Background and Brief Description

The Zika virus response necessitates the collection of county and sub-county level records for *Aedes aegypti* and *Ae. albopictus,* the vectors of Zika virus. This information will be used to update species distribution maps for the United States and to develop a model aimed at identifying where these vectors can survive and reproduce. CDC is seeking six months of OMB clearance to collect information.

In February, 2016, OMB issued emergency clearance for a county-level survey of vector surveillance records (OMB Control No. 0920–1101, expiration date 8/31/2016). This information collection will be nearly a repeat of that survey.

The previous survey aimed to describe the current reported distribution of the Zika virus vectors *Aedes aegypti* and *Ae. albopictus.* The survey revealed that we are lacking records from recent years of both species from areas where we expect to find Zika vectors based on historical records and environmental suitability. It is likely that the reason for this is because from 2004–2015 most vector surveillance focused on vectors of West Nile virus (*Culex spp.*) rather than Zika vectors. As part of the Zika response, efforts to identify *Ae. aegypti* and *Ae. albopictus* in the continental U.S. were substantially enhanced during 2016 and funding will be provided to states to continue to enhance surveillance for these vectors. By repeating the survey, we will have a more complete assessment of where these vectors are currently being reported. In the new survey, we will also seek information on locations of the mosquito traps at sub-county spatial scales. Such information will aid in (1) targeting vector control efforts to prevent mosquito-borne Zika virus transmission in the continental U.S. and (2) targeting future vector surveillance efforts.

The purpose of the mosquito surveillance survey is to collect county and sub-county-level records for *Aedes aegypti* and *Ae. albopictus,* the vectors of Zika virus. The resulting maps and models will: Inform the public and policy makers of the known distribution of these vectors, identify gaps in vector surveillance, and target allocation of surveillance and prevention resources.

Respondents will include vector control professionals, entomologists, and public health professionals who will be contacted by email, primarily through listserves of professional organizations. They will be asked for their voluntary participation in a short survey to assess the distribution of *Aedes aegypti* and *Aedes albopictus* at county and sub-county spatial scales in the U.S.

This information collection request is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). The total estimated annualized number of burden hours is 125. There will be no anticipated costs to respondents other than time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Vector control professionals, entomologists, and Public health biologists.	Survey of county-level surveillance records of *Aedes aegypti* and *Aedes albopictus*.	500	1	15/60	125
Total					125

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 Medicare & Medicaid Services

[Document Identifier: CMS–10463 and CMS–10469]

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

AGENCY: Centers for Medicare & Medicaid Services.

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 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: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and 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 *September 9, 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:* Cooperative Agreement to Support Navigators in Federally-facilitated and State Partnership Exchanges; *Use:* Section 1311(i) of the Affordable Care Act requires Exchanges (Marketplaces) to establish a Navigator grant program as part of its function to provide consumers with assistance when they need it. Navigators will assist consumers by providing education about and facilitating selection of qualified health plans (QHPs) within Marketplaces, as well as other required duties. Section 1311(i) requires that a Marketplace operating as of January 1, 2014, must establish a Navigator Program under which it awards grants to eligible individuals or entities who satisfy the requirements to be Exchange Navigators. For Federally-facilitated Marketplaces (FFMs) and State Partnership Marketplaces (SPMs), CMS will be awarding these grants. Navigator awardees must provide weekly, monthly, quarterly, and annual progress reports to CMS on the activities performed during the grant period and any sub-awardees receiving funds. CMS has modified the data collection requirements for the weekly, monthly, quarterly, and annual reports that were provided in 81 FR 29268 (May 11, 2016). *Form Number:* CMS–10463 (OMB control number: 0938–1215); *Frequency:* Annually; Quarterly; Monthly; Weekly; and Quarterly; *Affected Public:* Private sector; *Number of Respondents:* 102; *Total Annual Responses:* 102; 408; 1,224; 5,304; *Total Annual Hours:* 24,729. (For policy questions regarding this collection, contact Gian Johnson at 301–492–4323.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Issuer Reporting Requirements for Selecting a Cost-Sharing Reductions Reconciliation Methodology; *Use:* Sections 1402 and 1412 of the Affordable Care Act provide for reductions in cost sharing on essential health benefits for low- and moderate-income enrollees in silver level qualified health plans (QHP) on individual market Exchanges. It also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level. These cost-sharing reductions will help eligible individuals and families afford the out-of-pocket spending associated with health care services provided through Exchange-based QHP coverage.

The law directs QHP issuers to notify the Secretary of the Department of Health and Human Services (HHS) of cost-sharing reductions made under the statute for qualified individuals, and directs the Secretary to make periodic and timely payments to the QHP issuer equal to the value of those reductions. Further, the law permits advance payment of the cost-sharing reduction amounts to QHP issuers based upon amounts specified by the Secretary.

Under established HHS regulations, QHP issuers will receive advance payments of the cost-sharing reductions throughout the year. Each issuer will then be subject to one of two reconciliation processes after the year to ensure that HHS reimbursed each issuer the correct cost-sharing portion of advance payments. This information collection request establishes the data collection requirements for a QHP issuer to report to HHS which reconciliation reporting option the issuer will be subject to for a given benefit year. *Form Number:* CMS–10469 (OMB control number: 0938–1214); *Frequency:* Annually; *Affected Public:* Private sector (Businesses or other for-profits); *Number of Respondents:* 575; *Total Annual Responses:* 575; *Total Annual Hours:* 13,200. (For policy questions regarding this collection contact Pat Meisol at 410–786–1917.)

Dated: August 5, 2016.

William N. Parham, III,

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

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1721; FDA–2012–N–0248; FDA–2011–N–0449; FDA–2012–N–0748; FDA–2012–N–0961; FDA–2012–N–0921; FDA–2014–N–0189; FDA–2004–N–0258]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Investigational New Drug Regulations	0910–0014	2/28/2019