

should be directed to the Attention: 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

US Zika Pregnancy Registry—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vectorborne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in U.S. territories, including in Puerto Rico, the U.S. Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus

transmission. Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will increase, and sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where Aedes species mosquitoes are present.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy. In addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention

(CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

The objective of this Registry is to monitor the frequency and types of pregnancy and infant outcomes following Zika virus infection during pregnancy, so as to inform ongoing response efforts for this Zika virus disease outbreak, including recommendations for clinical care, planning for services for pregnant women and infants affected by Zika virus, and improved prevention of Zika virus infections during pregnancy.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 2,167.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
State, Territorial and Local Health Departments.	Maternal Health History Form	100	10	30/60
	Supplemental Imaging Form	100	10	10/60
	Laboratory Results Form	100	10	15/60
Clinicians and Other Providers	Assessment at Delivery Form	100	10	30/60
	Infant Health Follow-Up Form	100	30	15/60

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Acting 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2016-0064; 60 Day-16-0969]

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 “Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics,” a survey to assess dissemination and use of guidance documents about the use of contraceptives and the delivery of quality family planning services.

DATES: Written comments must be received on or before September 16, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0064 by any of the following methods:

Federal eRulemaking Portal: Regulations.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

Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics (OMB No. 0920-0969, exp. 5/31/2014)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Reproductive Health (DRH) at the Centers for Disease Control and Prevention (CDC) develops and disseminates guidance to improve the use of contraceptives and the delivery of quality family planning services. The *U.S. Medical Eligibility Criteria for Contraceptive Use* (US MEC), the first national guidance on family planning containing evidence-based recommendations for the safe use of contraceptive methods for women and men with specific characteristics and medical conditions, was published by the CDC in June 2010. The *US Selected Practice Recommendations for Contraceptive Use* (US SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate, was published by the CDC in June 2013. *Providing Quality Family Planning Services* (QFP), which provides evidence-informed recommendations to improve client care and service delivery infrastructure to support the provision of quality family planning services to women and men of reproductive age in the United States, was published by CDC and the Office of Population Affairs (OPA) in April 2014. The US MEC, US SPR, and QFP have been widely disseminated to health care providers and other constituents via

professional organizations, federal program grantees, scientific and programmatic meetings, scientific manuscripts, online resources, and other avenues.

In 2009-2010, CDC collected baseline information related to diffusion and use of the US MEC (OMB No. 0920-0008). In 2013-2014, CDC collected follow-up information related to the US MEC and baseline information related to the US SPR and QFP (OMB No. 0920-0969). These information collections provided useful knowledge about differences in attitudes and practices of family planning providers based on varying levels of key demographic characteristics (e.g., years since completion of formal health care training), and identification of attitudes not consistent with current scientific evidence (e.g., misconceptions that intrauterine devices are not safe for adolescents or nulliparous women). CDC used findings to develop educational materials and opportunities for health care providers.

In 2017, in collaboration with the HHS Office of Population Affairs (OPA), CDC plans to request a reinstatement of OMB No. 0920-0969, "Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics." The information collection will allow CDC and OPA to assess changes in attitudes and practices among family planning providers and clinics after the release of these three national guidance documents, and to identify persisting misconceptions and/or gaps in clinic-level practices (e.g., low provision of preconception health services) that may warrant continued and more tailored dissemination and educational activities. Specifically, the survey will allow CDC and OPA to improve family planning-related public health practice by (1) understanding the current use of contraception guidance in practice and valued sources of contraceptive information, including awareness and use of the US MEC, US SPR and QFP; (2) describing current attitudes and practices among family planning providers and clinics related to recommendations included in the US MEC, US SPR, and QFP and assessing changes from baseline; and (3) identifying targeted training needs in use of guidance and family planning service delivery (e.g., provider tools, continuing education modules).

In 2017-2018, CDC plans to administer a follow-up survey to a sample of 10,000 private- and public-sector family planning providers and clinic administrators in the United States. The design, methodology, and analytic approach are based on methods

previously approved for the 2013–2014 survey. Minor changes to survey content will be made to eliminate unnecessary questions, add new questions of interest, and improve formatting, usability, and data quality. As in 2013–2014, different versions of the survey instrument will be administered to providers and clinic administrators. The estimated burden per response for providers is 15 minutes and has not changed since the previous OMB approval. The estimated burden per response for administrators will be reduced from 40 minutes to 25 minutes.

Private-sector physicians will be randomly selected from sampling frames with individual-level information on physicians. To reach public-sector providers and clinic administrators, publicly funded clinics will be randomly selected; one provider

and the clinic administrator will be asked to complete surveys at sampled clinics. Specifically, surveys will be completed by: (a) 2,000 private-sector office-based physicians (*i.e.*, those specializing in obstetrics/gynecology, family medicine, and adolescent medicine), sampled from the American Medical Association Physician Masterfile; (b) 2,000 providers from Title X clinics, sampled from a database of publicly funded family planning clinics; (c) 2,000 providers from non-Title X clinics, sampled from a database of publicly funded family planning clinics; (d) 2,000 clinic administrators from Title X clinics, sampled from a database of publicly funded family planning clinics; and (e) 2,000 clinic administrators from non-Title X clinics, sampled from a database of publicly funded family planning clinics.

Each sampled provider and clinic will receive a mailed survey package. For private-sector family planning providers, each mailed survey package will include a single survey to be completed by the provider. For public-sector clinics, each mailed survey package will include two surveys—one to be completed by a randomly selected family planning provider at the clinic, and the second to be completed by the clinic administrator. Each mailed survey will be accompanied by a postage-paid return envelope. Individuals will also be given the option to complete the survey online via a password protected web-based data collection system.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Office-based physicians (private sector).	2017 Survey of Health Care Providers.	2,000	1	15/60	500
Title X clinic providers (public sector)	2017 Survey of Health Care Providers.	2,000	1	15/60	500
Non-Title X publicly funded clinic providers (public sector).	2017 Survey of Health Care Providers.	2,000	1	15/60	500
Title X clinic administrators (public sector).	2017 Survey of Administrators of Publicly-Funded Health Centers that Provide Family Planning.	2,000	1	25/60	834
Non-Title X publicly funded clinic administrators (public sector).	2017 Survey of Administrators of Publicly-Funded Health Centers that Provide Family Planning.	2,000	1	25/60	834
Total	3,168

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2016–0063; 60Day–16–16AVC]

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 “Generic Clearance for CDC/ATSDR Formative Research and Tool Development”. This information collection request is designed to allow CDC to conduct formative research information collection activities used to inform aspects of surveillance, communications, health promotion, and research project development.

DATES: Written comments must be received on or before September 16, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0063 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, 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.