

MODULE

6

VACCINE INFORMATION STATEMENTS

Immunization Section—Vaccines for Children Program

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MODULE 6: Vaccine Information Statements and Vaccine Adverse Event Reporting

What is a Vaccine Information Statement?

Vaccine Information Statements (VIS) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain both the benefits and risks of a vaccine. Federal law (National Childhood Vaccine Injury Act (NCVIA) 42 U.S.C. § 300aa-26) requires health care staff to provide a VIS to a patient, parent, or legal representative before each dose of a certain vaccination is given. This includes all vaccines administered through the VFC Program. VISs may be provided by paper copy; reviewing a permanent office copy; reviewing on a computer monitor; or downloading to an electronic device to be read when convenient.

Provider Responsibilities

- A. Give the patient, parent, or legal representative a VIS, for each dose of vaccine, *prior* to vaccine administration.
- B. Record the following specific information in the patient's medical record (which can include an electronic medical record), or in a permanent office log. The record should be both permanent and accessible.
 - Vaccine name
 - Date administered
 - VIS publication date
 - Date VIS provided to patient
 - Name of vaccine manufacturer
 - Vaccine lot number
 - Name and title of vaccinator
 - Clinic address

Providers may add the name, address, and contact information of their practice to an existing VIS, but may not make any substantive changes. In addition to providing a VIS, the provider may read it aloud, provide video version, or provide additional printed material, or in any other way that will help patients understand the disease and vaccine.

VISs are required for the following vaccines:

- Diphtheria, tetanus and pertussis containing vaccines (DTaP, DT, Td, and Tdap)
- *Haemophilus influenzae*, type b (Hib)
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza (both Inactivated and Live, Intranasal vaccines)
- Measles, Mumps, and Rubella (MMR)
- Measles, Mumps, Rubella, and Varicella (MMRV)

- Meningococcal (MCV4, MPSV4 and MenB)
- Pneumococcal Conjugate (PCV)
- Polio (IPV)
- Rotavirus
- Varicella (VZV)

Multi-Vaccine VIS

This VIS may be used in place of individual VISs for any or all routine birth through 6-month vaccines (DTaP, IPV, Hib, hepatitis B, PCV, and rotavirus) administered, or when combination vaccines were used. Using the multi-vaccine VIS is an alternative to providing single-vaccine VISs for each of these six vaccines. Providers could use this VIS when two or more of these vaccines were given together. Current VISs may be found at:

CDC's Vaccines and Immunizations website at:

www.cdc.gov/vaccines/hcp/vis/index.html

CDC's Contact Center:

Call 1-800-CDC-INFO (or 1-800-232-4636)

Immunization Action Coalition website at:

www.immunize.org/vis/

Vaccine Adverse Event Reporting System (VAERS)

The VAERS is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA) for collection of information about adverse events (possible side effects) following immunization with US-licensed vaccines. By monitoring such events, the VAERS helps to identify any important new safety concerns, and thereby assists in ensuring the benefits of vaccines continue to be far greater than the risks.

Federal law requires health care providers to report significant adverse events suspected to be caused by vaccines.

How Do I Report?

Internet: Complete the electronic form at:
www.vaers.hhs.gov/esub/step1

Mail: Print form from:
www.vaers.hhs.gov/resources/vaers_form.pdf
and mail it postage free to:
VAERS
P.O. Box 1100
Rockville, MD 20849-1100

Fax: Print form (from above link in "Mail") and fax it to:
1-877-721-0366 (toll-free)

E-mail: Submit VAERS inquiries to info@vaers.org

Phone: VAERS Hotline: 1-800-822-7967 (toll-free)

After a provider submits a report, the VAERS staff may contact the provider for follow-up. Be sure to provide a copy of your VAERS report to the:

Florida Department of Health
Immunization Section
4052 Bald Cypress Way, Bin A-11
Tallahassee, Florida 32399-1719

Or fax to the Immunization Section VAERS Coordinator at:
850-922-4195.