located in HPSAs must submit an NHSC Site Application and Site Recertification Application to determine the eligibility of sites to participate in the NHSC as an approved service site. The NHSC LRP participant application asks for personal, professional, and financial information needed to determine the applicant's eligibility to participate in the NHSC LRP. In addition, applicants must provide information regarding the loans for which repayment is being requested. NHSC policy requires behavioral health providers to practice in community-based settings that provide access to comprehensive behavioral health services. Accordingly, for those sites seeking to be assigned behavioral health NHSC participants, additional site information collected from an NHSC Comprehensive Behavioral Health Services Checklist is used. NHSC sites that do not directly offer all required behavioral health services must demonstrate a formal affiliation with a comprehensive, community-based primary behavioral health setting or facility to provide these services.

Likely Respondents: Likely respondents include: Licensed primary care medical, dental, and behavioral health providers who are employed or seeking employment, and are interested in serving underserved populations; health care facilities interested in participating in the NHSC and becoming an NHSC-approved service site; and NHSC sites providing behavioral health care services directly or through a formal affiliation with a comprehensive community-based primary behavioral health setting or facility providing comprehensive behavioral health services.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC LRP Application	8,200	1	8,200	1	8,200
Authorization for Disclosure of Loan Information Form	6,500	1	6,500	.10	650
Privacy Act Release Authorization Form	275	1	275	.10	27.5
Verification of Disadvantaged Background Form	600	1	600	.50	300
Private Practice Option Form	300	1	300	.10	30
NHSC Comprehensive Behavioral Health Services Checklist	*4,000	1	4,000	.13	520
NHSC Site Application (including recertification)	*3,700	1	3,700	.5	1,850
Total	19,875		19,875		11,577.50

*The same respondents are completing the NHSC Comprehensive Behavioral Services Checklist and the NHSC Site Application.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy McNulty,

Deputy Director, Division of the Executive Secretariat.

[FR Doc. 2016–31723 Filed 1–4–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Changes to the Black Lung Clinics Program for Consideration for the FY 2017 Funding Opportunity Announcement Development

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Response to comments.

SUMMARY: The Federal Office of Rural Health Policy (FORHP) in HRSA published a 30-day public notice in the **Federal Register** on August 22, 2016 soliciting feedback on a range of issues pertaining to the Black Lung Clinics Program (BLCP). In particular, FORHP requested feedback on how to best determine the needs of coal miners and their families, given the available data, and how to better equip future BLCP grantees to meet those needs. This notice responds to the comments received during this 30-day public notice.

ADDRESSES: Further information on the Black Lung clinics program is available at *http://www.hrsa.gov/gethealthcare/conditions/blacklung/*.

FOR FURTHER INFORMATION CONTACT: Allison Hutchings, Program Coordinator, Black Lung Clinics Program, Federal Office of Rural Health Policy, Health Resources and Services Administration, *blacklung@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Federal Office of Rural Health Policy (FORHP) in HRSA published a 30-day public notice in the **Federal Register** on August 22, 2016 (**Federal Register** volume 81, number 162, pp. 56660–56662) soliciting feedback on a range of issues pertaining to the Black Lung Clinics Program (BLCP). In particular, FORHP requested feedback on how to best determine the needs of coal miners and their families, given the available

data, and how to better equip future BLCP grantees to meet those needs.

Background

The BLCP is authorized by Section 427(a) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 937(a)), as amended, and accompanying regulations found at 42 CFR part 55a.

Following the release of the Fiscal Year (FY) 2014 BLCP funding opportunity announcement (FOA), HRSA received feedback on the funding approach used and other elements of the program. On August 22, 2016, through a **Federal Register** Notice (FRN), HRSA announced a 30-day public comment period to solicit input on BLCP and better understand the needs of coal miners and the clinics that serve them. In particular, HRSA received feedback on the following program components in response to the FRN:

- Funding Approach;
- Determining Need;
- Data Collection;
- Black Lung Center of Excellence (BLCE);
- Timeliness and Quality of U.S. Department of Labor (DOL) Exams;
- Grantee Collaboration;
- Pulmonary Rehabilitation; and
- Geographic Boundaries.

HRSA carefully reviewed and considered the comments it received and used them to both guide the development of the FY 2017 BLCP FOA and to inform the broader landscape in which the program operates.

Comments on the Proposed Changes to the Black Lung Clinics Program

HRSA received 17 comments to the FRN, representing 15 black lung clinics; the National Coalition of Black Lung and Respiratory Disease Clinics, Inc.; and attorneys from a law firm that represents claimants in black lung claims. HRSA has synthesized and summarized the comments below.

Funding Approach

Summary of Comments

Commenters provided a variety of input on funding allocations. Some commenters suggested that funding should be prioritized based on the level and quality of services offered at the site. For example, some commenters recommended that funding should be weighted toward sites that can offer all required testing at one location or whose service offerings are more comprehensive, with one commenter stating that funding levels should be based on providing all the services recommended in HRSA's 2002–08 Policy Information Notice entitled ''Black Lung Clinics Program Expectations and Principles of Practice.'' Others indicated that funding should prioritize services that are non-reimbursable, like benefits counseling. Several commenters said the funding tier system instituted in FY 2014 should be eliminated because it limited the clinics' ability to tailor services to meet their patients' needs and imposed standards that were difficult for rural clinics to meet, given workforce shortages and other challenges. Another commenter expressed concerns about the funding cap HRSA instituted on individual applicants. Most of the commenters agreed that funding should be allocated based on several factors, including the number of miners (active and inactive) served, the geographic service area, and/or historical funding amounts. Some commenters thought taking BLCP awardees' historical funding amounts into account was reasonable, while others thought historical funding amounts were irrelevant in a competitive cycle. Still another commenter suggested that HRSA give all BLCP awardees an equal base award amount and then add incremental award amounts based on the number of active and retired coal miners in a service area and the breadth and quality of services that require grant funding.

Response

In developing the new funding approach outlined in the FY 2017 BLCP FOA, HRSA sought to address respondents' concerns regarding the previous three-tiered funding structure and per-applicant cap, while also minimizing service disruption and adhering to statutory requirements.

The FY 2017 BLCP FOA does not include the previous per-applicant cap. Funding amounts are allocated to service areas based on the amount each area received in FY 2016, assuming the same level of appropriation as in the previous year. Each service area represents an area currently covered by a BLCP awardee. Any individual applicant can apply for the full amount awarded to an area, but they can only apply to serve one service area.

HRSA also removed the three-tiered funding structure. Instead, a set of minimum service and staffing requirements for all applicants was instituted. In addition, applicants applying to serve areas in which BLCP awardees are currently providing more advanced levels of service are encouraged to maintain those levels (referred to in the FY 2017 BLCP FOA as ''recommended guidelines'') in order to minimize service disruptions.

However, recognizing that BLCP awardees have developed different approaches to delivering care to coal miners in response to their patients' needs and organizational capacity, applicants may request to be excepted from up to two of the recommended guidelines. The exceptions give BLCP awardees flexibility to tailor their programs according to their patients' needs and organizational capacity.

The FY 2017 BLCP FOA assumes no increases in funding for the BLCP, so each service area is expected to receive the same ratio of funding it received in FY 2016 in order to minimize service disruptions. However, commenters' suggestions for how to allocate funding across applicants will be considered in future grant cycles.

Determining Need

Summary of Comments

Nearly all of the commenters agreed that there are limitations in the data for determining miners' needs for services and some said that the availability of patient-level data would strengthen their ability to determine need. One commenter stated that relying on data from areas with only active mines does not present an accurate picture of need since these data overlook miners with needs in service areas with non-active mines. Another commenter noted that they lack data on the number of disabled or retired miners in their service areas and that a possible solution to this would be to rely on claims data filed with DOL to determine the needs of that specific miner population. Still others recommended that HRSA take into account information available through data sources, research publications, academic medical centers and other government entities; the location of black lung clinics in relation to the populations they serve; miners' employment status; and the existence of coal-fired power plant workers to determine need. Finally, one commenter suggested using a weighted disability index system using age and level of impairment to determine need.

Response

HRSA recognizes that there are many different factors that should to be taken into account when assessing coal miners' needs, as well as challenges given the limited and fragmented data available on U.S. coal miners. As in previous FOAs, HRSA included ''Need'' as a review criterion in the FY 2017 BLCP FOA and applicants are encouraged to utilize a range of local, state, and national resources to describe

the number of coal miners in their service area as well as their health status and unmet health needs. While HRSA cannot implement all of the commenters' suggestions for how to determine need in this grant cycle, it will consider them in future cycles.

Grantee Collaboration

Summary of Comments

Nearly all of the commenters agreed that networking and peer-to-peer training and sharing of best practices are important components of successful program implementation. Most commenters supported a yearly peer-to-peer workshop and also stated that collaboration should continue through existing forums, such as the annual HRSA, Pipestem, and National Coalition of Black Lung and Respiratory Disease Clinics meetings. Commenters noted that it was ''essential'' that HRSA continue to support these trainings and collaboration forums and one stated that BLCP grant funds should be allowed for travel to the National Coalition of Black Lung and Respiratory Disease Clinic's annual educational conference.

Response

HRSA recognizes the important role that educational conferences play in strengthening the quality and breadth of services provided to coal miners. In the FY 2014 BLCP FOA, HRSA placed a restriction on using BLCP grant funds to subsidize attendance to the annual National Coalition of Black Lung and Respiratory Disease Clinics' annual educational conference. The FY 2017 BLCP FOA lifts this restriction, although applicants must justify the reasonableness of their proposed conference attendance and travel budgets and assure compliance with grant guidance related to advocacy activities. However, HRSA retained the restriction on using BLCP grant funds to subsidize membership dues and fees associated with the National Coalition of Black Lung and Respiratory Disease Clinics. Subject to the availability of travel funds and other factors, HRSA will continue to attend and participate in the existing education and collaboration forums.

Data Collection

Summary of Comments

Commenters were in near-universal agreement about the benefits of patient-level data collection and the inadequacies of the current performance measurement system, but some expressed concerns about the burden patient-level data collection would impose on clinics. Commenters noted that data collection methods and databases vary across the grantees, and that some grantees may need more IT support and funding than others to carry out new data collection activities. Others noted the administrative burden of reporting data into more than one database. Some commenters stated that the REDCap database, a patient-level database that has been piloted with a few grantees by the BLCE, was a promising start, and at least one commenter recommended that it be expanded to all grantees as one possible common platform. Other commenters said a patient-level database should be housed in and maintained by HRSA and not by the BLCE.

Response

Patient-level data collection and reporting will benefit the coal miners, clinics, and the broader medical and public health communities by enabling HRSA and BLCP awardees to better assess miners' needs and program impact. Therefore, for the purposes of the FY 2017–2020 grant cycle, HRSA will explore the development of a patient-level database and will work with its federal partners, the BLCE, and BLCP awardees to develop a new set of data measures for the program. By the third year of the grant (July 1, 2019–June 30, 2020), it is anticipated that all BLCP awardees will be expected to collect and report patient-level data to HRSA. In developing these requirements, efforts will be made to minimize administrative and financial burden on BLCP awardees.

BLCE

Summary of Comments

Commenters expressed mixed support for BLCE in its current form. In general, the training modules developed by the BLCE were well received and one commenter stated that they appreciated having training come from the BLCE as opposed to other grantees who may be in direct competition with them for patients. One commenter stated BLCE has not achieved its stated goals and that BLCE funding would be more effective if allocated to the clinics, while others questioned whether BLCE's services were being used or if they were relevant to non-hospital-based clinics. Still others suggested that the BLCE be restructured to encourage contributions from other grantees and that technical assistance around benefits counseling would be beneficial.

Response

HRSA established the BLCE in FY 2014 to provide technical assistance and training to BLCP awardees and to identify and disseminate best practices. HRSA agrees that the role and expectations of the BLCE should be better defined in order to maximize its impact. For the FY 2017–2020 grant cycle, HRSA refined the scope of the BLCE to focus on strengthening the operation of BLCP awardees and their ability to examine and treat respiratory and pulmonary impairments in active and inactive coal miners through improved data collection and analysis and contributing to the body of knowledge on the health status and needs of U.S. coal miners nationally. At the same time, the FY 2017 BLCE FOA allowed applicants to propose additional technical assistance and/or training activities in recognition of the ongoing and evolving need for these initiatives.

Timeliness and Quality of DOL Exams

Summary of Comments

Two commenters agreed with HRSA's proposal to hold 413(b) providers affiliated with FORHP-funded black lung clinics accountable to DOL's standards for medical exam timeliness. Another suggested that DOL issue ''report cards'' to 413(b) providers on timeliness so they can correct course if necessary before HRSA holds them accountable. A few commenters expressed concern that the timeliness requirement could affect the quality of the exam or have other unintended consequences. Regarding the proposal to require clinical personnel to take the DOL-sponsored training modules, some commenters agreed that the proposal was reasonable, while others expressed concern that the few providers performing DOL exams would shy away from participating if they were required to take the modules. One commenter stated that the requirement for BLCP staff to complete the DOL training modules should come from DOL and not HRSA, and another commenter disagreed entirely with the training requirement proposal.

Response

HRSA recognizes the importance of working closely with DOL's Office of Workers' Compensation Programs to ensure that providers performing DOL medical exams adhere to DOL's timeliness and quality standards and goals, while also understanding some of the limitations these providers face. Therefore, the FY 2017 BLCP FOA strongly encourages BLCP awardees performing DOL medical exams onsite 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. This last point encompasses the learning modules entitled ''Black Lung Disability Evaluation and Claims Training for Medical Examiners'' and available at *https://www.publichealthlearning.com/course/category.php?id=35.* HRSA will continue to work with DOL and BLCP awardees to strengthen this component of the BLCP.

Pulmonary Rehabilitation

Summary of Comments

All of the commenters agreed that onsite pulmonary rehabilitation is a vital service. However, most commenters expressed concerns that this service is not widely available to miners who need it because it is costly to operate, there are low rates of reimbursement, and miners often aren't able to travel to clinics that do offer treatment. Some commenters said that consideration should be given for non-traditional pulmonary treatment programs, such as in-home treatments, and that HRSA should further research the effectiveness of these programs. A few commenters argued that BLCP clinics should collaborate more with hospital-based pulmonary rehabilitation programs in multiple communities to make it more feasible for miners to receive treatment. Nearly all of the commenters expressed concerns that American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) certification is difficult to obtain and financially burdensome to the clinics, and that it is not cost-effective for the clinic to try to meet this standard for additional grant funding.

Response

In the FY 2014 BLCP FOA, BLCP awardees receiving the highest level of funding were required to provide AACVPR-certified pulmonary rehabilitation programs onsite. The FY 2017 BLCP FOA removes this requirement and instead requires all applicants to propose, at a minimum, onsite, contracted, or referral to accredited Phase II or Phase III pulmonary rehab services. BLCP awardees providing AACVPR-certified programs to coal miners may maintain their certification if they choose, but this is no longer a requirement.

Geographic Boundaries

Summary of Comments

A few commenters expressed concern over how HRSA defines the service areas of each clinic. At least two noted that in some cases, coal miners work or reside in closer proximity to clinics in neighboring states than to those within the same state, but that HRSA limits clinics' ability to conduct outreach in other states. Another commenter stated that some clinics provide complementary services in close proximity to one another.

Response

In certain cases, the FY 2017 BLCP FOA allows more than one BLCP awardee to provide services to coal miners in a given county, provided those awardees detail how they will avoid duplicating efforts of other black lung clinics. Applicants may also propose to provide services (including outreach) to coal miners in counties other than the ones listed in the FY 2017 BLCP FOA, including counties in neighboring states, provided that they demonstrate how their services will complement—rather than duplicate—existing efforts in those counties. A coal miner may receive services at a black lung clinic of his or her choosing, regardless of that clinic's location or service area designation.

Conclusion

HRSA considers many of the comments received to be useful and informative to future discussions on how to strengthen the BLCP in future years and appreciates the interest and dedication of the commenters who are committed to serving U.S. coal miners. Any questions or concerns should be directed to *Blacklung@hrsa.gov.*

Diana Espinosa,

Deputy Administrator.

[FR Doc. 2016–32003 Filed 1–4–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authority Under Title III, Part D, Section 340B(d)(1)(B)(vi) of the Public Health Service Act (PHSA)

Notice is hereby given that I have delegated to the Inspector General, Office of Inspector General, the authority vested in the Secretary of Health and Human Services under Title III, Part D, Section 340B(d)(1)(B)(vi) of the Public Health Service Act (PHSA), as amended, to impose sanctions in the form of civil monetary penalties against manufacturers that knowingly and intentionally charge a 340B covered entity a price for purchase of a drug that exceeds the maximum applicable ceiling price as defined by section 340B(a)(1) of the PHSA. In accordance with section 340B(d)(1)(B)(vi)(II) of the PHSA, such sanctions shall not exceed $5,000 for each instance of overcharging a 340B covered entity that may have occurred. This authority may be redelegated. This delegation excludes the authority to issue regulations.

I have affirmed and ratified any actions taken by the Inspector General, or subordinates, that involved the exercise of the authority delegated herein prior to the effective date of the delegation.

This delegation became effective upon date of signature.

Authority: 42 U.S.C. 256b(d)(1)(B)(vi)

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–31944 Filed 1–4–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.

Date: January 23–24, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westgate Hotel, 1055 Second Avenue, San Diego, CA 92101.

Contact Person: Stacey FitzSimmons, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114,