U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

Bureau of Primary Health Care

Health Center Program

Look-alike Renewal of Designation Application Instructions

Fiscal Year 2025

Issuance Date: July 4, 2024

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

Aileen Wood, MPH Public Health Analyst, Office of Policy and Program Development Bureau of Primary Health Care Contact: <u>BPHC Contact Form</u> Call: (301) 594-4300 Look-Alike Renewal of Designation Technical Assistance webpage

See <u>Section VII</u> for a complete list of agency contacts.

508 COMPLIANCE DISCLAIMER

Persons using assistive technology may not be able to fully access information in this file. For assistance, email or call one of the HRSA staff listed in <u>Section VII. Agency</u> <u>Contacts.</u>

SUMMARY

Application Availability:	HRSA Electronic Handbooks (EHBs) access will be available 180 calendar days before 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:	Applications are due 90 calendar days after EHBs access is granted (90 calendar days before the end of the current designation period).
Purpose:	To ensure continuity of affordable, accessible, and high-quality primary health care in the communities and populations currently served by Health Center Program look-alikes (LALs).
Program Objective(s):	 Improve the health of underserved populations, including individuals and families experiencing homelessness, migratory and seasonal agricultural workers, and residents of public housing by delivering comprehensive, culturally competent, high-quality primary health care and supportive services. Provide services regardless of the patient's ability to pay.

Eligible Applicants:	 You must be a LAL organization in the last year of your current designation period. At the time of Renewal of Designation (RD) submission, you must: a. Provide comprehensive primary medical care as its main purpose. b. Maintain one or more permanent primary care service delivery sites. c. Ensure access to services in the service area/target population for all individuals without regard for ability to pay. d. Serve a designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP). See the Eligibility section for complete eligibility information, including exclusions.
Agency Contacts:	Program issues or technical assistance: Aileen Wood, MPH Public Health Analyst Attn: LAL Renewal of Designation Bureau of Primary Health Care Health Resources and Services Administration Call: 301-594-4300 Contact: <u>BPHC Contact Form</u> Under Funding, select: 1. Look-Alike Designation 2. Select Renewal of Designation (LAL-RD)

Submission Schedule

Designation Period Start Date	EHBs Access*	EHBs Deadline ¹
January 1, 2025	July 4, 2024	October 2, 2024
February 1, 2025	August 4, 2024	November 2, 2024
March 1, 2025	September 1, 2024	November 30, 2024
April 1, 2025	October 2, 2024	December 31, 2025
May 1, 2025	November 1, 2024	January 30, 2025
June 1, 2025	December 2, 2024	March 2, 2025

Technical Assistance

The <u>Health Center Program Compliance Manual</u> explains the Health Center Program requirements. You need to understand the requirements and show how you meet them in your application.

The <u>RD Technical Assistance (TA) webpage</u> includes:

- Application resources, such as sample forms, attachments, instructions, and a User Guide,
- Applicant TA webinar and slides,
- Contact information for questions.

The HRSA-supported <u>Health Center Resource Clearinghouse</u> includes links to many health center resources.

Summary of Changes Since the FY 2024 LAL RD Designation Opportunity

• The <u>page limit</u> is reduced to 110 pages. This does not include required forms or the necessary attachments for eligibility, such as the bylaws, co-applicant agreement, and proof of non-profit public status.

¹ EHBs access and deadline dates are auto-generated by EHBs. Please work within these dates and, if needed, request technical assistance before the deadline if the deadline falls on a weekend or holiday.

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I. Renewal of Designation Description

1. Purpose

The <u>Health Resources and Services Administration (HRSA)</u> is accepting applications from existing Health Center Program look-alikes (LAL) for the fiscal year (FY) 2025 Renewal of Designation (RD). "Health Center" refers to both Health Center Program LALs and award recipients. It also includes Health Center Program LALs designated under the following statutory subsections of the Public Health Service (PHS) Act, as amended (42 USC 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

Health Center Program LALs are organizations that, like Health Center Program award recipients, improve the health of the nation's underserved communities and vulnerable populations by expanding access to comprehensive primary health care services in compliance with Health Center Program requirements. LALs were established to maximize health center access for medically underserved populations and communities by allowing organizations that don't receive Health Center Program funding to apply to become part of the Health Center Program.

While LALs do not receive Health Center Program grant funding, LAL designation allows these organizations to provide services and get federal benefits consistent with those funded under the Health Center Program. LAL designation is a basis for eligibility for Centers for Medicare and Medicaid Services (CMS) FQHC reimbursement, participation in the 340B Federal Drug Pricing Program, and the Vaccines for Children (VFC) program. LALs also receive automatic Health Professional Shortage Area designation and may access National Health Service Corp providers.

Through the HRSA Health Center Program, health centers ensure access to services and have an impact on improving the healthcare status of millions of medically underserved and vulnerable individuals throughout the United States and its territories. Health Center Program award recipients and LALs provide a system of care that is responsive to primary health care needs, provides services to all persons without regard for the ability to pay, and meets all Health Center Program requirements.

Designation Requirements and Expectations

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 You must propose a

²Requirements 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>).

comprehensive plan to 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 to provide health care to the underserved.

You must comply with all Health Center Program requirements as described in the <u>Health Center Compliance Manual</u> and applicable law and regulations. Failure to meet Look-alike and Health Center Program requirements may jeopardize LAL designation per Uniform Guidance <u>2 CFR Part 200</u>, as codified by the United States Department of Health and Human Services (HHS) at <u>45 CFR Part 75</u>.

- If you do not demonstrate compliance, you may receive a condition on your LAL designation and a 1-year designation period.
- If you do not resolve conditions through the progressive action process outlined in <u>Chapter 2: Health Center Program Oversight</u> of the <u>Health Center Program</u> <u>Compliance Manual</u>, HRSA will terminate your LAL designation.
- If you receive a 1-year designation period, you will submit a Compliance Achievement Plan for HRSA approval within 120 days of LAL designation. If you do not submit the required Compliance Achievement Plan³ within 120 days of designation or demonstrate good cause for not submitting it, HRSA will terminate your LAL designation.
- HRSA will not provide LAL designation for a third consecutive 1-year period unless we determine that you are compliant with all program requirements (see the <u>Designation Period Length Criteria</u> section for details).

In addition to the general Health Center Program requirements discussed above, applicants requesting LAL designation to serve special populations must also comply with additional requirements of the PHS Act as outlined below:

- Section 330(g) for Migrant Health Center applicants,
- Section 330(h) for Health Care of the Homeless applicants,
- Section 330(i) for Public Housing Primary Care applicants.

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 EHBs.

II. Designation Information

Designation may be granted for a period of up to 3 years. Continued designation depends on satisfactory LAL progress, 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

 $^{^{3}}$ Refer to Section 330(e)(1)(B) of the PHS Act.

Annual Certification (AC) applications and annual Uniform Data System (UDS) submissions.

III. Eligibility Information

You must meet all 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 Notice of Look-alike Designation (NLD). You must address these conditions to ensure ongoing designation.

Eligibility Requirement	What We Check
 Your organization must be a currently designated LAL organization.⁴ Current LAL organizations include private, non-profit entities or public agencies in the United States or territories. Tribes, tribal, faith-based, or community-based organizations are eligible.⁵ 	 Most recent NLD Form 1A: General Information Worksheet Evidence of non-profit or public agency status (if applicable)
 Your organization must not be owned, controlled, or operated by another entity.⁶ Organizational structures such as parent- subsidiary arrangements or network corporations may not be eligible for designation. 	 <u>Attachment 3: Project</u> <u>Organizational Chart</u> <u>Form 8: Health Center</u> <u>Agreements</u> and its attachments
 3) Your organization must perform a substantive role in the project and meet the program requirements. Note: LAL organizations that do not propose to perform a substantive role in the project will be considered non-responsive and will not be considered for designation. 	 <u>Budget Justification Narrative</u> <u>Attachment 2: Bylaws</u> <u>Form 5A:5 Services Provided</u> (Column 1) <u>Form 8: Health Center</u> <u>Agreements</u> and its attachments

⁴ For more information about becoming a LAL refer to the <u>LAL Initial Designation Technical Assistance</u> webpage.

⁵ Refer to Chapter 1: Health Center Program Eligibility of the Compliance Manual.

⁶ Section 1905(I)(2)(B)(iii) of the Social Security Act, as amended.

Eli	gibility Requirement	What We Check
4)	Your organization must provide comprehensive primary medical care as your main purpose.	 Project Narrative <u>NEED</u> section Form 1A: General Information <u>Worksheet</u> Form 5A: Services Provided (Columns 1 and 2)
5)	Your organization must provide all required health care services that are available and accessible in the service area without regard for the ability to pay. ⁷ You may not propose to provide only a single type of service, such as dental, behavioral, or prenatal services.	 Project Narrative <u>RESPONSE</u> section <u>Form 5A: Services Provided</u> (Columns 1, 2, and 3)
6)	Your organization must provide General Primary Medical Care directly and/or through contracts, the health center pays.	• <u>Form 5A: Services Provided</u> (Columns 1 and 2)
7)	You must make services accessible to all. You may not propose to serve only a single age group or disease or address a single health issue or disease. If you propose a site that targets only a sub-population (e.g., a school- based site), you must explain how you will make all required services available and accessible to others who seek services at the LAL site(s).	Project Narrative <u>RESPONSE</u> section
8)	Your organization (except applicants with designation for only serving special populations (i.e., MHC, HCH, and PHPC)) must continue to serve a defined geographic area currently federally designated, in whole or in part, as an MUA or an MUP.	 Form 5B: Service Sites Service Area Zip Codes: The zip codes listed on Form 5B: Service Sites (administrative-only sites will not be considered) Shortage Designation Area

⁷ Refer to the <u>Service Descriptors for Form 5A: Services Provided</u> for details regarding required primary health care services.

Eligibility Requirement	What We Check
9) Your organization must meet the application deadline (90 days before the end of your current designation period). See <u>Section VI</u> for detailed information about the application timeline and due date.	 HRSA EHBs submission receipt deadline

IV. APPLICATION AND SUBMISSION INFORMATION

We require you to apply online through EHBs. In addition to following these instructions, you should refer to the EHBs RD User Guide available on the <u>LAL RD Technical</u> <u>Assistance webpage</u> for submission instructions.

Your application is due 90 days before your organization's current designation period ends. We will send an email notice when your application is available to your organization's contacts in EHBs, which will be 180 days before the end of the current designation period. You will have 90 calendar days to complete your RD application and have your Authorizing Organization Representative (AOR) submit in EHBs.

Failure to submit your RD application by the due date (90 days before the end of your current designation period) may result in the termination of LAL designation and all corresponding benefits.

1. Content and Form of Application Submission

Application Format Requirements

Write your application in **English. Use U.S. dollars for your budget**. The following application components must be submitted in EHBs:

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

Application Page Limit

The page limit for your application is **110 pages**. We will not review any pages that exceed the page limit. Using the pages within the page limit, we will determine eligibility using <u>Section III. Eligibility Information</u> of these instructions.

These items do not count toward the page limit:

- Standard OMB-approved forms included in the workspace application package, including the program-specific forms in EHBs,
- Attachments that are uploaded to program-specific forms in EHBs,
- Attachments to determine eligibility including <u>Attachment 6: Co-Applicant</u> <u>Agreement</u>, evidence of non-profit status (if applicable), and <u>Attachment 2:</u> <u>Bylaws</u>.
- Indirect Cost Rate Agreement,
- Abstract (standard form (SF) "Project Abstract Summary").

It is important to make sure your application is within the specified page limit. We recommend only using the forms available in EHBs.

Applications must be complete, within the specified page limit, and submitted before the EHBs deadlines.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- When you submit your application, you certify that you and your principals⁸ (e.g., program director) can participate in this federal project. That is, no federal department or agency has debarred, suspended, proposed for debarment, claimed you ineligible, or you have voluntarily excluded yourself from participation.
- If you fail to make mandatory disclosures, we take an action like those in <u>45 CFR</u> <u>§ 75.371</u>. This includes suspending or debarring you.⁹
- If you cannot certify this, explain why in <u>Attachment 11: Other Relevant</u> <u>Documents</u>.

Application Content

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 PHPC)

The abstract should provide a brief description of your project, including the following:

⁸ See definitions at <u>eCFR: 2 CFR 180.995 -- Principal</u>. and <u>eCFR: 2 CFR 376.995 -- Principal (HHS</u> supplement to government-wide definition at 2 CFR 180.995).

⁹ See also 2 CFR parts <u>180</u> and <u>376</u>, <u>31 U.S.C. § 3354</u>, and <u>45 CFR § 75.113</u>.

- A brief history of your organization, the community you serve, and your target population(s),
- A summary of the major health care needs and barriers to care that you address through the project. This summary should include the needs of any targeted special population(s) (i.e., migratory and seasonal agricultural workers, people experiencing homelessness, and residents of public housing),
- A description of how your project addresses your community's need for comprehensive primary health care services, and
- The number of current and proposed patients, providers, and service delivery sites and locations.

iii. Project Narrative

An attachment that describes all aspects of the proposed project. Responses should be brief and clear.

Provide information in the order described in the sections below. Use the section headers to ensure that reviewers can understand your proposed project.

The application content that HRSA will use, in whole or in part, in the RD-based assessment of compliance is noted with a bolded, underlined asterisk (<u>*</u>). Refer to the RD Compliance Assessment Guide on the <u>RD TA webpage</u> for the specific <u>Compliance</u> <u>Manual</u> chapters and elements related to items with a bolded, underlined asterisk.

Your Project Narrative must:

- Address the specific Project Narrative items below, with the requested information appearing under the appropriate section header or in the designated forms and attachments.
- Reference attachments and forms as needed. Referenced items must be part of the EHBs submission.
- Demonstrate compliance with Health Center Program requirements, as detailed in the <u>Compliance Manual.</u>
- Reflect your currently approved scope of project. Any changes in scope must be requested 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 used to inform and improve the delivery of health center services.
- 1) Describe the proposed service area (consistent with <u>Attachment 1: Service Area</u> <u>Map and Table</u>), including:
 - a) The service area boundaries.
 - b) If the service area is located in an Opportunity Zone (if applicable).¹⁰

¹⁰ The list of Qualified Opportunity Zones is available at <u>Opportunity Zones Resources</u>.

- c) How you determined and will annually review the proposed service area, including the zip codes listed on Form 5B: Service Sites based on where the proposed patients reside. Updates must be consistent with data reported in the Uniform Data System (UDS). Your explanation should include how the boundaries of the service area 1) ensure that the services provided are available and accessible to the residents of the area, 2) overlap with political subdivisions, school districts, and areas served by Federal and State health and social service programs, and 3) eliminate barriers to access.
- 2) Describe how you determined the number of:
 - a) Unduplicated patients that you project to serve in calendar year 2026, as documented on Form 1A: General Information Worksheet.
 - b) Patients you project to serve for each service type, as documented on <u>Form 1A</u>: <u>General Information Worksheet</u>, in alignment with the services currently provided in the service area. If you have an increase in patients in other service types, describe how you are maintaining comprehensive primary medical care as your health center's main purpose and at one or more permanent service delivery sites.
- 3) Describe health care needs in your service area. Cite relevant data and their sources, which may include the unmet need score (UNS). Address the following:
 - a) Comprehensive health care services.
 - b) Enabling services (e.g., outreach, transportation, translation/interpretation).
 - c) Patient-centered care coordination, including health-related social needs.
 - d) Any other unique needs that impact health status (e.g., food insecurity, housing insecurity, neighborhood and the built environment, environmental issues or changes, intimate partner violence, human trafficking).
- 4) Describe any recent or potential changes in the local health care landscape and how those changes affect the needs of the target population.
- 5) Describe how you will conduct and update the needs assessment and regularly update your Scope of Project to reflect the need for additional services. Include how you will use patient and community input to inform and improve service delivery.

RESPONSE

- Describe how the proposed service delivery sites on <u>Form 5B: Service Sites</u> assure equitable availability and accessibility of services (consistent with <u>Form 5A: Services</u> <u>Provided</u>) and minimize barriers within the proposed service area, including:
 - a) Your plans for service delivery sites in relation to where the target population lives and works.
 - b) How you will address geographic barriers, location of sites and hours of operation.
- 2) Describe how your services will be comprehensive, affordable, and culturally and linguistically appropriate for all patients. Include how you will provide:

- a) Comprehensive services, including those required on <u>Form 5A: Services</u> <u>Provided</u> and, as appropriate and feasible, other additional services identified in your needs assessment.
- Enabling services (e.g., outreach, transportation, translation/interpretation) to address health-related social needs, enhance patient experience, and facilitate access to care.
- c) Patient-centered care coordination, informing patients about public and private health insurance options, helping patients apply for government assistance programs, and linking to community partners.
- d) Additional services to address unique needs that impact health status (e.g., food insecurity, housing insecurity, neighborhood, and the built environment, environmental issues or changes, intimate partner violence, and human trafficking).
- 3) <u>*</u>Describe how your sliding fee discount policies and schedule make services affordable for your target population. Describe how you will inform the public that you offer services on a sliding fee discount schedule and without regard for the ability to pay. Describe the following:
 - a) Uniform applicability to all patients.
 - b) Definitions of income and family.
 - c) Alignment with the current Federal Poverty Guidelines (FPG)
 - d) Methods for assessing all patients for sliding fee discount eligibility based only on income and family size.
 - e) Assurance that patient charges are adjusted based on ability to pay and consistent SFDS.
 - f) Policies related to nominal charges for patients with incomes at or below 100 percent of the current FPG. (Describe whether the nominal charge is flat, is set at a level that is nominal from the perspective of the patient or does not reflect the actual cost of the service being provided. Or state if you do not have a nominal charge for patients with incomes at or below 100 percent of FPG.)
- 4) Describe how you provide care that is respectful and responsive to individual preferences, cultures, needs, and values. Include how you will:
 - a) Engage patients to participate in their care and maximize their experience of their care.
 - b) Create partnerships with families and caregivers.
 - c) Train providers on cultural competence and working with underserved populations.
- 5) Describe your communication tools and protocols, referral processes, and electronic exchange of patient health records that facilitate 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.

COLLABORATION

- <u>*</u> Describe your collaboration with diverse partners to increase awareness of the community's health needs and social risk factors (consistent with <u>Attachment 1:</u> <u>Service Area Map and Table</u>), to provide access to services not available through the health center and 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) <u>*</u> Describe and document in <u>Attachment 8: Collaboration Documentation</u> how you coordinate services with other providers in your service area (consistent with <u>Attachment 1: Service Area Map and Table</u>). Include:
 - a) Other community health centers, including look-alikes. (If you cannot get a requested letter of support from other health centers, include documentation of efforts made to get the letter¹¹).
 - b) Providers of specialty services and other services not available through your health center.
 - c) Local hospitals, to reduce non-urgent use of hospital emergency departments.
 - d) Others that serve similar populations (such as health departments, schools, community organizations, environmental organizations, homeless shelters, and <u>Indian Health Services</u> health facilities).
- 3) Describe how you collaborate with the Primary Care Association (PCA) in your state or region and, if you are a participating health center in a Health Center Controlled Network (HCCN), how you engage with that network to leverage information technology and data to improve patient care.

RESOURCES/CAPABILITIES

- 1) Describe your organizational structure, including:
 - a) How your organization will play a substantive role in implementing the LAL project.
 - a) How any subrecipients and contractors will assist in carrying out the proposed project (consistent with <u>Attachments 2: Bylaws</u> and <u>3: Project Organizational</u> <u>Chart</u>, and, as applicable, Attachments <u>6: Co-Applicant Agreement</u> and <u>7:</u> <u>Summary of Contracts and Agreements</u>).
 - b) If your organization is part of a parent, affiliate, or subsidiary organization (consistent with <u>Form 8: Health Center Agreements</u>), describe these relationships.
- 2) Describe the key management team, including the Program Director (PD) or Chief Executive Officer (CEO), Clinical Director (CD), and Chief Financial Officer (CFO)

¹¹ You are encouraged to consider the impact on your application's page length when providing non-required documentation of collaboration.

(consistent with <u>Attachment 5: Biographical Sketches for Key Management staff</u>). Include:

- a) <u>*</u> Responsibilities of the PD/CEO¹² for reporting to the health center governing board, carrying out the independent, day-to-day activities of the proposed project, and overseeing other key management staff (consistent with <u>Attachment 4:</u> <u>Position Descriptions for Key Management Staff</u>).
- b) How they will promote innovation and a culture of quality improvement that is responsive to the community's needs.
- 3) Describe how you recruit, develop, engage, and retain a staffing mix of qualified providers to provide care to your target population.
- 4) Describe how your financial accounting and internal control systems and policies:
 - a) Ensure effective control over all health center funds, property, and other assets.
 - b) Track the financial performance of the health center.
 - c) Account for all federal award(s).
 - d) Mitigate conflict of interest by board members, employees, and others when buying supplies, property, equipment, and services.
- 5) <u>*</u> Describe how you conduct billing and collections, including:
 - a) How board-approved policies and operating procedures ensure that fees or payments will be waived or reduced based on specific circumstances due to any patient's inability to pay.
 - b) Participating in Medicare, Medicaid, Children's Health Insurance Program (CHIP), and, other public or private assistance programs or health insurance, as applicable (consistent with <u>Form 3: Income Analysis</u>).
- 6) Describe your past experience and plans for maintaining continuity of services and responding to urgent primary health care needs during natural or man-made disasters and public health emergencies.¹³ ¹⁴
- 7) Citing your UDS data for the number of unduplicated patients served in calendar year 2023, describe factors that have affected your 3-year patient trend since your last RD application. Explain any downward trend in your total unduplicated patients.

IMPACT

- 1) Describe how the health center's Quality Improvement/Quality Assurance (QI/QA) program:
 - a) Addresses patient safety.
 - b) Improves patient experience and satisfaction.

¹² The PD/CEO must be a direct employee of the health center.

¹³ Including natural or manmade disasters, as well as emergent or established public health emerge.

¹⁴ Consistent with the Center for Medicare & Medicaid Services (CMS) national emergency preparedness requirements. See details at the <u>Emergency Preparedness Rule</u>.

- c) Uses systems such as electronic health records or population management systems to monitor and track social risk factors that impact health and collect UDS data.
- 2) Describe how you will improve clinical quality, 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) Maternal and child health (e.g., early entry into prenatal care, low birth weight, childhood immunization status, dental sealants).
 - f) Ending the HIV epidemic (e.g., HIV screening, HIV linkage to care, pre-exposure prophylaxis (PrEP)).
 - g) Cancer screening (e.g., cervical, breast, and colorectal cancer screening).

GOVERNANCE

Items 1 through 4 do not apply to Native American tribes or tribal, Native American, or Urban Indian groups.

- 1) <u>*</u> Describe where in <u>Attachment 2: Bylaws</u> (and, if applicable, <u>Attachment 6: Co-</u><u>Applicant Agreement</u>) you document the following board composition requirements:
 - a) Board size is at least 9 and no more than 25 members, with a prescribed number or range of board members.¹⁵
 - b) At least 51 percent of board members are patients served by the health center.^{16, 17, 18}
 - 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).¹⁹
 - d) Non-patient members are representatives 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, other commercial and industrial concerns, and 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 healthcare industry.

¹⁵ List board members on Form 6A: Current Board Member Characteristics.

¹⁶ 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.

¹⁷ 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>.

¹⁸ You may request a waiver of this requirement on <u>Form 6B: Request for Waiver of Board Member</u> <u>Requirements</u> 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.

¹⁹ Board representation is demonstrated on Form 6A: Current Board Member Characteristics.

- 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.^{20, 21}
- 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 health center's operations.
 - g) Assuring the health center complies 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</u> <u>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 <u>Attachment 3: Project</u> <u>Organizational Chart</u>) reserves approval authority or has veto power over the board regarding 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 <u>Attachment 6: Co-Applicant Agreement</u>).
- 4) Describe how you have implemented effective governance to continually promote excellence in the delivery of care to your community. Specifically address:
 - a) How the governing board leverages their expertise (consistent with <u>Form 6A:</u> <u>Current Board Member Characteristics</u>) to improve patient-centered care provided by the health center.
 - b) How the governing board ensures that operations are compliant, cohesive, and function optimally and how they promote innovation, a community-minded approach, and a culture of quality improvement.

²⁰ Refer to <u>Chapter 20</u>: Board Composition of the Compliance Manual.

²¹ 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).

- c) How the governing board builds and maintains capacity to strengthen governance performance.
- 5) 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. <u>*</u> Budget Justification Narrative

You must provide a detailed budget narrative for **each requested 12-month** certification period of the 3-year designation period. In addition, classify year 1 of the budget narrative into federal and non-federal resources. For future budget years, the narrative should highlight the changes from year 1 or indicate no substantive changes during the designation period.

Format the budget narrative to have all columns fit on an 8.5 x 11 page in portrait orientation when printed. Upload as <u>Attachment 10: Budget Justification Narrative</u> in your RD application. See the <u>LAL RD Technical Assistance webpage</u> for a sample Budget Narrative.

Note: If your organization receives federal funding, you must have the necessary policies, procedures, and financial controls to 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.

v. Program-Specific Forms

All forms, except <u>Form 5C: Other Activities/Locations</u>, are required. You must complete these OMB-approved forms directly in EHBs. The forms that HRSA will use to assess your compliance with program requirements, as detailed in the <u>Compliance Manual</u>, are noted with a bolded, underlined asterisk (<u>*</u>).

Refer to the LAL RD TA webpage for samples and instructions.

* 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
* 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

<u>* Form 8: Health Center Agreements</u> Form 12: Organization Contacts Scope Certification Form

vi. Program Specific Attachments

Provide the following attachments in the order we list them. HRSA will assess your compliance with program requirements, as detailed in the <u>Compliance Manual</u>, using the attachments noted with a bolded, underlined asterisk (<u>*</u>).

Most attachments count toward the <u>application page limit</u>. Attachment 2: Bylaws, Attachment 6: Co-Applicant Agreement, Indirect Cost Rate Agreement, and evidence of non-profit status (if it applies) do not count toward the page limit.

Clearly label each attachment. Upload attachments into the application. Reviewers won't open any hyperlinks in the attachments.

Attachment 1: Service Area Map and Table (Required)

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

- Proposed health center site(s) listed on Form 5B: Service Sites.
- Proposed service area zip codes.
- Any medically underserved areas (MUAs) and 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 the <u>Health Center Program GeoCare Navigator</u>. The <u>HCP-GeoCare Navigator-User-Guide</u> is available under the Resources tab.

<u>*</u> Attachment 2: Bylaws (Required)

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, and presented in English. A public center with a co-applicant must submit the co-applicant governing board's bylaws. See the <u>GOVERNANCE</u> section of the Project Narrative for details.

<u>*</u> Attachment 3: Project Organizational Chart (Required)

Upload a one-page document that shows your current organizational structure, including the governing board, key personnel, staffing, and any subrecipients or affiliated organizations.

<u>*</u> Attachment 4: Position Descriptions for Key Management Staff (Required) Upload current position descriptions for key management staff: PD/CEO, CD, CFO, CIO, and COO. Indicate if key management positions are combined and part-time (consistent with Form 2: Staffing Profile). Limit each position description to **one page**, including training and experience qualifications, duties, and functions. The PD/CEO position description *must address how the PD/CEO*:

- Is directly employed 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 for the proposed project.

Attachment 5: Biographical Sketches for Key Management Staff (Required) Upload current biographical sketches for key management staff: PD/CEO, CD, CFO, CIO, and COO. Identify if a person will fill more than one key management position. Limit sketches to **two pages** each. Include training, language fluency, and experience working with the culturally and linguistically diverse populations to be served, as applicable.

<u>*</u> 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, signed by both the co-applicant governing board and the public center.²² See the <u>RESOURCES/CAPABILITIES</u> and <u>GOVERNANCE</u> 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 <u>Form 5A: Services Provided</u>, Columns II and III.
- Agreements for a substantial portion of the project. If you contract with one entity for most health care providers or have a sub-recipient agreement, you must include the contract or agreement in Form 8: Health Center Agreements. (Include an asterisk next to these providers.)
- Lease agreement(s) if applicable.

The summary must address the following items for each contract or agreement:

- Name of contract or referral organization.
- If it is a contract or referral arrangement.
- Brief description of the services the contractor or referral organization will provide, how and where they will provide these services, and the timeframe for the agreement.
- The process for tracking and referring patients back to the health center for appropriate follow-up care.

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 agreements²³ **must** be included in Form 8.

²² See the definition of a co-applicant in the <u>Eligible Applicants</u> footnotes for details.

²³ Contracting for substantive programmatic work applies to contracting with a single entity for most health care providers. The acquisition of supplies, material, equipment, or general support services is not considered programmatic work.

<u>*</u> Attachment 8: Collaboration Documentation (Required)

Upload letters of support and other current dated documentation of collaboration specific 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.

Note: Reviewers will only consider documentation submitted with your application.

<u>*</u> Attachment 9: Sliding Fee Discount Schedule(s) (Required)

Upload the current sliding fee discount schedule (SFDS). It must be consistent with the policy described in the <u>RESPONSE</u> section of the Project Narrative. Your SFDS must:

- Be based on the most current <u>FPG</u>²⁴.
- Provide a full discount for people with annual incomes at or below 100 percent of the current FPG. You may have a nominal charge if it is less than the fee paid by a patient in the first pay class above 100 percent of the FPG.
- Provide partial discounts for people with incomes above 100 percent of the current FPG and at or below 200 percent of the current FPG.
- Include at least three discount pay classes based on income levels.
- Not provide discounts to people with annual incomes above 200 percent of the current FPG.

Upload each SFDS if you have more than one, such as medical and dental. For more information about sliding fee requirements, see <u>Chapter 9: Sliding Fee Discount</u> <u>Program</u> of the Compliance Manual.

Attachment 10: <u>Budget Justification Narrative</u> (Required)

Upload your budget narrative. Refer to the <u>LAL RD TA 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). You are allowed a maximum of two uploads.

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

²⁴ In assessing compliance with sliding fee discount requirements, HRSA will take into consideration that the FPG may have been updated during the SAC open application period.

corresponding benefits. Review the RD to ensure it is complete and responsive before submission.

Designation Period Length Criteria²⁵

A comprehensive evaluation of compliance with program requirements by HRSA determines the length of the designation period.

- If you are a LAL RD applicant and have any conditions related to Health Center Program requirements²⁶ outlined in section 330(k)(3) of the PHS Act, at the time designation decisions are made, you will qualify for a 1-year designation period.
 - If you are an LAL RD applicant and any areas of non-compliance with Health Center Program requirements are identified, HRSA will contact your AOR to provide 14 calendar days to submit additional information documenting compliance with program requirements before making final designation decisions. Such information submissions do not guarantee that HRSA will make a designation to your organization, but it is necessary to determine the organization's eligibility for such designation.
 - If a designation is made but the conditions are not resolved, you will receive a 1year designation period if you did NOT have consecutive 1-year designation periods in the previous two years due to non-compliance with Health Center Program requirements.²⁷
 - You will NOT receive an FY 2025 renewal of your designation if you had consecutive 1-year designation periods in the previous two years.

When determining designation period length, HRSA may consider additional factors.²⁸ 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 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 before your current designation period end date if your RD application is timely, complete, and eligible.

²⁵ See <u>Chapter 2</u>: Health Center Program Oversight of the Compliance Manual.

²⁶ 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.

 ²⁷ Not applicable if the 1-year designation period was designated only because of being a new Look-alike and no conditions related to Health Center Program requirements were placed on the initial NLD.
 ²⁸ 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:

 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 must submit a UDS report consistent with HRSA guidance.

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 programspecific 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 (except the final year 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.

Failure to submit a timely or non-responsive AC submission may result in the termination of your LAL designation and all corresponding benefits.

VII. AGENCY CONTACTS

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

Aileen Wood, MPH Public Health Analyst Bureau of Primary Health Care (BPHC) Health Resources and Services Administration Telephone: (301) 594-4300 Contact: <u>BPHC Contact Form</u>

Under Funding, select:

- 1. Look-Alike Designation
- 2. Renewal of Designation (LAL-RD)

You may need help when working online to submit your information electronically through the <u>EHBs</u>. Always get a case number when calling for support. For assistance with submitting information in EHBs, contact the HRSA Electronic Handbooks Customer Support Center, Monday-Friday, 7 a.m. to 8 p.m. ET, excluding federal holidays at:

Call: 1-877-464-4772/ (877) Go4-HRSA TTY: (877) 897-9910 Web: <u>Electronic Handbooks Contact Center</u>

VIII. Other Information

Technical Assistance

Visit the <u>LAL RD TA webpage</u> for resources that may support developing your submission.

HRSA Primary Health Care Digest

The HRSA <u>Primary Health Care Digest</u> is a weekly newsletter with Health Center Program information and updates. We encourage you and your staff to <u>subscribe</u>.

340B Drug Pricing Program

The 340B Drug Pricing Program was created in 1992 and helps certain safety net providers known as covered entities stretch limited federal resources to reach more eligible patients and provide more comprehensive services. Eligible entities obtain discounts on covered outpatient drugs from drug manufacturers and are listed in section 340B (a)(4) of the Public Health Service Act. These providers include Federal Qualified Health Centers, AIDS Drug Assistance Programs, and certain disproportionate share hospitals. Manufacturers participating in the Medicaid Drug Rebate Program agree to charge covered entities a price that will not exceed the amount determined under the statute (ceiling price) when selling covered outpatient drugs. Covered entities receive these drugs at significantly reduced prices. Covered entities, including HRSA-funded health centers and look-alikes, must first register and be approved by HRSA's Office of Pharmacy Affairs before participating in the Program. Once enrolled, the entity must comply with all 340B Program requirements. For additional information and to register, visit the Office of Pharmacy Affairs <u>340B Drug Pricing Program webpage</u>.