

in 2014), 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; Marjorie Cadogan, Executive Deputy Commissioner, Department of Social Services; Jonathan Dauphine, Senior Vice President, AARP; Jason Dollarhide, Deputy Executive Director, Housing Authority of the Peoria Tribe of Indians of Oklahoma; Barbara Ferrer, Executive Director, Boston Public Health Commission; Shelby Gonzales, Senior Health Outreach Associate, Center on Budget & Policy Priorities; Richard Frank, Director, Whittingham Cancer Center; Jan Henning, Benefits Counseling & Special Projects Coordinator, North Central Texas Council of Governments’ Area Agency on Aging; Deeana Jang, Policy Director, Asian and Pacific Islander American Health Forum; Warren Jones, Executive Director, Mississippi Institute for Improvement of Geographic Minority Health; Madeline Lawson, President and Chief Executive Officer, Institute for the Advancement of Multicultural & Minority Medicine; John Lui, Executive Director, Stout Vocational Rehabilitation Institute; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; Miriam Mobley-Smith, Dean, Chicago State University, College of Pharmacy; Ana Natale-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

Bodén Schmidt, Associate Vice President, National Association of Community Health Centers; Winston Wong, Medical Director, Community Benefit Director, Kaiser Permanente and Donna Yee, Chief Executive Officer, Asian Community Center of Sacramento Valley.

The agenda for the July 28, 2011 meeting will include the following:

- Welcome and Listening Session with CMS Leadership.
- Swearing in of new members.
- Recap of the previous (October 13, 2010) meeting.
- Medicare, Medicaid & CHIP Outreach & Education Strategies.
- 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:** 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: June 16, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011–15613 Filed 6–23–11; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–1584–N]

### Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 10, 2011 Through August 12, 2011

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the second semi-annual meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2011. The purpose of the Panel is to review the APC groups and their associated weights and to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the APC groups and their associated weights. We will consider the Panel’s advice as we prepare the final rule that would update the hospital Outpatient Prospective Payment System (OPPS) for CY 2012.

**DATES: Meeting Dates:** We are scheduling the second semi-annual meeting in 2011 for the following dates and times:

- Wednesday, August 10, 2011, 1 p.m. to 5 p.m. eastern standard time (e.s.t.)<sup>1</sup>
- Thursday, August 11, 2011, 8 a.m. to 5 p.m. (e.s.t.)<sup>1</sup>
- Friday, August 12, 2011, 8 a.m. to 12 Noon (e.s.t.)<sup>2</sup>

**Note:** <sup>1</sup> The times listed in this notice are approximate times; consequently, the meetings may last longer than listed in this notice, but will not begin before the posted times.

<sup>2</sup> If the Panel’s business concludes on Thursday, August 11, 2011, there will be no meeting on Friday, August 12, 2011.

### Deadlines

*Deadline for Hardcopy Comments and electronic format suggested agenda topics*—5 p.m. (e.s.t.), Friday, July 15, 2011.

*Deadline for Hardcopy Presentations, including the required electronic documents as discussed below*—5 p.m. (e.s.t.), Friday, July 15, 2011.

*Deadline for Attendance Registration*—5 p.m. (e.s.t.), Wednesday, July 27, 2011.

*Deadline for Special Accommodations*—5 p.m. (e.s.t.), Wednesday, July 27, 2011.

**ADDRESSES:** The meeting will be held in the Auditorium, the Centers for Medicare & Medicaid Services (CMS) Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

**FOR FURTHER INFORMATION CONTACT:** Paula Smith, Designated Federal Officer (DFO), CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4–05–17, Baltimore, MD 21244–1850. Phone: (410) 786–3985.

**Note:** We recommend that you advise couriers of the following information: When

delivering hardcopies of presentations to CMS, if no one answers at the above phone number, please call (410) 786-4532 or (410) 786-7267.

The e-mail address for comments, presentations, and registration requests is [APCPanel@cms.hhs.gov](mailto:APCPanel@cms.hhs.gov).

News media representatives must contact our Public Affairs Office at (202) 690-6145.

**Advisory Committees' Information Lines:** The phone numbers for the CMS Federal Advisory Committee Hotline are 1-877-449-5659 (toll free) and (410) 786-9379 (local).

**Web Sites:** For additional information on the APC Panel and updates to the Panel's activities, we refer readers to our Web site available at: [http://www.cms.hhs.gov/FACA/05\\_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage](http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage).

**Note:** There is an UNDERSCORE after FACA/05; there is no space between the underscore and the capital A. You may also search information about the APC Panel and its membership in the Federal Advisory Committee Act (FACA) database at the following URL: <https://www.fido.gov/facadata/public.asp>.

### Submission of Materials to the Designated Federal Officer (DFO)

We require electronic versions of the written comments and presentations, in addition to hardcopies. Because of staffing and resource limitations, we cannot accept written comments and presentations by FAX, nor can we print written comments and presentations received electronically for dissemination at the meeting. Only hardcopy comments and presentations can be reproduced for public dissemination. All hardcopy presentations must be accompanied by Form CMS-20017 (revised May 2011). The form is now available through the CMS Forms Web site. To download Form CMS-20017, visit the following Web site: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>. Additionally, presenters must clearly explain the action that they are requesting CMS to take in the appropriate section of the form. They must also state their relationship to the organization that they are representing in the presentation.

**Note:** Issues that are vague, or that are outside the scope of the APC Panel's purpose, will not be considered for presentations and comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

In summary, presenters and/or commenters must do the following:

- Send both electronic and hardcopy versions of their presentations and written comments by the prescribed deadlines.
- Send electronic transmissions to the e-mail address below.
- Mail (or send by courier) to the Designated Federal Officer (DFO) all hardcopies, accompanied by Form CMS-20017 (revised 01/07), if they are presenting, as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.
- Commenters not presenting at the APC panel meeting are not required to send Form CMS-20017 with their written comments.
- Do not send images of patients in any of the documents unless their faces have been covered.

### SUPPLEMENTARY INFORMATION:

#### I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act) to consult with an expert, outside advisory panel on the clinical integrity of the APC groups and weights established under the Medicare Hospital Outpatient Prospective Payment System (OPPS).

The APC Panel meets up to three times annually. The Panel consists of up to 15 members, who are representatives of providers, and a Chair.

Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS. The Secretary or Administrator selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations.

All members must have technical expertise to enable them to participate fully in the Panel's work. The expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology (CPT) codes; and alpha-numeric Health Care Common Procedure Coding System (HCPCS) codes; and the use of, and payment for, drugs, medical devices, and other services in the outpatient setting, as well as other forms of relevant expertise. Details regarding membership requirements for the APC Panel are found on the FACA and CMS Web sites as listed above.

The Panel presently consists of the following members: (Note: The asterisk [\*] indicates the Panel members whose terms end on September 30, 2011.)

- E. L. 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., C.P.H.Q., A.C.M.
- Patrick A. Grusenmeyer, Sc.D., F.A.C.H.E.\*
- David Halsey, M.D.
- Brian D. Kavanagh, M.D., M.P.H.
- Judith T. Kelly, B.S.H.A., R.H.I.T., R.H.I.A., C.C.S.
- Scott Manaker, M.D., PhD
- John Marshall, CRA, RCC, RT.
- Agatha L. Nolen, PhD, M.S., F.A.S.H.P.\*
- Randall A. Oyer, M.D.
- Daniel Pothen, M.S., R.H.I.A., C.P.H.I.M.S., C.C.S.P, C.H.C.
- Gregory Przybylski, M.D.
- Neville B. Sarkari, M.D., FACP.

#### II. Agenda

The agenda for the August 2011 meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Evaluating APC group weights.
- Reviewing packaging the cost of items and services, including drugs and devices, into procedures and services, including the methodology for packaging and the impact of packaging the cost of those items and services on APC group structure and payment.
- Removing procedures from the inpatient list for payment under the OPPS.
- Using claims and cost report data for CMS' determination of APC group weights.
- Addressing other technical issues concerning APC group structure.

**Note:** The subject matter before the Panel will be limited to these and related topics. Issues related to calculation of the OPPS conversion factor, charge compression, revisions to the cost report, pass-through payments, payment adjustments, or correct code usage are not within the scope of the Panel's purpose. Therefore, these issues will not be considered for presentations or comments. There will be no exceptions to this rule. We appreciate your cooperation on this matter.

The Panel may use data collected or developed by entities and organizations other than the Department of Health and Human Services (DHHS) and CMS in conducting its review. We recommend that organizations submit data for the Panel's and CMS' review.

#### III. Written Comments and Suggested Agenda Topics

Hardcopy and electronic written comments and suggested agenda topics should be sent to the DFO as specified

in the **ADDRESSES** section of this notice. The DFO must receive these items by 5 p.m. (e.s.t.), Friday, July 15, 2011. We appreciate your cooperation on this matter.

#### IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must submit hardcopy and electronic versions of their presentations to the DFO by 5 p.m. (e.s.t.), Friday, July 15, 2011.

The number of oral presentations may be limited by the time available. Oral presentations cannot exceed 5 minutes in length for an individual or an organization.

The Chair may further limit time allowed for presentations due to the number of oral presentations, if necessary. Presentation times listed in the public agenda are approximate and presenters should be prepared to present earlier and later than indicated.

#### V. Presenter and Presentation Information

All presenters must submit Form CMS-20017 (Revised 05/11) that is required for all oral presentations. The DFO must receive the following information from those wishing to make oral presentations:

- The Form CMS-20017 (Revised 05/11) with all pertinent information completed.
- One hardcopy of presentation.
- Electronic copy of presentation.
- Personal registration information as described in the "Meeting Attendance" section below.

Those persons wishing to submit written comments only (and not make a 5 minute oral presentation at the Panel meeting) must send hardcopy and electronic versions of their comments, but they are not required to submit the Form CMS-20017 (Revised 05/11).

#### VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

#### VII. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Attendance will be determined on a first-come, first-served basis.

Persons wishing to attend this meeting, which is located on Federal property, must e-mail the DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, July 27, 2011. A

confirmation will be sent to the requester(s) by return e-mail.

The following personal information must be e-mailed to the DFO by the date and time above:

- Name(s) of attendee(s).
- Title(s).
- Organization including address(es).
- E-mail address(es).
- Telephone number(s).

#### VIII. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes before the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

**Note:** Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes before the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

#### IX. Special Accommodations

Individuals requiring sign-language interpretation or other special

accommodations must send a request for these services to the DFO by 5 p.m. (e.s.t.), Wednesday, July 27, 2011.

#### X. Panel Recommendations and Discussions

The Panel's recommendations at any APC Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day before the final adjournment.

#### XI. 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. Chapter 35).

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

Dated: June 15, 2011.

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

[FR Doc. 2011-15903 Filed 6-23-11; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0536]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Pharmacogenomic Data Submissions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Pharmacogenomic Data Submissions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Berbakos@fda.hhs.gov](mailto:Elizabeth.Berbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 7, 2011 (76