

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide VIS when vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer **to any child or adult** any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza (use of influenza VIS required effective January 1, 2006), pneumococcal conjugate, or varicella (chickenpox) vaccine shall, **prior to administration of each dose of the vaccine**, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, and
- to any adult to whom the provider intends to administer such vaccine. (In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative.* If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each immunization.)

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

The materials shall be supplemented with visual presentations or oral explanations, as appropriate.

*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating:

- (1) the edition date of the Vaccine Information Statement distributed and
- (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration and
- (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the Centers for Disease Control and Prevention's website at <http://www.cdc.gov/nip/publications/VIS>. Copies are available in English and in other languages.

Current Editions of VISs

Diphtheria, Tetanus, Pertussis (DTaP/DT): 7/30/01
Haemophilus influenzae type b: 12/16/98
Hepatitis B: 7/11/01
Inactivated Influenza: 10/20/05
Live, Intranasal Influenza: 10/20/05
Measles, Mumps, Rubella (MMR): 1/15/03
Pneumococcal conjugate: 9/30/02
Polio: 1/1/00
Tetanus Diphtheria (Td): 6/10/94
Varicella (chickenpox): 12/16/98

Reference 42 U.S.C. §300aa-26

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