immune response to provide a basis for development of non-blood-based diagnostic tools, and target and refine public health interventions to arrest ongoing spread of infection. To do so, we will conduct a prospective cohort study of individuals with reverse transcription-polymerase chain reaction (RT–PCR) positive ZIKV infection and a cross-sectional study of their household contacts. Results and analyses will be used to update relevant counseling messages and recommendations from the CDC.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 374.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Personnel	Shedding Questionnaire (Symptomatics)	200	8	10/60
	Shedding Questionnaire (Cross-Sectional Asymptomatics)	400	1	10/60
General Public	Shedding Eligibility Form	1,000	1	2/60
	Contact Information Form	200	1	2/60

Jeffrey M. Zirger,

Health Scientist, 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

[30Day–16–16ASR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Written comments and/or suggestions regarding the items contained in this notice 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

Persistence of Zika Virus in Semen and Urine of Adult Men in the United States with Confirmed Zika Virus Infection—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Zika virus is an arthropod-borne flavivirus that has recently emerged in the Americas. Maternal infection has been linked to congenital microcephaly, fetal loss, and other adverse reproductive health outcomes. Although spread primarily by mosquitoes, recent reports have highlighted the potential for sexual transmission of Zika virus through the semen of infected men. Detection of viral RNA in semen 62 days after illness onset has been reported; however the frequency and duration of virus shedding is largely unknown. Information on these parameters is needed urgently to better inform public health recommendations, particularly for couples contemplating pregnancy.

This study will fill gaps in the scientific knowledge base for Zika virus regarding the persistence and transmissibility of Zika virus in body fluids, and determine the frequency and duration of Zika virus shedding in semen and urine of infected men. Minimal health information and specimens from consenting men with recent Zika virus infection will be collected once every two weeks for up to 6 months post onset of symptoms (or up to 12 collections). Specimens will be tested for Zika RNA by reverse transcriptase polymerase chain reaction assay (RT–PCR) at CDC; those testing positive may be further evaluated by virus isolation techniques. Zika virus disease is a nationally notifiable condition, and participants will be recruited through contact with CDC personnel. Urine and semen specimens will be self-collected using home collection kits, a short questionnaire will be self-administered, and participants will be compensated for their time. Results of testing will be provided to participants at the conclusion of testing. The results of this study are expected to have immediate implications for public health recommendations and disease prevention.

This is a prospective, descriptive cohort study. The prospective nature of the proposed cohort study allows for determining the persistence of shedding Zika virus in semen and urine through serial specimen collection from individuals with confirmed Zika virus.

The results of this study will be of great relevance to provide evidence-based information to circumvent Zika virus transmission. They will inform the development of recommendations used in the current epidemic setting, as well as in future Zika virus situations. Results and analysis will be used to update and refine relevant counseling messages and recommendations.

Potential products include scientific abstracts and manuscripts, presentations, and guidance documents.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 134.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
General Public	Introductory Survey	250	1	20/60
	Follow-up survey	250	12	1/60

Jeffrey M. Zirger,

Health Scientist, 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.

[FR Doc. 2016–16298 Filed 7–8–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–367]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 10, 2016:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or*, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program—Monthly and Quarterly Drug Reporting Format; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto the CMS–64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS–367 (OMB control number: 0938–0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 610; *Total Annual Responses:* 12,810; *Total Annual Hours:* 3,618,703. (For policy questions regarding this collection contact Samone Angel at 410–786–1123.)

Dated: July 5, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–16221 Filed 7–8–16; 8:45 am]

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