

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
73.5 & 6	Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C).	1	1	30/60
73.5 & 6	Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance.	1,030	1	30/60
73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).	1	1	30/60
73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance.	1	1	30/60
73.3 & 73.4	Request for Exclusions	3	1	30/60
73.3 & 73.4	Request for Exclusions Guidance	3	1	30/60
73.9	Documentation of Self-inspection	238	1	1
73.1	Request for Expedited Review	1	1	15/60
73.1	Request for Expedited Review Guidance	1	1	15/60
73.11	Security Plan	238	1	5
73.11	Security Plan Guidance	238	1	30/60
73.11	Security Plan Template	238	1	30/60
73.12	Biosafety Plan	238	1	5
73.12	Biosafety Plan Guidance	238	1	30/60
73.12	Biosafety Plan Template	238	1	30/60
73.13	Request Regarding a Restricted Experiment	1	1	30/60
73.13	Request Regarding a Restricted Experiment Guidance	1	1	30/60
73.14	Incident Response Plan	238	1	5
73.14	Incident Response Plan Guidance	238	1	30/60
73.14	Incident Response Plan Template	238	1	30/60
73.15	Training	238	1	30/60
73.15	Training Guidance	238	1	30/60
73.17	Records	238	1	30/60
73.17	Guidance on the Inventory of Select Agents	238	1	30/60
73.20	Administrative Review	1	1	1

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2014-0015]

Vaccines Adverse Event Reporting System (VAERS) 2.0 Form

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the availability of the final Vaccines Adverse Event Reporting System (VAERS) 2.0 Form www.vaers.hhs.gov. The VAERS 2.0 Form replaces the

VAERS-1 Form which had been in use since 1990.

DATES: The VAERS 2.0 Form was implemented June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Tiffany Suragh, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D-26; Atlant, Georgia 30329-4018; Telephone: (404) 498-0681.

SUPPLEMENTARY INFORMATION: VAERS is an important and critical “early warning system” in the federal vaccine safety infrastructure for identifying adverse events after receipt of childhood, adolescent, and adult vaccines licensed for use in the United States. Healthcare providers and vaccine manufacturers are required under section 2125(b) of the Public Health Service Act (42 U.S.C. 300aa-25(b)) to submit VAERS reports regarding the occurrence of any event set forth in the Vaccine Injury Table which occurs within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table and the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer’s package insert. VAERS also accepts reports on adverse events following receipt of other

vaccines. Patients, parents and others aware of adverse events can also submit VAERS reports. Although VAERS is not designed to assess if a vaccine caused an adverse event, VAERS provides HHS/CDC and HHS/FDA with important early information that might signal a potential problem. If the VAERS data suggest a possible association between an adverse event and vaccination, the relationship will be further assessed. In recent years VAERS has received approximately 40,000 U.S. reports annually.

VAERS is a mandated activity for the Department of Health and Human Services (HHS) and VAERS data are used by Federal agencies, State Health Officials, health care providers, manufacturers, and the public. Therefore, it is important to maximize the usefulness of this system. The information collected by the final VAERS 2.0 Form will be similar to that from the current VAERS-1 Form so historical comparisons can be made. However, the changes in the final VAERS 2.0 Form should improve reporting efficiency and data quality. VAERS 2.0 Form offers standardized responses, clearer instructions and guidance, and improved online reporting capability. Select questions

have been updated, with questions added, removed, and reorganized to decrease response burden and maximize usability. The final VAERS 2.0 Form can be found at <http://www.regulations.gov> and www.vaers.hhs.gov.

During the development of the VAERS 2.0 Form, CDC and FDA sought input from key stakeholders in the Federal government, State Health Officials involved in vaccine safety and vaccine programs, and other public health partners. In addition, the VAERS 2.0 Form was presented to three Federal advisory committees, the Advisory Commission on Childhood Vaccines (September 5, 2014), the National Vaccine Advisory Committee (September 9, 2014), and the Advisory Committee on Immunization Practices (October, 2014). Finally, the final VAERS form was tested with potential users (e.g., physicians, nurses, pharmacists, patients, and parents).

On November 24, 2014 HHS/CDC published a notice in the **Federal Register** (79 FR 69853) announcing the opening of a docket to obtain public comment on the draft VAERS 2.0 Form. HHS/CDC received 19 comments on the draft VAERS 2.0 Form from members of the general public and professional and advocacy organizations. All comments were carefully reviewed and considered in the preparation of the final VAERS form.

Dated: July 31, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-17WE]

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

Knowledge, Attitudes, and Practices related to a Domestic Readiness Initiative on Zika Virus Disease—New—Office of the Associate Director for Communication, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since late 2015, Zika has rapidly spread through Puerto Rico. As of November 2016, there have been 35,136 confirmed cases of Zika in Puerto Rico, with 2,797 cases among pregnant women and 67 cases of Guillain-Barré caused by Zika. In the continental United States, there have been 4,432 travel-associated cases of Zika and 185 locally-acquired Zika cases in Florida and Texas. Due to the urgent nature of this public health emergency, CDC is implementing a Zika prevention communication and education initiative.

The purpose of this survey is to assess a domestic U.S. and Puerto Rico-based communication and education initiative aimed at encouraging at-risk populations to protect themselves and their families from Zika virus infection. CDC will assess the following communication and education

objectives: (1) Determine the reach and saturation of the initiative's messages in Puerto Rico and the domestic U.S.; (2) measure the extent to which messages were communicated clearly across multiple channels to advance knowledge and counter misinformation; and (3) monitor individual and community-level awareness, attitudes and likelihood to follow recommended behavior. This data collection includes 2,400 surveys conducted in four geographic locations following peak campaign activity to assess key outcomes of the initiative. The information will be used to make recommendations for improving communication and education regarding the prevention and spread of the Zika virus. Information may also be used to develop presentations, reports, and manuscripts to document the communication effort and lessons learned in order to inform future similar communication efforts.

The goal of this project is to determine knowledge, attitudes, and practices related to a Domestic Readiness Initiative on Zika Virus Disease being launched in the United States (U.S.) mainland and Puerto Rico.

CDC will seek to gain OMB approval of this new information collection request to conduct a final survey (wave 3) to evaluate the CDC Domestic Readiness Initiative for Zika Virus. The Zika Readiness Initiative campaign has been implemented in two phases with peak campaign activity coinciding with the height of mosquito season during the summer months of 2016 (phase 1) and 2017 (phase 2). OMB granted CDC an emergency review approval in 2016 (OMB Control Number 0920-1136, expiration 3/31/2017) to conduct the first two waves of data collection which captured the effectiveness of the first phase of the campaign. The third wave of data collection will allow CDC to capture the effectiveness of the second phase of the campaign being implemented through late summer/early fall 2017.

While the campaign objectives and the call to action remain the same across both phases, campaign materials have been modified between phases based the first two waves of data collection to better address misinformation about Zika and promote a sense of urgency to adopt preventive actions. The third and final wave of data collection is vital to CDC's continued understanding of how the campaign information is received by target audiences and what actions are being taken to prevent Zika virus transmission. Findings will be used to improve planning, implementation, refinements and demonstrate outcomes