Prevention and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15–15ADW; Docket No. CDC–2015–0025]

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 the proposed information collection request entitled ''Employer Perspectives of an Insurer-Sponsored Wellness Grant''. This collection is a part of an employer study to understand the impact of integrating wellness programs with traditional occupational safety and health (OSH) programs.

DATES: Written comments must be received on or before July 6, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0025 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

Employer Perspectives of an Insurer-Sponsored Wellness Grant—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. Under Public Law 91–596, sections 20 and 22 (Section 20–22, Occupational Safety and Health Act of 1970), NIOSH has the responsibility to conduct research to advance the health and safety of workers. In this capacity, NIOSH proposes to conduct a study among employers in Ohio insured by the Ohio Bureau of Workers' Compensation (OHBWC) to (1) assess the effectiveness and cost-benefit of an intervention that funds workplace wellness programs and (2) understand the impact of integrating wellness programs with traditional occupational safety and health (OSH) programs.

Work-related injuries and illnesses are common among US workers and result in pain, disability, and substantial cost to workers and employers. A recent, comprehensive analysis of the economic burden of work-related injuries and illnesses estimated that in 2007 alone medical and indirect costs for work-related injuries and illnesses were $250 billion. According to the Bureau of Labor Statistics there were 4,609 occupational fatalities in 2011 and approximately 2 million work-related injuries and illnesses that involved some lost work in 2010.

Workers' health is affected not only by workplace safety and health hazards, but also workers' own health behaviors. Reflecting this, two different, yet, complementary approaches exist in the workplace: OSH programs and wellness programs. Both types of programs aim to improve worker health and reduce costs to employers, workers' compensation (WC) insurers, and society. Since 2004, NIOSH has advocated an approach that coordinates wellness programs with OSH programs because emerging evidence suggests that integrating these two fields may have a synergistic effect on worker safety and health.

NIOSH has established an intramural program for protecting and promoting Total Worker Health™. The NIOSH Total Worker Health™ Cross-Sector

Program promotes the integration of health and safety protection with health and wellness promotion through research, interventions, partnerships, and capacity building to meet the needs of the 21st century workforce. The proposed project addresses three priority goals of the NIOSH Total Worker Health™ Program: (1) Investigate the costs/benefits associated with comprehensive, coordinated work-based health protection/health promotion interventions; (2) improve the understanding of how the work environment influences the effectiveness of health programs and identify opportunities for workplace interventions to prevent, control, recognize and manage common chronic conditions; and (3) conduct scientific research that more holistically investigates organizational and worker health and safety outcomes associated with emerging issues and addresses gaps in knowledge in the health protection/health promotion field.

There is a need for research to demonstrate a 'business case' for both wellness programs and integrated OSH-wellness programs and identify OSH organizational and management policies, programs and practices that effectively reduce work-related injuries, illnesses, disabilities and WC costs. To date small employers have been largely ignored in these areas and many studies have focused on the manufacturing industry. Real-world examples of effective interventions that apply to employers of all sizes and industries will ultimately improve workers' health and safety.

For the current study, NIOSH and OHBWC are collaborating on a project to determine the effectiveness and economic return of the Workplace Wellness Grant Program (WWGP) and to understand the impact of integrating of wellness with traditional OSH programs. In early 2012 OHBWC took steps to integrate wellness and OSH programs by launching the WWGP, in which an estimated 400 (currently 321) employers and 13,000 employees will be provided a total of $4 million in funds over four years to implement wellness programs.

The majority of the study aims will be accomplished through secondary analysis of pre- and post-intervention data being collected by OHBWC and shared with NIOSH. For the overall study, data for participating employers will include aggregate health risk appraisal data; aggregate biometric data; turnover data; health care utilization costs; information about occupational safety and health, wellness, and integrated occupational safety and health-wellness program elements; OHBWC WWGP expense records; yearly WC claims and cost data; data that details employer participation in other OHBWC programs; industry codes, and employer size. A sample of no more than 50 employers will be selected among grantees for 1–2 brief phone calls to confirm responses on an annual survey administered by OHBWC.

In addition, NIOSH will supplement the cost data extracted from existing sources with information collected through in-depth, semi-structured interviews with no more than 25, randomly selected, participating employers. Data gathered from these employer interviews are critical to compute ratios of total savings to total costs for the grant-supported wellness programs from the perspective of the participating employers.

NIOSH will ask a series of questions that will be used to estimate direct and indirect costs that were not directly funded by the WWGP during and after the grant funding period. This will be accomplished by collecting as detailed information as possible about the employer's wellness program and occupational and safety program costs. Topics will include questions about: The timeline and confirmation of grant funding (4 questions), non-grant funds used for wellness program costs after receiving the first grant (5 questions), non-grant funds used for wellness program costs before receiving the first grant (7 questions), time spent on wellness program after receiving the grant (3 questions), time spent on wellness program before receiving the grant (7 questions), other questions about the people planning and running the wellness program (2 or 4 questions), work time spent by employees for wellness activities (6 to 11 questions), changes to OSH plan and hazards after receiving the grant (8 to 13 questions), and other questions about their wellness program (3 to 5 questions).

The results of these interview-supplemented case studies will be used to estimate the proportion by which total employer costs exceed the cost of the primary wellness program vendor, as well as the proportion of these costs attributable to establishing the program in the first year versus operating the program in subsequent years. These estimates will be applied to generate total employer costs for all of the WWGP recipients, with sensitivity analysis based on the observed variability of employer costs in the case studies.

If the WWGP is effective at improving worker health, reducing WC claims and demonstrating a positive economic return, then other employers and insurance carriers may develop similar programs and drive the optimization of integrated OSH-wellness approaches. NIOSH expects to complete data collection in 2017.

There are no costs to respondents other than their time.

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 hours
Wellness Program Coordinators	Employer interviews on cost of wellness and occupational safety and health program.	25	1	2	50
Occupational Safety and Health Specialists.	Employer interviews on cost of wellness and occupational safety and health program.	25	1	2	50
The person in charge of the employer's wellness program.	Annual case study verification interview.	100	1	30/60	50
Total					150

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.

[FR Doc. 2015–10286 Filed 5–1–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care Development Fund, CCDF; Reporting Improper Payments; Instructions for States.

OMB No.: 0970–0323.

Description: Section 2 of the Improper Payments Act of 2002 provides for estimates and reports of improper payments by Federal agencies. Subpart K of 45 CFR, part 98 will require States to prepare and submit a report of errors occurring in the administration of CCDF grant funds once every three years.

The Office of Child Care (OCC) is completing the third 3-year cycle of case record reviews to meet the requirements for reporting under IPIA. The current forms and instructions expire September 30, 2015. OCC is submitting the information collection for renewal clearance with minor changes. Responders will now have additional guidance and clarification in the instructions and errors have been corrected. New language incorporates requirements from the 2014 Child Care and Development Fund Block Grant Act passed in November 2014.

Respondents: State grantees, the District of Columbia, and Puerto Rico

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sampling Decisions and Fieldwork Preparation Plan	17	1	106	1,802
Record Review Worksheet	17	276	6.33	29,700.36
State Improper Authorizations for Payment Report	17	1	639	10,863
Corrective Action Plan	8	1	156	1,248

Estimated Total Annual Burden Hours: 43,613.36.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV. Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–10296 Filed 5–1–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0785]

Determination of Regulatory Review Period for Purposes of Patent Extension; RELAY THORACIC STENT–GRAFT WITH PLUS DELIVERY SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the RELAY THORACIC STENT–GRAFT WITH PLUS DELIVERY SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is