



This document is scheduled to be published in the Federal Register on 04/20/2016 and available online at <http://federalregister.gov/a/2016-09167>, and on FDsys.gov

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2015-0089]

Final Revised Vaccine Information Materials for 9-valent HPV (Human Papillomavirus) Vaccine

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

ACTION: Notice

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. § 300aa-26), CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On October 22, 2015, CDC published a notice in the Federal Register (80 FR 64002) seeking public comments on proposed updated vaccine information materials for 9-valent HPV (Human Papillomavirus) Gardasil®-9 vaccine. Following review of comments submitted and consultation as required under the

law, CDC has finalized the materials. Copies of the final vaccine information materials for 9-valent HPV Gardasil®-9 vaccine are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2015-0089).

DATES: Beginning no later than July 1, 2016, each health care provider who administers 9-valent HPV (Human Papillomavirus) Gardasil®-9 vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials referenced in this notice, in conformance with the March 31, 2016 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road, N.E., 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 are found on the CDC Web site at:
<http://www.cdc.gov/vaccines/hcp/vis/index.html>.

Revised Vaccine Information Materials

The 9-valent HPV (Human Papillomavirus) Gardasil®-9 vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and healthcare provider organizations. Following consultation and review of comments submitted, the vaccine information materials covering 9-valent HPV Gardasil®-9 vaccine have been finalized and are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2015-0089). The Vaccine Information Statement (VIS) is "HPV (Human Papillomavirus) Vaccine: What You Need to Know [Gardasil®-9]," publication date March 31, 2016.

With publication of this notice, as of July 1, 2016, all health care providers will be required to provide copies of these updated 9-valent HPV Gardasil®-9 vaccine information materials prior to immunization in conformance with CDC's March 31, 2016 Instructions for the Use of Vaccine Information Statements.

Dated: April 15, 2016.

Veronica Kennedy
Acting Executive Secretary
Centers for Disease Control and Prevention
[FR Doc. 2016-09167 Filed: 4/19/2016 8:45 am; Publication Date: 4/20/2016]