IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled “Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable” have been approved under OMB control number 0910–0582.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: August 10, 2015.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015–20136 Filed 8–13–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 3, 2015, 9:00 a.m. to 4:30 p.m. EDT.

Place: Parklawn Building (and via audio conference call and Adobe Connect), 5600 Fishers Lane, Room 10–65, Rockville, MD 20857.

The ACCV will meet on Thursday, September 3, 2015, from 9:00 a.m. to 4:30 p.m. (EDT). The public can join the meeting by:

1. (In Person) Persons interested in attending the meeting in person are encouraged to submit a written notification to: Annie Herzog, DICP, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Since this meeting is going to be held in a federal government building, attendees will need to go through a security check to enter the building and participate in the meeting. Written notification is encouraged so a list of attendees can be provided to Annie Herzog to make entry through security quicker.

Persons may attend in person without providing written notification, but their entry into the building may be delayed due to security checks and the requirement to be escorted to the meeting by a federal government employee. To request an escort to the meeting after entering the building, call Mario Lombre at 301–443–3196. The meeting will be held at the Parklawn Building, 5600 Fishers Lane, Room 10–65, Rockville, Maryland 20857.

2. (Audio Portion) The conference phone number is 877–917–4913. When calling, provide the following information:

Leaders Name: Dr. A. Melissa Houston. Password: ACCV.

3. (Visual Portion) Connect to the ACCV Adobe Connect Pro meeting using the following URL: https://hrsa.connectsolutions.com/accv/ (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_text.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview. Call (301) 443–6634 or send an email to aherzog@hrsa.gov if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the September 2015 meeting will include, but are not limited to: updates from ACCV Adult Immunization Workgroup, the Division of Injury Compensation Programs (DICP), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (http://www.hrsa.gov/vaccinecompensation/ accv.htm) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DICP, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DICP will notify each presenter by email, mail, or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time allotted per person.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–6593, or email: aherzog@hrsa.gov.

Jackie Painter,
Director, Division of the Executive Secretariat.

[FR Doc. 2015–20136 Filed 8–13–15; 8:45 am]
BILLING CODE 4165–15–P
Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 14, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Outreach Benefits Counseling Program Measures OMB No. 0915–XXXX—NEW.

Abstract: The Rural Outreach Benefits Counseling Program (Benefits Counseling Program) is authorized by Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)), Public Law 113–76 as amended to “promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas.” The purpose of the 3-year Benefits Counseling Program is to expand outreach, education and enrollment efforts to eligible uninsured individuals and families, and newly insured individuals and families in rural communities.

The overarching goal of this grant program is to coordinate and conduct innovative outreach activities through a strong consortium in order to: (1) Identify and enroll uninsured individuals and families who are eligible for public health insurance such as Medicare, Medicaid, and Children’s Health Insurance Program; qualified health plans offered through Health Insurance Marketplaces; and/or private health insurance plans in rural communities; and, (2) educate the newly insured individuals in rural communities about their health insurance benefits, help connect them to primary care and preventive services to which they now have access, and help them retain their health insurance coverage.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) benefits counseling process and outcomes. Several measures will be used for the Benefits Counseling Program. All measures will speak to FORHP’s progress toward meeting the goals set.

A 60-day Federal Register Notice was published in the Federal Register on June 1, 2015 (80 FR 31051). There were no comments.

Likely Respondents: The respondents would be recipients of the Rural Outreach Benefits Counseling grant funding.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

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Jackie Painter, Director, Division of the Executive Secretariat.

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Advisory Committee on Children and Disasters

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) will be holding a meeting via teleconference. The meeting is open to the public.

DATES: The August 27, 2015, NACCD meeting is scheduled from 3:00 p.m. to 4:00 p.m. EST. The agenda is subject to change as priorities dictate. Please check the NACCD Web site, located at WWW.PHE.GOV/NACCD for the most up-to-date information on the meeting.

ADDRESSES: To attend the meeting via teleconference, call toll-free: 1–888–989–6485, international dial-in: 1–312–470–0178. The pass-code is: 5885575. Please call 15 minutes prior to the beginning of the conference call to facilitate attendance. Pre-registration is required for public attendance. Individuals who wish to attend the meeting should submit an inquiry via the NACCD Contact Form located at www.phe.gov/NACCDComments.

FOR FURTHER INFORMATION CONTACT: Please submit an inquiry via the NACCD Contact Form located at www.phe.gov/ NACCDComments.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as