

A total of 600 individuals who develop CDI will be contacted for a telephone interview annually and, of those, it is estimated that 500 will meet study inclusion criteria. The interview

screening is estimated to take 5 minutes and the full telephone interview is estimated to take 40 minutes. Therefore, the total estimated annualized burden

for this data collection is estimated to be 383 hours.

There are no costs to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Persons in the community infected with <i>C. difficile</i> .....	Screening Form .....	600	1	5/60
	Telephone interview .....	500	1	40/60

**Leroy Richardson,**

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-14-0200]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

*Proposed Project*—Coal Workers' Health Surveillance Program (CWHSP) (OMB Control No. 0920-0200, Expiration 06/30/2014)—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 an Information Collection Request (ICR) to revise the data collection instruments being utilized within the Coal Workers' Health Surveillance Program (CWHSP). The current ICR incorporates all four components that fall under the CWHSP. Those four components include: Coal Workers' X-ray Surveillance Program (CWXS), B Reader Program, Enhanced Coal Workers' Health Surveillance Program (ECWHSP), and National Coal Workers' Autopsy Study (NCWAS). The CWHSP is a congressionally-mandated medical examination program for monitoring the health of underground coal miners, established under the Federal Coal Mine Health and Safety Act of 1969, as amended in 1977 and 2006, Public Law 95-164 (the Act). The Act provides the regulatory authority for the administration of the CWHSP. This Program 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 4,420 is based on the following:

- Coal Mine Operators Plan (2.10)—Under 42 CFR Part 37.4, every coal operator and construction contractor for each underground coal mine must submit a coal mine operator's plan every 3 years, providing information on how they plan to notify their miners of the opportunity to obtain the chest radiographic examination. To complete this form with all requested information (including a roster of current

employees) takes approximately 30 minutes.

- Facility Certification Document (2.11)—X-ray facilities seeking NIOSH approval to provide miner radiographs under the CWHSP must complete an approval packet 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 from x-ray facilities in relation to coal miner examinations. In addition to completing this form, the process of capturing the chest image takes approximately 15 minutes.

- Chest Radiograph Classification Form (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 underground coal miners. Physicians (B Readers) fill out this form regarding their interpretations of the radiographs (each image has at least two separate 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 Testing—Miners participating in the ECWHSP component of the Program are asked to perform a spirometry test which requires no additional paperwork on the part of the miner, but does require approximately 15 to 20 minutes for the test itself. Since spirometry testing is offered as part of the ECWHSP only, the 2,500 respondents listed in the burden

table below account for about half of the total participants in the CWHSP.

- **Pathologist Invoice**—42 CFR 37.202 specifies procedures for 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 5 minutes is required for the pathologist to add this statement to the standard invoice that they routinely use.

- **Pathologist Report**—42 CFR 37.203 provides the autopsy specifications. 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 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 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 are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden/response (in hrs)	Total burden (in hrs)
Coal Mine Operators .....	Form 2.10 .....	200	1	30/60	100
X-ray Facility Supervisor .....	Form 2.11 .....	100	1	30/60	50
X-ray—Coal Miners .....	No form required .....	5,000	1	15/60	1,250
Coal Miners .....	Form 2.9 .....	5,000	1	20/60	1,667
B Reader Physicians .....	Form 2.8 .....	10,000	1	3/60	500
Physicians taking the B Reader Examination.	Form 2.12 .....	100	1	10/60	17
Spirometry Test—Coal Miners .....	No form required .....	2,500	1	20/60	833
Pathologist .....	Invoice—No standard form .....	5	1	5/60	1
Pathologist .....	Pathology Report—No standard form.	5	1	5/60	1
Next-of-kin for deceased miner .....	Form 2.6 .....	5	1	15/60	1
<b>Total .....</b>					<b>4,420</b>

**Leroy Richardson,**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**Statement of Organization, Functions, and Delegations of Authority**

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), (last amended at **Federal Register**, Vol. 76, No. 75, pp. 21908-21909, dated April 19, 2011, and Vol. 77, No. 140, p. 42740, dated July 20, 2012) is amended to reflect the abolishment of the Office of Public Engagement (OPE). The Offices of Hearings and Inquiries (OHI) was

established and reports directly to the Chief Operating Officer (COO).

CMS modified its structure to: (1) Conduct Marketplace eligibility appeals; (2) assist Medicare beneficiaries with complaints, inquiries, and grievances, and to gather the information necessary to file Medicare appeals; and (3) conduct administrative hearings for institutional appeals which fall under the jurisdiction of the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and the CMS Hearings Officers.

The functions in OPE include the Medicare Ombudsman, tribal affairs, and emergency preparedness and continuity of operations. The Medicare Ombudsman was moved to OHI, tribal affairs was moved to the Center for Medicaid and CHIP Services (CMCS), and emergency preparedness and continuity of operations was moved to the Consortium for Quality Improvement and Survey & Certification Operations (CQISCO). In addition, the Office of Marketplace Eligibility Appeals was established in OHI, and the Office of Hearings was moved from the

Office of Operations Management (OOM) to OHI.

Part F., Section FC. 10 (Organization) is revised as follows:

- Office of the Administrator (FC)
- Office of Equal Opportunity and Civil Rights (FCA)
- Office of Legislation (FCC)
- Office of the Actuary (FCE)
- Office of Strategic Operations and Regulatory Affairs (FCF)
- Center for Clinical Standards and Quality (FCG)
- Center for Medicare (FCH)
- Center for Medicaid and CHIP Services (FCJ)
- Center for Strategic Planning (FCK)
- Center for Program Integrity (FCL)
- Chief Operating Officer (FCM)
- Office of Minority Health (FCN)
- Center for Medicare and Medicaid Innovation (FCP)
- Federal Coordinated Health Care Office (FCQ)
- Center for Consumer Information and Insurance Oversight (FCR)
- Office of Communications (FCT)

**Delegations of Authority**

All delegations and re-delegations of authority made to officials and employees of affected organizational