).

- <u>Organizational Chart</u>) reserves approval authority or has veto power over the board with regard to the required authorities and functions.
- b) In cases where you collaborate with other entities in fulfilling the health center's proposed scope of project, such collaboration or agreements with other entities do not restrict or infringe upon the board's required authorities and functions.
- c) Public agency applicants with a co-applicant board: The health center has a co-applicant agreement that delegates the required authorities and functions to the co-applicant board and delineates the roles and responsibilities of the public agency and the co-applicant in carrying out the project (consistent with Attachment 6: Co-Applicant Agreement).
- 4) Native American tribes or tribal, Native American, or Urban Indian Applicants
 Only: Describe your governance structure and process for assuring adequate:
 - a) Input from the community/target population on health center priorities.
 - b) Fiscal and programmatic oversight of the proposed project.

iv. * Budget Narrative

Provide a budget narrative for **each requested 12-month period** (certification period) of the 3-year designation period. In addition, classify Year 1 of the budget narrative into federal and non-federal resources. For subsequent budget years, if applicable, the narrative should highlight the changes from Year 1 or clearly indicate that there are no substantive changes during the designation period. See the LAL RD Technical Assistance webpage for a sample Budget Narrative.

Note: If your organization receives any federal funding, you are required to have the necessary policies, procedures, and financial controls in place to ensure that you comply with all federal funding requirements and prohibitions such as lobbying, gun control, abortion, etc. The effectiveness of these policies, procedures, and controls may be subject to audit.

Format the budget narrative to have all columns fit on an 8.5 x 11 page in portrait orientation when printed. Upload as Attachment 10 in your RD application.

v. Program-Specific Forms

All of the following forms, with the exception of <u>Form 5C: Other Activities/Locations</u>, are required. You must complete these OMB-approved forms directly in EHBs. The forms that HRSA will utilize in its assessment of compliance, as detailed in the <u>Compliance Manual</u>, are noted with a bolded, underlined asterisk (_*_).

Refer to the <u>LAL RD Technical Assistance webpage</u> for Program-Specific Forms samples and instructions.

_ <u>*</u> _Cover Page	
Form 1A: General Information Worksheet	
Form 1C: Documents on File	
* Form 2: Staffing Profile	
* Form 3: Income Analysis	
Form 3A: Look-Alike Budget Information	วท

*_ Form 4: Community Characteristics

Form 5A: Services Provided

Form 5B: Service Sites

Form 5C: Other Activities/Locations (if applicable)

- _*_ Form 6A: Current Board Member Characteristics
- * Form 6B: Request for Waiver of Board Member Requirements
- * Form 8: Health Center Agreements

Form 12: Organization Contacts

Scope Certification Form

vi. Attachments

Provide the following items in the order specified below. The attachments that HRSA will utilize in its assessment of compliance, as detailed in the <u>Compliance Manual</u>, are noted with a bolded, underlined asterisk (_*_).

Unless otherwise noted, attachments count toward the application page limit. **You must clearly label each attachment** according to the number and title below (e.g., Attachment 2: Bylaws). Merge similar documents (e.g., collaboration documentation) into a single file.

Attachment 1: Service Area Map and Table

Upload a map of the service area for the proposed project, indicating the:

- Proposed health center site(s) listed on <u>Form 5B: Service Sites</u>.
- Proposed service area zip codes.
- Any medically underserved areas (MUAs) and/or medically underserved populations (MUPs).
- Health Center Program award recipients and look-alikes.
- Other health care providers serving the proposed zip codes, as described in the <u>COLLABORATION</u> section of the Project Narrative.

Create the map and table using UDS Mapper, available at http://www.udsmapper.org/. You may need to manually place markers for the locations of major private provider groups serving low income/uninsured patients. Note that the table will display Zip Code Tabulation Areas (ZCTAs)²⁸ and not zip codes.

See the <u>LAL RD Technical Assistance webpage</u> for samples and instructions on creating maps and tables using UDS Mapper. For a tutorial, see Specific Use Cases: Create a Service Area Map and Data Table, available at https://udsmapper.org/tutorialsandresources.

<u>*</u> Attachment 2: Bylaws

Upload a complete copy of your organization's most recent bylaws. Bylaws must be signed and dated, indicating review and approval by the governing board. A public

²⁸ ZCTAs are generalized areal representations of United States Postal Service ZIP Code service areas. ZCTAs were created to differentiate between areal service areas and mail delivery routes. See https://www.census.gov/programs-surveys/geography/guidance/geo-areas/zctas.html for more information.

center with a co-applicant must submit the co-applicant governing board's bylaws. See the GOVERNANCE section of the Project Narrative for details.

- * Attachment 3: Project Organizational Chart
 Upload a one-page document that depicts your current organizational structure, including the governing board, key personnel, staffing, and any subrecipients or affiliated organizations.
- _*_ Attachment 4: Position Descriptions for Key Management Staff
 Upload current position descriptions for key management staff: PD/CEO, CD, CFO,
 CIO, and COO. Indicate on the position descriptions if key management positions are
 combined and/or part time (consistent with Form 2: Staffing Profile). Limit each position
 description to **one page** and include, at a minimum, training and experience
 qualifications, duties, and functions.

The PD/CEO position description *must address* the following duties and responsibilities:

- Direct employment by the health center.
- Reports directly to the health center's governing board.
- Oversees other key management staff in carrying out the day-to-day activities necessary to carry out the proposed project.

Attachment 5: Biographical Sketches for Key Management Staff
Upload current biographical sketches for key management staff: PD/CEO, CD, CFO,
CIO, and COO. Identify if the individual will fill more than one key management position.
Biographical sketches should not exceed **two pages** each. Biographical sketches must include training, language fluency, and experience working with the cultural and linguistically diverse populations to be served, as applicable.

* Attachment 6: Co-Applicant Agreement (as applicable)
Public center applicants with a co-applicant board **must** submit the most recent copy of the formal co-applicant agreement, in its entirety, signed by both the co-applicant governing board and the public center.²⁹ See the <u>RESOURCES/CAPABILITIES</u> and GOVERNANCE sections of the Project Narrative for more details.

Attachment 7: Summary of Contracts and Agreements (as applicable)
Upload a brief summary describing all current or proposed patient service-related contracts and agreements, consistent with Form 5A: Services Provided, Columns II and III, respectively. The summary must address the following items for each contract or agreement:

- Name of contract/referral organization.
- Type of contract or agreement (e.g., contract, referral agreement, Memorandum of Understanding or Agreement).
- Brief description of the type of services provided and how and where services are provided.

²⁹ See the definition of a co-applicant in the Eligible Applicants footnotes for details.

• Timeframe for each contract or agreement (e.g., ongoing contractual relationship, specific duration).

If a contract or agreement will be attached to <u>Form 8: Health Center Agreements</u>, denote this with an asterisk (*). Contracts for substantive programmatic work and subrecipient agreements³⁰ **must** be included in Form 8.

* Attachment 8: Collaboration Documentation

Upload current dated documentation of collaboration activities to provide evidence of commitment to the project. See the <u>COLLABORATION</u> section of the Project Narrative for details on required documentation. Letters of support should be addressed to the organization's board, PD/CEO, or other appropriate key management staff member. You are encouraged to consider the impact on your application's page length when providing non-required documentation of collaboration.

* Attachment 9: Sliding Fee Discount Schedule(s)

Upload the current sliding fee discount schedule (SFDS) for services provided directly (consistent with <u>Form 5A: Services Provided</u>, Column I). The SFDS structure must be consistent with the policy (as described in the <u>RESPONSE</u> section of the Project Narrative) and provide discounts as follows:

- A full discount is provided for individuals and families with annual incomes at or below 100 percent of the current FPG, unless a health center elects to have a nominal charge, which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100 percent of the FPG.
- Partial discounts are provided for individuals and families with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG, and those discounts adjust based on gradations in income levels and include at least three discount pay classes.
- No discounts are provided to individuals and families with annual incomes above 200 percent of the current FPG.

Ensure the SFDS has incorporated the most recent <u>FPG</u>. If you have more than one SFDS for services provided directly (e.g., medical, dental), upload all SFDSs.

Attachment 10: Budget Narrative

Upload your budget narrative. Refer to the <u>LAL RD Technical Assistance webpage</u> for a sample budget narrative.

Attachment 11: Other Relevant Documents (as applicable)

Upload an indirect cost rate agreement, if applicable, and include other relevant documents to support the proposed project (e.g., charts, organizational brochures, lease agreements). Maximum of two uploads.

³⁰ Contracting for substantive programmatic work applies to contracting with a single entity for the majority of health care providers. The acquisition of supplies, material, equipment, or general support services is not considered programmatic work.

V. Review and Designation Process

If you do not include all required attachments and information, your application will be considered incomplete or non-responsive. Failure to submit the RD application by the established deadline or the submission of an incomplete or non-responsive RD application may result in conditions applied to the NLD that must be addressed to maintain designation, a delay in NLD issuance, or a lapse in designation and loss of corresponding benefits. Review the RD to ensure that it is both complete and responsive prior to submission.

Designation Period Length Criteria³¹

The length of designation period is determined by a comprehensive evaluation of compliance with program requirements by HRSA.

- If you are a LAL RD applicant and have any conditions related to Health Center Program requirements³² at the time designation decisions are made (inclusive of the requirements of section 330(k)(3) of the PHS Act), you will qualify for a 1-year designation period.
 - You will receive a 1-year designation period if you did not have consecutive 1-year designation periods in the previous two years.
 - You will NOT receive an FY 2022 renewal of your designation if you had consecutive 1-year designation periods in the previous two years.

When determining designation period length (see Designation Period Length Criteria section), HRSA may consider additional factors.³³ These factors include, but are not limited to, past performance, including unsuccessful Progressive Action condition resolution, management systems, compliance with public policy requirements, and continued eligibility. HRSA may conduct onsite visits and/or use the current compliance status to inform designation decisions. Designation decisions, including designation period length, are discretionary and not subject to appeal to any HRSA or HHS official or board.

VI. Designation and Reporting Information

1. Notice of Look-Alike Designation (NLD)

HRSA will issue a new NLD prior to your current designation period end date if your RD application is timely, complete, and eligible.

³¹ See Chapter 2: Health Center Program Oversight of the Compliance Manual.

³² Current unresolved conditions related to Health Center Program requirements carried over into the new designation period or new conditions related to Health Center Program requirements to be placed on the designation based on information included in this application and Assessment of Risk.

³³ See Chapter 2: Health Center Program Oversight of the Compliance Manual.

2. Reporting

If you are redesignated, you must comply with the following reporting and review activities:

- 1) Uniform Data System (UDS) Report The UDS collects data on all health centers to ensure compliance with legislative and regulatory requirements, improve health center performance and operations, and report overall program accomplishments. Award recipients and look-alikes are required to submit a UDS Universal Report and, if applicable, a UDS Grant Report annually, by the specified deadline. The Universal Report provides data on patients, services, staffing, and financing across all health centers. The Grant Report provides data on patients and services for special populations served (MHC, HCH, and/or PHPC). Failure to submit a complete UDS report by the specified deadline may result in conditions or restrictions being placed on your NLD.
- 2) Progress Report The LAL AC submission documents progress on program-specific goals. You will receive an email notification via EHBs that the AC is available for completion approximately 150 days from the end of each year within the designation period (with the exception of the final year of the designation period, when a new RD application must be submitted). You will have 60 days to complete and submit the AC. Submission and HRSA approval of the AC will trigger the certification period renewal as noted on the NLD. Lack of a timely AC submission may result in termination of your LAL designation and all corresponding benefits.

VII. AGENCY CONTACTS

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

Karen Fitzgerald, MPH
Public Health Analyst
Office of Policy and Program Development
Bureau of Primary Health Care (BPHC)
Health Resources and Services Administration
5600 Fishers Lane, Room 16N09
Rockville, MD 20857

Telephone: (301) 594-4300 Contact: <u>BPHC Contact Form</u>

You may need assistance when working online to submit your information electronically through EHBs. Always obtain a case number when calling for support. For assistance with submitting information in EHBs, contact Health Center Program Support, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET, excluding federal holidays at:

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

VIII. Other Information

Technical Assistance

A technical assistance webpage has been established to provide you with instructions for, and copies of, forms, FAQs, and other resources. To review available resources, visit the <u>LAL RD Technical Assistance webpage</u>.

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 have several staff subscribe.

340B Drug Pricing Program

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, codified as Section 340B of the Public Health Service Act, available at

http://www.hrsa.gov/opa/programrequirements/phsactsection340b.pdf. The program limits the cost of covered outpatient drugs for certain federal award recipients and lookalikes. Covered entities may realize a cost savings of 20-50 percent on outpatient drug purchases through participation in the 340B Program. If you are interested in 340B Program participation, you must register, be enrolled, and comply with all 340B Program requirements. There is no cost to participate in the 340B Drug Pricing Program or the 340B Prime Vendor Program, and eligible entities are not required to have an established in-house pharmacy to participate. For additional information, visit the Office of Pharmacy Affairs webpage at http://www.hrsa.gov/opa.