

contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Jennifer Kordonski, (410) 786-1840, or on the Internet at http://www.cms.gov/FACA/04_APOE.asp for additional information. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

SUPPLEMENTARY INFORMATION:

In accordance with section 10(a) of the Federal Advisory Committee Act (FACA), this notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel). Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is "in the public interest in connection with the performance of duties imposed * * * by law." Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for "activities * * * to broadly disseminate information to [M]edicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options."

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2011 (76 FR 11782, March 3, 2011).

Pursuant to the amended charter, the Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for,

Medicare, Medicaid and the Children's Health Insurance Program (CHIP).

- Enhancing the Federal government's effectiveness in informing Medicare, Medicaid, and CHIP consumers, providers and stakeholders pursuant to education and outreach programs of issues regarding these and other health coverage programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers and stakeholders.

- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, and CHIP education programs.

- Assembling and sharing an information base of "best practices" for helping consumers evaluate health plan options.

- Building and leveraging existing community infrastructures for information, counseling and assistance.

- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under health care reform.

The current members of the Panel are: Samantha Artiga, Principal Policy Analyst, Kaiser Family Foundation; Joseph Baker, President, Medicare Rights Center; Philip Bergquist, Manager, Health Center Operations, CHIPRA Outreach & Enrollment Project and Director, Michigan Primary Care Association, Marjorie Cadogan, Executive Deputy Commissioner, Department of Social Services; Jonathan Dauphine, Senior Vice President, AARP; Barbara Ferrer, Executive Director, Boston Public Health Commission; Shelby Gonzales, Senior Health Outreach Associate, Center on Budget & Policy Priorities; Jan Henning, Benefits Counseling & Special Projects Coordinator, North Central Texas Council of Governments' Area Agency on Aging; Warren Jones, Executive Director, Mississippi Institute for Improvement of Geographic Minority Health; Cathy Kaufmann, Administrator, Oregon Health Authority; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; Miriam Mobley-Smith, Dean, Chicago State University, College of Pharmacy; Ana Natal-Pereira, Associate Professor of Medicine, University of Medicine & Dentistry of New Jersey; Megan Padden, Vice President, Sentara Health Plans; David W. Roberts, Vice-

President, Healthcare Information and Management System Society; Julie Bodën Schmidt, Associate Vice President, National Association of Community Health Centers; Alan Spielman, President & Chief Executive Officer, URAC; Winston Wong, Medical Director, Community Benefit Director, Kaiser Permanente and Darlene Yee-Melichar, Professor & Coordinator, San Francisco State University.

The agenda for the November 17, 2011 meeting will include the following:

- Recap of the Previous (July 28, 2011) Meeting
- Listening Session with CMS Leadership
- Affordable Care Act Initiatives
- An opportunity for public comment
- 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 the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available.

Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Section 222 of the Public Health Service Act (42 U.S.C. 217a) and section 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: September 28, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0247]

Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Agency's Compliance and Enforcement Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: As part of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled "Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Agency's Compliance and Enforcement Data." This report includes eight draft proposals to make FDA's publicly available compliance and enforcement data more accessible and user-friendly. FDA is seeking public comment on these draft proposals. The Transparency Task Force will ultimately recommend specific draft proposals to the Commissioner of Food and Drugs (the Commissioner) for consideration based on the comments it receives, the feasibility of the draft proposal, relative priority, and available resources.

DATES: Submit either electronic or written comments by December 2, 2011.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments 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 at the heading of this document and the draft proposal(s) that the comments address.

FOR FURTHER INFORMATION CONTACT: Lisa M. Dwyer, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4228, Silver Spring, MD 20993, 301-796-4709, FAX: 301-847-8616, e-mail: lisa.dwyer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a report entitled "FDA Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency By Promoting Greater Access to the Food and Drug Administration's Compliance and Enforcement Data." FDA is responsible for a broad range of compliance and enforcement activities. Increasing the transparency of these activities allows the public to better understand the Agency's decisions, and it promotes accountability of the Agency and the regulated industry.

On January 18, 2011, President Obama issued a Presidential Memorandum on Regulatory Compliance, 76 FR 3825 (January 21, 2011), requiring Federal Agencies to make publicly available compliance

information easily accessible, downloadable, and searchable online. In that memorandum, the President highlighted the achievements of the Environmental Protection Agency (EPA) and the Department of Labor (DOL) in developing Web sites (<http://www.epa-echo.gov> and <http://ogesdw.dol.gov>, respectively) that make their regulatory compliance information more accessible to the public.

FDA responded to the Presidential Memorandum on Regulatory Compliance in a memorandum to the Department of Health and Human Services (HHS), on May 6, 2011 (FDA Response). The FDA Response summarized the actions that the Agency already had implemented, as well as those that were underway or proposed, to make its regulatory compliance and enforcement information more accessible to the public. FDA took those actions in response to the Presidential Memorandum on Transparency and Open Government, 74 FR 4685 (January 26, 2009), which the President issued in January 2009, and as part of FDA's own Transparency Initiative, which the Commissioner, Dr. Margaret A. Hamburg, launched in June 2009.

In the FDA response, the Agency also committed to examining the manner in which EPA and DOL disclose compliance and enforcement information to determine whether there are additional steps FDA could take to make comparable information more accessible. Specifically, FDA stated that it would: (1) Within 150 days (by October 3, 2011), issue proposals for public comment, if it concluded that there were additional opportunities to increase the transparency of its compliance and enforcement data and (2) within 270 days (January 31, 2012), determine whether to adopt those proposals.

After meeting with EPA and DOL to discuss their methods for making compliance and enforcement data more accessible, FDA has determined that there are additional steps that it could take to make its own information more transparent and accessible to the public. This report contains FDA's draft proposals for public comment.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify the draft proposal(s) which your comment addresses by the number assigned to the proposal. 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.

Dated: September 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-25354 Filed 10-3-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0270; formerly Docket No. 2007N-0357]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2012 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where the Agency will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993-0002, 301-796-5678.

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting