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To: Maine Immunization Providers
From: Maine Immunization Program
Subject: VAERS Reporting Requirements for COVID-19
Date: April 5, 2022

Vaccine safety is very important to the Maine Immunization Program and the Center for Disease Control and Prevention. COVID-19 Vaccine Providers can find COVID-19 Vaccine safety information here.

As of January 31, 2022, there are three vaccines available to protect against COVID-19 disease:

- Pfizer-BioNTech COVID-19 Vaccine (Comirnaty®) is FDA-approved for people ages 16 years and older; it is authorized for emergency use in people ages 5 years and older.
- Moderna COVID-19 Vaccine (Spikevax®) is FDA-approved for people ages 18 years and older.
- Johnson & Johnson's Janssen COVID-19 Vaccine is authorized for emergency use in people ages 18 years and older.

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use or licensed by the FDA. Healthcare providers who administer COVID-19 vaccines are **required** to report the following to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event (AE).
    - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, VAERS reporting **is** required.
    - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), VAERS reporting **is** required.
    - **VAERS reporting is not required for the following situations:**
        - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
        - Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)
- Serious AEs regardless of whether the reporter thinks the vaccine caused the AE. Serious AEs per FDA are defined as:
    - Death
    - A life-threatening AE
    - Inpatient hospitalization or prolongation of existing hospitalization
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
    - A congenital anomaly/birth defect

    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure whether the vaccine caused the event.

Healthcare providers should also report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) or any approved COVID-19 vaccine as outlined in the Fact Sheet for Healthcare Providers.

Two ways to submit an online report to VAERS:

- Report online to VAERS: VAERS - Report an Adverse Event Step 1 (hhs.gov)
- Report using a Writable PDF Form: VAERS - Download / Upload a Writable PDF Form (hhs.gov)

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

For questions on any immunization-related issue, please call the Maine Immunization Program at (207) 287-3746 or email ImmunizeME.DHHS@maine.gov. Thank you for all that you do to keep Maine citizens safe from vaccine-preventable diseases.