

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| 516.20; content and format of MUMS request | 15 | 5 | 75 | 16 | 1200 |
| 516.26; requirements for amending MUMS designation | 3 | 1 | 3 | 2 | 6 |
| 516.27; change in sponsorship | 1 | 1 | 1 | 1 | 1 |
| 516.29; termination of MUMS designation | 2 | 1 | 2 | 1 | 2 |
| 516.30; requirements of annual reports | 15 | 5 | 75 | 2 | 150 |
| 516.36; insufficient quantities | 1 | 1 | 1 | 3 | 3 |
| Total | | | | | 1,362 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: August 16, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Changes to the Black Lung Clinics Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for Public Comment on Proposed Changes to the Black Lung Clinics Program for Consideration for the FY 2017 Funding Opportunity Announcement Development.

SUMMARY: This notice seeks comments on a range of issues pertaining to the Black Lung Clinics Program (BLCP), which will be competitive in Fiscal Year (FY) 2017. HRSA's Federal Office of Rural Health Policy allocates funds for state, public, or private entities that provide medical, educational, and outreach services to active, inactive, and retired coal miners with disabilities. Funding allocations take into account the number of miners to be served; their medical, outreach, and educational needs; and the quality and breadth of services that are provided. HRSA requests 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.

DATES: Submit written comments no later than September 21, 2016.

ADDRESSES: Written comments should be submitted to Blacklung@hrsa.gov.

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:

I. Background

a. Authorizing Legislation and Program Regulations

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 ("BLCP regulations"). HRSA began administering the program in FY 1979, when \$7.5 million was appropriated. HRSA awarded approximately \$6.5 million to clinics in FY 2015.

The primary goal of the BLCP is to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease. The BLCP regulations (42 CFR part 55a) state that BLCP grantees must provide for the following services to active and inactive miners, in consultation with a physician with special training or experience in the diagnosis and treatment of respiratory diseases: primary care; patient and family education and counseling; outreach; patient care coordination; antismoking advice; and other symptomatic treatments. Additionally, BLCP grantees must serve as payers of last resort and be able to administer, or provide referrals for, U.S. Department of Labor (DOL) disability examinations.

b. Eligibility and Funding Criteria

The BLCP funding opportunity is open to any state or public or private entity that meets the requirements of the BLCP as described above. These entities include faith-based and community-based organizations, as well as federally recognized Tribes and Tribal organizations.

The BLCP regulations state that the funding criteria for applicants should take into account: (1) *The number of miners to be served and their needs;* and (2) *the quality and breadth of services to be provided.* The regulations also state that "the Secretary will give preference to a State, which meets the requirement of this part and applies for a grant under this part, over other applications in that State".

c. Application Cycle

HRSA administers the BLCP over 3-year grant cycles. The program was last competitive in FY 2014, and current BLCP grantees finished their second year of the cycle on June 30, 2016. The program will be competitive again in FY 2017.

II. Current Challenges

a. Growing Need for Black Lung Services

In FY 2000, surveillance data from the Centers for Disease Control and Prevention's National Institute of Occupational Safety and Health (NIOSH) showed an unexpected increase in the national prevalence of coal workers' pneumoconiosis (CWP), also known as black lung disease, after nearly three decades of steady decline following the enactment of the Federal Coal Mine Health and Safety Act of 1969. The overall CWP prevalence among U.S. coal workers declined from 11 percent in 1970 to 2 percent in 1999. However, since 2000, the prevalence of CWP has increased to 3 percent and continues to rise. According to NIOSH surveillance data, the rise in CWP has been the most severe among coal miners

in Kentucky, Virginia, and West Virginia. Compared with coal miners in other states, these miners tend to be younger, with fewer years of work experience in underground mines. Investigators from NIOSH 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. This level of prevalence of PMF has not been seen since the 1970s. Additionally, NIOSH has reported that coal miners are developing severe CWP at relatively young ages.

Finally, the U.S. coal industry is currently experiencing a downturn. Industry analysts estimate that nearly 50 coal companies have sought bankruptcy court protection since 2012, resulting in layoffs and, in some cases, lost retirement benefits for coal miners. According to a 2016 report by the Appalachian Regional Commission, Appalachian Kentucky experienced a coal mining job decline of 56 percent between 2011 and 2015, while Tennessee and Virginia both experienced declines of approximately 40 percent during the same time period. The West Virginia Office of Miners Health Safety and Training has estimated that there are currently 12,000 coal miners employed in the state, down from 22,000 in 2011. Widespread coal mining job losses have also been reported in other states such as Pennsylvania, Ohio, and Alabama. These trends have the potential to affect coal miners' economic welfare and, by extension, their ability to access or afford health care. Indeed, some current BLCP grantees have noted in their annual progress reports to HRSA, submitted April 2016, and in written email communication ahead of the March 2016 HRSA BLCP Grantee Workshop, that they have witnessed a recent uptick in the number of coal miners visiting their clinics, which some attribute to industry layoffs.

b. Ongoing Challenges in Meeting Those Needs

Current BLCP grantees reported facing several challenges in meeting the needs of coal miners in their service areas during a March 2016 BLCP Grantee Workshop hosted by HRSA. First, recruitment, training, and retention of qualified clinical and benefits counseling staff remain difficult, particularly in rural areas. Second, coal miners often face transportation and other barriers to accessing health services, which is problematic given that many suffer from chronic

conditions that require regular management and treatment. Third, BLCP grantees have indicated that some miners, including those who have been laid off or are not part of a union, are difficult to locate, which can complicate outreach and service delivery efforts. Finally, there continues to be a shortage of clinicians willing and able to perform exams related to the emerging DOL standards for x-rays, pulmonary testing, and medical documentation, particularly in rural areas.

c. Limited Available Data

Overarching these challenges is the lack of a single, comprehensive, national dataset that contains information on active, inactive and retired, and disabled U.S. coal miners who have worked in surface and underground mines. DOL's Office of Workers' Compensation Programs and Mine Safety and Health Administration, along with NIOSH's Coal Workers' Health Surveillance Program, each regularly collect health and safety data on coal miners, but these data address specific and separate aspects of this population. HRSA also collects yearly performance data from BLCP grantees, but these data are in aggregate form making it problematic to analyze patient-level data or link to DOL or NIOSH's datasets. As a result, it is difficult to ascertain both the total number of active, inactive and retired, and coal miners with disabilities in a given service area, as well as the complete health and wellness profile of U.S. coal miners. This makes it difficult for HRSA to assess where U.S. coal miners reside and what their needs are. Per statute, HRSA is required to allocate BLCP grant funds based in part on "the number of miners to be served and their needs." Additionally, the lack of comprehensive data on coal miners is a challenge to current BLCP grantees that use BLCP funds to target and deliver services to miners.

III. FY 2014 Funding Approach and Current BLCP Cohort

a. Overview of FY 2014 Funding Approach

In FY 2014, HRSA tested a new funding approach that aimed to respond to the growing national need for BLCP services, as well as the BLCP regulations' requirement to allocate BLCP grant funds according to: (1) *The number of miners to be served and their needs;* and (2) *the quality and breadth of services to be provided.* The new funding approach enabled individual applicants to apply for a specific tier of funding, depending on the level of

services they intended to provide (see pp. 6–9 of the FY 2014 Funding Opportunity Announcement). Historically, the mix of BLCP grantees and applicants has been broad in terms of those who are very clinically focused and those who are more geared towards outreach, education, and counseling. The tiered-based funding approach was designed, in part, to account for these differences. Additionally, the funding methodology took into account available data on the number of coal miners and coal mines in a service area, as reported by the U.S. Department of Energy's Energy Information Administration (EIA) and other national, state, and local resources.

b. Current BLCP Cohort

Following a competitive application process, HRSA allocated approximately \$6.5 million among 15 BLCP grantees. These grantees provided medical, outreach, educational, and counseling services to 11,843 miners across 14 states in FY 2014.

c. Black Lung Center of Excellence

HRSA also funded one Black Lung Center of Excellence (BLCE) through a cooperative agreement in FY 2014 to strengthen the quality of the BLCP and respond to some of the challenges faced by BLCP grantees and the program as a whole, including around the emerging clinical requirements related to DOL's black lung claims process.

IV. Request for Public Comment on Next Funding Opportunity Announcement (FOA)

a. Background

The BLCP will be competitive again in FY 2017, and HRSA is seeking public comment on issues pertaining to the program, including:

b. Funding Approach

Following the release of the new funding approach in FY 2014, some stakeholders expressed concern that the funding tiers increased the administrative burden on applicants and, in some cases, reduced funding for applicants that experienced a high demand for black lung services in their service areas. With this request, HRSA invites public comment on the FY 2014 funding approach and suggestions for other funding methodologies that will allocate BLCP grant funds based on the healthcare needs of coal miners and the ability of applicants to meet those needs, while minimizing service disruption, aligning with the program's statutory and regulatory requirements, and taking into account the amount of available funding.

One approach HRSA would like to seek feedback on includes a service area competition whereby HRSA allocates funds to states based on the need for services (which includes the number of miners in the state) and the implications of taking into account historical funding amounts in administering the program.

c. Determining Need

HRSA's FY 2014 funding methodology aimed to better align the BLCP with the regulations, which require HRSA to allocate funds based on: (1) *The number of miners to be served and their needs; and (2) the quality and breadth of services to be provided.* To that end, the FY 2014 funding methodology took into account the number of coal miners and coal mines in a service area, as reported by EIA and other national, state, and local resources, as well as the level of services an applicant intended to provide. HRSA recognizes that these data do not necessarily encapsulate important factors like disease severity and comorbidity, disability, and employment status, all of which could affect the time and resources grantees must devote to delivering health and social services to coal miners. With the recent downturn of the U.S. coal industry, and the corresponding layoffs of coal miners, the numbers of active coal miners and coal mines in a service area may not be the most accurate indicators of need for services. Therefore, HRSA invites public comment on how to better define and measure the diverse needs of coal miners based on publicly available data to ensure that HRSA allocates BLCP grant funds to areas of the country where they are most needed.

d. Data Collection

Currently, BLCP grantees report performance data on the number of coal miners they serve and the number and type of services they provide to HRSA. These aggregated data provide little insight into the quality of services clinics provide, nor relevant factors such as comorbid conditions, smoking history, and insurance coverage. Requiring BLCP grantees to collect and report on patient-level data would strengthen the quality of the BLCP by enabling HRSA to better understand coal miners' needs, the ability of BLCP grantees to meet those needs, and, importantly, how to better allocate BLCP grant funds. Additionally, given that the majority of coal miners served by BLCP grantees are retired, collecting patient-level data would enable HRSA to add to the limited body of knowledge on this population.

However, despite the benefits of patient-level data collection, HRSA recognizes that this process may be administratively and financially burdensome for BLCP grantees. Therefore, HRSA invites public comment on whether it should require grantees to collect and report patient-level data, either through the current performance measurement system or a separate black lung clinical database.

e. The Black Lung Center of Excellence (BLCE)

In FY 2014, HRSA funded one BLCE through a cooperative agreement to focus on the quality aspect of the BLCP. The current BLCE grantee, with assistance from HRSA, has implemented a number of activities aimed at achieving HRSA's goals around quality, including:

- Developing and launching the BLCE Web site to provide BLCP grantees, miners, and others who provide services to miners with educational expertise and resources on coal mine dust lung disease;
 - Creating four training modules in collaboration with the DOL, Division of Coal Mine Workers Compensation, for medical providers and Black Lung examiners that provide in-depth information on screening, diagnosis, and treatment of coal mine lung dust disease;
 - Providing technical assistance to BLCP grantees; and
 - Developing and piloting the Black Lung Clinical Research Database (REDCap) to standardize clinical data collection and performance data submission by HRSA BLCP grantees.
- HRSA invites public comment on how HRSA can better leverage the BLCE's expertise and quantify the BLCE's impact on BLCP grantees and the coal miners they serve through performance measures.

f. Timeliness and Quality of DOL Exams

One of the goals of the BLCP, as outlined in the FY 2014 funding opportunity announcement, is to "provide well-reasoned medical opinions and timely scheduling/ completion of DOL medical exams to facilitate the filing of Federal Black Lung Benefits claims." HRSA proposes to work with DOL's Office of Workers' Compensation Programs (OWCP) to hold BLCP grantees to standards for medical exam timeliness. In particular, these standards would require clinicians performing 413(b) examinations, who are affiliated with BLCP clinics, to complete initial 413(b) requests within 90 days and 413(b) supplemental medical evidence development within

60 days. Additionally, to strengthen the quality of services provided by BLCP grantees, HRSA proposes requiring medical and non-medical personnel from all BLCP clinics to complete the OWCP-sponsored training modules entitled "Black Lung Disability Evaluation and Claims Training for Medical Examiners" prior to applying for BLCP grant funds. HRSA invites public comment on whether these requirements are reasonable and attentive approaches to strengthening the quality of medical services provided by BLCP grantees.

g. Grantee Collaboration

The current BLCP grantees and applicants are mixed in terms of those who are clinically focused and those who are service focused. Encouraging grantees to share best practices and provide technical assistance to one another could help strengthen the quality of the BLCP. Proposed mechanisms for achieving greater collaboration include allowing grantees to allocate a portion of their award towards providing on-site or remote technical assistance to other clinics and/or encouraging grantees to participate in a yearly peer learning workshop hosted by HRSA. HRSA invites public comment on these strategies as well as how the BLCE can play a role in facilitating grantee collaboration.

h. Pulmonary Rehabilitation

The current BLCP grant guidance requires grantees to provide for accredited pulmonary rehabilitation services. The first two funding tiers require BLCP grantees to provide "on-site or contracted accredited Phase II or Phase III rehabilitation services," while the third and highest funding tier requires BLCP grantees to provide an "on-site" and "American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)-certified" pulmonary rehabilitation program. Current BLCP grantees have expressed concerns that these standards are difficult to meet, particularly in rural areas where miners have to travel long distances to attend multiple sessions a week. Thus, HRSA invites public comment on how to revise the BLCP requirements around pulmonary rehabilitation such that they are feasible but still ensure that miners receive a variation of this beneficial service.

Dated: August 15, 2016.

James Macrae,

Acting Administrator.

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