

Model Plan: Reporting Adverse Events Following Vaccination

School Located Vaccine Clinic (SLVC) staff should report any vaccine adverse events occurring in the SLVC setting to the Vaccine Adverse Event Reporting System (VAERS).

Background

VAERS, administered by the Food and Drug Administration (FDA) and Centers for Disease Control Prevention (CDC), is a safety surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the US.

- Each report provides valuable information that is added to the VAERS database that supplies the information needed for evaluation of vaccine safety.
- Anyone can file a VAERS report; including health care providers, vaccine recipients and parents or guardians.
- Vaccine recipients and parents/guardians should consult their health care provider if they suspect an adverse event associated with the vaccine.
- FDA and CDC do not provide individual medical treatment, advice, or diagnosis.

What can be reported to VAERS?

- Report any clinically significant medical event that occurs after vaccination, even if you are not sure whether the vaccine caused the adverse event.
- The National Childhood Vaccine Injury Act requires health care providers to report
 any adverse event listed by the vaccine manufacturer as a contraindication to
 receive additional doses of the vaccine and any adverse event listed in the <u>"VAERS</u>
 <u>Table of Reportable Events Following Vaccination"</u> that occurs within the specified
 time period after vaccination. For influenza this includes events described in
 manufacturer's package insert as contraindications to additional doses of vaccine
 (interval see package insert).

How to report to VAERS:

- **Anyone may report** but preferably the SLVC Vaccinator or Clinic Authority should complete the VAERS report if the event occurs in the SLVC setting.
- Download the VAERS Form (located at https://vaers.hhs.gov/uploadFile/index.jsp)
- Request a VAERS Form by sending email to <u>info@vaers.org</u>, by calling (800)822-7967, or by faxing a request to (877)721-0366.
- Before you begin review the Instructions for Completing the VAERS Paper Form.
- Fax a completed VAERS Form to (877)721-0366.
- Mail a completed VAERS Form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. A pre-paid postage stamp is included on the back of the form.
- Federal CDC will send you a confirmation after the report is received.