VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Items **2, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and must be completed.
Patient identity kept confidential. Use **Continuation Page** *(page 2)* if necessary.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

*Use **Continuation Page** (page 2) for nos. 9-12, if necessary*

1. Patient name: *(First)* _____ *(Last)* _____
Street address: _____
City: _____ State: _____ County: _____
ZIP code: _____ Tele: (____) _____ Email: _____

2. Date of birth: *(mm/dd/yyyy)* ____/____/____ 3. Sex: ☐ Male ☐ Female ☐ Unknown

4. Date and time of vaccination: *(mm/dd/yyyy)* ____/____/____ Time: _____ ☐AM ☐PM

5. Date and time adverse event started: *(mm/dd/yyyy)* ____/____/____ Time: _____ ☐AM ☐PM

6. Age at vaccination: ____ Years ____ Months 7. Today's date: *(mm/dd/yyyy)* ____/____/____

8. Report is about vaccine administered to a pregnant woman: ☐ No or unknown ☐ Yes
(If Yes, describe pregnancy history, estimated date of delivery, birth weight if available, and the event in no. 18)

9. Prescriptions, over-the-counter medications, dietary supplements or herbal remedies being taken at time of vaccination:

10. Allergies to medications, food, or other products: *(Explain)*

11. Other illness at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: *(Name)* _____

Relation to patient: ☐ Healthcare professional/staff ☐ Patient *(yourself)*
☐ Parent/guardian/caregiver ☐ Other: _____

Street address: _____ ☐ *Check if same as no. 1*
City: _____ State: _____ ZIP code: _____
Tele: (____) _____ Email: _____

14. Best doctor/healthcare professional to contact about the patient: Name: _____
Tele: (____) _____ Ext: _____

INFORMATION ABOUT FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: (____) _____
Street address: ☐ *Check if same as no. 13* _____
City: _____
State: _____ ZIP code: _____
Tele: (____) _____
Email: _____

16. Type of facility:
☐ Doctor's office or hospital
☐ Pharmacy or drug store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School/student health clinic
☐ Other: _____
☐ Unknown

WHAT VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

*Use **Continuation Page** (page 2) for nos. 17-19, if necessary*

17. Enter all vaccines given on date listed in no. 4: *(Route is HOW vaccine was given, body site is WHERE vaccine was given)*

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

18. Describe event(s), treatment and outcome(s), if any: *(symptoms, signs, time course, etc.,)*

19. Medical tests and laboratory results related to event(s): *(Include dates)*

20. Patient has recovered from event: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of event: *(Check all that apply)*
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room or emergency department visit
☐ Hospitalization: Number of days _____ *(if known)*
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization
(Vaccine received during existing hospitalization)
☐ Life threatening illness
☐ Disability or permanent damage
☐ Patient died: Date of death ____/____/____ *(mm/dd/yyyy)*
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

*Use **Continuation Page** (page 2) for nos. 22-23, if necessary*

22. Any other vaccines received within one month prior to the date listed in no. 4: *(Route is HOW vaccine was given, body site is WHERE vaccine was given)*

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

23. Has the patient ever had an adverse event following any previous vaccine: *(If yes, describe and include patient age, vaccination dates, and vaccine type and brand name)*
☐ No or unknown ☐ Yes _____

24. Patient's race: *(Check all that apply)*
☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander
☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report no.: *(Health Dept use only)* _____

FOR U.S. MILITARY/DEPT OF DEFENSE (DoD) RELATED REPORTS *(Complete only if applicable)*

27. Status at time of vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Other: _____

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

9. Prescriptions, over-the-counter medications, dietary supplements or herbal remedies being taken at time of vaccination (CONTINUED):

10. Allergies to medications, food, or other products (CONTINUED): *(Explain)*

11. Other illness at the time of vaccination and up to one month prior (CONTINUED):

12. Chronic or long-standing health conditions (CONTINUED):

17. Enter all vaccines given on date listed in no. 4 (CONTINUED):

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

18. Describe event(s), treatment and outcome(s), if any (CONTINUED): *(symptoms, signs, time course, etc.,)*

19. Medical tests and laboratory results related to event(s) (CONTINUED): *(Include dates)*

22. Any other vaccines received within one month prior to the date listed in no. 4 (CONTINUED):

Vaccine *(type and brand name)*	Manufacturer	Lot number	Route	Body site	Dose no. in series

23. Has the patient ever had an adverse event following any previous vaccine (CONTINUED): *(Describe and include patient age, vaccination dates, and vaccine type and brand name)*

COMPLETING THE VAERS FORM

The Vaccine Adverse Event Reporting System (VAERS) improves our understanding of vaccine safety. The Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) thank you for helping with this important public health responsibility.

GENERAL INSTRUCTIONS

- You MUST submit this form electronically. For instructions, visit www.vaers.hhs.gov/esub/index.
- Use a separate VAERS form for each patient.
- Fill out the VAERS form as completely as possible.
- If you do not know exact numbers, dates or times, please provide your best guess (you may leave these spaces blank if you are not comfortable guessing).
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.htm for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how to best complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 4, 5, 6, 17, 18 and 21 are ***ESSENTIAL*** and must be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know if it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** Provide age in years for people who are 24 months or older (2 years or older). If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, list year and months (e.g., 1 year 6 months).
- **Item 8:** If report is about a vaccine given to a pregnant woman, select "Yes" and describe pregnancy history, estimated date of delivery, birth weight of child if available, and the adverse event in no. 18. Otherwise, check "No or unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, or other non-traditional/alternative medicines being taken when the vaccine(s) was given.
- **Item 10:** List any allergies to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date the vaccine(s) was given AND up to one month prior to this date (e.g. cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** State the name of the person who is completing the form. Select "Check if same as no. 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in no. 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 15:** Select "Check if same as no. 13" box if the person completing the form works at the facility where the vaccine(s) was given. The contact information provided in no. 13 will be automatically entered for you. Otherwise, provide new contact information.

- **Item 16:** Select the single best answer for the type of facility where the vaccine(s) was given.
- **Item 17:** Include only vaccines given on the date listed in no. 4. For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose no. in series" (e.g., if this is the second time you are getting the same vaccine, write "2").
- **Item 18:** Describe the adverse event(s), treatment and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccine or "No" if the patient has not returned to the same state of health as before the vaccine, and provide details in no. 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient was hospitalized and received a vaccine during their hospital stay. An adverse event following vaccination occurred and resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in no. 4.
- **Item 23:** List adverse events following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** This is for health department use only.
- **Items 27 and 28:** These items should only be completed if the patient is associated with the U.S. Military or Department of Defense.

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The HIPAA Privacy Rule permits reporting of protected health information to public health authorities including CDC and FDA (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- VAERS is primarily concerned with monitoring adverse health events. Using clinical judgment, healthcare professionals can decide whether or not to report a medical error at their own discretion.
- The Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.