VACCINE ADVERSE EVENT REPORTING SYSTEM  24 Hour Toll Free Information 1-800-822-7967 P.O. Box 1100, Rockville, MD 20849-1100  PATIENT IDENTITY KEPT CONFIDENTIAL			For CDC/FDA Use Only  VAERS Number  Date Received			
Patient Name:	Vaccine administered	Form completed by (Name):				
Last First M.I. Address	Responsible Physician Facility Name/Address		Relation			
City State Zip Telephone no. ()  1. State 2. County where administered	City Telephone no. () _	State Zip  4. Patient age	5. Sex	6. Da	State Zip	
2. County where auministered	<u> </u>	yy anom ago		F	mm dd yy	
7. Describe adverse events(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			<u> </u>		11 Adverse event onset	
12. Relevant diagnostic tests/laboratory data						
13. Enter all vaccines given on date listed in no. 10					No. Previous	
Vaccine (type) Manufacturer Lot number a			Route/Site Doses			
b c d						
14. Any other vaccinations within 4 weeks prior to the date listed in no. 10					Date	
Vaccine (type) Manufacturer a. ————————————————————————————————————	Lot number Route/Site		No. Previous Date doses given			
15. Vaccinated at:  □ Private doctor's office/hospital □ Public health clinic/hospital □ Public health clinic/hospital						
18. Illness at time of vaccination (specify)	19. Pre-existing phys	sician-diagnosed allergies,	birth defects, r	medial conditi	ons(specify)	
To its and the points of the p			nly for children 5 and under			
this adverse event previously?			23. No. of brother and sisters			
21. Adverse event following prior vaccination (check all applicable, specify) Only for reports submit				acturer/lmmu	unization project	
Adverse Onset Type Dose no. Event Age Vaccine in series  24. Mfr./imm. proj. report			no. 25	. Date receive	ed by mfr./imm.proj.	
☐ In patient		26. 15 day report?	27	27. Report type		
or sister		☐ Yes ☐ No		☐ Initial ☐ Follow-Up		
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.						

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

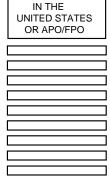


# **BUSINESS REPLY MAIL**

FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE





NO POSTAGE NECESSARY IF MAILED

Intelligent of the formal and the other date.

### **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 orthat person's legal representativewill 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: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- Item 11: 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 priorvaccine, 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.