

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
IHC focus group	Pathology Chairs	33	1	1
	Laboratory Directors	33		
	Laboratory Managers	34		
	Laboratory Supervisors	33		
	Histotechnologists	33		
	Pathologists	4		
	Pathology Chairs	4		
	Laboratory Directors	4		
	Laboratory Managers	4		
	Laboratory Supervisors	4		
	Histotechnologists	4		

LeRoy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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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 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 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force

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

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces the next meeting of the Community Preventive Services Task Force (Task Force). The Task Force is an independent, nonpartisan, nonfederal, and unpaid panel. Its members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion, and public health, and are appointed by the CDC Director. The Task Force was convened in 1996 by the Department of Health and Human Services (HHS) to identify community preventive programs, services, and policies that increase healthy longevity, save lives and dollars and improve Americans’ quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the Task Force. During its meetings, the Task Force considers the findings of systematic reviews on existing research and issues recommendations. Task Force recommendations are not mandates for compliance or spending. Instead, they

provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The Task Force’s recommendations, along with the systematic reviews of the scientific evidence on which they are based, are compiled in the *Guide to Community Preventive Services (Community Guide)*.

DATES: The meeting will be held on Wednesday, June 22, 2016 from 8:30 a.m. to 6:00 p.m. EDT and Thursday, June 23, 2016 from 8:30 a.m. to 1:00 p.m. EDT.

ADDRESSES: The Task Force Meeting will be held at CDC Edward R. Roybal Campus, Tom Harkin Global Communications Center (Building 19), and 1600 Clifton Road NE., Atlanta, GA 30329. You should be aware that the meeting location is in a Federal government building; therefore, Federal security measures are applicable. For additional information, please see Roybal Campus Security Guidelines under **SUPPLEMENTARY INFORMATION**. Information regarding meeting logistics will be available on the Community Guide Web site (www.thecommunityguide.org).

Meeting Accessibility: This meeting is open to the public, limited only by space availability. All meeting attendees must RSVP to ensure the required security procedures are completed to gain access to the CDC’s Global Communications Center.

U.S. citizens must RSVP by June 20, 2016.

Non U.S. citizens must RSVP by May 23, 2016 due to additional security steps that must be completed. Failure to RSVP by the dates identified could result in the inability to attend the Task Force meeting due to the strict security regulations on federal facilities.

Meeting Accessibility: This meeting is available to the public via Webcast. The Webcast URL will be sent to you upon receipt of your RSVP. All meeting attendees must RSVP to receive the webcast information which will be emailed to you upon receipt of registration to the CPSTF@cdc.gov mailbox.

For Further Information and to RSVP Contact: Onslow Smith, Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-E-69, Atlanta, GA 30329, phone: (404) 498-6778, email: CPSTF@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of the meeting is for the Task Force to consider the findings of systematic reviews and issue findings and recommendations. Task Force recommendations provide information about evidence-based options that decision makers and stakeholders can consider when determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents.

Matters to be discussed: Cancer prevention and control, cardiovascular disease prevention and control, diabetes prevention and control, and increasing physical activity.

Roybal Campus Security Guidelines: The Edward R. Roybal Campus is the headquarters of the U.S. Centers for Disease Control and Prevention and is located at 1600 Clifton Road NE., Atlanta, Georgia. The meeting is being held in a Federal government building; therefore, Federal security measures are applicable.

All meeting attendees must RSVP by the dates outlined under *Meeting Accessibility*. In planning your arrival time, please take into account the need to park and clear security. All visitors must enter the Edward R. Roybal Campus through the front entrance on Clifton Road. Your car may be searched, and the guard force will then direct visitors to the designated parking area. Upon arrival at the facility, visitors must present government issued photo identification (e.g., a valid federal identification badge, state driver’s license, state non-driver’s identification card, or passport). Non-United States citizens must complete the required security paperwork prior to the meeting date and must present a valid passport, visa, Permanent Resident Card, or other type of work authorization document upon arrival at the facility. All persons entering the building must pass through a metal detector. Visitors will be issued a visitor’s ID badge at the entrance to Building 19 and may be escorted to the meeting room. All items brought to HHS/CDC are subject to inspection.

Dated: April 16, 2016.

Veronica Kennedy,

Acting Executive Secretary, Centers for Disease Control and Prevention.

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