DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2014–0007]

Final Revised Vaccine Information Materials for Td, Tdap, Hib, and Rotavirus Vaccines

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

ACTION: Notice.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa–26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On June 25, 2014, CDC published a notice in the **Federal Register** (79 FR 36068) seeking public comments on proposed new vaccine information materials for Td, Tdap, *Haemophilus influenzae* type b (Hib), and rotavirus vaccines. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. Copies of the final vaccine information materials for Td, Tdap, Hib, and rotavirus are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2014–0007).

DATES: Beginning no later than November 1, 2015, each health care provider who administers any Td, Tdap, Hib, or rotavirus vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials contained in this notice, in conformance with the April 15, 2015 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon (*msj1@cdc.gov*), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A–19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660), as amended by section 708 of Public Law 103–183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa–26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

(1) A concise description of the benefits of the vaccine,

(2) A concise description of the risks associated with the vaccine,

(3) A statement of the availability of the National Vaccine Injury Compensation Program, and

(4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: *http://www.cdc.gov/vaccines/hcp/vis/index.html.*

New Vaccine Information Materials

The Td, Tdap, Hib, and rotavirus vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering Td, Tdap, Hib, and rotavirus vaccine have been finalized and are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2014–0007). The Vaccine Information Statements (VIS), are: ''Td Vaccine: What You Need to Know'' (publication date February 24, 2015), ''Tdap Vaccine: What You Need to Know'' (publication date February 24, 2015), ''*Haemophilus influenzae* type b Vaccine: What You need to Know'' (publication date April 2, 2015), and ''Rotavirus Vaccine: What You Need to Know'' (publication date April 15, 2015).

With publication of this notice, as of November 1, 2015, all health care providers will be required to provide copies of these updated Td, Tdap, Hib, and rotavirus vaccine information materials prior to immunization in conformance with CDC's April 15, 2015 Instructions for the Use of Vaccine Information Statements.

Dated: June 1, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2015–13694 Filed 6–4–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0042; 60Day–15–0981]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on Assessing and Evaluating Human Systems Integration needs in mining. CDC objective is to conduct

research to improve working conditions to prevent accidents and occupational disease in underground coal and metal/nonmetal mines in the U.S.

DATES: Written comments must be received on or before August 4, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0042 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Assessing and Evaluating Human Systems Integration Needs in Mining (OMB No. 0920–0981, expires 08/31/2015)—Extension—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91–173 as amended by Public Law 95–164 (Federal Mine Safety and Health Act of 1977), and Public Law 109–236 (Mine Improvement and New Emergency Response Act of 2006) has the responsibility to conduct research to improve working conditions and to prevent accidents and occupational diseases in underground coal and metal/nonmetal mines in the United States of America. NIOSH proposes to request additional time through an extension of the approved OMB control number in order to collect assessment and evaluation data.

The project is aimed at determining the following information with regards to the necessary inclusion of Human Systems Integration into research related to underground coal mining: (1) What information is critical for a miner to safely perform his job, (2) what processes (*e.g.,* expertise, decision making, attention, etc.) are necessary for a miner to effectively perform his job, and (3) how do the miner and the machine interact. In order to accomplish these goals, the following data collection instruments are being used:

The General Preference Questionnaire was designed to determine how and when miners working in an underground coal mine prefer to have information about their work environment, the location of themselves, others, and equipment communicated to them while they are working. This questionnaire will be administered to 75 miners working in an underground coal mine.

The Subject Matter Expert (SME) Questionnaire was designed to determine how subject matter experts (*e.g.,* experienced continuous miner operators) prefer to have information about their work environment, the location of themselves, others and equipment communicated to them while they are working. The questionnaire will be administered to 50 miners working in an underground coal mine in one of two positions: Continuous miner operator or fire boss.

The Safety Director Questionnaire was designed to determine what machinery and equipment is currently being used within the underground coal mining environment. This questionnaire will be administered to up to 50 Safety Directors working at an underground mining operation.

Vest Usability Testing was designed to examine the effectiveness and viability of physically integrating equipment. This will be done by asking a group of miners to wear mining vests during their normal work hours and complete a questionnaire before and after the vest wearing period. Approximately 60 underground coal miners will be asked to take part in Vest Usability Testing.

The Roof Bolter Questionnaire will be used to assess the functional lighting needs and problems around roof bolting machines and the usability of a lighting feedback system for specific controls. Approximately 30 Roof Bolter Operators will be asked to complete the Roof Bolter Questionnaire (half before the intervention and half after).

There are no costs to the miners as study participation will take place during their normal working hours. Thus, any cost associated with the experiment will be incurred by the mining company. The total estimated annual burden hours are 442.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Mine Employee	Informed Consent	285	1	5/60	24
Mine Employee	Talent Waiver	285	1	2/60	10
Mine Employee	Demographic Questionnaire	285	1	2/60	10
Mine Employee	Task and Cognitive Task Analyses: Continuous Miner Operator.	10	1	2	20
Mine Employee	Task and Cognitive Task Analyses: Fire Boss.	10	1	2	20
Mine Employee	Direct Observation: Continuous Miner Operator.	10	1	4	40
Mine Employee	Direct Observation: Fire Boss	10	1	4	40
Mine Employee	General Preference Questionnaire	75	1	30/60	38
Mine Employee	Subject Matter Expert Questionnaire	50	1	1	50
Mine Employee	Safety Director Questionnaire	50	1	30/60	25
Mine Employee	Roof Bolter Questionnaire	30	2	15/60	15
Mine Employee	Vest Usability Testing	60	2	45/60	90
Mine Employee	Focus Groups	30	1	1	30
Mine Employee	Lab Experiments	30	1	1	30
Total					442

Leroy A. 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–15–15AME; Docket No. CDC–2015–0043]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a Monitoring and Reporting System for the National Tobacco Control Program. CDC will use the information collected to monitor cooperative agreement awardees and to identify facilitators and challenges to program implementation and achievement of outcomes.

DATES: Written comments must be received on or before August 4, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0043 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology