

groups with approximately 75 providers.

Information collected through follow-up surveys of patients and providers will be used to assess changes in knowledge, attitudes, beliefs and behavior regarding cervical cancer screening. Qualitative information collected during the focus groups with providers will be used to identify

facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. Findings from the CX3 study will help inform NBCCEDP standards for primary cervical cancer screening, including reimbursement guidelines for the HPV DNA test.

Participation in the CX3 study is voluntary and there are no costs to

respondents other than their time. OMB approval is requested for one year. Because the majority of information collection activities were completed in the first three years of the study, the estimated burden to respondents will decrease in the final year of OMB approval. The total estimated annualized burden hours are 135.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Patients .....	Follow-up Patient Survey .....	150	1	10/60
Providers .....	Follow-up Provider Survey .....	70	1	30/60
	Focus Group Moderator Guide .....	75	1	1

**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

##### Centers for Disease Control and Prevention

[30Day-12-0566]

##### 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 the CDC at (404) 639-7570 or send an email to [omb@cdc.gov](mailto: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

Evaluation of Worker Notification Program (0920-0566, Expiration 2/28/2011)—Reinstatement—National Institute for Occupational Safety and

Health (NIOSH), Centers for Disease Control and Prevention (CDC).

##### Background and Brief Description

The National Institute for Occupational Safety and Health (NIOSH), under Section 20(a)(1), (a)(4), (a)(7)(c), and Section 22(d), (e)(5)(7) of the Occupational Safety and Health Act (29 U.S.C. 669), “has the responsibility to conduct research relating to occupational safety and health relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.” Although the research studies continued, the notification activities were discontinued after the extension ICR was not submitted to OMB before the original expiration date.

Since the Right to Know movement in the late 1970s, NIOSH has been developing methods and materials to notify subjects of its epidemiological studies. Within NIOSH, notifying workers of past exposures is done to inform surviving cohort members of findings from NIOSH studies. Current NIOSH policy dictates how and when worker notification should occur. The extent of the notification effort depends upon the level of excess mortality or the extent of the disease or illness found in the study population. Current notification efforts range from posting results at the facilities studied to mailing individual letters to surviving members of the study population and other stakeholders. Each year, the

NIOSH Industrywide Studies Branch (IWSB), Division of Surveillance, Hazard Evaluation, and Field Studies (DSHEFS) typically prepares materials for two to three completed studies. This often requires individual letters be mailed to study populations ranging in size from 200–20,000 workers each. An evaluation instrument would gauge the effectiveness of notification materials and improve future communication of risk information.

The purpose of the proposed Reader Response Postcard is to obtain feedback from workers that would improve the quality and usefulness of the Institute’s worker notification activities. The actual number of notifications required in a given year cannot be known in advance. Each year, the NIOSH IWSB, DSHEFS, typically prepares materials for two to three completed studies. This often requires individual letters be mailed to study populations ranging in size from 200–20,000 workers each, averaging 8,000/yr. Researchers from NIOSH propose to routinely include a Reader Response postcard with notification materials to assess the value and usefulness of said materials. The Reader Response postcard was tested internally and the average time to complete was 10 minutes. We are requesting approval for three years. Participation is voluntary and there is no cost to respondents except for their time. The total estimated annual burden hours are 1,333.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses	Avg. burden per response (hours)
Reader Response Card .....	8,000	1	10/60

**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

[Docket No. CDC-2012-0004]

#### **Draft Public Health Action Plan—A National Public Health Action Plan for the Detection, Prevention, and Management of Infertility**

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

**ACTION:** Notice of availability and request for public comment.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is publishing this notice requesting public comment on the draft *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility*. The draft plan can be found at <http://www.regulations.gov> Docket No. CDC-2012-0004. Also found in the docket is a supporting document for reference, the *Outline for a National Action Plan for the Prevention, Detection, and Management of Infertility*, which was subsequently developed into the present Plan.

**DATES:** Written comments must be received on or before June 15, 2012.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2012-0004, by any of the following methods:

- **Internet:** Access the Federal eRulemaking portal at <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health, Attn: National Public Health Action Plan for the Detection, Prevention, and Management of Infertility, Docket No. CDC-2012-0004, 4770 Buford Highway NE., Mailstop K-34, Atlanta, Georgia, 30341.

**Instructions:** All submissions received must include the agency name and docket number for this notice. All relevant comments received will be posted publicly without change, including any personal or proprietary

information provided. To download an electronic version of the plan, access <http://www.regulations.gov>. Written comments, identified by Docket No. CDC-2012-0004, will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Daylight Time, at 2900 Woodcock Blvd., Atlanta, Georgia 30341. Please call ahead to (770) 488-5200 and ask for a representative from the Division of Reproductive Health to schedule your visit. Comments may also be viewed at [www.regulations.gov](http://www.regulations.gov).

#### **FOR FURTHER INFORMATION CONTACT:**

Denise Jamieson, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health, 4770 Buford Highway NE., Mailstop K-34, Atlanta, Georgia 30341, (770)488-5200.

**SUPPLEMENTARY INFORMATION:** In 2007, a CDC-wide ad hoc workgroup formed to examine the full scope of infertility activities across the agency. This workgroup conducted an assessment to identify gaps and opportunities in public health surveillance, research, communications, programs, and policy development, which led to the 2010 publication of a white paper outlining the need for a national plan, with a public health focus, on infertility prevention, detection, and management. In consultation with many governmental and nongovernmental partners, CDC developed the National Public Health Action Plan for the Detection, Prevention and Management of Infertility. Addressing both male and female infertility, the plan outlines and summarizes actions needed to promote, preserve, and restore the ability of women in the United States to conceive, carry a pregnancy to term, and deliver a healthy infant. This goal extends beyond simply addressing the inability to conceive but also focuses on reducing the burden of impaired fecundity by promoting behaviors that maintain fertility; by promoting prevention, early detection, and treatment of medical conditions; and by reducing environmental and occupational threats to fertility. Given the public health focus of this action plan, promoting healthy pregnancy outcomes associated with treating and managing infertility is also important, as is improving the efficacy and safety of infertility treatment.

The document is organized into three chapters: "Detection of Infertility," "Prevention of Infertility," and "Management of Infertility." Each chapter addresses the topic's public

health importance, existing challenges, and opportunities for action to decrease the impact of infertility on the public's health. The suggested opportunities provide federal and other government agencies, professional and consumer organizations, and other partners and stakeholders a foundation and platform to work together to decrease the burden of infertility in the United States.

Dated: May 9, 2012.

**Kathleen Sebelius,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0009]

#### **Cooperative Agreement To Support Innovation in Vaccine Clinical Trial Design and Collaboration in Pharmacovigilance To Advance Global Access to Safe and Effective Vaccines**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for an award of a cooperative agreement to the World Health Organization (WHO) in support of collaborative efforts to advance innovative approaches to vaccine clinical trial design and to enhance the utilization of a range of pharmacovigilance tools as a means to further vaccine safety and potentially facilitate more rapid introduction of new vaccines. The goal of FDA's Center for Biologics Evaluation and Research (CBER) is to enhance technical collaboration and cooperation between FDA, WHO, and its Member States to facilitate strengthening regulatory capacity globally.

**DATES:** Important dates are as follows:

1. The application due date is June 15, 2012.
2. The anticipated start date is September 15, 2012.
3. The expiration date is June 16, 2012.

**ADDRESSES:** Submit the paper application to: Vieda Hubbard, Grants Management (HFA-500), 5630 Fishers Lane, Rockville, MD 20857, and a copy to Leslie Haynes, Center for Biologics Evaluation and Research, Office of the Director (HFM-30), 1401 Rockville Pike, Rockville, MD 20852-1448. For more