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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2014-0015]

Request for Comment on Draft Vaccines Adverse Event Reporting System (VAERS) 2.0 Form

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

ACTION: Notice of request for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is publishing this notice requesting public comment on the proposed VAERS 2.0 form, which is intended to replace the current VAERS-1 form (https://vaers.hhs.gov/resources/vaers_form.pdf). CDC and the U.S. Food and Drug Administration (FDA) co-administer the Vaccines Adverse Event Reporting System (VAERS), a post-licensure (i.e., after vaccines have been licensed by the FDA and are being used in the community) reporting system

that accepts submitted reports of adverse events that occur after vaccination from healthcare providers, manufacturers, and the public. Healthcare providers and vaccine manufacturers are required to submit VAERS reports. The National Childhood Vaccine Injury Act of 1986, section 2125 of the Public Health Service Act (42 U.S.C. 300aa-25) authorized VAERS. The current VAERS form has been used since 1990.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by docket number CDC-2014-0015 by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: You may also submit written comments to the following address: Centers for Disease Control and Prevention, (CDC), National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Immunization Safety Office, Attn: VAERS 2.0 form Docket No. CDC-2014-0015, 1600 Clifton Rd, NE, Mailstop A-07, Atlanta, Georgia, 30333.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to http://regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to http://www.regulations.gov. All materials submitted will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Standard Time, at 1600 Clifton Road, NE, Atlanta, Georgia 30333. Please call ahead to (404) 639-4000 and ask for a representative from Immunization Safety Office to schedule your visit. You should be aware that this office is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see **Roybal Campus Security Guidelines** under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Tiffany Suragh; Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, Immunization Safety Office, 1600 Clifton Road NE, Mailstop D-26; Atlanta, Georgia, 30329-4018; Telephone: (404) 639-4000.

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 (US). 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 file 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 file VAERS reports. Although VAERS is not designed to assess if a vaccine caused an adverse event, VAERS provides CDC and 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 30,000 US reports annually.

VAERS is a mandated activity for the U.S. 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 proposed VAERS 2.0 form will be similar to that on the current VAERS-1 form so historical comparisons can be made; however, the changes in the draft VAERS 2.0 form should improve reporting efficiency and data quality. VAERS 2.0 offers standardized responses, clearer instructions and guidance, and improved online reporting. Select questions have been updated, with questions added, removed, and reorganized to decrease response burden and maximize usability. The draft VAERS 2.0 form can be found at http://www.regulations.gov.

During the development of the draft 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) and was tested with potential reporters (e.g., physicians,

nurses, pharmacists, patients, and parents). All public comments will be reviewed and considered prior to finalizing the VAERS 2.0 form.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road, N.E., Atlanta, Georgia. The Immunization Safety Office is in a Federal government building; therefore, Federal security measures are applicable.

In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Roybal Campus through the entrance on Clifton Road; the guard force will direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the visit date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor's ID badge at

the entrance to Building 19 and will be escorted to a room to view the available materials. **All items brought to HHS/CDC are subject to inspection.**

Dated: November 18, 2014.

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Ron A. Otten,

Acting Deputy Associate Director for Science,

Centers for Disease Control and Prevention.

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