

Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials, also known as Vaccine Information Statements (VIS), prior to administration of any of these vaccines. As new vaccines have been added to the National Vaccine Injury Compensation Program, materials for those vaccines have also been developed. Since June 1, 1999, health care providers are required to provide copies of vaccine information materials for the following vaccines: hepatitis B, haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines. And, effective December 15, 2002, use of vaccine information materials for pneumococcal conjugate vaccine was mandated.

Revised Vaccine Information Materials for Measles, Mumps & Rubella (MMR) Vaccines

The Advisory Committee on Immunization Practices revised its recommendations for administration of rubella-containing vaccines to change the recommended interval between receiving MMR vaccine and becoming pregnant from 3 months to 4 weeks ("Revised ACIP Recommendations for Avoiding Pregnancy After Receiving a Rubella-Containing Vaccine" MMWR 50/49, Dec 14, 2001). Interim vaccine information materials reflecting this change were posted on the CDC Web site on June 13, 2002. We proposed slightly different language to further clarify this recommendation when the proposed revised MMR vaccine information materials were published for public comment in the **Federal Register** on October 10, 2002 (67 FR 63106).

Following consultation and review of comments submitted, these vaccine information materials have been finalized and are contained in this notice. They are entitled "Measles, Mumps & Rubella Vaccines: What You Need to Know," and are dated January 15, 2003. CDC has also revised the Instructions for the Use of Vaccine Information Statements. The revised instructions, dated January 15, 2003, are included in this notice. These instructions and copies of the materials for all covered vaccines can also be found on the CDC Web site at: <http://www.cdc.gov/nip/publications/VIS/>. In addition, single camera-ready copies of the materials, and the instructions for their use, are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

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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 any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), or pneumococcal conjugate 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, or
- To any adult to whom the provider intends to administer such vaccine.

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

If there is not a single VIS for a combination vaccine (e.g., hepatitis A/ Hepatitis B), use the VISs for both component vaccines.

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

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 materials, and

(2) The date these materials were 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.

Additional Recommended Use

Health care providers may also want to give parents copies of all vaccine information materials prior to the first immunization visit, such as at the first well baby visit.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirements to provide the vaccine information materials supplement 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 Web site 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
 Tetanus Diphtheria (Td): 6/10/94
 Measles, Mumps, Rubella (MMR): 1/15/03
 Hepatitis B: 7/11/01
 Polio: 1/1/00
Haemophilus influenzae type b: 12/16/98
 Varicella (chickenpox): 12/16/98
 Pneumococcal conjugate: 9/30/02
 Reference 42 U.S.C. 300aa-26
 1/15/03
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Measles, Mumps & Rubella Vaccines: What You Need to Know

1. Why Get Vaccinated?

Measles, mumps, and rubella are serious diseases.