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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,

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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 US 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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