

not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential,” as discussed in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you must follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, the Commission encourages you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/contactlensrulepra> by following the instructions on the Web-based form. If this Notice appears at <http://www.regulations.gov>, you also may file a comment through that Web site.

If you file your comment on paper, write “Contact Lens Rule: FTC File No. P054510” on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610, (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610, (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before July 19, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the

Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

David C. Shonka,

Acting General Counsel.

[FR Doc. 2016–11952 Filed 5–19–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1665–N]

Medicare Program; Announcement of the Advisory Panel on Hospital Outpatient Payment (the Panel) Meeting on August 22–23, 2016 and Announcement of Transition to One Meeting of the Panel Per Year

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

ACTION: Notice.

SUMMARY: This notice announces the summer meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for 2016. It also announces that the Panel will begin meeting once a year in the summer, beginning in Calendar Year 2017. Currently, the Panel convenes twice yearly. The purpose of the Panel is 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) on the clinical integrity of the Ambulatory Payment Classification (APC) groups and their associated weights and hospital outpatient therapeutic services supervision issues.

DATES: Meeting Dates: The second semi-annual meeting in 2016 is scheduled for the following dates and times. The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times; consequently, the meetings may last longer or be shorter than the times listed in this notice, but will not begin before the posted times:

- Monday, August 22, 2016, 9 a.m. to 5 p.m. EDT.
- Tuesday, August 23, 2016, 9 a.m. to 5 p.m. EDT.

Meeting Information Updates: The actual meeting hours and days will be posted in the agenda. As information and updates regarding the onsite, webcast and teleconference meeting, and agenda become available, they will be posted to the CMS Web site at: <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelon>

AmbulatoryPaymentClassificationGroups.html.

Deadlines

Deadline for Presentations and Comments

Presentations or comments and form CMS–20017, (located at <http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf>) must be received by 5 p.m. EDT, Friday, July 15, 2016. Presentations and comments that are not received by the due date and time will be considered late and will not be included on the agenda. In commenting, please refer to file code CMS–1665–N.

Meeting Registration Timeframe: Monday, June 27, 2016, through Friday, July 29, 2016 at 5 p.m. EDT.

Participants planning to attend this meeting in person must register online, during the above specified timeframe at: <https://www.cms.gov/apps/events/default.asp>. On this Web page, double click the “Upcoming Events” hyperlink, and then double click the “HOP Panel” event title link and enter the required information. Include any requests for special accommodations.

Note: Participants who do not plan to attend the meeting in person should not register. No registration is required for participants who plan to view the meeting via webcast.

Because of staff and resource limitations, we cannot accept comments and presentations by facsimile (FAX) transmission.

Meeting Location, Webcast, and Teleconference

The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view this meeting via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at: <http://cms.gov/live>. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

News Media

Representatives must contact our Public Affairs Office at (202) 690–6145.

Advisory Committees’ Information Lines

The phone number for the CMS Federal Advisory Committee Hotline is (410) 786–3985.

Web Sites

For additional information on the Panel and updates to the Panel's activities, we refer readers to view our Web site at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

Information about the Panel and its membership in the Federal Advisory Committee Act (FACA) database are also located at: <http://facadatabase.gov/>.

FOR FURTHER INFORMATION CONTACT:

Carol Schwartz, Designated Federal Official (DFO), 7500 Security Boulevard, Mail Stop: C4-04-25, Woodlawn, MD 21244-1850. Phone: (410) 786-3985. Email: APCPanel@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (DHHS) (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and is allowed by section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside panel, that is, the Advisory Panel on Hospital Outpatient Payment (the Panel) regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory panels. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the hospital outpatient prospective payment system (OPPS). The Panel (formerly the Advisory Panel on Ambulatory Payment Classification Groups) was originally chartered on November 21, 2000, and most recently re-chartered on November 6, 2014. The Panel Charter provides that the Panel shall meet up to 3 times annually. The first meeting of the Panel (was in Calendar Year (CY) 2001). For CY 2001 and 2002, the Panel convened once a year. At that time, the OPPS was new and there were many issues where the Panel provided important technical advice to the Centers for Medicare & Medicaid (CMS). Agendas for these 2-day meetings were very full and it was decided that two, 2-day meetings per year would be warranted to accommodate the workload of the Panel. Beginning in CY 2003, the Panel has convened twice yearly, in the summer and in the winter. Over time and as the OPPS has matured, policies have become more stable and the volume of issues that the Panel has been requested

to provide technical advice on has decreased significantly. The duration of these meetings has decreased significantly, with the most recent four meetings each averaging a half day or less in length.

Beginning in CY 2016, new Current Procedural Terminology (CPT) codes (effective on January 1 of the following year) are assigned status indicators and APC assignments in the OPPS proposed rule instead of being first assigned status indicators and APC assignments in the final rule. With this process change, stakeholders now provide their comments on the status indicators and APC assignments during the proposed rule comment period.

II. Panel Meeting Transition to One Meeting of the Panel Per Year

Beginning in CY 2003 and through CY 2016, we had 13 consecutive years of two Panel meetings a year. However, due to a significant decline in the volume of requests for technical advice from the Panel, beginning in CY 2017, we will transition back to 1 Panel meeting a year, which will be scheduled in the summer. Since the summer meeting occurs during the comment period for the OPPS proposed rule, we anticipate that there will be more requests for technical advice including the CMS treatment of new CPT codes, during this meeting than during a winter meeting. The winter Panel meeting is no longer necessary as a forum to discuss interim final status indicators and APC assignments of new codes because this process no longer exists. In CY 2017 and thereafter, (unless CMS programmatic need suggests otherwise) there will not be a winter Panel meeting; there will be only one Panel meeting per year that will occur in the summer.

III. Agenda

The agenda for the August 22 through August 23, 2016 Panel 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 structure.
- Reviewing the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.
- Removing procedures from the inpatient-only list for payment under the OPPS.
- Using single and multiple procedure claims data for CMS' determination of APC group weights.

- Addressing other technical issues concerning APC group structure.
- Recommending the appropriate supervision level (general, direct, or personal) for individual hospital outpatient therapeutic services.

The Agenda will be posted on the CMS Web site at <http://cms.hhs.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html> approximately 1 week before the meeting.

IV. Presentations

The subject matter of any presentation and/or comment matter must be within the scope of the Panel designated in the Charter. Any presentations or comments outside of the scope of this Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to, the conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services.

The Panel may use data collected or developed by entities and organizations other than DHHS and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either one or more agenda items.

Section 508 Compliance

For this meeting, we are aiming to have all presentations and comments available on the CMS Web site. Materials on the CMS Web site must be Section 508 compliant to ensure access to federal employees and members of the public with and without disabilities. We encourage presenters and commenters to refer to guidance on making documents Section 508 compliant as they draft their submissions, and, whenever possible, to submit their presentations and comments in a 508 compliant form. Such guidance is available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/508-Compliant-doc.html>. CMS will review

presentations and comments for 508 compliance, and place compliant materials on its Web site. As resources permit, CMS will also convert non-compliant submissions to 508 compliant forms, and offer assistance to submitters who wish to make their submissions 508 compliant. All non-508 compliant presentations and comments will be shared with the public onsite and through the webcast and made available to the public upon request.

Those wishing to access such materials should contact the DFO (the DFO's address, email and phone number are provided below).

In order to consider presentations and/or comments, we will need to receive the following:

1. An *email copy* of the presentation or comments sent to the DFO mailbox, APCPanel@cms.hhs.gov or, if unable to submit by email, a hard copy sent to the DFO at the address noted under **FOR FURTHER INFORMATION CONTACT**.

2. Form *CMS-20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and commenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation. Presenters and commenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's/commenter's relationship with the organization that they represent must also be clearly listed.

- 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>.

- We encourage presenters to make efforts to ensure that their presentations and comments are 508 compliant.

V. Oral Comments

In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an 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.

VI. Meeting Attendance

The meeting is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on Federal

property, must register by following the instructions in the "Meeting Registration Timeframe" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

VII. Security, Building, and Parking Guidelines

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

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.

- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- 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.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.
- Foreign nationals visiting any CMS facility require prior approval. If you are a foreign national and wish to attend the meeting onsite, in addition to registering for the meeting, you must also send a separate email to APCPanel@cms.hhs.gov prior to the close of registration to request authorization to attend as a foreign national.

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VIII. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

IX. Panel Recommendations and Discussions

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

will be posted to the CMS Web site after the meeting.

X. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: April 28, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016-11949 Filed 5-19-16; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2015.

ADDRESSES: Copies are available at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. You also may access the docket at <http://www.regulations.gov> for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2015. Insert the docket number found in brackets in the heading of this document at <http://www.regulations.gov> into the "Search" box, clear filter under Document Type (left side of screen), and check "Supporting and Related Material," then Sort By Best Match (from the drop-down menu; top right side of screen), "ID Number (Z-A)" or Sort By Best Match (from the drop-down menu) "Title (A-Z)," also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Director and Committee Management Officer,