



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2021-0001]

Proposed Revised Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on proposed updated vaccine information statements for vaccines covered by the National Vaccine Injury Compensation Program (VICP).

DATES: Written comments must be received on or before
[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE
FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0001, by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Written comments should be addressed to Suzanne Johnson-DeLeon (VISComments@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop H24-6, 1600 Clifton Road, NE, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop H24-6, 1600 Clifton Road, NE, Atlanta, Georgia 30329; VISComments@cdc.gov.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the patient's parent or legal representative in the case the patient is a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as vaccine information statements (VISs), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on 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 prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring provision of vaccine information materials before vaccine administration for them as well: hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine

information materials are found on the CDC Web site at:
<https://www.cdc.gov/vaccines/hcp/vis/index.html>.

CDC is proposing updated versions to simplify, streamline, and standardize the content and formatting of the vaccine information statements.

As proposed, each of the updated VISs contains the same seven sections. Formatting of the documents is identical, using the same fonts and layout.

Section 1 ("Why get vaccinated?") provides an overview of the disease(s) prevented by the vaccine. This section is being updated to provide a clearer, more plain-language description of the disease and its impact.

Section 2 (e.g., "Hepatitis A vaccine") describes the vaccine and recommendations for its use. A general description of the usually-recommended schedule is provided and groups of people for whom the vaccine is typically recommended are identified. Updates to the text in this section remove some of the more specific details related to schedules and numbers of doses, which can vary depending on an individual patient's circumstances.

Section 3 ("Talk with your health care provider") highlights conditions and medical history that should be brought to the vaccine provider's attention when deciding whether the vaccine is appropriate for an individual patient. Previously entitled "Some people should not get this vaccine," this section has been refocused to be

broader in scope. Some of the conditions listed in this section are contraindications or precautions to vaccination, while others are intended to prompt the patient and provider to ask additional questions and investigate further.

Section 4 ("Risks of a vaccine reaction") sets forth adverse events that could occur after vaccination. Included are discussion of the risk of severe allergic reaction and the remote possibility of serious injury or death. Language for this section has been standardized across VISs to the extent possible while still adhering to vaccine-specific information from the recommendations of the Advisory Committee on Immunization Practices (ACIP).

The complete text of section 5 ("What if there I a serious problem?"), section 6 ("The National Vaccine Injury Compensation Program"), and section 7 ("How can I learn more?"), as proposed, matches exactly across all of the vaccine information materials, except for the VIS for rotavirus vaccine which includes additional information related to the risk of intussusception (a very serious adverse event that is specific to rotavirus vaccine) in sections 5 and 6.

Text in all sections of the VISs is updated using plain language terms and concepts, and removing some of the more detailed numerical and statistical data, to make the documents more easily understandable to the general public.

Because the vaccine information statements are intended for patient education, content that is relevant for providers but not for patients is removed. Language has been updated to reflect a provider-neutral approach, reflecting the fact that vaccines may be administered by medical professionals in a variety of specialty fields (e.g., using the term "health care provider" instead of "doctor" or "nurse").

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials. Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2021-0001). Comments submitted will be considered in finalizing these materials. When the final materials are published in the Federal Register, the notice will include an effective date for their mandatory use.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.