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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Docket No. CDC-2014-0007]

**Proposed Revised Vaccine Information Materials for Td, Tdap, *Haemophilus influenzae* type b, and Rotavirus Vaccines**

**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) (42 U.S.C. 300aa-26), 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 materials for tetanus/diphtheria vaccine (Td), tetanus/diphtheria and

acellular pertussis vaccine (Tdap), *Haemophilus influenzae* type b (Hib) vaccine, and rotavirus vaccine.

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

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2014-0007, 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 ([msj1@cdc.gov](mailto:msj1@cdc.gov)), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

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:** Skip Wolfe ([crw4@cdc.gov](mailto:crw4@cdc.gov)), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road, NE., Atlanta, Georgia 30329.

**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 parent or legal representative in the case of 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 (VIS), 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 use of vaccine information materials 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 and copies of the materials can be found on the CDC Web site at:

<http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the Td, Tdap, Hib, and rotavirus vaccine information statements. We also propose to revise the August 26, 2013 Instructions for the Use of Vaccine Information Statements to include a reference to these vaccine information materials.

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 entitled "Td Vaccine: What You Need to Know;" "Tdap Vaccine: What You Need to Know;" "*Haemophilus influenzae* type b Vaccine: What You need to Know;" and "Rotavirus Vaccine: What You Need to Know." Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2014-0007). 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.

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Ron A. Otten,  
Acting Deputy Associate Director for Science,  
Centers for Disease Control and Prevention.

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