

reach a pediatric audiology facility. For example, parents who reside in western region of Nebraska and Iowa on average have to drive over 100 miles and in Montana over 200 miles to reach a pediatric audiology facility.

CDC is requesting an Office of Management and Budget (OMB) approval to continue collecting audiology facility information from audiologists or facility managers so both parents, physicians and state EHDI programs will have a tool to find where the pediatric audiology facilities are located. This survey will continue to allow the CDC-EHDI team and state EHDI programs to compile a systematic, quantifiable distribution of audiology facilities and the capacity of each facility to provide services for children age five and younger. The data collected will also allow the CDC-EHDI team to analyze facility distribution data to improve technical assistance to state EHDI programs.

There will be no revision done to the survey because the data collected in the past three years has proven to be valuable and appropriate as evidenced by the high usage rate. Consumers have accessed the facility information over 140,000 times as of April 2016. To minimize burden and improve convenience, the survey will continue to be available via a secure password protected Web site. Placing the survey on the internet ensures convenient, on-demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to this survey.

EHDI-PALS currently has 1,005 facilities in the database since the beginning of the data collection. All 1,005 facilities' contact will receive a brief email from the University of Maine to remind them to review their survey answers. It is estimated that approximately 800 audiologists will do so. It takes approximately two minutes per person to review the survey

answers. Both the American Speech-Language-Hearing Association and the American Academy of Audiology are members of the EHDI-PALS workgroup and will continue to disseminate a request through association e-newsletters and e-announcements to all audiologists who provide services to children younger than five years of age to complete the EHDI-PALS survey. It is estimated that potentially an additional 400 new audiologists will read through the purpose statement located on page one of the survey to decide whether or not to complete the survey. This will take one minute per person. It is estimated that 200 audiologists will complete the survey which will average nine minutes per respondent. The nine minutes calculation is based on a previous timed pre-test with six volunteer audiologists. There are no costs to respondents other than their time.

The total burden hours are 64.

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Annual Survey Review .....	800	1	2/60	27
Survey Introduction .....	400	1	1/60	7
Survey .....	200	1	9/60	30
Total .....	1,400	.....	.....	64

#### 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-2016-0015]

#### Final Revised Vaccine Information Materials for Hepatitis A and Hepatitis B Vaccines

**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 February 8, 2016, CDC published a notice in the **Federal Register** (81 FR 6520) seeking public comments on proposed updated vaccine information materials for hepatitis A and hepatitis B vaccines. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials for hepatitis A and hepatitis B vaccines. Copies of the final vaccine information materials for hepatitis A and hepatitis B vaccines are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2016-0015).

**DATES:** Beginning no later than November 1, 2016, each health care provider who administers hepatitis A or hepatitis B 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 August 9, 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](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 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 hepatitis A and hepatitis B 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 hepatitis A and hepatitis B vaccines 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-2016-0015). The Vaccine Information Statements (VIS) are "Hepatitis A Vaccine: What You Need to Know" and "Hepatitis B Vaccine:

What You Need to Know," publication date July 20, 2016.

With publication of this notice, by November 1, 2016, all health care providers must discontinue use of the previous edition of each and provide copies of these updated hepatitis A and hepatitis B vaccine information materials prior to immunization in conformance with CDC's August 9, 2016 Instructions for the Use of Vaccine Information Statements.

Dated: September 1, 2016.

**Sandra Cashman,**

*Executive Secretary, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10287]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by November 7, 2016.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured

consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

#### CMS-10287 Medicare Quality of Care Complaint Form

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before