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 serogroup B meningococcal 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 serogroup B meningococcal 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–2015–0059). The Vaccine Information Statement (VIS) is ''Serogroup B Meningococcal (MenB) Vaccine: What You Need to Know,'' publication date August 9, 2016.

With publication of this notice, as of December 1, 2016, all health care providers will be required to provide copies of these updated serogroup B meningococcal 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.

[FR Doc. 2016–21574 Filed 9–7–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0029]

Final Revised Vaccine Information Materials for Polio 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 March 15, 2016, CDC published a notice in the **Federal Register** (81 FR 13794) seeking public comments on proposed updated vaccine information materials for polio vaccine and varicella vaccine. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials for polio vaccine. Copies of the final vaccine information materials for polio vaccine are available to download from *http://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2015–0029). CDC will publish the final vaccine information materials for varicella vaccine when they are completed.

DATES: Beginning no later than November 1, 2016, each health care provider who administers polio 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*), 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 polio 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 polio 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–2015–0029). The Vaccine Information Statement (VIS) is ''Polio 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 and provide copies of these updated polio 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.

[FR Doc. 2016–21575 Filed 9–7–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–16–0955; Docket No. CDC–2016–0089]

Proposed Data Collections Submitted for Public Comment and Recommendations

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as requires by the Paperwork Reduction Act of 1995. This notice invites comments on Early Hearing Detection and Intervention Pediatric Audiology Links to Services (EDHI–PALS)

DATES: Written comments must be received on or before November 7, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0089 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instruction for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, 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 *Regulation.gov,* including any personal information provided. For access to the docket to read the background documents or comments received, go to *Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, and each reinstatement of previously approved information collection before submitting the collect to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Early Hearing Detection and Intervention—Pediatric Audiology Links to Service (EHDI–PALS) Survey (OMB No. 0920–0955, Expiration 03/31/2017)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Human Development and Disability, located within NCBDDD, promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. Since the passage of the Early Hearing Detection and Intervention (EHDI) Act, 98% of newborn infants are now screened for hearing loss prior to hospital discharge. However, many of these infants have not received needed hearing tests and follow up services after their hospital discharges. The 2013 national average loss to follow-up/loss to documentation rate is at 32%. This rate remains an area of critical concern for state EHDI programs and CDC–EHDI team's goal of timely diagnosis by 3 months of age and intervention by 6 months of age. Many states cite the lack of audiology resources as the main factor behind the high loss to follow-up. To compound the problem, many pediatric audiologists may be proficient evaluating children age 5 and older but are not proficient with diagnosing infants or younger children because children age 5 and younger require a different skill set. There is still no existing literature or database available to help states verify and quantify their states' true follow up capacity until this project went live in 2013.

Meeting since April 2010, the EHDI–PALS workgroup has sought consensus on the loss to follow-up/loss to documentation issue facing the EHDI programs. A survey based on standard of care practice was developed for state EHDI programs to quantify the pediatric audiology resource distribution within their state, particularly audiology facilities that are equipped to provide follow up services for children age five and younger. After three years of data collection, data suggested that children residing in certain regions of the US who were loss to follow up were due to the distance parents had to travel to