

COAL WORKERS' HEALTH SURVEILLANCE PROGRAM (CWHSP)

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Supporting Statement B

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Because this program provides medical monitoring for all coal miners, this collection of information does not employ statistical methods in the selection of respondents. There are a total of 11 CDC/NIOSH-numbered forms that are completed by various respondents: government employees/contractors, physicians, miners, coal mine operators, coal mine contractors, and medical facility employees. The following discusses respondents and data collection procedures:

1. **Respondent Universe and Sampling Methods**

Coal Mine Operator Plan (Attachment 3)

Form No. CDC/NIOSH (M) 2.10

and

Coal Contractor Plan (Attachment 4)

Form No. CDC/NIOSH (M) 2.18

Under 42 CFR Part 37, every coal operator and coal contractor in the U.S. must submit a plan approximately every four years, providing information on how they plan to notify their miners of the opportunity to obtain the medical examination.

These forms record plans and arrangements for offering the coal miner examinations and are used by coal operators and contractors for that purpose. Both forms include a section to specify NIOSH-approved spirometry testing facilities in proximity to the mine. Completion of these forms with all requested information (including a roster of current employees) takes approximately 30 minutes. Based on data received from MSHA, there are approximately 425 underground coal mines and 1,125 surface mines for a total of 1,550. With each of these mines being required to submit a plan approximately every four years, 388 plans would be submitted annually. Likewise, there are approximately 2,300 coal contractors which would result in 575 annual plans being submitted.

Radiographic Facility Certification Document (Attachment 6)

Form No. CDC/NIOSH (M) 2.11

This form records the radiograph facility equipment/staffing information. Radiograph facilities seeking NIOSH-approval to provide miner radiographs under the CWHSP must complete an approval packet. It takes approximately 30 minutes for completion of this form. An estimate of 40 new facilities will join in the upcoming year.

Miner Identification Document (Attachment 8)

Form No. CDC/NIOSH (M) 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 from radiograph facilities in relation to coal miner examinations. It is estimated that a total of 14,560 miners might participate in the upcoming year based on FY17 participation in the CWHSP and using the overall 40% of the total mining industry participation rate. In addition to completing this form, acquiring the chest image from the miner takes approximately 15 minutes.

Chest Radiograph Classification Form (**Attachment 11**)
Form No. CDC/NIOSH (M) 2.8

Under 42 CFR Part 37, 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 classifications of the radiographs (each radiograph has at least two separate classifications; approximately 7% require additional classifications). The CWHSP uses an average of 10 B Readers to provide these classifications. Based on prior practice it takes the B Reader approximately 3 minutes per form/classification. By using a participate number of 14,560, multiplied by 2 classifications and adding the 7% (1,019) that require additional classifications, the total number of anticipated classifications would be 30,139. When the 30,139 classifications are distributed among the 10 CWHSP-contracted B Readers, the number of responses per respondent is 3,014.

Physician Application for Certification (**Attachment 12**)
Form No. CDC/NIOSH (M) 2.12

Physicians taking the B Reader Examination are asked to complete this registration form which provides demographic information as well as information regarding professional practices. It takes approximately 10 minutes to complete this form and is filled out one time per physician. It is estimated that 100 new physicians will sit for the examination in the coming year.

Spirometry Facility Certification Document (**Attachment 15**)
Form No. CDC/NIOSH (M) 2.14

This form is analogous to the Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, **Attachment 6**) 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. It is estimated that it will take approximately 30 minutes for this form to be completed at the facility. Recruiting approximately 100 spirometry facilities would adequately serve the U.S. coal miner population.

Respiratory Assessment Form (**Attachment 16**)
Form No. CDC/NIOSH (M) 2.13

This form is designed to assess respiratory symptoms and certain medical conditions and risk factors of the miners participating in the CWHSP. It is estimated that it will take approximately 5 minutes for this form to be administered to the miner by an employee at the facility. This annual burden is based on the estimated participation rate of 14,560 miners as previously explained.

Spirometry Results Notification Form (**Attachment 17**)
Form No. CDC/NIOSH (M) 2.15

This form is used to: 1) collect information that will allow NIOSH to identify the miner in order to provide notification of the spirometry test results; 2) assure that the test can be done safely; 3) record certain factors that can affect test results; 4) provide documentation that the required components of the spirometry examination have been transmitted to NIOSH for processing; and, 5) conduct quality assurance audits and interpretation of results. This annual burden is based on the estimated participation rate of 14,560 miners as previously explained. 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.

Consent, Release and History Form (**Attachment 19**)
Form No. CDC/NIOSH (M) 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 the occupational history and smoking history. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete this form. There have been no autopsy specimens sent to the CWHSP in the past few years.

42 CFR 37.202 Autopsy Invoice (**Attachment 20**)

42 CFR Part 37.200 specifies the procedures for the NCWAS. Specifically, Part 37.202 addresses payment to pathologists for autopsies performed. 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 his/her individual invoice as long as this statement is added. It is estimated that only 5 minutes is required for the pathologist to add this statement to the standard invoice that s/he routinely use.

42 CFR 37.203 Pathologist Report of Autopsy (**Attachment 21**)

42 CFR Part 37.203 provides the autopsy findings. 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 are 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 a final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the pathologist's report.

Authorization for Payment of Autopsy (Attachment 22)

Form No. CDC/NIOSH (M) 2.19

Revised 42 CFR Part 37.204 outlines a need for a pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in § 37.202 (a) by completing the Authorization for Payment of Autopsy form and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. This is a new form. It will be completed by the pathologist who intends on conducting an autopsy and the form will collect: demographic information on the deceased miner, characteristics of the miner's pneumoconiosis (if known by the pathologist), demographic and medical licensure information from the requesting pathologist, and proposed payment amount to complete the autopsy in accordance with § 37.203. The number of autopsy requests will vary substantially between years. For example, more requests might be granted following a mine disaster. Over a period of years, NIOSH expects an average of about four requests for prior authorization annually. It is estimated that 15 minutes is required for the pathologist to complete this form.

2. Procedures for the Collection of Information

Based on notification by MSHA regarding the establishment of, or a change in the status of, a coal mine operation, NIOSH notifies the mine operator/mine contractor of the requirement to file a coal mine operator's/coal contractor's examination plan. Subsequent plans must be filed upon notification by NIOSH at approximately five-year increments. In the event that a mine does not file on time as required, NIOSH is authorized to establish a plan for the mine and inform the operator/contractor of its terms. In the event that the mine files a faulty plan, NIOSH will contact the mine operator/contractor and provide instructions for correcting their submission. Upon approval, NIOSH forwards a copy of the plan for mandatory posting at the mine site. The miners can then check the posting to determine the time and place where they can receive their free medical examination. Along with each mine plan, a roster of employees is required which lists contact information for each mine employee. NIOSH sends a letter, along with information about the CWHSP, to each miner listed on this roster, outlining the time and place where they can receive their free medical examination. Other than a mandatory medical examination upon entry in to the mining industry, participation is voluntary on the part of the miner; however, filing of the mine examination plan is mandatory for each operator and mining contractor.

Following posting of the examination plan at the mine site, eligible miners may visit the designated NIOSH approved radiograph facility to have a chest radiograph made at no cost to the miner and may visit the designated NIOSH

approved spirometry facility to have a spirometry test completed at no cost to the miner (See Endnote 1 regarding approved facilities). At the NIOSH approved facility, the miner will complete the Miner Identification Document (Form No. CDC/NIOSH (M) 2.9, **Attachment 8**). This document records the miner's demographic information, contact information, and occupational history. For each chest radiograph obtained at an approved facility, a qualified and licensed physician (or B Reader) who reads chest radiographs in the normal course of practice must provide an initial clinical interpretation and notification to the miner of any significant abnormal findings other than pneumoconiosis. The chest radiograph, along with the completed Miner Identification Document and the Chest Radiographic Classification Form (completed by a physician at the facility), are forwarded to NIOSH. Similarly, at the spirometry facility, the Miner Identification Document, Spirometry Results Notification Form and the Respiratory Assessment are forwarded to NIOSH after completion.

When the chest radiographs, spirometry test results and all accompanying forms arrive at NIOSH, all submitted materials are reviewed for compliance with applicable regulations, and all information on the collection instruments are coded for data entry. After the initial data entry and verification are completed, the Spirometry Facility is notified of satisfactory data transfer, and all electronic data files (both spirometry and radiograph) are added to the Mine Health System (MHS) database. As an additional assurance that the miner has been notified, NIOSH will contact participants by mail if any clinically important health findings are noted on the chest radiograph other than CWP, and a phone consultation to explain the finding will be offered. All radiographs are sent to at least two NIOSH certified B Readers for classification according to the ILO System. (See Endnote 2 regarding B Readers).

All subsequent classifications of the chest radiographs are also recorded on the Chest Radiographic Classification Form and are then coded for data entry and added to the MHS database. A computer program compares the first and second classifications of the radiograph to determine if there is agreement with respect to the presence or absence and severity of CWP as specified by regulation 42 CFR 37. If the first two classifications are not in agreement, the radiograph is sent for additional classification from B Readers until consensus is obtained. At that point, the miner is notified of the final determination.

Spirometry results are first verified for name, birth date, medical record number, and demographic information on the Spirometry Results Notification Form (Form No. CDC/NIOSH (M) 2.15, **Attachment 17**). Once this information is confirmed, the spirometry results are evaluated for any quality assurance factors that may affect reporting of results using computer programs and experienced spirometry personnel. Spirometry results are coded for interpretation and saved in the MHS database. Miners are then notified of results.

Revised 42 CFR Part 37.204 outlines that NIOSH can compensate pathologists

for conducting autopsies on a discretionary basis as needed for public health purposes as part of the National Coal Workers Autopsy Study (NCWAS). Initiating the approval for obtaining an autopsy with reimbursement of costs from NIOSH requires a pathologist to obtain written authorization from NIOSH and agreement regarding payment amount for services specified in §37.202 (a) by completing Authorization for Payment of Autopsy Form (Form No. CDC/NIOSH (M) 2.19, **Attachment 22**) and submitting it to the CWHSP for authorization prior to completing an autopsy on a coal miner. This form is filled out by the requesting pathologist and includes demographic and pneumoconiosis classification information (if known) about the deceased miner as well as the pathologist's contact information and board certification and proposed compensation for conducting the autopsy according to §37.203. Additionally, the family of the deceased miner submits written consent for autopsy (Consent, Release and History Form – Form No. CDC/NIOSH (M) 2.6, **Attachment 19**). This information will be reviewed by CWHSP program and if approved the pathologist will conduct the autopsy and provide NIOSH with material and information outlined in §37.203.

When the autopsy materials and all accompanying forms arrive at NIOSH, all submitted materials are reviewed for compliance with applicable regulations, and all information on the collection instruments and within the autopsy report are coded for data entry. Nosologists are used to assign final cause of death codes using the final diagnosis information from the pathology reports. After the initial data entry and verification are completed, all electronic data files are added to the Mine Health System (MHS) database and all hard copy files are scanned and added to the MHS.

3. Methods to Maximize Response Rates and Deal with Non-response

After a mandatory examination at the time of first employment in coal mining, participation in this program is voluntary for miners as specified in 42 CFR 37. In an attempt to increase participation by miners, data collection forms are prefilled to the extent possible and then mailed directly to each miner's residence with descriptive information about the CWHSP. The CWHSP also provides an outreach program through exhibits and presentations at coal mining shows, conferences, black lung clinics, and health fairs in an effort to increase overall awareness of the program as well as the causes and consequences of coal-related respiratory disease.

From October 1, 1999 through September 30, 2002, the Mine Safety and Health Administration (MSHA), in consultation with NIOSH, conducted a pilot health surveillance program for both underground and surface miners (The Miners' Choice Program). The concept of the Miners' Choice Program is being continued as an extension of the CWHSP (currently called the Enhanced Coal Workers' Health Surveillance Program – ECWHSP). The enhanced program utilizes a mobile examination unit which travels to mining regions to provide locally

accessible health surveillance, including chest radiography, spirometry, respiratory health assessment questionnaire, and blood pressure screening. In addition, past participants of the ECWHSP are notified of scheduled screenings to aid NIOSH in adequately assessing progression of disease by obtaining longitudinal measurements of previous participants.

4. Tests of Procedures or Methods to be Undertaken

No new tests of procedures are planned. This is a federally-mandated program which has operated since 1970 and as such will have budgetary support throughout the approval period.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The design of the collection instruments and subsequent revisions since 1970 were accomplished by NIOSH employees in conjunction with key stakeholders as outlined under Supporting Statement A.8.b. (Attachment 24) NIOSH collects and analyzes the information obtained. Key contacts for the CWHSP are listed below.

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Endnotes

1. Approved Facility -- A radiograph or spirometry provider (hospital, clinic, private physician) that has submitted to NIOSH a Radiographic Facility Certification Document (Form No. CDC/NIOSH (M) 2.11, **Attachment 6**) or a Spirometry Facility Certification Document (Form No. CDC/NIOSH (M) 2.14, **Attachment 15**) and has demonstrated meeting all requirements as specified in 42 CFR 37. These are the only facilities permitted to submit radiographs or spirometry tests under the CWHSP. A list of all approved facilities is available on the program's website and is provided to the coal mine operator/contractor when they are notified that it is time to file an examination plan.
2. B Reader -- A licensed physician who has demonstrated a high level of proficiency in classifying chest radiographs for the pneumoconioses as set forth in 42 CFR 37. B Readers must demonstrate a high level of expertise by obtaining a passing grade on the NIOSH B Reader Certification Examination, and every five years thereafter must demonstrate ongoing competence by obtaining a passing grade on the NIOSH B Reader Re-certification Examination.