DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–12–12NT]

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 Kimberly S. Lane, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email 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

Early Hearing Detection and Intervention—Pediatric Audiology Links to Service (EHDI–PALS) Survey—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. Since the passage of the Early Hearing Detection and Intervention (EHDI) Act, 97% of newborn infants are now screened for hearing loss prior to hospital discharge. However, many of these infants have not received needed hearing test and follow up services after their hospital discharges. The 2009 national average loss to follow-up/loss to documentation rate is at 45%. This rate remains an area of critical concern for state EHDI programs and CDC–EHDI team's goal of timely diagnosis by 3 months of age and intervention by 6 months of age. Many states cite the lack of audiology resource as the main factor behind the high loss to follow up. To compound the problem, many pediatric audiologists may be proficient evaluating children age 5 and older but are not proficient with diagnosing infants or younger children because children age 5 and younger require a different skill set. To date, no existing literature or database is available to help states verify and quantify their states' true follow-up capacity.

EHDI–PALS is a project conceptualized by the CDC–EHDI team with input from an advisory group of external partners. EHDI–PALs workgroup has broad representation from American Speech-Language-Hearing Association (ASHA), American Academy of Audiology (AAA), Joint Committee on Infant Hearing (JCIH), National Centre for Hearing Assessment and Management (NCHAM), Directors of Speech and Hearing Programs in State Health & Welfare Agencies (DSHPSHWA), Healthcare Resources and Services Administration (HRSA), University of Maine Center for Research and Evaluation, and Hands & Voices (H&V). Meeting since April 2010, the EHDI–PALS workgroup has sought consensus on the loss to follow up/loss to documentation issue facing the EHDI programs. A survey, based on standard of care practice, was developed for state EHDI programs to quantify the pediatric audiology resource distribution within their state, particularly audiology facilities that are equipped to provide follow-up services for children age 5 and younger. The survey will also capture how often providers report diagnostic hearing test results to their state EHDI jurisdiction.

CDC is requesting OMB approval to collect audiology facility information from audiologists or facility managers over a one-year period. The survey will allow CDC–EHDI team and state EHDI programs to compile a systematic, quantifiable distribution of audiology facilities and the capacity of each facility to provide services for children age 5 and younger. The data collected will also allow the CDC–EHDI team to analyze facility distribution data to improve technical assistance to State EHDI programs.

Respondents will all be audiologists who manage a facility or provide audiologic care for children age 5 and younger. Based on calculations from ASHA's biannual membership survey (available in ASHA.org), we estimate approximately 1,000 audiologists will respond to the survey. To minimize burden and improve convenience, the survey will be available via a secure password protected Web site. Placing the survey on the Internet ensures convenient, on-demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to this survey.

It is estimated that, potentially, 1,500 audiologists will read through the opening introduction page of the survey to decide whether or not to complete the survey. This will take 1 minute per person. It is estimated 1,000 audiologists will complete the survey, which will average 9 minutes per respondent. There are no costs to respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
Audiologists	survey introduction	1,500	1	1/60	25
Audiologists	survey	1,000	1	9/60	150
Totals					175

Kimberly S. Lane,

Deputy Director, 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

[30-Day–12–12EF]

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 (404) 639–7570 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluating the Effectiveness of Occupational Safety and Health Program Elements in the Wholesale Retail Trade Sector—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For the current study, the National Institute for Occupational Safety and Health (NIOSH) and the Ohio Bureau of Workers Compensation (OBWC) will collaborate to examine the association between survey-assessed Occupational Safety and Health (OSH) program elements (organizational policies, procedures, practices) and workers compensation (WC) injury/illness outcomes. The study will be conducted using a stratified sample of OBWC-insured wholesale/retail trade (WRT) firms. Crucial OSH program elements with particularly high impact on WC losses will be identified in this study and disseminated to the WRT sector.

There are expected to be up to 4,404 participants per year. Surveys will be administered twice to the same firms in successive years (e.g. from January–December 2013 and again from January–December 2014). An individual responsible for the OSH program at each firm will be asked to complete a survey that includes a background section related to respondent and company demographics and a main section where individuals will be asked to evaluate organizational metrics related to their firm's OSH program. The firm-level survey data will be linked to five years of retrospective injury and illness WC claims data and two years of prospective injury and illness WC claims data from OBWC to determine which organizational metrics are related to firm-level injury and illness WC claim rates. A nested study will ask multiple respondents at a subset of 60 firms to participate by completing surveys. A five-minute interview will be conducted with a 10% sample of non-responders (up to 792 individuals).

In order to maximize efficiency and reduce burden, a web-based survey is proposed for the majority (95%) of survey data collection. Collected information will be used to determine whether a significant relationship exists between self-reported firm OSH elements and firm WC outcomes while controlling for covariates. Once the study is completed, benchmarking reports about OSH elements that have the highest impact on WC losses in the WRT sector will be made available through the NIOSH–OBWC internet sites and peer-reviewed publications.

In summary, this study will determine the effectiveness of OSH program elements in the WRT sector and enable evidence-based prevention practices to be shared with the greatest audience possible. NIOSH expects to complete data collection in 2014. There is no cost to respondents other than their time. The total estimated annual burden hours are 1,681.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Safety and Health Managers	Occupational Safety and Health Program Survey Year 1 and Year 2.	4,404	1	20/60
	Informed Consent Form	4,404	1	2/60
	Non-Responder Interview	792	1	5/60

Kimberly S. Lane,

Deputy Director, Office of Science 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

Food and Drug Administration

[Docket No. FDA–2011–N–0568]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Disease Information in Branded Promotional Material

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 July 20, 2012.

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 emailed to