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
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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[50Day–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 required by the Paperwork Reduction Act of 1995. This notice invites comments on Early Hearing Detection and Intervention Pediatric Audiology Links to Services (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).

Proposed Project


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 areas of the US who were lost to follow up were due to the distance parents had to travel to