

to augment the agency's current surveillance capabilities. The proposed system will enable queries of distributed data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Operations will adhere to strict privacy and security safeguards.

The success of this Initiative will depend largely on the content, quality, searchability, and responsiveness of participating data sources and/or data environments. It is essential that FDA understand the strengths and limitations of potential data sources that might be included in the Sentinel Initiative. This

survey will be used to collect information from potentially participating data sources and/or environments. The data we are seeking will describe the characteristics of the data available, not personally identifiable information. The findings will help FDA plan for this proposed system and for future work related to the Sentinel Initiative.

This survey will collect information on the scope, content, structure, quality, and timeliness of data; patient population(s), duration of followup, and capture of care across all settings; availability, experience, and interest of investigators with knowledge of the data in using it for post-market product

safety surveillance as well as plans for further data source enhancements; availability, experience, and interest of investigators with knowledge of the data in participating in a distributed data system; and barriers that exist to including each data source in the Sentinel Initiative.

In the **Federal Register** of March 9, 2009 (74 FR 10053), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received but was outside the scope of the PRA.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Data Source and/or Environment Survey	250	1	250	24.5	6,125

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that approximately 250 respondents will participate in this voluntary survey. These respondents will consist mostly of other Federal agencies, health plan data sources, health information exchanges, large multi-specialty medical groups and academic medical centers, large hospital systems, pharmacies, medical societies, consumer-oriented Web sites, commercial data sets, research networks, lab data, and registries.

Each respondent will extend approximately 24.5 hours to complete one survey for a total of 6,125 hours (250 x 1 x 24.5 = 6,125).

Dated: August 27, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-09-09BW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these

requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Postural Analysis in Low-Seam Mines—Existing collection without an OMB control number—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91-596, sections 20 and 22 (section 20-22, Occupational Safety and Health Act of 1970) has the responsibility to conduct research relating to innovative methods, techniques, and approaches dealing with occupational safety and health problems.

According to the Mining Safety and Health Administration (MSHA) injury database, 227 knee injuries were reported in underground coal mining in 2007. With data from the National Institute for Occupational Safety and Health (NIOSH), it can be estimated that the financial burden of knee injuries was nearly three million dollars in 2007.

Typically, mine workers utilize kneepads to better distribute the pressures at the knee. The effectiveness of these kneepads is to be investigated in a study by NIOSH. Thus, NIOSH will

be determining the forces, stresses, and moments at the knee while in postures associated with low-seam mining. At this time, the postures utilized by low-seam mine workers and their frequency of use are unknown. Therefore, before conducting this larger, experimental study, the existing collection without an OMB control number was required.

The aim of the field study described in this document was to determine the postures predominantly used by low-seam mine workers such that they may complete the various tasks associated with their job duties. A questionnaire was developed for each of the major job types seen in low-seam mines with continuous miners (continuous miner operator, roof bolter operator, shuttle car operator, mobile bridge operator, mechanic, beltman, maintenance shift worker, foreman). The questionnaire asked basic demographic information (e.g., time in job type, years in mining, age). Additionally, a series of questions were asked such that it could be determined if a mine worker is likely to have a knee injury, even if it is undiagnosed. These questions were developed with the help of a physical therapist. A schematic of possible postures was then presented to the mine workers and they were asked to identify the primary two postures they utilize to complete their job duties. The questionnaire then asked mine workers to identify the primary postures they utilize to complete specific tasks (e.g., hanging curtain, building stoppings) that are part of their job duties. Finally,

mine workers were asked to identify those postures that are least and most

comfortable/stressful. There is no cost to respondents other than their time. The

total estimated annual burden hours are 12.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Continuous miner operator	Continuous Miner Operator Form	5	1	10/60
Foreman	Foreman Form	5	1	10/60
Maintenance Shift Worker	Maintenance Shift Worker Form	10	1	10/60
Mobile Bridge Operator	Mobile Bridge Operator Form	10	1	10/60
Roof Bolter Operator	Roof Bolter Operator Form	14	1	10/60
Scoop Operator	Scoop Operator Form	6	1	10/60
Shuttle Car Operator	Shuttle Car Operator Form	6	1	10/60
Mechanic	Mechanic Form	6	1	10/60
Beltman	Beltman Form	2	1	10/60

Dated: August 27, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10079 and CMS-10293]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital Wage

Index Occupational Mix Survey and Supporting Regulations in 42 CFR, Section 412.64; *Use:* Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. Refer to the summary of changes document for a list of current changes. *Form Number:* CMS-10079 (OMB#: 0938-0907); *Frequency:* Reporting—Yearly, Biennially and Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 3,522; *Total Annual Responses:* 3,522; *Total Annual Hours:* 1,690,560. (For policy questions regarding this collection contact Taimyra Jones at 410-786-1562. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Tribal Consultation State Plan Amendment Template; *Use:* Effective July 1, 2009, section 5006 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) amended section 1902(a)(73) of the Act to require that certain States utilize a process for the State to seek advice on a regular, ongoing basis from designees of the Indian Health Service (IHS) and Urban Indian Organizations concerning Medicaid and Children's Health Insurance Program (CHIP) matters having a direct effect on them. The consultation process is required for the 37 States in which 1 or more Indian

Health Programs or Urban Indian Organizations furnish health care services. The State Medicaid agency for each of these States will complete the template page and submit it for approval as part of a State plan amendment, to document how it meets the requirements for tribal consultation. *Form Number:* CMS-10293 (OMB#: 0938-NEW); *Frequency:* Reporting—Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 37; *Total Annual Responses:* 37; *Total Annual Hours:* 37. (For policy questions regarding this collection contact Mary Corddry at 410-786-6618. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by November 3, 2009:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development,