WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

# VACCINE ADVERSE EVENT REPORTING SYSTEM

**24 Hour Toll-Free Information 1-800-822-7967**
**PATIENT IDENTITY KEPT CONFIDENTIAL**

**For CDC/FDA Use Only**
**VAERS Number** _____
**Date Received** _____

Patient Name:
_____
Last First M.I.

Address
_____
_____
_____
_____
City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):
_____
Responsible Physician _____
Facility Name/Address
_____
_____
_____
_____
City State Zip

Telephone no. (____) _____

Form completed by (Name):
_____
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*
_____
_____
_____
_____
City State Zip

Telephone no. (____) _____

| 1. State | 2. County where administered | ☐ 3. Date of birth | ☐ 4. Patient age | 5. Sex | 6. Date form completed |
|---|---|---|---|---|---|
| | | ____/____/____ mm dd yy | | ☐ M ☐ F | ____/____/____ mm dd yy |

☐ 7. Describe adverse event(s) (symptoms, signs, time course) and treatment, if any.

☐ 8. Check all appropriate:
- ☐ Patient died (date ____/____/____ mm dd yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

☐ 10. Date of vaccination
____/____/____ mm dd yy
Time _____ AM PM

☐ 11. Adverse event onset
____/____/____ mm dd yy
Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

☐ 13. Enter all vaccines given on date listed in no. 10

| | Vaccine (type) | Manufacturer | Lot number | Route/Site | No. Previous doses |
|---|---|---|---|---|---|
| a. | | | | | |
| b. | | | | | |
| c. | | | | | |
| d. | | | | | |

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

| | Vaccine (type) | Manufacturer | Lot number | Route/Site | No. Previous doses | Date given |
|---|---|---|---|---|---|---|
| a. | | | | | | |
| b. | | | | | | |

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military Funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously?
☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under

*22. Birth weight* _____ lb. _____ oz.

*23. No. of brothers and sisters*

21. Adverse event following prior vaccination (check all applicable, specify)

| | Adverse Event | Onset Age | Type Vaccine | Dose no. in series |
|---|---|---|---|---|
| ☐ In patient | | | | |
| ☐ In brother or sister | | | | |
| | | | | |

Only for reports submitted by manufacturer/immunization project

*24. Mfr./imm. proj. report no.*

*25. Date received by mfr./imm.proj.*

*26. 15 day report?* ☐ Yes ☐ No

*27. Report type* ☐ Initial ☐ Follow-Up

**Form VAERS-1(FDA)** Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

**BUSINESS REPLY MAIL**
FIRST-CLASS MAIL PERMIT NO. 239 AUSTIN TX

POSTAGE WILL BE PAID BY ADDRESSEE

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

**VAERS**
**C/O DEPARTMENT OF STATE HEALTH SERVICES**
**IMMUNIZATION BRANCH**
**MC1946**
**PO BOX 149347**
**AUSTIN TX 78714-9909**

**"Fold in thirds, tape & mail --- DO NOT STAPLE FORM"**

## DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

### GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

### SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.

Item 10 and 11: Give dates and times as specifically as you can remember. If you do not know the exact time, please indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in Item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.

Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.