

intervals, most recently, August 3, 2011, and will expire on August 3, 2013.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: The agenda for the conference call includes: SEC Petition for Battelle Laboratories—King Avenue (Columbus, Ohio); Subcommittee and Work Group Updates; SEC Petition Evaluations Update for the December 2012 Advisory Board Meeting; Plans for December 2012 Advisory Board Meeting; and Advisory Board Correspondence.

The agenda is subject to change as priorities dictate. Because there is not an oral public comment period, written comments may be submitted. Any written comments received will be included in the official record of the meeting and should be submitted to the contact person below in advance of the meeting.

Contact Person for More Information: Theodore M. Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road NE., Mailstop: E-20, Atlanta, Georgia 30333, Telephone (513)533-6800, Toll Free 1-800-CDC-INFO, Email ocas@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.

Dated: October 5, 2012.

John Kastenbauer,

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 Medicare & Medicaid Services

[Document Identifier: CMS-10237 and CMS-10137]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment.

Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Part C Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* Collection of this information is mandated in Part C of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) in Subpart K of 42 CFR 422 entitled "Contracts with Medicare Advantage Organizations." In addition, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended titles XVII and XIX of the Social Security Act to improve the Medicare program.

In general, coverage for the prescription drug benefit is provided through prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA) organizations that offer integrated prescription drug and health care products (MA-PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) either must offer a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA-PFFS) may

choose to offer enrollees a Part D benefit. Employer Group Plans may also provide Part D benefits. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application, file a bid, and receive final approval from CMS. Existing MA plans may request to expand their contracted service area by completing the Service Area Expansion (SAE) application. Applicants may offer a local MA plan in a county, a portion of a county (i.e., a partial county) or multiple counties. Applicants may offer a MA regional plan in one or more of the 26 MA regions.

Since the publication of the 60-day notice, the information collection request has been revised to provide clarification to applicants, to ensure consistency throughout the entire application, and to reduce confusion among applicants. As a result of those changes, the overall burden associated with the collection has decreased from 22,995 to 21,581 hours. *Form Number:* CMS-10237 (OCN 0938-0935). *Frequency:* Yearly. *Affected Public:* Private Sector (Business or other for-profits, Not-for-profit institutions). *Number of Respondents:* 566. *Total Annual Responses:* 566. *Total Annual Hours:* 21,581. (For policy questions regarding this collection contact Barbara Gullick at 410-786-0563. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Application for New and Expanding Medicare Prescription Drug Plans and Medicare Advantage Prescription Drug (MA-PD), including Cost Plans and Employer Group Waiver Plans; *Use:* The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the voluntary Prescription Drug Benefit Program ("Part D"). The MMA was amended on July 15, 2008 by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), on March 23, 2010 by the enactment of the Patient Protection and Affordable Care Act and on March 30, 2010 by the

enactment the Health Care and Education Reconciliation Act of 2010 (collectively the Affordable Care Act).

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in Subpart K of 42 CFR 423 entitled "Application Procedures and Contracts with PDP Sponsors."

Effective January 1, 2006, the Part D program established an optional prescription drug benefit for individuals who are entitled to Medicare Part A or enrolled in Part B. In general, coverage for the prescription drug benefit is provided through PDPs that offer drug-only coverage, or through MA organizations that offer integrated prescription drug and health care coverage (MA-PD plans). PDPs must offer a basic drug benefit. Medicare Advantage Coordinated Care Plans (MA-CCPs) must offer either a basic benefit or may offer broader coverage for no additional cost. Medicare Advantage Private Fee for Service Plans (MA-PFFS) may choose to offer a Part D benefit. Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Plans may also provide a Part D benefit. If any of the contracting organizations meet basic requirements, they may also offer supplemental benefits through enhanced alternative coverage for an additional premium.

Applicants may offer either a PDP or MA-PD plan with a service area covering the nation (i.e., offering a plan in every region) or covering a limited number of regions. MA-PD and Cost Plan applicants may offer local plans.

There are 34 PDP regions and 26 MA regions in which PDPs or regional MA-PDs may be offered respectively. The MMA requires that each region have at least two Medicare prescription drug plans from which to choose, and at least

one of those must be a PDP.

Requirements for contracting with Part D Sponsors are defined in Part 423 of 42 CFR.

This clearance request is for the information collected to ensure applicant compliance with CMS requirements and to gather data used to support determination of contract awards. *Form Number:* CMS-10137(OCN: 0938-0936); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 241; *Total Annual Responses:* 241; *Total Annual Hours:* 2,132. (For policy questions regarding this collection contact Linda Anders at 410-786-0459. For all other issues call 410-786-1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on November 13, 2012.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: October 5, 2012.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Risk Communication 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: Risk Communication 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 November 2, 2012, from 8 a.m. to 3 p.m.

Location: FDA White Oak Campus, Building 31 Conference Center, Great

Room, 10903 New Hampshire Ave., Silver Spring, MD 20993. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Lee L. Zwanziger, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3278, Silver Spring, MD 20993, 301-796-9151, FAX: 301-847-8611, email: RCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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.

Agenda: On November 2, 2012, the Committee will discuss general factors in risk communication about FDA regulated products, including approaches to avoid message fatigue and related communication barriers such as prevention or warning fatigue or inaccurate risk perception.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 25, 2012. Oral presentations from the public will