

400. (For policy questions regarding this collection contact JoAnn Cerne at 410-786-4530. For all other issues call 410-786-1326.)

**4. Type of Information Collection Request:** Revision of a currently approved Collection; **Title of Information Collection:** Home Health Advance Beneficiary Notice (HHABN); **Use:** Home health agencies (HHAs) are required to provide written notice to Medicare beneficiaries under various circumstances involving the initiation, reduction, or termination of services. The vehicle used in these situations is the Home Health Advance Beneficiary Notice (HHABN). The notice is designed to ensure that beneficiaries receive complete and useful information regarding potential financial liability or any changes made to their plan of care (POC) to enable them to make informed consumer decisions. The notice must provide clear and accurate information about the specified services and, when applicable, the cost of services when Medicare denial of payment is expected by the HHA. **Form Number:** CMS-R-296 (OMB#: 0938-0781); **Frequency:** Reporting—Hourly, Daily, Weekly, Monthly, Yearly, Quarterly, Semi-annually, Biennially, Once and Occasionally; **Affected Public:** Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 9024; **Total Annual Responses:** 12,349,787; **Total Annual Hours:** 1,028,737. (For policy questions regarding this collection contact Evelyn Blaemire at 410-786-1803. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (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 August 31, 2009.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, e-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: July 23, 2009.

**Michelle Shortt,**

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

[FR Doc. E9-18379 Filed 7-30-09; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10191]

#### Agency Information Collection Activities: Proposed Collection; 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) 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 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.

**1. Type of Information Collection Request:** Revision of a currently approved collection; **Title of Information Collection:** Medicare Parts C and D Universal Audit Guide; **Use:** Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR parts 422 and 423 Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. 42 CFR 422.502 describes CMS' regulatory authority to evaluate, through inspection or other means, Medicare Advantage Part C organizations. These records include books, contracts, medical records, patient care documentation and other records that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable. 42 CFR 423.503 states that CMS must oversee a Part D plan

sponsor's continued compliance with the requirements for a Part D plan sponsor. § 423.514 states that the Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics regarding areas such as cost of operations, patterns of utilization availability, accessibility, and acceptability of services.

The explosive growth of these sponsoring organizations has forced CMS to update its current auditing strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy will reflect a move away from routine audits to more targeted, data-driven and risk-based audits. CMS will also focus on high-risk areas that have the greatest potential for beneficiary harm. The goal of the audits will be the earliest possible detection and correction of issues and improvement in quality and performance of Part D sponsors and Medicare Advantage organizations.

To accomplish these goals, we have combined all Part C and Part D audit elements into one universal guide which will also promote consistency, effectiveness and reduce financial and time burdens for both CMS and Medicare-contracting entities. Please refer to the crosswalk document for a list of changes. **Form Number:** CMS-10191 (OMB#: 0938-1000); **Frequency:** Reporting—Yearly; **Affected Public:** Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 195; **Total Annual Responses:** 195; **Total Annual Hours:** 24,180. (For policy questions regarding this collection contact Laura Dash at 410-786-8623. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *September 29, 2009*:

**1. Electronically.** You may submit 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) 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: Document Identifier/OMB Control Number (CMS-10078), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: July 23, 2009.

**Michelle Shortt,**

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

[FR Doc. E9-18378 Filed 7-30-09; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0352]

#### Preparation for International Cooperation on Cosmetics Regulations Meetings in Tokyo, Japan; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulations (ICCR)—Preparation for ICCR—3 Meetings in Tokyo, Japan" to provide information and receive comments on the International Cooperation on Cosmetics Regulations (ICCR) as well as the upcoming meetings in Tokyo, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICCR steering committee meeting. The purpose of the meeting is to solicit public input prior to the next steering committee and expert working group meetings in Tokyo, Japan, scheduled for the week of September 7, 2009.

**Date and Time:** The meeting will be held on September 2, 2009, from 1:30 p.m. to 3 p.m.

**Location:** The meeting will be held in University Station, rm. 2073, 4300 River Rd., College Park, MD 20740.

**Contact Person:** All participants must register with Mary Morrison, Office of the Commissioner (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: [mary.morrison@fda.hhs.gov](mailto:mary.morrison@fda.hhs.gov), FAX: 301-827-0003.

**Registration and Requests for Oral Presentations:** Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentation, to the contact person by August 30, 2009.

If you need special accommodations due to a disability, please contact Mary Morrison (see *Contact Person*) at least 7 days in advance.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:** The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics' industry trade associations. Currently, the ICCR members are Health Canada; the European Directorate General for Enterprise and Industry; the Ministry of Health, Labor and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by the consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will require input from stakeholders.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by August 30, 2009, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses,

telephone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at <http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/default.htm>.

Dated: July 27, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-18321 Filed 7-30-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Insulin Binding and Signaling.

**Date:** August 20, 2009.

**Time:** 1:30 p.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call)

**Contact Person:** Lakshmanan Sankaran, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, [ls38z@nih.gov](mailto:ls38z@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Immunology in Liver Disease.