

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0059]

Final Revised Vaccine Information Materials for Meningococcal ACWY 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 October 14, 2015, CDC published a notice in the **Federal Register** (80 FR 61819) seeking public comments on proposed updated vaccine information materials for Meningococcal ACWY and Serogroup B Meningococcal vaccines. Following review of comments submitted and consultation as required under the law, CDC has finalized the materials for Meningococcal ACWY vaccines. Copies of the final vaccine information materials for Meningococcal ACWY vaccines are available to download from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.regulations.gov> (see Docket Number CDC–2015–0059). CDC will publish the final vaccine information materials for Serogroup B Meningococcal vaccines when they are completed.

DATES: Beginning no later than July 1, 2016, each health care provider who administers Meningococcal ACWY 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 March 31, 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 Meningococcal ACWY 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 meningococcal ACWY 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–2015–0059). The Vaccine Information Statement (VIS) is “Meningococcal ACWY Vaccines (MenACWY and MPSV4): What You Need to Know,” publication date March 31, 2016.

With publication of this notice, as of July 1, 2016, all health care providers will be required to provide copies of these updated meningococcal ACWY vaccine information materials prior to immunization in conformance with CDC’s March 31, 2016 Instructions for the Use of Vaccine Information Statements.

Dated: April 15, 2016.

Veronica Kennedy,
Acting Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2016–09166 Filed 4–19–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: The Tribal TANF Financial Report (ACF–196T).

OMB No.: 0970–0345.

Description: Tribes use Form ACF–196T to report expenditures for the Tribal TANF grant. Authority to collect and report this information is found in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), Public Law 104–193. Tribal entities with approved Tribal plans for implementation of the TANF program are required by Section 412(h) of the Social Security Act to report financial data. Form ACF–196T provides for the collection of data regarding Federal expenditures. Failure to collect this data would seriously compromise the Administration for Children and Families’ (ACF) ability to monitor expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget

submissions to Congress. Financial management of the program would be seriously compromised if the expenditure data were not collected.

45 CFR part 286 Subpart E requires the strictest controls on funding requirements, which necessitates review of documentation in support of Tribal expenditures for reimbursement.

Comments received from previous efforts to implement a similar Tribal TANF report Form ACF-196T were used to guide ACF in the development of the product presented with this submittal.

Respondents: All approved Tribal TANF Agencies. Those with consolidated Tribal TANF programs

plans under 102-477 may submit the Tribal TANF Financial Report to BIA with a copy to: ACF Division of Mandatory Grants, 330 C Street SW., Washington, DC 20201. Or at their convenience may elect to use the On-Line Data Collection System to electronically submit their quarterly Tribal TANF Financial Report.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-196T	72	4	1.25	360

Estimated Total Annual Burden Hours: 360.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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)

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.
 [FR Doc. 2016-09123 Filed 4-19-16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Form ACF-696T, "Child Care and Development Fund Annual Financial Report for Tribes"

OMB No.: 0970-0195.

Description: This form is used by Tribes and Tribal Organizations that have been approved as grantees to administer the Child Care and Development Fund program (CCDF). This form is submitted annually to report CCDF program expenditures to the Administration for Children and Families.

The authority to collect and report this information can be found in Section 658G of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101-508), as amended, and in Federal regulations at 45 CFR 98.65(g) and 98.67(c)(1) which authorize the Secretary to require financial reports as necessary.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
<i>Form ACF-696T, "Child Care and Development Fund Annual Financial Report for Tribes"</i>	272	1	6	1,632

Estimated Total Annual Burden Hours: 1,632.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All

requests should be identified by the title of the information collection.

The Department specifically requests comments 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