

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|----------------------------------|--|-----------------------|------------------------------------|--|
| Safety and Health Managers | Occupational Safety and Health Program Survey. | 4,404 | 1 | 20/60 |
| | Informed Consent Form | 4,404 | 1 | 2/60 |
| | Non Responder Interview | 792 | 1 | 5/60 |

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.

[FR Doc. 2015-25194 Filed 10-2-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Initial review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) PS16-001, Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers.

DATES: 10:00 a.m.–5:00 p.m., December 9–10, 2015 (Closed).

ADDRESSES: Teleconference.

FOR FURTHER INFORMATION CONTACT:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718-8833.

SUPPLEMENTARY INFORMATION:

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of

applications received in response to “Minority HIV/AIDS Research Initiative (MARI) to Build HIV Prevention Treatment and Research Capacity in Disproportionately Affected Black and Hispanic Communities and Among Historically Underrepresented Researchers”, FOA PS16-001.

The Director, Management Analysis and Services Office, 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.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, 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-2015-0016]

Final Revised Vaccine Information Materials for Seasonal Influenza 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), the HHS/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 May 20, 2015, CDC published a notice in the **Federal Register** (80 FR 29009) seeking public comments on proposed new vaccine information materials for inactivated and live attenuated influenza vaccines. Following review of comments submitted and consultation as required

under the law, CDC has finalized the materials. Copies of the final vaccine information materials for inactivated and live attenuated influenza vaccines are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC-2015-0016).

DATES: Beginning no later than March 1, 2016, each health care provider who administers any seasonal influenza vaccine to any child or adult in the United States shall provide copies of the relevant revised vaccine information materials contained in this notice, in conformance with the August 7, 2015 CDC Instructions for the Use of Vaccine Information Statements prior to providing such vaccinations. These revised vaccine information materials may also be used earlier than that date. Prior to March 1, 2016, the previous edition of these two VISs can be used.

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 revised inactivated and live attenuated influenza 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 inactivated and live attenuated influenza 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-2015-0016). The Vaccine Information Statements (VIS), are: “Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know” (publication date August 7, 2015) and

“Influenza (Flu) Vaccine (Live, Intranasal): What you need to know” (publication date August 7, 2015).

With publication of this notice, as of March 1, 2016, all health care providers will be required to provide copies of these updated inactivated and live attenuated influenza vaccine information materials prior to immunization in conformance with HHS/CDC’s August 7, 2015 Instructions for the Use of Vaccine Information Statements. Prior to that date, the previous edition of these two VISs can be used.

Dated: September 29, 2015.

Sandra Cashman,

Acting Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10565]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *November 4, 2015*.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

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.

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

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

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. 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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Off-cycle Submission of Summaries of Model of Care Changes; *Use:* All Medicare Advantage (MA) Special Needs Plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA). The SNPs must submit Models of Care (MOC) as a component of the Medicare Advantage application process. Approval is based