

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day–21–0020; Docket No. CDC–2021–0095]

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Coal Workers' Health Surveillance Program (CWHSP). The CWHSP is a Congressionally mandated medical examination program for monitoring the health of coal miners and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all subsequent amendments (the Act). HHS proposes to revise the National Institute for Occupational Safety and Health (NIOSH) CWHSP regulations by amending existing regulatory text to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis as needed for public health purposes.

**DATES:** CDC must receive written comments on or before November 15, 2021.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC–2021–0095 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–8, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to [Regulations.gov](https://www.regulations.gov).

*Please note:* Submit all Federal comments through the Federal eRulemaking portal ([regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–8, Atlanta, Georgia 30329; phone: 404–639–7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

### Proposed Project

Coal Workers' Health Surveillance Program (CWHSP), (OMB Control No. 0920–0020, Exp. 09/30/2021)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

NIOSH would like to submit a Revision Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP). This request incorporates all components of the CWHSP. Those components include: Coal Workers' X-ray Surveillance Program (CWXP), 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 and was originally established under the Federal Coal Mine Health and Safety Act of 1969 with all 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, and also in documenting trends and patterns in the prevalence of coal workers' pneumoconiosis ('black lung' disease) among U.S. coal miners.

HHS proposes to revise the CWHSP regulations (42 CFR part 37) by amending existing regulatory text to allow compensation for pathologists who perform autopsies on coal miners at a market rate, on a discretionary basis as needed for public health purposes. These changes to 42 CFR 37 have necessitated this revision ICR.

The total estimated annualized burden hours of 11,741 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 four 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.

- 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 at least two separate interpretations, and approximately 7% of the images require additional interpretations). Based on prior practice it takes the physician approximately three 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 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 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 this form to be administered to the miner by an employee at the facility.

- Spirometry Results Notification Form (2.15)—This form 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.

- 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 five 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.

- Authorization for Payment of Autopsy Form (2.19)—Revised 42 CFR part 37.204 outlines a need for a physician 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. It is estimated that 15 minutes is required for the pathologist to complete this form.

CDC requests OMB approval for an estimated 11,741 annual burden hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Coal Mine Operator .....	2.10 .....	220	1	30/60	110
Coal Mine Contractor .....	2.18 .....	160	1	30/60	80
Radiograph Facility Supervisor .....	2.11 .....	20	1	30/60	10
Coal Miner .....	2.9 .....	8,500	1	20/60	2833
Coal Miner—Radiograph .....	No form required .....	8,500	1	15/60	2125
B Reader Physician .....	2.8 .....	10	1,760	3/60	880
Physicians taking the B Reader Examination.	2.12 .....	220	1	10/60	37
Spirometry Facility Supervisor .....	2.14 .....	15	1	30/60	8
Spirometry Facility Employee .....	2.13 .....	8,500	1	5/60	708
Spirometry Technician .....	2.15 .....	8,500	1	20/60	2833
Coal Miner—Spirometry .....	No form required .....	8,500	1	15/60	2125
Pathologist .....	2.19 .....	4	1	15/60	1
Pathologist .....	Invoice—No standard form .....	4	1	5/60	1
Pathologist .....	Pathology Report—No standard form.	4	1	5/60	1
Next-of-kin for deceased miner .....	2.6 .....	4	1	15/60	1

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Total .....	.....	.....	.....	.....	11,741

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-21-1039]

**Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Information Collection on Cause-Specific Absenteeism in Schools to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on March 1, 2021 to obtain comments from the public and affected agencies. CDC received and replied to two non-substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(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.

Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

**Proposed Project**

Information Collection on Cause-Specific Absenteeism in Schools (OMB Control No. 0920-1039)—Reinstatement with Change—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Information Collection on Cause-Specific Absenteeism in Schools aims to improve: (1) understanding of the role of influenza-like illness (ILI)-specific absenteeism in schools in predicting community-wide influenza transmission, and (2) to detect within-household transmission of influenza in households from which a student has been absent from school due to ILI.

Due to children’s naïve immunity, their susceptibility to infectious diseases, and congregation of children at schools, schools serve as amplification points for influenza transmission. Therefore, the collection of ILI-specific absenteeism could provide information needed to detect influenza outbreaks early, before infection spreads to a wider community. Such early detection

of outbreaks will enable public health and school authorities to implement appropriate infection control and prevention measures.

School children are frequently the main introducers of influenza to their families. Evaluating influenza transmission within households where students are absent from school because of ILI may serve as an additional layer of influenza surveillance, and could contribute to understanding of influenza transmission dynamics within the surrounding community. Insights gained from this information collection will be used to strengthen the evidence-base of CDC’s Pre-Pandemic Guidance prior to the next pandemic.

Since obtaining OMB approval in December 2014, 2,466 Oregon School District students with ILI have been enrolled in the study. Of them, 68% were positive for at least one respiratory pathogen included in the PCR panel that tests for presence of 17 common respiratory viruses, and 29% of students were found to be positive for influenza. It was demonstrated that absenteeism due to ILI in school children was highly correlated with PCR-confirmed influenza in enrolled school children, and medically-attended influenza in the surrounding community, suggesting that ILI-specific school absenteeism can be considered a useful tool for predicting influenza outbreaks in the surrounding community. For all six seasons, (2015–2021) significant, positive cross-correlations were achieved for absenteeism due to illness (a-ILI) and absenteeism due to ILI (a-ILI) at least 14 days in advance of MAI. Further observations during influenza seasons caused by other influenza strains are needed to make these findings more robust.

In the currently approved information collection, information and biospecimens are collected only from students who were absent from school because of ILI. This reinstatement with change to the currently approved information collection adds a household transmission component, in which information and biospecimens will be collected from household members of students absent from school because of ILI. This aims to enhance current knowledge and understanding around