

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*: Extension of a currently approved collection; *Title of Information Collection*: Eligibility Error Rate Measurement in Medicaid and the Children's Health Insurance Program; *Use*: The collection of information is necessary for CMS to produce national error rates for Medicaid and CHIP as required by Public Law 107-300, the IPIA of 2002. The collection of information is also necessary to implement provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3) with regard to the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs. The information collected from the States selected for review will be used by CMS to ensure States use a statistically sound sampling methodology, to ensure the States complete reviews on all cases sampled, and will be used by the federal contractor to calculate State and national Medicaid and CHIP eligibility error rates. *Form Number*: CMS-10184 (OMB#: 0938-1012); *Frequency*: Reporting—Occasionally; *Affected Public*: State, Local, Tribal Governments; *Number of Respondents*: 34; *Total Annual Responses*: 53; *Total Annual Hours*: 942,764. (For policy questions regarding this collection contact Jessica Woodard at 410-786-9249. 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 address 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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *March 29, 2010*:

OMB, Office of Information and Regulatory Affairs,  
Attention: CMS Desk Officer,  
Fax Number: (202) 395-6974,  
E-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: February 22, 2010.

**Michelle Shortt**,

Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory Affairs.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60 Day-10-10BR]

#### 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 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail 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 through 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

Evaluation and Development of Hearing Loss Interventions—New—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.

This research relates to reducing the incidence of noise induced hearing loss in the coal mining industry through improved development and dissemination of hearing loss prevention products. The overall objective of this project is to improve the effectiveness of hearing loss prevention research products through development, refinement, promotion, and long term evaluation. Research products developed in previous projects and new products developed in current projects will be evaluated and promoted for industry-wide adoption and impact.

Noise-induced hearing loss (NIHL) is the most common occupational illness in the United States today, with 30 million workers exposed to excessive noise levels. Mining has the highest prevalence of hazardous noise exposure of any major industry sector (Tak, Davis, & Calvert, 2009) and is second only to the railroad industry in prevalence of workers reporting hearing difficulty (Tak & Calvert, 2008). The Hearing Loss Prevention Branch at NIOSH Office of Mine Safety and Health Research (OMSHR) has developed multiple hearing loss prevention research products with the intent of controlling noise exposure and reducing the occurrence of NIHL in mining. However, many of the products are not widely used in industry. The current project has several goals related to determining the effectiveness of our products and developing additional products; however it is also necessary to determine why the products are not receiving greater field utilization so that we can amend the procedure for dissemination and to assure that future products are transferred to industry in a more efficient manner.

The outcomes of this project will include a culmination of various physical measures such as noise dosimetry, noise measures, and audiometry. These are common industry hygiene methods that typically do not require special approval. However, it will also be necessary to conduct semi-structured interviews and questionnaire-based assessments with various mine personnel who are using NIOSH-developed noise controls to gain an understanding of the barriers to acceptance. Employees will be asked about their motivation to implement noise controls, their attitude towards the specific control being assessed, their attitude toward safety, and the methods they use to find and implement health and safety information. These interviews will take place with health

and safety managers, mine foremen, maintenance supervisors, production coordinators and operators of equipment with installed noise controls. The proposed time schedule for conducting these assessments is before installation of a control and on a predetermined schedule for the duration

of the life of the control. For example, one noise control may have an expected performance life of 6 months. In that case the interviews will occur before installation, 2 weeks, 6 weeks, 14 weeks, and 24 weeks post installation. Although we plan to follow this general time table, due to the nature of

the mining industry, slight deviation may occur. No noise control will require greater than 5 interviews per respondent. The goal is to achieve 6 mines and 6 individuals per mine per noise control.

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 (in hours)
Managers Foreman Supervisors Coordinators Operators.	Assessment of the Urethane-Coated Chain for Continuous Mining Machines.	36	5	20/60	60
Managers Foreman Supervisors Coordinators Operators.	Assessment of the Roof Bolting Machine Noise Control Products.	36	5	20/60	60
Managers Foreman Supervisors Coordinators Operators.	Assessment for the Enclosure for Vibrating Screen.	36	5	20/60	60
Total .....	.....	108	.....	.....	180

Dated: February 22, 2010.  
**Maryam I. Daneshvar,**  
*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0373]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 29, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to

*aira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-NEW and title Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, *Elizabeth.Berbakos@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Mental Models Study of Recruitment and Retention of Pregnant Women Into An Asthma Pregnancy Registry—(OMB Control Number 0910)—NEW**

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The proposed information collection will help FDA advance public health by identifying priorities, perceptions, and communication needs about how pregnant women and their health care providers make decisions about participation in a pregnancy registry. Understanding these priorities, perceptions, and communication needs will foster more effective approaches to recruitment of pregnant women into

pregnancy registries and full retention of those women until the end of the registry study period. Ultimately, early enrollment and complete followup of women in pregnancy registries will strengthen the quality of safety data about use of needed medications during pregnancy.

Before a medication is approved by FDA for sale in the United States, pregnant women are rarely included in experimental research studies of the medication because of concerns that the experimental treatment may harm the developing fetus and/or the pregnant woman. As a result, when a medication is approved for marketing in the United States, little systematically collected human data are available to define the chance of serious side effects in pregnant women and/or their developing fetuses from use of the medication during pregnancy.

A pregnancy registry is a research study conducted after a medication has been approved, during which pregnant women being treated with the medication are observed to identify possible harms to the woman and/or to her developing fetus. Pregnant women voluntarily enroll in a pregnancy registry; data about the pregnancy, labor, delivery, and newborn are collected and analyzed to identify any serious adverse outcomes and consider whether use of the medication may be linked to any observed harm. The quality of pregnancy registry data is enhanced by enrollment of women early in their pregnancy and by complete followup of all enrolled pregnancies to the end of the registry study period. Ultimately, high quality human