

time available. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=mcac.

We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating the meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and e-mail address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

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 prior to 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 30 to 45 minutes prior to the convening of the meeting.

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

Authority: 5 U.S.C. App. 2, section 10(a). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 17, 2008.

Barry M. Straube,

Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. E8-14649 Filed 6-26-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1394-N]

Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 27–29, 2008

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

ACTION: Notice.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix 2), this notice announces the second semi-annual meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups (the Panel) for 2008. 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 updates the hospital Outpatient Prospective Payment System (OPPS) for CY 2009.

DATES: *Meeting Dates:* We are scheduling the second semi-annual meeting in 2008 for the following dates and times:

- Wednesday, August 27, 2008, 1 p.m. to 5 p.m. (e.d.t.)¹
- Thursday, August 28, 2008, 8 a.m. to 5 p.m. (e.d.t.)¹
- Friday, August 29, 2008, 8 a.m. to 12 noon (e.d.t.)²

Deadlines

Deadline for Hardcopy Comments/Suggested Agenda Topics

5 p.m. (e.d.t.), Monday, August 4, 2008.

Deadline for Hardcopy Presentations

5 p.m. (e.d.t.), Monday, August 4, 2008.

Deadline for Attendance Registration

5 p.m. (e.d.t.), Wednesday, August 13, 2008.

Deadline for Special Accommodations

5 p.m. (e.d.t.), Wednesday, August 13, 2008.

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

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 01/07)*. The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>.

Presenters must use the most recent copy of CMS-20017 (updated 01/07) at the above URL. Additionally, presenters must *clearly* explain the action(s) that they are requesting CMS to take in the appropriate section of the form. They must also clarify their relationship to the organization that they represent in the presentation.

¹ 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.

² If the business of the Panel concludes on Thursday, August 28, 2008, there will be no Friday (August 29, 2008) meeting.

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.

We are also requiring electronic versions of the written comments and presentations, in addition to the hardcopies, to be sent electronically to the Panel members for their review before the meeting.

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.
- Do not send pictures of patients in any of the documents unless their faces have been blocked out.
- Do not send documents electronically that have been archived.
- Mail (or send by courier) to the DFO all hardcopies, accompanied by Form CMS-20017 (revised 01/07), if they are presenting, as specified in the **FURTHER INFORMATION CONTACT** section of this notice.
- Commenters are not required to send Form CMS-20017 with their written comments.

ADDRESSES: The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: Shirly Ackerman-Ross, DFO, CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244-1850. *Phone:* (410) 786-4474.

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, call (410) 786-4532 or (410) 786-9316. E-mail address for comments, presentations, and registration requests is CMS-APCPanel@cms.hhs.gov.

Note: There is NO underscore in this e-mail address; there is a SPACE between CMS and APCPanel.

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: The following information is available on the CMS Web site at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

Note: There is an UNDERSCORE after FACA/05(like this); there is no space.

- Additional information on the APC meeting agenda topics.
- Updates to the Panel's activities.
- Copies of the current Charter.
- Membership requirements.

You may also search information about the APC Panel and its membership in the FACA database at the following URL: <https://www.fido.gov/facadatabase/public.asp>.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary is required by section 1833(t)(9)(A) of the Social Security Act (the Act), as amended by section 201(h) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), and re-designated by section 202(a)(2) of the BBRA to establish and consult with an expert outside advisory panel regarding the clinical integrity of the APC groups and weights that are components of the hospital OPPS.

The APC Panel meets up to three times annually. The Charter requires that the Panel must be fairly balanced in its membership in terms of the points of view represented and the functions to be performed. 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. All Panel members must have technical expertise that enables them to participate fully in the work of the Panel. The expertise encompasses hospital payment systems, hospital medical-care delivery systems, provider billing systems, outpatient payment requirements, APC groups, Current Procedural Terminology codes, and the use and payment of drugs and medical devices 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:

- E.L. Hambrick, M.D., J.D., Chair.
- Glorienne Bryant, B.S., R.H.I.A., R.H.I.T., C.C.S.
- Patrick Grusenmeyer, Sc.D.
- Hazel Kimmel, R.N., C.C.S., C.P.C.
- Michael Mills, Ph.D.
- Thomas Munger, M.D.
- Agatha Nolen, D.Ph., M.S.
- Beverly Khnie Philip, M.D.
- Louis Potters, M.D., F.A.C.R.
- Russ Ranallo, M.S.
- James V. Rawson, M.D.
- Michael Ross, M.D.
- Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.

- Patricia Spencer-Cisek, M.S., APRN-BC, AOCN®
- Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.
- Robert M. Zwolak, M.D., Ph.D. F.A.C.S.

II. Agenda

The agenda for the August 2008 meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Reconfiguring APCs (for example, splitting of APCs, moving Healthcare Common Procedure Coding System (HCPCS) codes from one APC to another and moving HCPCS codes from new technology APCs to clinical APCs).
- Evaluating APC weights.
- Packaging device and drug costs into APCs: Methodology, effect on APCs, and need for reconfiguring APCs based upon device and drug packaging.
- Removing procedures from the inpatient list for payment under the OPPS.
- Using single and multiple procedure claims data.
- Addressing other APC structure technical issues.

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, pass-through payments, or wage adjustments are not within the scope of the Panel's purpose. Therefore, these issues will not be considered for presentations and/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 DHHS and CMS, in conducting its review. We recommend organizations to submit data for the Panel's and CMS staff's review.

III. Written Comments and Suggested Agenda Topics

Send hardcopy and electronic written comments and suggested agenda topics to the DFO at the address indicated above. The DFO must receive these items by 5 p.m. (e.d.t.), Monday, August 4, 2008. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the August 2008 APC Panel meeting must fall within the subject categories outlined in the Panel's Charter and as listed in the Agenda section of this notice.

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.d.t.), Monday, August 4, 2008, for consideration.

The number of oral presentations may be limited by the time available. Oral presentations should not 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.

V. Presenter and Presentation Information

All presenters must submit Form CMS-20017 (revised 01/07). Hardcopies are required for oral presentations; however, electronic submissions of Form CMS-20017 are optional. The DFO must receive the following information from those wishing to make oral presentations:

- Form CMS-20017 completed with all pertinent information identified on the first page of the presentation.
- One hardcopy of presentation.
- Electronic copy of presentation.
- Personal registration information as described in the Meeting Attendance section below.
- Those persons wishing to submit comments only must send hardcopy and electronic versions of their comments, but they are not required to submit Form CMS-20017.

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.d.t.), Wednesday, August 13, 2008. 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;
- E-mail address(es); and
- Telephone number(s).

VIII. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security

reasons, any persons wishing to attend this meeting must register by close of business on Wednesday, August 13, 2008. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. Seating capacity is limited to the first 250 registrants.

The on-site check-in for visitors will be held 30 to 45 minutes before the meeting start time each day. You should allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 12:15 p.m. for the 1 p.m. meeting on Wednesday, August 27, 2008. Plan to arrive at the building by 7:15 a.m. on Thursday, August 28, 2008 (and Friday, August 29, 2008—if we have a meeting that day) to ensure that you are able to arrive promptly at the meeting by 8 a.m. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection.

Security measures will include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, including personal items such as desktops, cell phones, and palm pilots, are subject to physical inspection.

The following are the security, building, and parking guidelines:

- Persons attending the meeting including presenters must be registered and on the attendance list by the prescribed date.
- Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.
- Attendees must present photographic identification to the Federal Protective Service or Guard Service personnel before entering the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- 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.d.t.), Wednesday, August 13, 2008.

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

Dated: May 16, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8-13828 Filed 6-26-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0154]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 28, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to baguilar@omb.eop.gov. All comments should be identified with the OMB control number 0910-0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.