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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-0020]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Coal Workers' Health Surveillance Program (CWHSP) - (0920-0020)
- Reinstatement with Change - National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH would like to submit an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP).

On May 1, 2014, the Mine Safety and Health Administration (MSHA) published final rule 30 CFR 70, 71, 72, 75, and 90. The new MSHA rule added surface coal miners, a respiratory health assessment, and spirometry testing for chronic obstructive pulmonary disease (COPD) to the previously mandated chest x-ray examination program. These additions are being referred to as the Expanded CWHSP (an additional component under the current CWHSP).

This request incorporates all components that now fall under the CWHSP. Those components include: Coal Workers' X-ray Surveillance Program (CWXS), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), Expanded Coal Workers' Health Surveillance Program, and National Coal Workers' Autopsy Study (NCWAS).

The CWHSP is a congressionally-mandated medical examination program for monitoring the health of coal miners. The Program

was originally authorized under the 1969 Federal Coal Mine Health and Safety Act and is currently authorized under the 1977 Federal Mine Safety and Health Act and its subsequent amendments (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program, which operates in accordance with 42 CFR Part 37, is useful in providing information for protecting the health of miners (whose participation is entirely voluntary), and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among miners employed in U.S. coal mines.

The total estimated annualized burden hours of 20,282 is based on the following collection instruments:

- Coal Mine Operator Plan (2.10) and Coal Contractor Plan (2.18) - Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every 4 years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination. Completion of this form with all requested information (including a roster of current employees) takes approximately 30 minutes.
- Radiographic Facility Certification Document (2.11) - X-ray facilities seeking NIOSH approval to provide miner

radiographs under the CWHSP must complete an approval packet including this form which requires approximately 30 minutes for completion.

- Miner Identification Document (2.9) - Miners who elect to participate in the CWHSP must fill out this document which requires approximately 20 minutes. This document records demographic and occupational history, as well as information required under the regulations in relation to the examinations. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes.
- Chest Radiograph Classification Form (2.8) - NIOSH utilizes a radiographic classification system developed by the International Labour Office (ILO) in the determination of pneumoconiosis among coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately 3 minutes per form.
- Physician Application for Certification (2.12) - Physicians taking the B Reader examination are asked to complete this registration form which provides demographic information as well as information regarding their medical

practices. It typically takes the physician about 10 minutes to complete this form.

- Spirometry Facility Certification Document (2.14) - This new form is analogous to the Radiographic Facility Certification Document (2.11) and records the spirometry facility equipment/staffing information. Spirometry facilities seeking NIOSH approval to provide miner spirometry testing under the CWHSP must complete an approval packet which includes this form. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility.
- Respiratory Assessment Form (2.13) - This new form is designed to assess respiratory symptoms and certain medical conditions and risk factors. It is estimated that it will take approximately five minutes for administration of this form to the miner by an employee at the facility.
- Spirometry Results Notification Form (2.15) - This new form replaces previous forms 2.15, 2.16 and 2.17. It is used to: collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; assure that the test can be done safely; record certain factors that can affect test results; provide documentation that the required components of the spirometry examination have been transmitted to

NIOSH for processing; and conduct quality assurance audits and interpretation of results. It is estimated that it will take the facility approximately 20 minutes to complete this form. In addition to completing this form, acquiring an acceptable spirometry test from the miner takes approximately 15 minutes.

- Pathologist Invoice - Under the NCWAS, the invoice submitted by the pathologist must contain a statement that the pathologist is not receiving any other compensation for the autopsy. Each participating pathologist may use their individual invoice as long as this statement is added. It is estimated that only five minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.
- Pathologist Report - Under the NCWAS the pathologist must submit information found at autopsy, slides, blocks of tissue, and a final diagnosis indicating presence or absence of pneumoconiosis. The format of the autopsy reports is variable depending on the pathologist conducting the autopsy. Since an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request for a clinical abstract of terminal illness and final diagnosis relating to pneumoconiosis.

Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

- Consent, Release and History Form (2.6) - This form documents written authorization from the next-of-kin to perform an autopsy on the deceased miner. A minimum of essential information is collected regarding the deceased miner including an occupational history and a smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Coal Mine Operator	2.10	388	1	30/60
Coal Mine Contractor	2.18	575	1	30/60
Radiograph Facility Supervisor	2.11	40	1	30/60
Coal Miner	2.9	14,560	1	20/60
Coal Miner - Radiograph	No form required	14,560	1	15/60
B Reader Physician	2.8	10	3014	3/60
Physicians taking the B Reader Examination	2.12	100	1	10/60
Spirometry Facility	2.14	100	1	30/60

Supervisor				
Spirometry Facility Employee	2.13	14,560	1	5/60
Spirometry Technician	2.15	14,560	1	20/60
Coal Mine - Spirometry	No form required	14,560	1	15/60
Pathologist	Invoice--No standard form	5	1	5/60
Pathologist	Pathology Report -- No standard form	5	1	5/60
Next-of-kin for deceased miner	2.6	5	1	15/60

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