

computer problems or lack of software or memory card compatibility. Please note that CMS headquarters is a smoke-free facility.

**Authority:** Section 503 of Public Law 108-173.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 1, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-4112-N]

#### Medicare Program; Meeting of the Advisory Panel on Medicare Education, January 26, 2006

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92-463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on January 26, 2006. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public.

**DATES:** The meeting is scheduled for January 26, 2006 from 9 a.m. to 3:30 p.m., e.s.t.

**Deadline for Presentations and Comments:** January 19, 2006, 12 noon, e.s.t.

**ADDRESSES:** The meeting will be held at the Wyndham City Center, 1143 New Hampshire Avenue, NW., Washington, DC 20036, (202) 775-0800.

**FOR FURTHER INFORMATION CONTACT:** Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2-23-05, Baltimore, MD 21244-1850, (410) 786-

0090. Please refer to the CMS Advisory Committees' Information Line (1-877-449-5659 toll free)/(410-786-9379 local) or the Internet (<http://www.cms.hhs.gov/faca/apme/default.asp>) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at [Lynne.Johnson@cms.hhs.gov](mailto:Lynne.Johnson@cms.hhs.gov). Press inquiries are handled through the CMS Press Office at (202) 690-6145.

**SUPPLEMENTARY INFORMATION:** Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of Health and Human Services (the Secretary) the authority to establish an advisory panel for the purpose of advising the Secretary in connection with any of his functions. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 14, 2005. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

*The goals of the Panel are as follows:*

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

*The current members of the Panel are:* Dr. Drew E. Altman, President and Chief Executive Officer, Henry J. Kaiser Family Foundation; Dr. Jane Delgado, Chief Executive Officer, National Alliance for Hispanic Health; Clayton Fong, President and Chief Executive Officer, National Asian Pacific Center on Aging; Thomas Hall, Chairman and Chief Executive Officer, Cardio-Kinetics, Inc.; The Honorable Bobby Jindal, United States Congress; David Knutson, Director, Health System Studies, Park Nicollet Institute for Research and Education; Dr. David Lansky, Director, Health Program, Markle Foundation; Dr. Frank I. Luntz, President and Chief Executive Officer, Luntz Research

Companies; Dr. Daniel Lyons, Senior Vice President, Government Programs, Independence Blue Cross; Dr. Frank B. McArdle, Manager, Hewitt Research Office, Hewitt Associates, Katherine Metzger, Director, Medicare and Medicaid Programs, Fallon Community Health Plan; Dr. Keith Mueller, Professor and Section Head, Health Services Research and Rural Health Policy, University of Nebraska; Lee Partridge, Senior Health Policy Advisor, National Partnership for Women and Families; Dr. Marlon Priest, Professor of Emergency Medicine, University of Alabama at Birmingham; Susan O. Raetzman, Associate Director, Public Policy Institute, AARP; Rebecca Snead, Administrative Manager, National Council of State Pharmacy Association Executives; Catherine Valenti, Chairperson and Chief Executive Officer, Caring Voice Coalition, and Grant Wedner, Manager, Business Development Team, Cosmix Corporation.

*The agenda for the January 26, 2006 meeting will include the following:*

- Recap of the previous (September 27, 2005) meeting.
- Centers for Medicare & Medicaid Services update.
- Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173): outreach and education strategies.
- Public comment.
- Listening session with CMS leadership.
- Next steps.

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2-23-05, Baltimore, MD 21244-1850 or by e-mail at [Lynne.Johnson@cms.hhs.gov](mailto:Lynne.Johnson@cms.hhs.gov), no later than 12 noon, e.s.t., January 19, 2006. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to Ms. Johnson by 12 noon, (e.s.t.), January 19, 2006. The meeting is open to the public, but attendance is limited to the space available.

**Special Accommodation:** Individuals requiring sign language interpretation or other special accommodations should contact Ms. Johnson at least 15 days before the meeting.

**Authority:** Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102-3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 16, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E5-7757 Filed 12-22-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0484]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting.

**DATES:** Submit written or electronic comments on the collection of information by February 21, 2006.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** 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. "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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Medical Device Reporting; Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910-0437)

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63578 at 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform to the changes reflected in the FDA Modernization Act of 1997.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19	55	4	220	3	660
803.30	700	5	3,500	1	3,500
803.33, FDA Form 3419	700	1	700	1	700
803.40	40	17	680	1	680
803.50	1,465	57	83,505	1	83,505
803.55, FDA Form 3417	700	5	3,500	1	3,500
Total					92,545

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.