

*Place:* Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027.

*Agenda:* To review and evaluate grant applications.

**FOR FURTHER INFORMATION CONTACT:**

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road, NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, (404) 718–8833, [ganderson@cdc.gov](mailto:ganderson@cdc.gov).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2021–00282 Filed 1–8–21; 8:45 am]

BILLING CODE 4163–18–P

## 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 March 12, 2021.

**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](mailto: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://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:**

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](mailto: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 website 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 is 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.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

**[OMB No. 0970–0356]**

#### **Submission for OMB Review; Formative Data Collections for ACF Research and Evaluation**

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) proposes to extend data collection under the existing overarching generic clearance for Formative Data Collections for ACF Research and Evaluation (OMB #0970–0356). There are no changes to the proposed types of information collection or uses of data, but the request does include an increase to the estimated number of respondents and, therefore, the overall burden estimate.

**DATES:** *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

#### **SUPPLEMENTARY INFORMATION:**

*Description:* ACF programs promote the

economic and social well-being of families, children, individuals, and communities. OPRE studies ACF programs, and the populations they serve, through rigorous research and evaluation projects. These include evaluations of existing programs, evaluations of innovative approaches to helping low-income children and families, research syntheses, and descriptive and exploratory studies. OPRE’s research serves to provide further understanding of current programs and service populations, explore options for program improvement, and assess alternative policy and program designs. OPRE anticipates undertaking a variety of new research projects related to welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, family and youth services, home visiting, child welfare, and other areas of interest to ACF. Under this generic clearance, ACF engages in a variety of formative data collections with researchers, practitioners, technical assistance providers, service providers, and potential participants throughout the field to fulfill the following goals: (1) Inform the development of ACF research, (2) maintain a research agenda that is rigorous and relevant, (3) ensure that research products are as current as possible, and (4) inform the provision of technical assistance. ACF uses a variety of techniques including semi-structured discussions, focus groups, surveys, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

*Respondents:* Example respondents include: key stakeholder groups involved in ACF projects and programs, state or local government officials, service providers, participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF research and programs, or others involved in conducting ACF research or evaluation projects.