

Background

The Patient Safety Act, Public Law 109-41, 42 U.S.C. 299b-21—b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety Rule, 42 CFR Part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

Medical Informatics failed to respond to a Notice of Preliminary Finding of Deficiency sent by AHRQ pursuant to 42 CFR 3.108(a)(2) and a Notice of Proposed Revocation and Delisting sent by AHRQ pursuant to 42 CFR 3.108(a)(3)(iii)(C) which found that Medical Informatics failed to have, within every 24-month period following the PSO’s date of initial listing, at least two bona fide contracts with different providers for the purpose of receiving and reviewing patient safety work product, and to notify AHRQ no later than 45 calendar days prior to the last day of the pertinent 24-month period that the PSO has met this requirement. Medical Informatics did not exercise its opportunity to be heard in writing to respond to the deficiencies specified in the notices, and has not provided any evidence of a good faith effort to correct the deficiency. Accordingly, AHRQ has revoked the listing of Medical Informatics, PSO number P0086, a component entity of Medical Informatics, LLC, effective at 12:00 Midnight ET (2400) on June 1, 2012.

More information on PSOs can be obtained through AHRQ’s PSO Web site at <http://www.pso.AHRQ.clov/index.html>.

Dated: June 19, 2012.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0214]

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

National Health Interview Survey (NHIS), (OMB No. 0920-0214)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States.

The annual National Health Interview Survey is a major source of general statistics on the health of the U.S. population and has been in the field continuously since 1957. Clearance is sought for three years, to collect data for 2013, 2014, and 2015. This voluntary household-based survey collects demographic and health-related information on a nationally representative sample of persons and households throughout the country. Personal identification information is requested from survey respondents to facilitate linkage of survey data with health related administrative and other records. Each year we collect information from approximately 55,000 households, which would contain about 137,500 individuals.

Information is collected using computer assisted personal interviews (CAPI). A core set of data is collected each year while sponsored supplements vary from year to year. For 2013, supplement information will be collected on cancer screening, asthma, immune suppression, arthritis, epilepsy, and sexual identity. In addition, a Web-based multimode follow-back survey will be conducted from sample adult respondents from the 2012 NHIS. The follow-back survey will focus on adult health, health care access and use, and health insurance coverage and will include Web, telephone, and mail interviews.

In accordance with the 1995 initiative to increase the integration of surveys within the Department of Health and Human Services, respondents to the NHIS serve as the sampling frame for the Medical Expenditure Panel Survey conducted by the Agency for Healthcare Research and Quality. The NHIS has long been used by government, university, and private researchers to evaluate both general health and specific issues, such as cancer, diabetes, and access to health care. It is a leading source of data for the Congressionally-mandated “Health US” and related publications, as well as the single most important source of statistics to track progress toward the National Health Promotion and Disease Prevention Objectives, “Healthy People 2020.”

There is no cost to the respondents other than their time.

ANNUALIZED BURDEN TABLE

| Questionnaire (respondent) | Number of respondents | Number of responses per respondent | Average burden per respondent in hours | Total burden in hours |
|------------------------------|-----------------------|------------------------------------|--|-----------------------|
| Screener Questionnaire | 12,000 | 1 | 5/60 | 1,000 |

ANNUALIZED BURDEN TABLE—Continued

| Questionnaire (respondent) | Number of respondents | Number of responses per respondent | Average burden per respondent in hours | Total burden in hours |
|--|-----------------------|------------------------------------|--|-----------------------|
| Family Core (adult family member) | 55,000 | 1 | 23/60 | 21,083 |
| Adult Core (sample adult) | 44,000 | 1 | 15/60 | 11,000 |
| Child Core (adult family member) | 17,000 | 1 | 10/60 | 2,833 |
| Child/Teen Record Check (medical provider) | 10,000 | 1 | 5/60 | 833 |
| Supplements (adult family member) | 60,000 | 1 | 12/60 | 12,000 |
| Multi-mode study (adult family Member) | 5,000 | 1 | 30/60 | 2,500 |
| Reinterview Survey | 5,000 | 1 | 5/60 | 417 |
| Total Burden Hours | | | | 51,666 |

Dated: June 21, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), 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: Extension of public comment period.

SUMMARY: On May 16, 2012, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) published a notice in the **Federal Register** requesting public comment on the draft *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility* (77 FR 28883). Written and electronic comments were to be received on or before June 15, 2012. HHS/CDC has received a request asking for a 30 day extension of the comment period. In consideration of this request, HHS/CDC is extending the comment period to July 16, 2012.

DATES: Written comments must be received on or before July 16, 2012. Please refer to **SUPPLEMENTARY INFORMATION** for additional information.

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.

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, please 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.

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.

Since the draft plan was published on May 16, 2012, HHS/CDC has received a request to extend the comment period by an additional 30 days. HHS/CDC is committed to affording the public a meaningful opportunity to comment on the draft plan and welcomes comments.