

# Attachment B: 60-Day Federal Register Notice

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nina Goodman, Senior Public Health Advisor, Office of Communications and Education (OCE), NCI, NIH, 6116 Executive Blvd., Suite 400, Rockville, MD 20892, call non-toll-free number 301-435-7789 or e-mail your request, including your address to: [goodmann@mail.nih.gov](mailto:goodmann@mail.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: October 21, 2009.

**Vivian Horovitch-Kelley,**  
*NCI Project Clearance Liaison, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-10191]

#### Agency Information Collection Activities: Submission for OMB Review; 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), Department of Health and Human Services, 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 function; (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:* Medicare Parts C and D Universal Audit Guide; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR Parts 422 and 423 Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. 42 CFR 422.502 describes CMS' regulatory authority to evaluate, through inspection or other means, Medicare Advantage Part C organizations. These records include books, contracts, medical records, patient care documentation and other records that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable. 42 CFR 423.503 states that CMS must oversee a Part D plan sponsor's continued compliance with the requirements for a Part D plan sponsor. Section 423.514 states that the Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics regarding areas such as cost of operations, patterns of utilization availability, accessibility, and acceptability of services.

The rapid growth of these sponsoring organizations has forced CMS to update its current auditing strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy will reflect a move to more targeted, data-driven and risk-based audits. CMS will also focus on high-risk areas that have the greatest potential for beneficiary harm. The goal of the audits will be the earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and Medicare Advantage organizations.

To accomplish these goals, we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. Please refer to the crosswalk document for a list of changes. *Form Number:* CMS-10191 (OMB#: 0938-1000); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 195; *Total Annual Responses:* 195; *Total Annual Hours:* 24,180. (For policy questions regarding this collection contact Laura Dash at 410-786-8623. 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 November 27, 2009.

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: October 21, 2009.

**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

[60Day-10-09AX]

#### 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.

*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**

National Survey of Long-Haul Truck Driver Injury and Health—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health at work for all people through research and prevention. The Occupational Safety and Health Act of 1970, Public Law 91-596 (Section 20[a][1]) authorizes NIOSH to conduct research to advance the health and safety of workers. In this capacity, NIOSH will conduct a national survey of long-haul truck drivers.

Truck drivers are at increased risk for numerous preventable diseases and health conditions; previous research suggests that truck drivers are at increased risk for lower back pain, heart disease, hypertension, stomach ulcers, and cancers of the bladder, lung, prostate, and stomach. Truck drivers also face extraordinary risk of on-the-job mortality. In 2007, the fatality rate for “driver/sales workers and truck drivers” was 28.2 per 100,000 workers, compared with a rate of 3.8 per 100,000

for all workers. Drivers of heavy and tractor-trailer trucks had more fatal work injuries than any other single occupation (822 deaths in 2007).

Truck drivers experience high rates of occupational injury and illness, but little is known about the prevalence of factors suspected to place them at increased risk. Information is needed on the role of occupation in driver health and on mechanisms of driver injuries. In evaluating the potential health effects of the 2005 hours-of-service ruling, the Federal Motor Carrier Safety Administration stated that due to a lack of evidence specific to trucking operations, information from different fields had to be adapted to a trucking environment. Research needs cited by stakeholders include detailed data on the prevalence of selected health conditions and risk factors among truck drivers, and data on working conditions, injury causes and outcomes, and health behaviors.

NIOSH has obtained input on plans for this survey through stakeholder meetings, a webinar, an Internet blog, and from comments received through NIOSH Docket 110 and during a focus group discussion with 7 truck drivers. The survey instrument has been reviewed by 6 subject matter experts and 9 cognitive interviews have been conducted using the survey instrument. Input received was used to guide development of the survey instrument and plans for survey implementation. Subjective data on understanding and phrasing of questions were collected during the focus group discussion and cognitive interviews.

The proposed national survey will be based upon a probability sample of truck stops. The survey will be conducted at locations along freight corridors in 5 geographic regions (Northeast, South, Great Lakes, Central, and West). The number of locations to be visited within each region will be related to the traffic load in that region. Eligible truck drivers stopping at selected truck stops will provide all survey data. The major objectives of the survey will be to: (1) Determine the prevalence of selected health conditions and risk factors; (2) characterize drivers' working conditions, occupational injuries, and health behaviors; (3) explore the associations among health

status, individual risk factors, occupational injuries and occupational exposures related to work organization. The survey will eliminate significant gaps in occupational safety and health data for long-haul truck drivers. The results will assist regulatory agencies in focusing rulemaking, furnish industry and labor with safety and health information needed by their constituents, and stimulate future research and advocacy to benefit truck drivers.

*The target population of drivers for this survey will be limited to drivers who:* Have truck driving as their main job; drive a heavy truck (class 8 vehicle over 26,000 lbs. gross vehicle weight); sleep away from home at least one night per delivery run; and who have been a heavy truck driver 12 months or longer.

The study instrument will be interviewer-administered to approximately 2,400 eligible truck drivers at 50 truck stops. Individuals will first be asked a series of questions to determine if they are eligible to participate in the survey, followed by administration of the main interview. Respondents will not be asked to report names or any other identifying information.

The project supports the NIOSH surveillance function to advance the usefulness of surveillance information for the prevention of occupational injuries, illnesses, and hazards, and actively promoting the dissemination and use of NIOSH surveillance data and information. This survey will allow NIOSH to explore the inter-relationships among dimensions of health status, individual risk factors, occupational injuries, sleep disorders, and occupational exposures. It will also provide detailed demographic data on long-haul truck drivers, which have not been available previously, and could provide baseline data to inform future cohort and prospective studies.

NIOSH will use the information to calculate prevalence and customize safety and health interventions for long-haul truck drivers. Once the study is completed, results will be made available via various means. NIOSH expects to complete data collection no later than Fall of 2010. There is no cost to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
Truck Drivers .....	Screening Interview .....	3000	1	3/60	150

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
	Main Interview .....	2400	1	40/60	1600
Total .....	.....	.....	.....	.....	1750

Dated: October 22, 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 Disease Control and Prevention

[60Day-10-0017]

#### 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

Application for Training (OMB No. 0920-0017 exp. 3/31/2010)—Revision—Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

OWCD requests an additional three years to continue CDC's and the Agency for Toxic Substances and Disease Registry's (ATSDR's) use of the training application forms described below.

CDC offers public health training activities to professionals worldwide. Employees of hospitals, universities, medical centers, laboratories, State and Federal agencies, and State and local health departments apply for training to learn up-to-date public health practices. CDC's training activities include laboratory training, classroom study, online training, and distance learning.

CDC uses training application forms to collect information necessary to manage and conduct training pertinent to the agency's mission. This information allows CDC to send confirmation of registration to participants, provide certificates of attendance or continuing education credits as proof of participants' attendance, and generate management reports to identify training needs, design courses, select location for courses, and evaluate programs.

*CDC is accredited by six different continuing education (CE) organizations to award CE credit:* (1) The International Association for Continuing Education and Training (IACET) to provide Continuing Education Units (CEUs), (2) the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education credits (CME), (3) the American Nurses Credentialing Center (ANCC) to provide Continuing Nurse Education credits (CNE), (4) the National Commission for Health Education Credentialing (NCHEC) to award CHES credit, (5) the Accreditation Council for Pharmacy Education (ACPE) to provide continuing

pharmacy credit, and (6) the American Association of Veterinary State Boards to award Registry of Approved Continuing Education (RACE) credit. The accrediting organizations require a method of tracking participants who complete an educational activity, and demographic data allows CDC to do so. Also, several of the organizations require a permanent record that includes the participant's name, address, and phone number, to facilitate retrieval of historical information about when a participant completed a course or several courses during a time period. This information provides the basis for a transcript or for determining whether a person is enrolled in more than one course. CDC uses the e-mail address to verify the participant's electronic request for transcripts, verify course certificates, and send confirmation a participant is registered for a course.

CDC uses the information on the training application forms request to (1) grant public health professionals the CE credits they need to maintain professional licenses and certifications, (2) create a transcript or summary of training at the participant's request, (3) generate management reports, and (4) maintain training statistics. Management reports help CDC identify training needs, design courses, select locations for courses, evaluate programs, and conduct impact analysis.

Tracking course attendance and meeting accrediting organizations' standards for reporting, require uniform standardized training application forms. The standardized data these forms request for laboratory training, classroom study, online training, and distance learning are not requested elsewhere. In other words, these forms do not duplicate requests for information from participants. Data are collected only once per course or once per new registration.

The annual burden table has been updated to reflect an increase in distance learning. There is no cost to respondents other than their time.