

Dated: December 24, 2014.

Myles Vaughan,

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Management & Services Programs Division,
U.S. GSA, Mid-Atlantic Region.*

[FR Doc. 2014-30791 Filed 1-8-15; 8:45 am]

BILLING CODE 6820-89-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2015-0001]

Proposed Revised Vaccine Information Materials for Multiple Pediatric Vaccines (“Your Baby’s First 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 the proposed updated vaccine information statement for multiple pediatric vaccines.

DATES: Written comments must be received on or before March 10, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0001, 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 (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.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://www.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), 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>. Copies of the Vaccine Information Statements are found in the docket at www.regulations.gov (Docket CDC-2015-0001) under “Supporting and Related Materials.”

HHS/CDC is proposing an updated version of the multiple pediatric vaccines (“Your Baby’s First Vaccines”) vaccine information statement.

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 material entitled “Your Baby’s First Vaccines: What You Need to Know.” A copy of the proposed vaccine information statement is available at www.regulations.gov (see Docket ID CDC-2015-0001). 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.

Dated: January 5, 2015.

Ron A. Otten,

*Acting Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

[FR Doc. 2015-00171 Filed 1-8-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 79 FR 21760-21763, dated April 17, 2014) is amended to reflect the reorganization of the Office of Safety, Security and Asset Management.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete items (1), (2) and (3) of the functional statement for the *Office of Operations (CAJ13), Office of the*

Director (CAJS1), Office of the Safety, Security and Asset Management (CAJS), and renumber the remaining items accordingly.

Delete item (7) of the functional statement for the *Physical Security Laboratory and Technical Branch (CAJSEB)*, *Security Services Office (CAJSE)*, *Office of the Safety, Security and Asset Management (CAJS)*, and renumber remaining items accordingly.

Delete item (11) of the functional statement for the *Physical Security Operations Branch (CAJSEC)*, *Security Services Office (CAJSE)*, *Office of the Safety, Security and Asset Management (CAJS)*, and renumber remaining items accordingly.

After the mission statement for the *Security Services Office (CAJSE)*, insert the following:

Internal Emergency Management Branch (CAJSEE). To lead a comprehensive internal emergency management program that efficiently coordinates CDC resources to, first and foremost, protect lives, then to safeguard the environment and property through mitigation, preparedness training, response, continuity and recovery from all natural, man-made and technological hazards that may impact CDC facilities: (1) Implements, maintains, and updates CDC's Occupant Emergency Plan/Program (OEP); (2) conducts and evaluates annual tabletop, functional, and full-scale exercises for all CDC facilities with Designated Officials and Occupant Emergency Organizations (OEO); (3) recommends future emergency management and emergency response-related programs, policies, and/or procedures; (4) provides leadership and coordination in planning and implementation for internal emergencies; and (5) provides leadership and coordination in planning and implementation for internal emergency incidents affecting the CDC facilities, including incident response and support.

James D. Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2015-00146 Filed 1-8-15; 8:45 am]

BILLING CODE 4160-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of

Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 6772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 79 FR 32739-32740, dated June 7, 2014) is amended to reflect the reorganization of the Global Immunization Division within the Center for Global Health.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and the mission and function statements for the *Global Immunization Division (CWK)* and insert the following:

Global Immunization Division (CWK). The Global Immunization Division (GID) protects the health of Americans and global citizens by preventing disease, disability, and death worldwide from vaccine-preventable diseases. In carrying out its mission, GID: (1) Provides national leadership and coordination of the Center for Global Health (CGH) efforts to eradicate polio; eliminate measles and rubella in World Health Organization (WHO) regions; strengthens global surveillance to prevent, detect, and respond to vaccine preventable diseases; strengthens routine immunization programs; introduces new and under-utilized vaccines; and promotes safe injection practices in collaboration with international organizations and CDC Centers/Institute/Offices (CIOs); (2) provides technical expertise to global partners—WHO, United Nations International Children's Emergency Fund (UNICEF), Global Alliance for Vaccine Immunization (GAVI), and the Bill and Melinda Gates Foundation (BMGF)—involved in global immunization activities and participates in international advisory group meetings on immunization issues; (3) ensures provision of technical expertise on evidence-based research, strategies, and policy at global and country levels in collaboration with multilateral and bilateral partners; (4) collaborates with other countries and administers grants to WHO, Pan American Health Organization (PAHO), UNICEF, and other international partners and advocacy groups as appropriate for the provision of technical, programmatic, and laboratory support, and vaccine procurement for initiatives to support global immunization targets; (5) improves surveillance for polio, measles, rubella, and other vaccine preventable diseases by working with individual countries and the WHO regional offices to improve surveillance and to collaborate with groups within

and outside CDC to expand environmental surveillance; (6) achieves global immunization targets by supporting the strengthening of the implementation of national immunization policies; (7) strengthens appropriate vaccination policy development and implementation, identifies barriers to vaccine acceptance, and develops communication strategies to promote vaccine uptake and disease reduction; (8) develops strategies to improve the technical skills and problem-solving abilities of program managers and health care workers in other countries; (9) prepares immunization articles based on findings for publication in international professional journals and for presentation at international conferences; and (10) provides technical and operational leadership for CDC's activities in support of the initiatives.

Office of the Director (CWK1). (1) Provides leadership, management, and oversight for all division activities including administrative, budget, finance, research, workforce development, management and operations; (2) assists leadership in the formulation and defense of GID budget requests, and monitors and seeks strategies to mitigate division risks; (3) provides coordination and oversight of the division's personnel actions including liaison with CGH and CDC's human resource office; (4) provides oversight for workforce planning, recruitment, deployment, field staff support, professional development, and monitoring and evaluation; (5) develops and promotes partnerships with other organizations to support global immunization activities and works closely with partners in academia; (6) liaises and coordinates with other CDC offices engaged in global immunization activities; (7) provides leadership and oversight for scientific and programmatic activities related to the implementation of GID's objectives and ensures that the research and economic portfolios are integrated across the branches and with field activities; (8) identifies program policy priorities through strategic planning and other processes as appropriate; (9) clears all scientific publications from the division working in close collaboration with management of GID; (10) provides coordination of the division's communications activities including liaison with other CDC communications offices and those of our partner agencies; (11) represents CDC, CGH, and the division at global and national meetings and other fora for global immunization activities; (12) provides