U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration

Federal Office of Rural Health Policy Black Lung Clinics Program

Black Lung Clinics Program

Announcement Type: New and Competing Continuation **Funding Opportunity Number:** HRSA-17-023

Catalog of Federal Domestic Assistance (CFDA) No. 93.965

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2017

Application Due Date: March 6, 2017

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

Deadline extensions are not granted for lack of registration.

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

may take up to one month to complete.

Issuance Date: January 5, 2017

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Authority: Sec. 427(a) of the Federal Mine Safety and Health Act of 1977, as amended

(30 U.S.C. 937); 42 C.F.R. part 55a.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Federal Office of Rural Health Policy, is accepting applications for fiscal year (FY) 2017 Black Lung Clinics Program (BLCP). The purpose of this program is to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease through the provision of quality medical, outreach, educational, and benefits counseling services.

Funding Opportunity Title:	Black Lung Clinics Program
Funding Opportunity Number:	HRSA-17-023
Due Date for Applications:	March 6, 2017
Anticipated Total Annual Available	\$6,606,469
Funding:	
Estimated Number and Type of Award(s):	Up to 15
Estimated Award Amount:	Varies
Cost Sharing/Match Required:	No
Project Period:	July 1, 2017 through June 30, 2020
	(3 years)
Eligible Applicants:	Any state, public, private entity including
	faith-based and community organizations,
	as well as federally-recognized Indian
	tribal governments and organizations.
	[See Section III-1 of this funding
	opportunity announcement (FOA) for
	complete eligibility information.]

Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this FOA to do otherwise. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

The Federal Office or Rural Health Policy will hold a technical assistance webinar on **Wednesday**, **January 18**, **2017 from 12:00-1:00 p.m. EST** to assist applicants in preparing their applications. The Adobe Connect webinar and call-in information is as follows:

Conference line (for audio): 888-989-7534, passcode: 1899090

URL (for web): https://hrsa.connectsolutions.com/blacklungfoa/

(Please enter as a "Guest.")

Note: you must dial into the conference line to hear the audio portion of the webinar. No pre-registration is required.

For your reference, the technical assistance call will be recorded and available for playback within one hour of the end of the call and will be available until **March 25**, **2017.** The phone number to hear the recorded call is 866-499-4576, passcode: 9819.

The Technical Assistance call is open to the general public. The purpose of the call is to review the FOA and to provide any additional or clarifying information that may be necessary regarding the application process. There will be a Q&A session at the end of the call to answer any questions. While the call is not required, it is highly recommended for any organization interested in applying for the Black Lung Clinics Program.

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for the Black Lung Clinics Program (BLCP). BLCP's primary goal is to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease (CMDLD)¹ through the provision of medical, outreach, educational, and benefits counseling services.

2. Background

BLCP is authorized by Section 427(a) of the Federal Mine Safety and Health Act of 1977, as amended,² and accompanying regulations found at 42 CFR Part 55a.³ Through BLCP, public, private, and state entities provide medical, outreach, educational, and benefits counseling services to active, inactive, and disabled coal miners⁴ throughout the country with the goal of reducing the morbidity and mortality associated with occupationally-related CMDLD. Per statute, funding allocations to BLCP awardees must take into account (1) The number of miners to be served and their needs; and (2) the quality and breadth of services to be provided⁵ and applicants must describe both the need for services in their target area and how they intend to meet that need.

Since the program's inception, BLCP awardees have served as critical access points for coal miners seeking education and medical services pertaining to their occupationally-related lung disease and guidance on how to apply for Federal Black Lung Benefits. Between July 1, 2015 and June 30, 2016, BLCP awardees reported serving over 13,000 coal miners⁶ across 14 states.

Recent data highlight the continued need for these services. After nearly three decades of steady decline following the enactment of the Federal Coal Mine Safety and Health Act of 1969, the national prevalence of coal workers' pneumoconiosis (CWP), also known as black lung disease, has been on the rise since FY 2000.⁷ Investigators from

¹ CMDLD is used here to refer to a spectrum of lung diseases caused by inhaling coal mine dust that includes coal workers' pneumoconiosis, mixed dust pneumoconiosis, silicosis, dust-related diffuse fibrosis, and chronic obstructive pulmonary disease. See, e.g., Petsonk et al (2013), "Coal Mine Dust Lung Disease: New Lessons from an Old Exposure," American Journal of Respiratory and Critical Care Medicine 187(11), pp. 1178-1184.

² Sec. 427(a) of the Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 937(a))

³ 42 CFR part 55a

⁴ Per 42 CFR part 55a, a "coal miner" is defined as: Any individual who works or has worked in or around a coal mine or coal preparation facility in the extraction or preparation of coal. The term also includes an individual who works or has worked in coal mine construction or transportation in and around a coal mine, to the extent that the individual was exposed to coal dust as a result of employment.

⁵ 42 CFR part 55a

⁶ According to annual performance data submitted to HRSA by the grant recipients

⁷ CDC (2011), "Coal Mine Dust Exposures and Associated Health Outcomes," Current Intelligence Bulletin 64, http://www.cdc.gov/niosh/docs/2011-172/pdfs/2011-172.pdf

the National Institute for Occupational Safety and Health (NIOSH) have also reported that the prevalence of progressive massive fibrosis (PMF), the most severe form of black lung disease, increased 900 percent between 2000 and 2012, affecting over 3 percent of miners with over 25 years of work experience.⁸ This level of prevalence of PMF has not been seen since the 1970s.

Response to the Federal Register Notice (FRN)9

HRSA published a 30-day public notice in the Federal Register on August 22, 2016 soliciting feedback on a range of issues pertaining to BLCP. On January 5, 2017, HRSA published an FRN responding to the comments it received during the 30-day notice. The response is viewable at the following link: https://www.federalregister.gov/documents/2017/01/05/2016-32003/proposed-changes-to-black-lung-clinics-program-for-consideration-for-fy-2017-funding-opportunity.

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New and Competing Continuation

Funding will be provided in the form of a grant.

2. Summary of Funding

Approximately \$6,606,469 is expected to be available annually to fund up to fifteen (15) recipients. This funding is based on prior year (FY 2016) funding as the FY 2017 budget for the program is awaiting final approval. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is July 1, 2017 to June 30, 2020 (three (3) years). Funding beyond the first year is dependent on the availability of appropriated funds for BLCP in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award are subject to the Uniform Guidance 2 CFR part 200 as codified by HHS at 45 CFR part 75, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

Funding Allocations and Service Areas:

⁸ Blackley & Halldin (2014), "Resurgence of a Debilitating and Entirely Preventable Respiratory Disease among Working Coal Miners," *American Journal of Respiratory and Critical Care Medicine* 190(6), http://www.atsjournals.org/doi/pdf/10.1164/rccm.201407-1286LE.

 $^{^{9}}$ 81 FR 56660, <u>https://www.federalregister.gov/documents/2016/08/22/2016-19938/proposed-changes-to-the-black-lung-clinics-program.</u>

In response to the comments to the FRN, HRSA removed the previous per-applicant cap and funding tier structure. Instead, HRSA allocated funds to service areas based on the level of BLCP funding that each service area received in FY 2016. Applicants applying to serve a particular service area should propose a level of services commensurate with current efforts in that service area, though limited exceptions can be made. This approach is intended to minimize service disruptions and ensure continuity of care to coal miners in service areas currently served by BLCP awardees, while maintaining alignment with program regulations.¹⁰

Applicants must propose to serve the entirety of the service area they are applying to cover, as outlined below (See Section II.2.Table A). Applicants may only propose to serve one (1) service area, but they may propose to serve additional counties so long as they demonstrate how they will avoid duplication of services. HRSA recognizes that more than one clinic may be providing complementary services to coal miners in a given county. Applicants proposing to serve Service Areas A, B, I, J, and K must detail how they intend to avoid duplicating efforts of other black lung clinics in the counties where there is overlap.

Table A: Current BLCP Funding Allocations and Service Areas*

Service Area	<u>Counties</u>	FY 2016 Funding Amount (\$)
Service Area A:	Arizona: Apache, Coconino, Navajo	215,766
Service Area B:	Colorado: All counties Arizona: Apache, Clark, Coconino, Maricopa, Navajo, Yavapai	609,642
Service Area C:	Illinois: All counties; Indiana: All counties	632,786
Service Area D:	Kentucky: Bell, Breathitt, Floyd, Harlan, Knott, Leslie, Letcher, Pike, Perry 422,896	
Service Area E:	Kentucky: Butler, Christian, Daviess, Henderson, Hopkins, Logan, McLean, Muhlenberg, Ohio, Todd, Union, Webster 632,786	
Service Area F:	New Mexico: All counties	491,740
Service Area G:	Ohio: Belmont, Carroll, Columbiana, Harrison, Jefferson, Mahoning, Monroe, Stark, Tuscarawas, Washington West Virginia: Brooke, Hancock, Marshall, Ohio, Tyler, Wetzel	234,035

¹⁰ 42 CFR Part 55(a)

Service Area H:	Ohio: Athens, Coshocton, Fairfield, Gallia, Guernsey, Hocking, Holmes, Jackson, Licking, Meigs, Morgan, Muskingum, Noble, Perry, Ross, Vinton	234,035
Service Area I:	Pennsylvania: Allegheny, Armstrong, Beaver, Butler, Cambria, Clarion, Clearfield, Fayette, Greene, Indiana, Jefferson, Lawrence, Somerset, Washington, Westmoreland, Jefferson	288,622
Service Area J:	Pennsylvania: Fayette, Greene, Washington	302,697
Service Area K:	Pennsylvania: Adams, Bedford, Berks, Blair, Bradford, Bucks, Cambria, Cameron, Carbon, Centre, Chester, Clearfield, Clinton, Columbia, Cumberland, Dauphin, Delaware, Elk, Franklin, Fulton, Huntingdon, Indiana, Jefferson, Juniata, Lackawanna, Lancaster, Lebanon, Lehigh, Luzerne, Lycoming, McKean, Mifflin, Monroe, Montgomery, Montour, Northampton, Northumberland, Perry, Philadelphia, Pike, Potter, Schuylkill, Snyder, Somerset, Sullivan, Susquehanna, Tioga, Union, Wayne, Wyoming, York	248,616
Service Area L:	Tennessee: All counties	162,099
Service Area M:	Virginia: Buchanan, Dickenson, Lee, Russell, Scott, Smyth, Tazewell, Washington, Wise	632,786
Service Area N:	West Virginia: Taylor, Preston, Grant, Kanawha, Greenbrier, Fayette, Raleigh, Mercer, McDowell, Logan, Mingo, Lincoln, Wyoming, Boone	1,265,572
Service Area O:	Wyoming: All counties; Montana: all counties; Utah: all counties	232,391

^{*}Service areas represent counties served by current BLCP awardees and funding amounts reflect the amount of BLCP grant funds BLCP awardees received in FY 2016.

Funding requirements for current BLCP awardees:

- Current BLCP awardees, whose awards expire on June 30, 2017, should request a funding amount less than or equal to the amount allocated to the service area they propose to serve, as listed in *Section II.2.Table A*:
 - o Exceptions:
 - If an applicant previously served a service area as a part of a consortium, but is now applying to serve that area separately:

- Request a funding amount that is less than or equal to the amount you received under the consortium or contractual agreement.
- If an applicant previously served a service area(s) separately, but is now applying to serve that area(s) as a consortium:
 - Request a funding amount that is less than or equal to the combined amount that each individual BLCP awardee received in FY 2016.
- Under both of these exceptions, applicants should demonstrate how they will ensure continuity of care to coal miners in the service areas they served in FY 2014-2017.
- Note: any individual applicant can request the full amount allocated to the service area they are proposing to serve.

Funding requirements for new BLCP applicants:

 New applicants should request a funding amount less than or equal to the amount allocated to the service area they propose to serve, as listed in Section II.2. Table A.

Programmatic requirements:

In response to comments to the FRN, HRSA removed the funding tier structure and replaced it with minimum required services for all applicants, along with recommended guidelines for applicants proposing to serve certain service areas.

Minimum Required BLCP Services

All applicants, at a minimum, must provide the following services to coal miners in their service areas ("Minimum Required BLCP Services"):

- **Staffing:** Contracted or onsite board-certified pulmonologist or internal or family medicine physician who has at least one (1) year experience in the diagnosis and treatment of respiratory diseases. Mid-level providers working under the direct supervision of the clinic physician may also be employed.
- Patient education and outreach: Current, evidence-based information should be delivered to coal miners in a variety of formats and forums. Education should include risks associated with coal mine dust lung exposure as well as available medical and compensation services available to them.
- Lung function testing: Onsite resting spirometry and oximetry, with or without a bronchodilator challenge. Staff must have training in the proper interpretation of results and NIOSH certification in spirometry.
- **Chest imaging:** This should include a Postero-Antero chest x-ray (CXR) that must be provided by a contracted or onsite board-certified radiologist and interpreted by a NIOSH-certified B-reader. Every effort must be taken to meet International Labour Organization (ILO) technical standards¹¹ and facilities must be contracted or onsite.

¹¹ ILO International Classification of Radiographs of Pneumoconiosis (rev. 2011), http://www.ilo.org/safework/areasofwork/occupational-health/WCMS_108548/lang--en/index.htm.

- **Pulmonary rehabilitation:** Accredited Phase II and Phase III pulmonary rehabilitation services provided onsite, through contract, or by referral.
- Medical case management: Staffing should include a patient care coordinator, who may be a lay health care worker or trained health care personnel. The coordinator is responsible for assisting the clinic physician(s) in maintaining contact with the patient's primary care physician and assuring optimum patient participation in the prescribed treatment. Current, evidence-based information and treatment of coal mine dust induced lung diseases (e.g., medications, nutrition, vaccinations, smoking cessation, and referrals to specialty care) should be provided. Applicants must also evaluate and treat (or refer) coal miners for commonly associated conditions, including hearing loss, substance abuse, depression, hypertension, and cardiovascular disease.
- **Compensation counseling:** Compensation counselors should have a minimum of a high school diploma and training to competently assist miners in filing Federal Black Lung, State Worker's Compensation, and Social Security Disability Insurance claims as appropriate.
- **Department of Labor (DOL) examination:** The applicant must have the ability to refer patients to an approved and certified DOL medical examiner.
- **Data collection:** Patient-level data collection and reporting to HRSA in year 3 of the grant (July 1, 2019 to June 30, 2020).

Recommended Guidelines

The recommended guidelines are intended to ensure that all service areas receive a level of services commensurate with current efforts in those areas and that the quality and breadth of services delivered to coal miners is sustained. Applicants proposing to serve these service areas may request up to two exceptions to the recommended guidelines for their service area. If the Objective Review Committee (ORC) determines that an applicant's request for exception is justified, the ORC will not penalize the applicant for excluding the excepted service or standard from their project narrative. This approach will give these applicants greater flexibility to tailor services to their patients' and organizations' needs.

In addition to the **Minimum Required BLCP Services** outlined above, and in order to sustain the quality and breadth of services provided to coal miners, HRSA recommends that applicants applying to **Service Areas D, G, H, I, J, K, and O** provide the following services and meet the following standards in order to ensure that the service areas receive a level of services commensurate with current efforts by BLCP awardees:

- **Staffing:** Onsite, board-certified pulmonologist or internal or family medicine physician with at least two (2) years of experience in the diagnosis and treatment of respiratory diseases.
- Patient education and outreach: In addition to outreach to miners, applicants should aim to conduct structured educational activities that involve other community partners within and outside of the black lung community.
- Lung function testing and chest imaging: Should have access to full resting pulmonary function testing, including a bronchodilator challenge, lung volume

- measurements, diffusion capacity, and resting arterial blood gases. Testing equipment and methods must meet American Thoracic Society/European Respiratory Society (ATS/ERS) standards.
- Pulmonary rehabilitation: Onsite or contracted accredited Phase II or Phase III rehabilitation services.
- **Medical case management:** Patient care coordinators should have an Associate degree or at least three (3) years of experience in patient care coordination. Trained nurse care managers or certified nurse assistants are preferred.
- Compensation counseling: Staff should have a minimum of a high school diploma and at least three (3) years of experience. They should guide coal miners through the Federal Black Lung Benefits process, assist with interpretation of legal correspondence and DOL medical exam results.
- **DOL examination:** The applicant must have the ability to refer patients to an approved and certified DOL medical examiner.

Finally, in addition to the **Minimum Required BLCP Services** and the requirements outlined for Service Areas D, G, H, I, J, K, and O, and in order to sustain the quality and breadth of services provided to coal miners, HRSA recommends that **Service Areas B, C, E, F, M, and N** provide the following services and meet the following standards in order to ensure that the service areas receive a level of services commensurate with current efforts by BLCP awardees:

- **Staffing:** Onsite, board-certified pulmonologist or internal or family medicine physician with at least four (4) years of experience, preferably with occupationally-related lung disease.
- Patient education and outreach: Provide educational sessions at local and national conferences.
- Lung function and other testing: Access to testing, including cardiopulmonary exercise testing with metabolic cart, as well as resting and exercise arterial blood gases. Onsite chest x-ray with B-reader interpretation. Have capability to do advanced chest imaging.
- Medical case management: Nurse case manager or certified medical assistant with five (5) years of experience to provide assistance for medical follow-up of patients.
- **Compensation counseling:** Providers with medical/legal expertise to write expert medical reports and provide expert testimony and supplemental reports. Ability to refer patients for legal assistance provided by a licensed attorney specializing in Black Lung Benefits claims.
- **DOL examination:** Onsite DOL medical exams by an approved provider. Must meet all criteria by the DOL under 20 CFR part 725 to perform "complete and qualitative" medical exams as well as provide treatment under the Federal Mine Safety and Health Act of 1977, as amended. In addition, HRSA-funded entities are strongly encouraged to (1) adhere to the performance measures as outlined in DOL-Office of Workers' Compensation Programs Performance Measures as it relates to the Black Lung Program, (2) to submit documents relevant to active Black Lung benefits claims electronically into Claimant Online Access Link

(C.O.A.L.) and (3) to follow other procedures and training related to diagnostic and medical providers.

Exceptions to the recommended guidelines:

HRSA recognizes that not all of the recommended guidelines may be appropriate or feasible for current BLCP awardees and new applicants due to organizational, clinical, or environmental factors and the fluid nature of the target population. This is particularly true for current BLCP awardees who face challenges related to ongoing activity targets due to changes in their target population or organizational capacity.

As a result, applicants applying to serve **Service Areas B, C, D, E, F, G, H, I, J, K, M, N, and O** (see *Section II.2.Table A*) may propose **up to two exceptions** to the recommended guidelines for their service area in a separate attachment (**Attachment 2**). If the ORC determines that an applicant's request for exception is justified, the ORC will not penalize the applicant for excluding the excepted guideline from their project narrative.

Note: Applicants may not request to be excepted from any of the Minimum Required BLCP Services. Service Areas A and L are not eligible to apply for exceptions since current efforts and funding levels in those service areas are commensurate with the Minimum Required BLCP Services.

Applicants must include the following in the attachment in order for the proposed exception(s) to be considered:

- A detailed description of the requested exception(s);
- A detailed justification for the exception(s), including why the exception(s) are necessary to the applicant's ability to carry out the goals of the BLCP and how the exception(s) will affect the applicant's work and staffing plans and budget;
 - Note: If the applicant proposes to reduce or eliminate a recommended guideline for their service area, they must provide the following information in the attachment in order for their proposal to be considered:
 - A detailed justification for why they intend to reduce or eliminate the service or staffing guideline;
 - A description of how and where coal miners in their service area(s) will learn about and access a same or higher quality version of the service(s) (including distance to the nearest facility/ies offering the service); and
 - A detailed description for how the applicant will compensate for the reduced or eliminated service by either enhancing or adding to the other services they provide to coal miners.

Applicants should not propose the following changes:

 Receipt of a funding amount greater than the FY 2016 funding amount allocated to the applicant's service area¹² (as defined by Section II.2.Table A);

¹² Unless, as noted earlier in this funding opportunity announcement, the applicant is proposing to apply as a single entity or a consortium for the purposes of the FY 2017-2020 grant cycle, in which case they must request a funding amount that is less than or equal to the combined amount that each individual BLCP awardee received in FY 2016.

- Provision of services to fewer counties than the ones listed in the applicant's service area (see Section II.2.Table A); and/or
- Elimination or reduction of any of the Minimum Required BLCP Services, as outlined above.

Each exception request should not exceed one page, single-spaced. HRSA Program Staff reserve the right to disapprove or seek clarification on any proposed exception(s) if they appear to significantly harm access or quality of services provided to coal miners; violate BLCP program regulations (as defined by 42 CFR part 55(a)); or otherwise negatively impact the goals of the BLCP. If HRSA disapproves or seeks clarification on a proposed exception(s), they will notify the BLCP awardee upon issuance of the award by placing a condition on the grant. The BLCP awardee will then be required to submit a revised budget and/or scope of project to HRSA in the Electronic Handbooks (EHBs).

Additional funding for patient-level data pilot:

For the FY 2017-2020 grant period, HRSA will explore the development of a patient-level database. The goal of the database is to strengthen the quality of data collected by BLCP awardees to better assess patient/provider needs and program impact.

Subject to the availability of funds, HRSA proposes to provide additional funding for up to five BLCP awardees that will work with HRSA and the software vendor to pilot test the patient-level database in year 2 of the grant (July 1, 2018 to June 30, 2019). If your organization is interested in participating in the pilot, please submit the following in **Attachment 3**:

- A description of how your organization currently captures patient-level data and, if a current BLCP awardee, how your organization captures BLCP performance data required by HRSA;
- The staffing plan your organization currently has in place to collect, input, and report patient-level and performance data. Please include the title(s)/position(s) and FTE of the staff member(s) responsible for collecting, inputting, and reporting BLCP performance data to HRSA and
- A description of the level and type of technical assistance you anticipate requiring to collect and report patient-level data to HRSA.

HRSA will select up to five pilot participants from the pool of BLCP applicants that express interest and will notify them of their selection upon issuance of their award. HRSA will aim to select participants with varying capacity levels and data collection methods.

III. Eligibility Information

1. Eligible Applicants

Any state, public, or private entity may apply for this funding opportunity, assuming they meet the requirements of the Black Lung Clinics Program. This includes faith-based and community-based organizations as well as federally recognized tribes and tribal organizations.

Applicant organizations that are federally recognized tribes or tribal organizations are eligible to apply if all proposed grant activities are to be conducted within federally recognized tribal areas. Documentation of federally recognized tribal status must be included for this consideration (**Attachment 1**).

The requirements of this announcement may be met by a state or a single entity or consortium within a state.

In addition to the 50 states and the District of Columbia, applicants can be located in the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Territories of the Virgin Islands, Guam, American Samoa, the Compact Free Association Jurisdictions of the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia, if they meet the eligibility requirements.

Foreign entities are not eligible for HRSA awards, unless the authorizing legislation specifically authorizes awards to foreign entities or the award is for research. This exception does not extend to research training awards or construction of research facilities.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization are not allowable to this funding opportunity. Any eligible entity may apply to both the Black Lung Center of Excellence (BLCE) (HRSA-17-024) and BLCP (HRSA-17-023) funding opportunities, but they must submit a separate application for each announcement.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA *requires* applicants for this FOA to apply electronically through Grants.gov. You must download the SF-424 application package associated with this FOA following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the FOA to do otherwise.

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **70 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives,

attachments, and letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge you 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 validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Where the prospective recipient is unable to attest to any of the statements in this certification, such prospective recipient shall attach an explanation to this proposal.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on this and other certifications.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's SF-424 Application Guide

If requesting a funding preference or priority outlined in this funding opportunity announcement, please note that in the abstract.

ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project. Use the following section headers for the Narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion(a) 1 ("Need")
 Briefly describe the purpose of the proposed project, summarizing the project
 goals, objectives, and expected outcomes. Please include the service area that
 you are applying to serve in this section, as listed in Section II.2.Table A, as well
 as the names of any additional counties you intend to serve.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion(a) 1 ("Need")

Please provide the following information to demonstrate the needs of your organization, patient population, and community:

- Number of coal miners in service area: The best estimate of the number of active, inactive, and retired coal miners residing in the service area you are proposing to serve, based on all available data from the U.S. Department of Labor, U.S. Energy Information Administration, and other national, state, and local resources.
- Health care access and utilization in service area: A description of current patterns for obtaining health care in the service area you are proposing to serve and the role of your organization (e.g., approximately what percentage of coal miner patients seek their primary and/or specialty care at the applicant site?)
- Unmet health needs in service area: A description of unmet health needs in the service area you are proposing to serve. Use local data where possible and compare them to state and/or national data. Only use indicators that are relevant to the proposed project (e.g., specific health status indicators (including those related to the prevalence and/or severity of CMDLD in your proposed service area, if available), age, employment status, insurance coverage, poverty level, transportation access, etc.)
- Health care and social services in service area: An overview of the current health care and social services available within and around the service area you are proposing to serve. Reviewers must be able to understand both the number and type of relevant services (e.g., pulmonary and respiratory health care, compensation counseling, legal services, etc.) available to coal miners in within and around your proposed service area, and the relationship of these services to your organization/proposed project. HRSA recognizes that more than one clinic may be providing complementary services to coal miners in a given county. Applicants proposing to serve Service Areas A, B, I, J, and K must detail how they intend to avoid duplicating efforts of other black lung clinics in the counties where there is overlap. All applicants must also describe the potential impact of your project on existing providers (e.g., changes in referral and practice patterns, provider reimbursement).

impact, etc.) who are located within or around your proposed service area but are not part of your project. Finally, you must provide a clear, well-reasoned justification for why other grant programs and/or resources within or around your proposed service area are unable to fill the health care gaps you have identified. Your local health department and/or State Office of Rural Health may be valuable resources for acquiring the data and information necessary to respond to this section.

- Other: You may include any other relevant information that demonstrates the need for BLCP services in the service area you are proposing to serve.
- METHODOLOGY -- Corresponds to Section V's Review Criterion(a) 2 ("Response")

Note: Please use the following subheadings for this section: "Methods for Delivering Minimum Required BLCP Services"; "Methods for Delivering the Recommended Guidelines for Proposed Service Area"; "Exception requests"; and "Payer of Last Resort"

Please propose methods that will be used to meet each of the **Minimum Required BLCP Services** and, if applicable, each of the recommended guidelines for the service area you are proposing to serve as enumerated in *Section II.2*. If you are requesting an exception(s) to any of the recommended guidelines, please note it/them here, but do not go into detail.

Additionally, per statute, the BLCP is the payer of last resort.¹³ As such, all BLCP awardees must make every effort to ensure that alternate sources of payment are pursued and that program income is used consistent with grant requirements. Applicants should provide descriptions of the following:

- How they will ensure charges shall be made for services rendered as described in post-award requirements (Section VI. Award Administration Information) of this opportunity.
- Their organizational capacity to coordinate billings with multiple payers/sources of funding.
- The procedures and reasonable efforts for ensuring payments are collected from third-party payers.
- WORK PLAN -- Corresponds to Section V's Review Criterion(a) 2 ("Response") & 4 ("Impact")

Applicants should provide a clear and coherent work plan that is aligned with the project's and overall BLCP's goals and objectives.

¹³ 42 CFR Part 55a, consistent with the requirements of part 55a.201(b) and (c).

The work plan should be in a table format and include, at a minimum, the following components:

- Activities: All minimum required activities, as outlined in Section II.2 should be included. Additionally, if applicable, all recommended guidelines for the service area you are proposing to serve should be accounted for, unless you are requesting an exception.
- Responsible individual and/or organization: For each activity, list the individual and/or organization responsible for carrying out the activity.
- <u>Timeline</u>: Applicants must include a timeline for each activity completed during the three-year grant period.
- Process measures (as defined by CDC's Workplace Health Promotion <u>Evaluation</u>): 14 For each activity, list the process measures you will use to evaluate the outputs the activities will generate.
- Outcome measures (as defined by CDC's Workplace Health Promotion <u>Evaluation</u>): 15 For each activity, list the short, intermediate, and long-term outcome measures you will use to evaluate your project's effectiveness.

Additionally, applicants should describe specific and detailed plans and methods for disseminating project activities and outcomes to various target audiences, including program stakeholders (e.g., policymakers, researchers, etc.) and the general public.

 RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion(a) 2 ("Response")

Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that will be used to resolve such challenges. You should be as specific as possible both in the identification of potential or documented challenges (e.g., barriers to transportation, workforce, linguistic, socioeconomic, geographic, etc.) and your specific plans to reduce or eliminate each one of them.

 EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion(a) 3 ("Evaluative Measures") & 5 ("Resources and Capabilities")

Note: Please use the following sub-headings when responding to this section: Logic Model, Data Collection Strategy, and Staffing Plan.

¹⁴ CDC Workplace Health Promotion Evaluation,

http://www.cdc.gov/workplacehealthpromotion/model/evaluation/index.html

¹⁵ CDC Workplace Health Promotion Evaluation,

http://www.cdc.gov/workplacehealthpromotion/model/evaluation/index.html

- <u>Logic Model</u>: Applicants are required to submit a logic model that pictorially illustrates the relationship between the resources invested in a program and the desired outcomes. A logic model shows the logical relationship among the resources invested, the activities that take place, and the benefits or changes that result. Include your project's logic model and narrative description in **Attachment 4.**
 - Note: A logic model is not a work plan. A work plan is an "action guide" with a timeline that is used during program implementation. Information on how to distinguish between a logic model and a work plan can be found at the following website:
 http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf
 More information on developing logic models can be found at the following website:
 http://www.cdc.gov/ORALHEALTH/state_programs/pdf/logic_models_pdf
- <u>Data collection strategy</u>: Describe your strategy to collect, analyze, and track data to measure process and impact/outcomes and explain how data will be used to inform your project development and service delivery.
- <u>Staffing plan</u>: All applicants should describe a clear, comprehensive plan for staffing that meets the educational and professional requirements of the project and those by relevant certification bodies in **Attachment 5**. Staffing plans should include, at a minimum, a board-certified pulmonologist or internal or family medicine physician; a compensation counselor; and a patient care coordinator. In addition, the staffing plan should include position descriptions for other staff, which may include a dietician, audiologist, physical therapist, and a pharmacist, among others. All staffing plans should include the following components:
 - The number and types of staff, qualification levels, and full-time equivalents (FTEs):
 - The information necessary to illustrate both the capabilities (current experience, skills, knowledge, and experience with previous work of a similar nature) of key staff listed above and the requirements that the applicant has established to fill other key positions if the grant is awarded;
 - Job descriptions for each of the key staff mentioned above; and
 - Staffing needs should have a direct link to the activities proposed in the project narrative and budget portion of the application.
- ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion(a) 5 ("Resources and Capabilities")

All applicants should describe the abilities and contributions of the applicant organization(s). Provide information on the applicant organization's current mission and structure, scope of current activities, as well as **an organizational**

chart (**Attachment 6**). The applicant should clearly explain how all of these aspects contribute to the organization's ability to meet program requirements and expectations. This includes, but is not limited to, financial and accounting management systems in place and capacity to exercise administrative and programmatic direction over the project. The applicant may also include letters of support in **Attachment 7**, although this is not required. A letter of support is from a non-consortium organization and indicates awareness and acceptance of the proposed project.

o Consortium coordination, if applicable (Attachment 8): If you intend to form a consortium with one or more entities, you must submit a Letter of Commitment (LOC) or a Memorandum of Agreement (MOA) with the application that, at a minimum, affirms each consortium member's commitment and support to the project; outlines the frequency and method of communication (e.g., in-person, e-mail, etc.) between consortium members; and describes the proposed process for soliciting and incorporating input from each consortium member into decisionmaking, problem solving, and urgent or emergency situations. The LOC or MOA must be submitted with the application as Attachment 8. Please note that a LOC/MOA represents a promise to provide the specified organizational resources for the success of the project. A LOC/MOA is not the same as a Letter of Support. A LOC/MOA is from a consortium member organization providing substantial commitment and support to the project. In addition, you must provide a detailed narrative of: the work that the consortium will engage in; how that work aligns with this funding opportunity; and how the formation of the consortium will result in systemic improvements in miner health and safety.

iii. Budget

Corresponds to Section V's Review Criterion(a) 6 ("Support Requested")

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Please follow the instructions included in the Application Guide and, *if applicable*, the additional budget instructions provided below.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

The applicant's proposed budget may not exceed the amount allocated to the service area they propose to serve, as listed in *Section II.2. Table A.*

iv. Budget Narrative

Corresponds to Section V's Review Criterion(a) 6

See Section 4.1.v. of HRSA's SF-424 Application Guide.

NARRATIVE GUIDANCE

In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

v. Attachments

Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled**.

Attachment 1: Federally Recognized Tribe(s) or Organizations (if applicable) Applicant organizations that are federally-recognized tribes or organizations are eligible to apply if all proposed grant activities will be conducted within federally-recognized tribal areas. These applicants must submit documentation of the federally-recognized tribal status.

Attachment 2: Exception(s) from recommended guidelines (not applicable to Service Areas A and L)

Applicants applying to serve Service Areas B, C, D, E, F, G, H, I, J, K, M, N, and O (see *Section II.2.Table A*) may propose up to two exceptions to the recommended guidelines for their service area using the instructions in *Section II.2.*

Attachment 3: Application to apply in patient-level data collection pilot

Applicants interested in participating in the proposed patient-level data collection pilot in Year 2 of the grant (July 1, 2018 to June 30, 2019) should express their interest using the instructions in *Section II.2*.

Attachment 4: Logic Model

Applicants are required to submit a logic model and narrative that illustrates the inputs, activities, outputs, outcomes, and impact of the project.

Attachment 5: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's <u>SF-424 Application Guide</u>)

Provide a staffing plan for the proposed project and the job descriptions and biographical sketches for key personnel listed in the application. Keep each job description and biographical sketch to two pages in length as much as is possible. Please refer to *Section IV.ii* (Evaluation & Technical Capacity > Resources/Capabilities) for further instructions.

Attachment 6: Organizational Chart

Provide an organizational chart of the applicant organization(s).

Attachment 7: Letters of Support (not required)

A list of non-consortium organizations providing substantial support and/or relevant resources to the project should be attached and clearly labeled, if applicable. Provide the organization name, contact person(s), full address, phone number(s), fax number, e-mail address, and a brief account of one to two-sentences of the relevant support/resource(s) being provided. If an applicant would like to submit actual letters of support, they can include them here.

Attachment 8: Consortium Plan, if applicable

Please refer to Section IV.ii (Organizational Information) for instructions on how to complete this attachment.

Attachment 9: Request for Funding Preference or Priority

To receive a funding preference, include a statement that you are eligible for a funding preference and identify the preference. Include documentation of this qualification. See Section V.2.

To receive a funding priority (current BLCP awardees only), please include a screenshot or printout of your annual PIMS report to HRSA for the dates July 1, 2015 to June 30, 2016 that depicts the total number of active and retired coal miners served for that year. If you were previously part of a consortium, or funded through a contractual agreement in FY 2014-2017, and are applying as an individual entity for the purposes of the FY 2017-2020 grant cycle, please submit aggregated data for the consortium or lead applicant on the grant.

Attachments 10 – 14: Other Relevant Documents

Include here any other documents that are relevant to the application.

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is excepted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

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

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

- Dun and Bradstreet (http://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (http://www.grants.gov/)

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

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

4. Submission Dates and Times

Application Due Date

The due date for applications under this FOA is *March 6, 2017 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's <u>SF-424 Application</u> Guide for additional information.

5. Intergovernmental Review

The BLCP is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's SF-424 Application Guide for additional information.

6. Funding Restrictions

You may request funding for a project period of up to number (3) years. Applicants must request a funding amount per year less than or equal to the amount allocated to the service area they propose to serve, as listed in *Section II.2.Table A.* Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

Funds under this announcement may not be used for purposes not authorized by the statute and accompanying regulations including:

Membership dues and fees for the National Coalition of Black Lung and Respiratory Disease Clinics, Inc.

The Consolidated Appropriations Act, 2016, Division H, § 202, (P.L. 114-113) states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." As of January, 2017, the Executive Level II salary limitation is now \$187,000 (formerly \$185,100) and the HRSA Application Guide will be updated accordingly in the near future. Please see Section 4.1.iv Budget – Salary Limitation of HRSA's \$\frac{SF-424 Application Guide}{SF-424 Application Guide}\$ for additional information. Note that these or other salary limitations may apply in FY 2017, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with the all federal funding requirements and prohibitions such as lobbying, gun control, abortion, etc. The effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The BLCP has six (6) review criteria:

Criterion 1: NEED (15 points) – Corresponds to Section IV's "Introduction" and "Needs Assessment"

The quality and extent to which the application does the following:

- Describes the purpose of the proposed project, summarizing the project goals, objectives, and expected outcomes;
- Provides the best estimate of the number of active, inactive, and retired coal
 miners residing in the service area the applicant is proposing to serve, based on
 all available data from the U.S. Department of Labor, U.S. Energy Information
 Administration, and other national, state, and local resources;
- Details current patterns for obtaining health care in the service area the applicant is proposing to serve and the role of the applicant organization (e.g., approximately what percentage of coal miner patients seek their primary and/or specialty care at the applicant site?);
- Describes unmet health needs in the service area the applicant is proposing to serve, using local data where possible and comparing them to state and/or national data;
- Provides indicators that are relevant to the proposed project—examples include, but are not limited to, specific health status indicators (including, if available, those related to the prevalence and/or severity of CMDLD in the proposed service area), age, employment status, insurance coverage, poverty level, transportation access, etc.;
- Gives an overview of the current health care and social services available within
 and around the applicant's proposed service area. Reviewers must be able to
 understand both the number and type of relevant services (e.g., pulmonary and
 respiratory health care, compensation counseling, legal services, etc.) available
 to coal miners in within and around the proposed service area, and the
 relationship of these services to the applicant organization/proposed project;
- (For applicants proposing to serve Service Areas A, B, I, J, and K): details how they intend to avoid duplicating efforts of other black lung clinics in the counties where there is overlap.
- Describes the potential impact of the applicant's project on existing providers (e.g., changes in referral and practice patterns, provider reimbursement impact, etc.) who are located within or around the proposed service area but are not part of the applicant's project;
- Provides a clear, well-reasoned justification for why other grant programs and/or resources within or around the applicant's proposed service area are unable to fill the health care and social service gaps the applicant has identified.

Criterion 2: RESPONSE (45 points) – Corresponds to Section IV's "Methodology," "Work Plan," and "Resolution of Challenges."

The quality and extent to which the application does the following:

• "Minimum Required BLCP Services" (all applicants) (15 points):

- Describes how services are conducted under a contracted or onsite board-certified pulmonologist or internal or family medicine physician who has at least one (1) year experience in the diagnosis and treatment of respiratory diseases. Mid-level providers working under the direct supervision of the clinic physician may also be employed.
- Describes a clear plan to provide current, evidence-based information that is delivered to coal miners in a variety of formats and forums. Education should include risks associated with coal mine dust lung exposure as well as available medical and compensation services available to them.
- Details how they will provide onsite resting spirometry and oximetry, with or without a bronchodilator challenge. Staff should have training in the proper interpretation of results and NIOSH certification in spirometry.
- Describes how a Postero-Antero chest x-ray (CXR) will be provided by a contracted or onsite board-certified radiologist and interpreted by a NIOSH-certified B-reader. Every effort must be taken to meet ILO technical standards and facilities must be contracted or onsite.
- Details how accredited Phase II and Phase III pulmonary rehabilitation services will be provided to coal miners, as needed, onsite, through contract, or by referral.
- Describes how medical case management, including current, evidencebased treatment of coal mine dust lung diseases and referral to specialty care when appropriate, will be provided by a lay health care worker or trained health care personnel.
- Details how current, evidence-based information and treatment of coal mine dust-induced lung diseases—including medications, nutrition, vaccinations, smoking cessation, and specialty care referrals—will be provided.
- Describes how evaluation and treatment (or referral) of coal miners for commonly associated conditions, such as hearing loss, substance abuse, depression, hypertension, and cardiovascular disease, will be provided.
- Compensation counselors have a minimum of a high school diploma and training to competently assist miners in filing Federal Black Lung, State Worker's Compensation, and Social Security Disability Insurance claims as appropriate.
- Details how the applicant has the ability to refer patients to an approved and certified DOL medical examiner.
- Describes a plan to ensure that the staffing and resources to collect and report patient-level data collection and reporting to HRSA in year 3 of the grant (July 1, 2019 to June 30, 2020) will be in place.
- "Recommended Guidelines for Service Areas D, G, H, I, J, K, and O" (in addition to the Minimum Required BLCP Services) (15 points)

- Describes how services will be supervised by an onsite, board-certified pulmonologist or internal or family medicine physician with at least two (2) years of experience in the diagnosis and treatment of respiratory diseases.
- Describes how the applicant intends to conduct structured educational activities that involve other community partners within and outside of the black lung community.
- Details how the clinic has access to full resting pulmonary function testing, including a bronchodilator challenge, lung volume measurements, diffusion capacity, and resting arterial blood gases. Testing equipment and methods must meet American Thoracic Society/European Respiratory Society standards.
- Applicant has onsite or contracted accredited Phase II or Phase III rehabilitation services.
- Patient care coordinators should have an Associate degree or at least three (3) years of experience in patient care coordination. Trained nurse care managers or certified nurse assistants are preferred.
- Describes how compensation counselors have a minimum of a high school diploma and at least three (3) years of experience. They should guide coal miners through the Federal Black Lung Benefits process, assist with interpretation of legal correspondence and DOL medical exam results.
- The applicant clearly describes their ability to refer patients to an approved and certified DOL medical examiner.
- IF APPLICABLE: Exception request(s)—the quality and extent to which the applicant:
 - Provides no more than two exceptions
 - Provides a detailed description of each requested exception(s);
 - Provides a detailed justification for the exception(s), including why
 the exception(s) are necessary to the applicant's ability to carry out
 the goals of the BLCP and how the exception(s) will affect the
 applicant's work and staffing plans and budget;
 - Note: If the applicant proposes to reduce or eliminate a recommended guideline for their service area, they must provide the following information in the attachment in order for their proposal to be considered:
 - A detailed justification for why they intend to reduce or eliminate the service or staffing guideline;
 - A description of how and where coal miners in their service area(s) will learn about and access a same or higher quality version of the service(s) (including distance to the nearest facility/ies offering the service); and
 - A detailed description for how the applicant will compensate for the reduced or eliminated service by either enhancing or adding to the other services they provide to coal miners.
 - Does not propose any of the following changes:

- Receipt of a funding amount greater than the FY 2016 funding amount allocated to the applicant's service area¹⁶ (as defined by Section II.2. Table A);
- Provision of services to fewer counties than the ones listed in the applicant's service area (see Section II.2.Table A); and/or
- Elimination or reduction of any of the **Minimum Required BLCP Services**.
- Does not propose exception(s) that appear to do any of the following:
 - Significantly harm access or quality of services provided to coal miners;
 - Violate BLCP program regulations (as defined by 42 CFR part 55(a)); and/or
 - Otherwise negatively impact the goals of the BLCP.
- If ORC determines that an applicant's requested exception(s) are justified, applicants may not be penalized for not including the excepted services or standards in their project narrative.
- HRSA Program Staff reserve the right to disapprove or seek clarification on any proposed exception(s) if they appear to significantly harm access or quality of services provided to coal miners; violate BLCP program regulations (as defined by 42 CFR part 55(a)); or otherwise negatively impact the goals of the BLCP.
- "Recommended Guidelines for Service Areas B, C, E, F, M, and N" (in addition to Minimum Required BLCP Services and Recommended Guidelines for Service Areas D, G, H, I, J, K, and O) (15 points)
 - Describes how services will be supervised by an onsite, board-certified pulmonologist or internal or family medicine physician with at least four (4) years of experience, preferably with occupationally-related lung disease.
 - Describes how educational sessions at local and national conferences will be provided by staff at the applicant organization.
 - Describes how the clinic has access to testing, including cardiopulmonary exercise testing with metabolic cart, as well as resting and exercise arterial blood gases. Onsite chest x-ray with B-reader interpretation. Have capability to do advanced chest imaging.
 - Describes how a case manager or certified medical assistant with five (5) years of experience will be available to provide assistance for medical follow-up of patients.
 - Describes how compensation counseling services will be provided by providers with medical/legal expertise to write expert medical reports and provide expert testimony and supplemental reports. Details ability to refer

¹⁶ Unless, as noted earlier in this funding opportunity announcement, the applicant is proposing to apply as a single entity or a consortium for the purposes of the FY 2017-2020 grant cycle, in which case they must request a funding amount that is less than or equal to the combined amount that each individual BLCP awardee received in FY 2016.

- patients for legal assistance provided by a licensed attorney specializing in Black Lung Benefits claims.
- Provides an overview of how onsite DOL medical exams by an approved provider will be provided. Applicants must meet all criteria by the DOL under 20 CFR part 725 to perform "complete and qualitative" medical exams as well as provide treatment under the Federal Mine Safety and Health Act of 1977, as amended.
- IF APPLICABLE: Exception request(s)—the quality and extent to which the applicant:
 - Provides no more than two exceptions
 - Provides a detailed description of each requested exception(s);
 - Provides a detailed justification for the exception(s), including why
 the exception(s) are necessary to the applicant's ability to carry out
 the goals of the BLCP and how the exception(s) will affect the
 applicant's work and staffing plans and budget;
 - Note: If the applicant proposes to reduce or eliminate a recommended guideline for their service area, they must provide the following information in the attachment in order for their proposal to be considered:
 - A detailed justification for why they intend to reduce or eliminate the service or staffing guideline;
 - A description of how and where coal miners in their service area(s) will learn about and access a same or higher quality version of the service(s) (including distance to the nearest facility/ies offering the service); and
 - A detailed description for how the applicant will compensate for the reduced or eliminated service by either enhancing or adding to the other services they provide to coal miners.
 - Does not propose any of the following changes:
 - Receipt of a funding amount greater than the FY 2016 funding amount allocated to the applicant's service area¹⁷ (as defined by Section II.2. Table A);
 - Provision of services to fewer counties than the ones listed in the applicant's service area (see Section II.2. Table A); and/or
 - Elimination or reduction of any of the **Minimum Required BLCP Services**.
 - Does not propose exception(s) that appear to do any of the following:
 - Significantly harm access or quality of services provided to coal miners;
 - Violate BLCP program regulations (as defined by 42 CFR part 55(a)); and/or

¹⁷ Unless, as noted earlier in this funding opportunity announcement, the applicant is proposing to apply as a single entity or a consortium for the purposes of the FY 2017-2020 grant cycle, in which case they must request a funding amount that is less than or equal to the combined amount that each individual BLCP awardee received in FY 2016.

- Otherwise negatively impact the goals of the BLCP.
- If ORC determines that an applicant's requested exception(s) are justified, applicants may not be penalized for not including the excepted services or standards in their project narrative.
- HRSA Program Staff reserve the right to disapprove or seek clarification on any proposed exception(s) if they appear to significantly harm access or quality of services provided to coal miners; violate BLCP program regulations (as defined by 42 CFR part 55(a)); or otherwise negatively impact the goals of the BLCP.

"Payer of Last Resort" (5 points)

- Provides descriptions of the following:
 - How they will ensure charges shall be made for services rendered as described in post-award requirements (Section VI. Award Administration Information) of this opportunity.
 - Their organizational capacity to coordinate billings with multiple payers/sources of funding.
 - The procedures and reasonable efforts for ensuring payments are collected from third-party payers.

• "Work Plan" (5 points)

- Provides a clear and coherent work plan that is aligned with the project's and overall BLCP's goals and objectives.
- The work plan is in a table format and includes, at a minimum, the following components:
 - Activities: All Minimum Required BLCP Services, as outlined in Section II.2 should be included. Additionally, if applicable, all recommended guidelines for the service area the applicant is proposing to serve should be accounted for, unless they are requesting exceptions.
 - Responsible individual and/or organization: For each activity, they list the individual and/or organization responsible for carrying out the activity.
 - <u>Timeline</u>: For each activity completed during the three-year grant period, they list a timeframe for implementation and completion.
 - Process measures (as defined by CDC's Workplace Health Promotion Evaluation): ¹⁸ For each activity, they list the process measures they will use to evaluate the outputs the activities will generate.
 - Outcome measures (as defined by CDC's Workplace Health Promotion Evaluation):¹⁹ For each activity, they list the short, intermediate, and long-term outcome measures they will use to evaluate their project's effectiveness.

¹⁸ CDC Workplace Health Promotion Evaluation,

http://www.cdc.gov/workplacehealthpromotion/model/evaluation/index.html

¹⁹ CDC Workplace Health Promotion Evaluation,

http://www.cdc.gov/workplacehealthpromotion/model/evaluation/index.html

• "Resolution of Challenges" (5 points)

- Discusses challenges that they are likely to encounter in designing and implementing the activities described in the work plan, and approaches that will be used to resolve such challenges.
- Applicants should be as specific as possible both in the identification of potential or documented challenges (e.g., barriers to transportation, workforce, linguistic, socioeconomic, geographic, etc.) and their specific plans to reduce or eliminate each one of them.

Criterion 3: EVALUATIVE MEASURES (5 points) – Corresponds to Section IV's "Evaluation and Technical Support Capacity"

The quality and extent to which the application does the following:

• "Logic Model" (please reference Attachment 4):

- Pictorially illustrates the relationship between the resources invested in a program and the desired outcomes.
- Shows the logical relationship among the resources invested, the activities that take place, and the benefits or changes that result.

"Data Collection Strategy":

- Describes the applicant's strategy to collect, analyze, and track data to measure process and impact/outcomes.
- Explains how data will be used to inform their project development and service delivery.

Criterion 4: IMPACT (5 points) – Corresponds to Section IV's "Work Plan"

The quality and extent to which the application does the following:

• Describes specific and detailed plans and methods for disseminating project activities and outcomes to various target audiences, stakeholders (e.g., policymakers, research community, etc.), including the general public.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's "Evaluation and Technical Support Capacity" and "Organizational Information"

The quality and extent to which the application does the following:

• "Staffing Plan" (10 points):

- Describes a clear, comprehensive plan for staffing that meets the educational and professional requirements of the project and those by relevant certification bodies in **Attachment 5**.
- Includes, at a minimum, a board-certified pulmonologist or internal or family medicine physician; a compensation counselor; and a patient care coordinator in the staffing plan.

- Describes position descriptions for other staff, which may include a dietician, audiologist, physical therapist, and a pharmacist, among others in the staffing plan.
- The staffing plan includes the following components:
 - The number and types of staff, qualification levels, and full-time equivalents (FTEs)
 - The information necessary to illustrate both the capabilities (current experience, skills, knowledge, and experience with previous work of a similar nature) of key staff listed above and the requirements that the applicant has established to fill other key positions if the grant is awarded
 - Job descriptions for each of the key staff mentioned above
- Demonstrates how staffing needs have a direct link to the activities proposed in the project narrative and budget portion of the application

• "Organizational Information (10 points):

- o Describes the abilities and contributions of the applicant organization(s).
- Provides information on the applicant organization's current mission and structure and scope of current activities.
- Provides an organizational chart (Attachment 6).
- Explains how all of these aspects contribute to the organization's ability to meet BLCP program requirements and expectations. This includes, but is not limited to, financial and accounting management systems in place and capacity to exercise administrative and programmatic direction over the project.
- o Consortium coordination, if applicable (Attachment 8):
 - Includes a Letter of Commitment (LOC) or a Memorandum of Agreement (MOA) with the application that, at a minimum, affirms each consortium member's commitment and support to the project; outlines the frequency and method of communication (e.g., inperson, e-mail, etc.) between consortium members; and describes the proposed process for soliciting and incorporating input from each consortium member into decision-making, problem solving, and urgent or emergency situations.
 - Provides a detailed narrative of the work that the consortium will engage in; how that work aligns with this funding opportunity; and how the formation of the consortium will result in systemic improvements in miner health and safety.

Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's "Budget" and "Budget Narrative"

The reasonableness of the proposed budget for each year of the project period in relation to the goals of the BLCP; the number of coal miners to be served and their needs; and the breadth and quality of the proposed activities. Additionally:

 The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the level of effort and scope of work proposed.

- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- The extent to which the applicant justifies the reasonableness of their proposed conference attendance and travel budgets and how they will enhance the quality and breadth of services provided to coal miners.
- The extent to which the applicant requests a funding amount less than or equal to the amount of funding allocated to the service area that they are applying to serve (as outlined in *Section II.2.Table A*).

2. Review and Selection Process

The objective review provides advice to the individuals responsible for making award decisions. The highest ranked applications receive priority consideration for award within available funding. In addition to the ranking based on merit criteria, HRSA approving officials also may apply other factors in award selection, (e.g., geographical distribution), if specified below in this FOA. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's SF-424 Application Guide for more details.

For this program, HRSA will use funding priorities and preference:

Funding Priorities

This program includes one (1) funding priority. A funding priority is defined as the favorable adjustment of combined review scores of individually approved applications when applications meet specified criteria. An adjustment is made by a set, predetermined number of points. The funding factor will be determined by the Objective Review Committee.

Priority 1: Program Performance (5 points)

An applicant will be granted a funding priority if they are a current BLCP awardee and provided services to at least 100 coal miners between July 1, 2015 and June 30, 2016, as reported to HRSA in the Performance Improvement Management System (PIMS). If your organization was operating as a consortium or under contract in FY 2014-2017, but is applying as an individual entity for FY 2017-2020, you may submit the total number of coal miners served by the consortium. To calculate this figure, add the total number of active and former/retired miners under the "Number of Medical Users by Occupation" section. Please submit this information in **Attachment 9.**

Funding Preferences

This program provides a funding preference for some applicants as authorized by 42 CFR part 55(a). Applicants receiving the preference will be placed in a more competitive position among applications that can be funded. Applications that do not receive a funding preference will be given full and equitable consideration during the review process. The funding preference will be determined by the Objective Review Committee. Funding preference will be granted to any qualified applicant that specifically requests and demonstrates that they meet the criteria for preference as follows:

Qualification 1: State Preference

State applicants will be given preference over other entities that apply in the same state.

3. Assessment of Risk and Other Pre-Award Activities

The Health Resources and Services Administration may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (45 CFR § 75.205).

Applications receiving a favorable objective review that HRSA is considering for funding are reviewed for other considerations. These include, as applicable, cost analysis of the project/program budget, assessment of the applicant's management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. You may be asked to submit additional programmatic or grants information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that an award will be made. Following review of all applicable information, the HRSA approving and business management officials will determine whether an award can be made, if special conditions are required, and what level of funding is appropriate.

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

Effective January 1, 2016, HRSA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may review and comment on any information about itself that a federal awarding agency previously entered. HRSA will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of July 1, 2017.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of July 1, 2017. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2 of HRSA's SF-424 Application Guide.

3. Reporting

The successful applicant under this FOA must comply with Section 6 of HRSA's <u>SF-424</u> <u>Application Guide</u> and the following reporting and review activities:

- 1) **Progress Reports**. The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.
- 2) Other required reports and/or products.
 - a. Audit requirements of the Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at: https://www.whitehouse.gov/omb/circulars_default
 - b. Payment management requirements, including submission of a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. This report identifies cash expenditures against authorized funds for the cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Visit https://www.dpm.psc.gov/ for more information.
 - c. **Status reports.** HRSA/FORHP has developed a range of BLCP performance measures to assess the impact the program is having on the target populations and to enhance ongoing quality improvement. For the first two years of the grant period (July 1, 2017 to June 30, 2019), all BLCP awardees will report on PIMS through HRSA's Electronic Handbooks (EHBs) after each budget period. Beginning the third year of the grant period (July 1, 2019 to June 30, 2020), all BLCP awardees will be required to collect and report patient-level data to HRSA through a system housed and maintained by HRSA.

Payer of last resort/billing for services. The BLCP awardee is expected to be the payer of last resort, per regulations.²⁰ BLCP awardees must make reasonable efforts to pursue available means of coverage for

²⁰ 42 CFR part 55(a)

services (public or private insurance, federal funding, etc.). In accordance with the regulations,²¹ all BLCP awardees must provide an assurance that charges shall be made for services rendered as follows:

- A schedule should be maintained listing fees or payments for the provision of services, designed to cover reasonable costs of operations;
- A schedule of discounts adjusted on the basis of a patient's ability to pay must be maintained. The schedule of discounts must provide for a full discount to individuals and families with annual incomes at or below the poverty line established in accordance with section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), (except that nominal fees for service may be requested, but not required, from individuals and families with annual incomes at or below the poverty line). No discounts will be provided to individuals with annual incomes greater than twice the poverty line; and
- Where third-party payers (including government agencies) are authorized or under a legal obligation to pay all or a portion of such charges, all services covered by that reimbursement plan will be billed and every reasonable effort will be made to obtain payment.

All funded applicants must provide assurance that charges for services will be billed, and where appropriate, third party payers will pay all or a portion of such charges. Furthermore, no person (coal miner or family member) will be denied services because of inability to pay.

BLCP awardees are required to use effective strategies to coordinate with third party payers that are ultimately responsible for covering the cost of services provided to eligible or covered persons. Third party sources include Worker's Compensation, U.S. Department of Labor, Federal Black Lung Benefits, Medicaid, State Children's Health Insurance Programs, Medicare, including Medicare Part D, basic health plans, and private insurance. Subcontractors providing Medicaid eligible services must be Medicaid certified. Where third-party payers (including Government Agencies) are authorized or under a legal obligation to pay all or a portion of such charges, all services covered by that reimbursement plan will be billed and every reasonable effort will be made to obtain payment.

Program Income: HHS Grants Regulations require grant recipients and/or subgrant recipients to collect and report program income. The program income shall be returned to the funded program and used to provide eligible services to eligible clients. "Program income is gross income—

²¹ 42 CFR part 55(a)

earned by a recipient, sub-recipient, or a contractor under a grant—directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed (e.g., direct payment, or reimbursements received from Medicaid, Medicare and third-party insurance); and income a recipient or sub-recipient earns as the result of a benefit made possible by receipt of a grant or grant funds, e.g., income as a result of drug sales when a recipient is eligible to buy the drugs because it has received a federal grant."

VII. Agency Contacts

You may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Potie Pettway
Grants Management Specialist
HIV\AIDS Rural Health Branch
Division of Grants Management Operations,
Office of Federal Assistance and Management
Health Resources and Services Administration
5600 Fishers Lane, Room 18-105J.6
Rockville, MD 20857
Telephone: (301) 443-1014

Telephone: (301) 443-1014 Fax: (301) 443-9810

E-mail: ppettway@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Allison Hutchings
Public Health Analyst
Attn: Black Lung Clinics Program
Federal Office of Rural Health Policy
Health Resources and Services Administration
5600 Fishers Lane, Room 17W-17A
Rockville, MD 20857

Telephone: (301) 945-9819

Fax: (301) 443-9810

E-mail: blacklung@hrsa.gov

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

Grants.gov Contact Center

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

E-mail: support@grants.gov

Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET, excluding federal holidays at:

HRSA Contact Center Telephone: (877) 464-4772

TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance:

The Federal Office or Rural Health Policy will hold a technical assistance webinar on **Wednesday**, **January 18**, **2017 from 12:00-1:00 p.m. EST** to assist applicants in preparing their applications. The Adobe Connect webinar and call-in information is as follows:

Conference line (for audio): 888-989-7534, passcode: 1899090

URL (for web): https://hrsa.connectsolutions.com/blacklungfoa/

(Please enter as a "Guest.")

Note: you must dial into the conference line to hear the audio portion of the webinar. No pre-registration is required.

For your reference, the technical assistance call will be recorded and available for playback within one hour of the end of the call and will be available until **March 25**, **2017.** The phone number to hear the recorded call is 866-499-4576, passcode: 9819.

The Technical Assistance call is open to the general public. The purpose of the call is to review the FOA and to provide any additional or clarifying information that may be necessary regarding the application process. There will be a Q&A session at the end of the call to answer any questions. While the call is not required, it is highly recommended for any organization interested in applying for the Black Lung Clinics Program.

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's SF-424 Application Guide.