

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 BCLP awardees to strengthen this component of the BCLP.

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 BCLP 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 BCLP FOA, BCLP awardees receiving the highest level of funding were required to provide AACVPR-certified pulmonary rehabilitation programs onsite. The FY 2017 BCLP 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. BCLP 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 BCLP FOA allows more than one BCLP 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 BCLP 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 BCLP 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.

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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.

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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,