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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: February 7, 2012.

**Elaine L. Baker,**

*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

[CMS-1594-N]

#### Medicare Program: Notice of Six Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice announces six new membership appointments to the Advisory Panel on Hospital Outpatient Payment (HOP, the Panel). The six appointments to the 19 member Panel will each serve a 4-year period. Five of the new members will have terms that begin on February 1, 2012 and continuing through January 31, 2016. The sixth member's term will begin on August 1, 2012 and continuing through July 31, 2016. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their weights. The Panel also addresses and makes recommendations regarding supervision of outpatient services. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

**FOR FURTHER INFORMATION CONTACT:** For additional information on the Panel meeting dates, agenda topics, copy of the charter, as well as updates to the Panel's activities, search our Internet

Web site: [https://www.cms.gov/FACA/05\\_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage](https://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage). (**Note:** There is an UNDERSCORE after FACA/05\_ ; there is no space.)

For other information regarding the Panel, contact Paula Smith, the Designated Federal Officer at CMS, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Outpatient Care, 7500 Security Boulevard, Mail Stop C4-05-13, Baltimore, MD 21244-1850, phone (410) 786-4709. Information can also be obtained by contacting the CMS Advisory Committees' Information Line at 1-877-449-5659 (toll free) and (410) 786-9379 (local).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) (42 U.S.C. 1395l(t)(9)(A)) and section 222 of the Public Health Service Act (PHS Act) (42 U.S.C. 217a) to consult with an expert outside advisory panel on the clinical integrity of the Ambulatory Payment Classification groups and weights. The Advisory Panel on Hospital Outpatient Payment (HOP, the Panel) is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92-463, as amended (5 U.S.C. Appendix 2)), which sets forth standards for the formation and use of advisory panels. The Panel Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the outpatient prospective payment system for the next calendar year.

The Panel shall consist of a chair and up to 19 members who are full-time employees of hospitals, hospital systems, or other Medicare providers. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines.

The Panel presently consists of the following members and a Chair: (The asterisk [\*] indicates a Panel member whose term expires on July 31, 2012).

- Edith Hambrick, M.D., J.D., Chair, CMS Medical Officer.
- Ruth L. Bush, M.D., M.P.H.
- Kari S. Cornicelli, C.P.A., FHFMA.
- Dawn L. Francis, M.D., M.H.S.
- Kathleen Graham, R.N., M.S.H.A. \*

- David A. Halsey, M.D.
- Brian D. Kavanagh, M.D., MPH.
- Judith T. Kelly, R.H.I.T., R.H.I.A., C.C.S.
- Scott Manaker, M.D., Ph.D.
- John Marshall, CRA, RCC, CIRCC, RT(R), FAHRA.
- Jacqueline Phillips.
- Randall A. Oyer, M.D.
- Daniel J. Pothan, M.S., RHIA, CHPS.
- Gregory Przybylski, M.D.
- Marianna V. Spanaki-Varela, MD, Ph.D., M.B.A.

##### II. Provisions of the Notice

We published a notice in the **Federal Register** on November 25, 2011, entitled "Medicare Program; Renaming and Other Changes to the Advisory Panel on Hospital Outpatient Payment Charter (Formerly the Advisory Panel on Ambulatory Payment Classification Groups) and Request for Nominations" (76 FR 72708). The notice requested nominations to be added to the Panel by replacing one Panel member whose term expires on July 31, 2012; replacing one Panel member who resigned; and by adding four new Panel members (two of these designated as Critical Access Hospital representatives (see the November 30, 2011 final rule, (76 FR 74363)) to address appropriate supervision level for hospital outpatient services. As a result of that November 25, 2012 notice and the November 30, 2011 final rule, we are announcing six new members to the Panel. Their appointments are for 4-year terms commencing on February 1, 2012 and August 1, 2012.

*New Appointments to the Panel*—The new members of the Panel with terms beginning on February 1, 2012 and continuing through January 31, 2016 are as follows:

- Lanny Copeland, M.D.,
- Jim Nelson,
- Leah Osbahr,
- Traci Rabine; and
- Gale Walker

The new member of the Panel with a term beginning on August 1, 2012, and continuing through July 31, 2016 is:

- Karen Borman, M.D.

##### III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

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

Medicare—Supplementary Medical Insurance Program)

Section 1833(t)(9)(A) of the Act (42 U.S.C. 1395l(t)(9)(A)). The Panel is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Dated: February 8, 2012.

**Marilyn Tavenner,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2012–3643 Filed 2–15–12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0123]

#### Design and Methodology for Postmarket Surveillance Studies Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled “Design and Methodology for Postmarket Surveillance Studies under Section 522 of the Federal Food, Drug and Cosmetic Act”. The purpose of the public workshop is to provide a forum for discussion among FDA, industry, governmental agencies, academia, clinicians and various stakeholders with experience in epidemiology, statistics, and biomedical research to advance the design and methodologies for medical device surveillance studies in the “postmarket” setting, i.e., after FDA premarket approval or clearance of the device and marketing of the device has begun.

**DATES:** The meeting will be held on March 7, 2012, from 8 a.m. to 5:30 p.m.

**ADDRESSES:** The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm 1503 (the Great Room), Silver Spring, MD 20993. For parking and security information, please visit the following Web site: <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. The public workshop will also be available to be viewed online via webcast.

**FOR FURTHER INFORMATION CONTACT:** Samantha Jacobs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 4201C, Silver Spring, MD 20993, 301–796–6897, email: [samantha.jacobs@fda.hhs.gov](mailto:samantha.jacobs@fda.hhs.gov); or Mary Beth Ritchey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4118, Silver Spring, MD 20993, 301–796–6638, email: [maryelizabeth.ritchey@fda.hhs.gov](mailto:maryelizabeth.ritchey@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

**Registration:** To register for the public workshop, please visit the following Web site: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm289465.htm> (or go to <http://www.fda.gov> and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. For persons interested in attending this workshop and without Internet access, please call one of the people listed in the **FOR FURTHER INFORMATION CONTACT** section in this document in order to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist. There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Persons interesting in attending this workshop must register online by February 29, 2012. Registration is mandatory as space is limited and onsite registration will not be available. FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Susan Monahan at [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than March 1, 2012.

**Security:** Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please visit the Web site address in the **ADDRESSES** section of this document.

**Streaming Webcast of the Public Workshop:** This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. on February 29, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one

connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after March 1, 2012. If you have never attended a Connect Pro meeting before, test your connection at: [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

**Background:** Under section 522(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act), enacted by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115, § 212, 111 Stat. 2346), codified at 21 U.S.C. 360l(a), FDA may order a manufacturer to conduct postmarket surveillance for any Class II or Class III device (i) Intended to be implanted in the human body for more than 1 year or to be used to sustain or support life outside a device user facility, or (ii) whose failure would be reasonably likely to have serious adverse health consequences. The Food and Drug Administration Amendments of 2007 (FDAAA) (Pub. L. 110–85, § 307, 121 Stat. 865) expanded the scope of section 522 to include devices intended for pediatric use.

#### Agenda for the Public Workshop

##### 1. Why are we holding this public workshop?

The purpose of the proposed workshop is to facilitate discussion among the FDA, industry, governmental agencies, academia, clinicians, and key stakeholders with experience in epidemiology, statistics, and biomedical research in the scientific community to advance the design and methodologies for medical device surveillance studies in the postmarket setting.

##### 2. Who is the target audience for this public workshop? Who should attend this public workshop?

This workshop is open to all interested parties. The target audience is professionals in the scientific community interested in advancing the infrastructure and methodology for postmarket surveillance studies.

##### 3. What are the topics we intend to address at the public workshop?

We intend to discuss a large number of issues at the workshop, including, but not limited to the following: