

MODULE

6

VACCINE INFORMATION STATEMENTS

Bureau of Immunization-Vaccines for Children Program

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MODULE 6 – Vaccine Information Statements

What is a Vaccine Information Statement?

A Vaccine Information Statement (VIS) is a one-page (two-sided) information sheet, produced by the Centers for Disease Control and Prevention (CDC). Each VIS provides information to the adult vaccine recipient, the minor child's parent, or legal representative about the benefits and risks of a vaccine **prior to the administration** of any vaccine.

By federal law, all vaccine providers must give patients, their parents, or legal representatives the appropriate VIS whenever a vaccination is given. It is a requirement of the National Childhood Vaccine Injury Act of 1986. This would include all vaccines the provider administers through the VFC Program.

Provider Responsibilities

Providers should:

- A. Give the appropriate VIS to the patient or to the patient's parent or legal representative with each dose of vaccine. Providers must give a VIS prior to administration of the vaccine each time the vaccine is given.
- B. Record the following information in either the patient's permanent medical record or in a permanent office log (the record should be both permanent and accessible):
 1. Name of the VIS given.
 2. Publication date of the VIS.
 3. Date the VIS was given.
 4. Name, address, and title of the person who administered the vaccine.
 5. Date of the vaccine administration.
 6. Vaccine manufacturer.
 7. Vaccine lot number.

As needed, supplement VISs orally, with videotapes, additional printed material, or in any other way that will help patients understand the disease and vaccine.

Providers should not change or make a VIS. The law requires providers to use those developed by the CDC.

Vaccines Covered by the National Childhood Vaccine Injury Act

The VFC provider should give the current version of a VIS to their patients for the following vaccines:

- Diphtheria, Tetanus, and Pertussis (DTaP)
- Tetanus, Diphtheria, and acellular Pertussis (Tdap)
- Tetanus Diphtheria (Td)
- *Haemophilus influenzae*, type b (Hib)
- Hepatitis A (Hep A)
- Hepatitis B (Hep B)
- Human Papillomavirus (HPV)
- Trivalent Inactivated Influenza (TIV)
- Live, Intranasal Influenza (LAIV)
- Measles, Mumps, and Rubella (MMR)
- Meningococcal Conjugate (MCV4)
- Pneumococcal Conjugate (PCV7)
- Polio (IPV)
- Rotavirus (RV)
- Varicella (chickenpox)

Providers should check the following sites for current VISs:

A. The internet:

1. The CDC's Vaccines and Immunizations website at <http://www.cdc.gov/vaccines/pubs/vis/>.

2. The Immunization Action Coalition website at <http://www.immunize.org/vis/>.
- B. **CDC Contact Center** (English and Spanish immunization information):
Call 800-CDC-INFO (or 800-232-4636).

Multi-vaccine VIS

On January 30, 2008, CDC posted a multi-vaccine VIS on its website at <http://www.cdc.gov/vaccines/pubs/vis/default.htm#multi>. This new VIS may be used in place of individual VISs whenever routine birth through 6-month vaccines (DTaP, IPV, Hib, hepatitis B, PCV, and rotavirus) are administered, or when combination vaccines are used (e.g., Pediarix[®] or Comvax[®]). Using the multi-vaccine VIS is an alternative to providing single-vaccine VISs for each of these six vaccines. Providers do not need to give all six vaccines at one time in order to use this new VIS. Providers may use this VIS when two or more of these vaccines are given together at any pediatric visit (e.g., 12 to 15 months or 4 to 6 years).

Before providers hand this new VIS to the patient, they **MUST** go to page 1 of the VIS and place a check mark in front of the name of each vaccine they will be administering at that visit.

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is the means for reporting injuries or adverse events (possible side effects). The VAERS is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA). The VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, the VAERS has received over 123,000 reports, most of which describe mild side-effects, such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, the VAERS helps to identify any important new safety concerns, and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Federal law requires that healthcare providers report any significant adverse event suspected to be caused by vaccines.

How Do I Report?

It is very easy to report to the VAERS. VFC providers should also submit a copy of the report to the Bureau of Immunization. Providers can submit the VAERS report forms by:

- **Internet:** Complete on-line form at:
 - <https://secure.vaers.org/VaersDataEntryintro.htm>.
 - Before submitting electronically, print the completed form and mail to:
Bureau of Immunization
4052 Bald Cypress Way
Bin A-11
Tallahassee, FL 32399-1719
Attn: VAERS Coordinator

Or fax to Bureau of Immunization Clinical Nurse at (850) 922-4195.

- **Mail:** Print a report form from http://www.vaers.hhs.gov/pdf/vaers_form.pdf and mail it to:
 - VAERS
P.O. Box 1100
Rockville, MD 20849-1100
 - Bureau of Immunization
4052 Bald Cypress Way
Bin A-11
Tallahassee, FL 32399-1719
Attn: VAERS Coordinator
- **Fax:** Print a report form from http://www.vaers.hhs.gov/pdf/vaers_form.pdf and fax a copy to:
 - VAERS at (877) 721-0366 (toll-free number)
 - Bureau of Immunization VAERS Coordinator at (850) 922-4195.

For more information on the VAERS, contact:

- **VAERS Hotline:** Report forms are available by calling (800) 822-7967. Operators are on duty from 8:00 a.m. to 6:00 p.m. Eastern Standard Time.
- **E-mail:** Send VAERS inquiries to info@vaers.org.

After a provider submits a report form, the VAERS staff may contact the provider for follow-up information.