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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0001]

Final Revised Vaccine Information Materials

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), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all healthcare providers are required to give to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) prior to administration of specific vaccines. On January 11, 2021, CDC published a notice in the **Federal Register** (86 FR 1977) seeking public comments on proposed updated vaccine information materials for vaccines covered by the National Vaccine Injury Compensation Program. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials. By March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization.

DATES: No later than March 31, 2022, each healthcare provider who administers a vaccine covered by the National Vaccine Injury Compensation Program to any child or adult in the United States shall discontinue use of previous editions and provide copies of the updated vaccine information materials referenced in this notice, in conformance with the CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021, prior to administering such vaccinations.

FOR FURTHER INFORMATION CONTACT: Suzanne Johnson-DeLeon, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop: H 24–6, 1600 Clifton Road NE, Atlanta, Georgia 30329. Telephone: (404) 639–8817.

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 (the Secretary) to develop and disseminate vaccine information materials for distribution by all healthcare providers in the United States to any patient (or to the patient's parent or legal representative in the case where the patient is a minor child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials, also known as Vaccine Information Statements, have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires 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 healthcare provider and parent organizations, and the Food and Drug Administration. Section 2126 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 healthcare 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 website at: *https://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html.*

Revised Vaccine Information Materials

The revised 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 pertaining to vaccines covered under the National Vaccine Injury Compensation Program have been finalized and are available to download from *https://www.cdc.gov/vaccines/hcp/vis/index.html* or *http://www.regulations.gov* (see Docket Number CDC–2021–0001). The revised Vaccine Information Statements are the following:

''DTaP (Diphtheria, Tetanus, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Hepatitis A Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Hepatitis B Vaccine: What You Need to Know,'' publication date October 15, 2021.

''*Haemophilus influenzae* type b (Hib) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''HPV (Human Papillomavirus) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Live, Intranasal): What You Need to Know,'' publication date August 6, 2021.

''Influenza (Flu) Vaccine (Inactivated or Recombinant): What You Need to Know,'' publication date August 6, 2021.

''MMR Vaccine (Measles, Mumps, and Rubella): What You Need to Know,'' publication date August 6, 2021.

''MMRV Vaccine (Measles, Mumps, Rubella, and Varicella): What You Need to Know,'' publication date August 6, 2021.

''Meningococcal ACWY Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Meningococcal B Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know,'' publication date August 6, 2021.

''Polio Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Rotavirus Vaccine: What You Need to Know,'' publication date October 15, 2021.

''Tdap (Tetanus, Diphtheria, and Pertussis) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Td (Tetanus and Diphtheria) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Varicella (Chickenpox) Vaccine: What You Need to Know,'' publication date August 6, 2021.

''Your Child's First Vaccines: What You Need to Know,'' publication date October 15, 2021.

With publication of this notice, by March 31, 2022, all healthcare providers must discontinue use of the previous editions and provide copies of these updated vaccine information materials prior to immunization in conformance with CDC Instructions for Use of Vaccine Information Statements dated October 15, 2021.

Dated: December 20, 2021.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–22–0852]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 13, 2021 to obtain comments from the public and affected agencies. CDC received one non-substantive comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use in U.S. Acute Care Hospitals (OMB Control No. 0920–0852, Exp. 10/31/2022)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) and improving antimicrobial use (AU) are CDC and national priorities. An essential step in reducing the occurrence of HAIs is to accurately estimate the burden of these infections in U.S. acute care hospitals and to describe the types of HAIs and causative pathogens. Periodic assessments of the magnitude and types of HAIs and AU occurring in all patient populations within acute care hospitals are needed to inform decisions by policy makers and hospital infection control personnel (ICP) regarding appropriate targets and strategies for HAI prevention and antimicrobial stewardship.

Since 2009, CDC has conducted four prevalence surveys (*i.e.,* pilot survey in 2009, limited-scale survey in 2010, and two full-scale surveys in 2011 and 2015) in partnership with the CDC's Emerging Infections Program (EIP) sites. Findings from the most recent survey showed a reduction in the percentage of patients with healthcare-associated infections compared with 2011. We granted approval from OMB to conduct the fifth survey in 2020, but due to the COVID–19 pandemic the survey was postponed to 2023.

Minor adjustments to data collection instruments since the previous 2019 OMB approval have been made. These adjustments were made to enhance future analyses and utility of the survey data. These changes are non-substantive and are not expected to increase the public reporting burden. An extension of the prevalence survey's existing OMB approval is sought to allow a repeat HAI and AU Prevalence Survey to be performed in 2023. A repeat survey will allow assessment of changes in HAI and AU prevalence, pathogen distribution, and quality of antimicrobial prescribing. These data will also allow CDC and its partners to continue to monitor HAI and AU trends, to measure progress in meeting national targets, and to further refine prevention strategies.

In the 2023 survey, data collection will occur within acute care general hospitals of varying size in each of the 10 EIP sites (*i.e.,* CA, CO, CT, GA, MD, MN, NM, NY, OR, & TN). Infection Control Personnel in participating hospitals may assist EIP site personnel in collecting demographic and limited clinical data from the electronic or paper-based medical records of a sample of randomly selected patients on a single day in 2023. Patients will not be interviewed, and no direct interaction with patients will occur. Hospital and patient-level data will be collected using unique identification codes. EIP site personnel will submit hospital and patient-level data to CDC using a secure data management system.

Based on experiences from previous surveys, the time required to complete the Healthcare Facility Assessment Form (HFA) and Patient Information Form (PIF) is estimated to be 45 and 17 minutes, respectively. To conduct the full-scale survey in a three-year approval period, 100 hospital respondents will complete the HFA once, and the PIF on average 63 times per year. The total estimated annualized public burden is 1,860 hours, which represents no change from the 2019 OMB approval.

To assess changes in HAIs and AU over time, EIP sites will seek participation from the same hospitals that participated in prior surveys. These hospitals were originally selected for participation using a stratified random