

Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

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

Healthcare Infection Control Practices Advisory Committee (HICPAC)

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 the following meeting for the aforementioned committee:

Times and Dates

9:00 a.m.–5:00 p.m., December 4, 2014

9:00 a.m.–12:00 p.m., December 5, 2014

Place: Emory Conference Center, The Silverbell Pavilion, 1615 Clifton Rd, Atlanta, Georgia, 30329.

Status: Open to the public, limited only by the space available. Please register for the meeting at www.cdc.gov/hicpac.

Purpose: The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion, the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters for Discussion: The agenda will include updates on CDC's activities for prevention of healthcare associated infections (HAIs), updates on antimicrobial resistance, an update on Draft Guidelines, and updates on healthcare preparedness and emerging infections.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Erin Stone, M.S., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE., Mailstop A-07, Atlanta, Georgia 30333 Telephone (404) 639-4045. Email: hicpac@cdc.gov

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.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10371]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed. We are seeking emergency approval for modifications to the information collection request (ICR)

currently approved under Office of Management and Budget (OMB) control number 0938-1119 in order to collect additional information during the 2015 open enrollment periods from the 14 operational SBMs (including Washington, DC) to enhance the agency's understanding of the demographic makeup of the citizens enrolling in the various health plans as well as the affordability of those plans. Existing collections gather information from the grant awardee to ensure the CMS is able to conduct their statutory oversight responsibilities. The revision to the weekly reporting requirement is necessary to obtain more accurate and consistent enrollment data during the upcoming Open Enrollment Period which begins November 15, 2014. The immediate need for this revision is due to the State-Based Marketplaces (SBM) maturing business processes and the requirement for more precise reporting of comparison data between the first and second years of ACA implementation. The changes to the revised format of the Weekly Report have been presented to all participating states. CMS is requesting an emergency modification to the weekly reporting template in order to capture certain demographic data and information on new versus re-enrolled individuals in accordance with uniform definitions so as not to produce misleading results.

DATES: Comments must be received by November 14, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS-10371/OMB Control Number 0938-1119, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10371 Cooperative Agreement To Support Establishment of State-Operated Health Insurance Exchanges

Under the 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. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Cooperative Agreement to Support Establishment of State-Operated Health Insurance Exchanges; *Use:* Section 1311 of the Affordable Care Act provides for grants to States for the planning and establishment of Marketplaces. Given the innovative nature of Marketplaces and the statutorily-prescribed relationship between the Secretary and States in their development and operation, it has been critical that the Secretary work closely with States to

provide necessary guidance and technical assistance to ensure that States can meet the prescribed timelines, federal requirements, and goals of the statute. These grants are funded through the Health Insurance Marketplaces Cooperative Agreement to Support Establishment of the Affordable Care Act's Health Insurance Exchanges (Funding Opportunity Number: IE-HBE-12-001). A critical part of this guidance and assistance is the collection of precise information to measure the performance of the individual exchanges.

The revised data collection instrument has been developed in coordination with the states, based on an understanding of their current data collection efforts and capabilities. The tool will enable us to: (1) Distinguish new enrollees from renewals; (2) capture language preference (Spanish, other language, or no preference) to assist in targeting potentially underserved individuals; (3) obtain a better understanding of enrollment activity by certain demographic breakdowns to better target our activities through more refined cross-tabulations of data by age and gender, by age and Metal Level, and by financial assistance status (with/without) and Metal Level; (4) distinguish Special Enrollment Period activity for the 2014 coverage year during the period that overlaps with the first 2.5 months of Open Enrollment [November 15-December 31] in order to avoid contamination of 2015 data, to assess the extent of Special Enrollment activity during the last phase of 2014 activity; (5) identify stand-alone dental plans to better measure the extent to which individuals are enrolling in these products in order to provide input into ASPE's monthly report to the public; (6) codify providing enrollment data for all issuers in the individual marketplaces, if available, compared to the template that asks only for the top three in the individual marketplaces [These data, if available, have been provided to us as a write-in to the previous template on a voluntary basis.]. *Form Number:* CMS-10371 (OMB control number: 0938-1119); *Frequency:* Weekly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 16; *Total Annual Responses:* 208; *Total Annual Hours:* 6,240. (For policy questions regarding this collection contact Dena Puskin 301-492-4342.)

We are requesting OMB review and approval of this collection by November 15, 2014, with a 180-day approval period. Written comments and recommendations will be considered

from the public if received by the date and address noted above.

Dated: November 4, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-26584 Filed 11-5-14; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 5, 2014, from 8 a.m. to 4:30 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, The Ballroom, 3501 University Blvd. East, Adelphi, MD 20783. The conference center's telephone number is 301-985-7300.

Contact Person: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, AIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.