exceeded the Medicare conditions for coverage for ASCs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAAASF's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared AAAASF's ASC requirements and survey process with the Medicare conditions for coverage and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of AAAASF's ASC application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 416.41(b)(2), AAAASF revised its standards to ensure the ASC's transfer agreement is with a local, Medicare-participating hospital that meets the requirements for emergency services.
- To meet the requirements at § 416.44(a)(2), AAAASF revised its standards to address the requirement that ''the ASC must have a separate recovery room and waiting area.''
- AAAASF revised its crosswalk to ensure that all regulatory references are correct for the following citations: § 416.42(a)(2), § 416.42(c)(2), § 416.44(c)(3), § 416.50(c)(1), § 416.50(e), and § 416.50(g).
- To meet the requirements at § 488.4(a)(4), AAAASF modified its policies to ensure all personnel files are accurate and complete.
- To meet the requirements at § 488.4(a)(5), AAAASF modified its policies to improve the accuracy and consistency of data submissions to CMS.
- To meet the requirements at § 488.4(a)(6), AAAASF modified its policies to ensure all compliant investigations are conducted in accordance with the requirements in chapter Five of the SOM.
- To meet the requirements at § 488.6(a), AAAASF revised its policies and procedures to ensure deemed status survey files are complete and accurate.
- To meet the requirements at § 488.12, AAAASF modified its policies to ensure all pertinent survey information, including all surveys conducted, is included in the final accreditation decision letters.
- To meet the medical record requirements at Appendix L of the SOM, AAAASF revised its policies to ensure surveyors review the required number of medical records during a survey.
- To meet the requirements at Section 2728 of the SOM, AAAASF modified its policies regarding timeframes for sending and receiving a plan of correction.
- To meet the requirements at Section 3012 of the SOM, AAAASF modified its policies to ensure follow-up, focused surveys for condition level noncompliance are conducted timely.
- To meet the requirements at Section 2700A of the SOM, AAAASF modified its policies to ensure all surveys are conducted unannounced.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that AAAASF's requirements for ASCs meet or exceed our requirements. Therefore, we approve AAAASF as a national accreditation organization for ASCs that request participation in the Medicare program, effective November 27, 2012 through November 27, 2018.

V. Collection of Information Requirements

This document does not impose any information reporting, recordkeeping or third-party disclosure 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).

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—ASC Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 20, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–28640 Filed 11–23–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1597–N]

Medicare Program; Semi-Annual Meeting of the Advisory Panel on Hospital Outpatient Payment (HOP Panel)—March 11 and 12, 2013

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the first semi-annual meeting of the Advisory Panel on Hospital Outpatient Payment (HOP, the Panel), (the Ambulatory Payment Classification (APC) Panel) for 2013. 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 APC groups and their associated weights, and hospital outpatient therapeutic supervision issues.

DATES: *Meeting Date:* The first semi-annual meeting in 2013 is scheduled for the following dates and times.

Note: The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times; consequently, the meetings may last longer than the times listed in this notice, but will not begin before the posted times:

- Monday, March 11, 2013, 1 p.m. to 5 p.m. EDT
- Tuesday, March 12, 2013, 9 a.m. to 5 p.m. EDT

Deadlines

Deadline for Presentations and Comments

The email copy of a presentation or comment and form CMS–20017 must be in the Designated Federal Official's (DFO's) email inbox (*APCPanel@cms.hhs.gov*) by 5 p.m. EDT, Friday, January 25, 2013. The hardcopy of the presentation must be received by the DFO on or before Friday, February 1, 2013. Presentations and comments that are not received by the due dates will be considered late and will not be included on the agenda. (See below for submission instructions for both hardcopy and electronic submissions.)

Meeting Registration Timeframe: Monday, January 9, 2013 through Friday, February 22, 2013 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 this meeting in person should not register. No registration is required for participants that plan to view the meeting via webcast.

Submission Instructions for Presentations and Comments

Because of staffing and resource limitations, we cannot accept written comments and or presentations by FAX.

Presentations

Presentation subject matter must be within the scope of the Panel designated in the Charter. Any presentations outside of the scope of this Panel will be returned and/or amendments requested. 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.

All presentations are limited to 5 minutes total presentation time, 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.

All presentations will be considered public information and may be posted on the CMS Web site and will be shared with the public. Presenters should not send pictures of patients or Medicare beneficiaries in any of the documents (unless their faces have been blocked out) or include any examples with personally identifiable information.

In order to consider presentation and/or comment requests, we will need to receive the following information:

1. A hardcopy of your presentation; only hardcopy comments and presentations can be reproduced for public dissemination.

2. An email copy of your presentation sent to the DFO mailbox, *APCPanel@cms.hhs.gov*.

3. Form CMS–20017 with complete contact information that includes name, address, phone, and email addresses for all presenters and a contact that can answer any questions and or provide revisions that are requested for the presentation.

○ Presenters must clearly explain the action(s) that they are requesting CMS to take in the appropriate section of the form. A presenter's relationship to 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*.

Meeting Location and Webcast: The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850.

Alternately, the public may view this meeting via a webcast. During the scheduled meeting, webcasting is accessible online at: *http://cms.gov/live* or *http://www.ustream.tv*. Viewers interested in receiving the webcast from *http://www.ustream.tv* will need to type ''CMS Public Events'' in the search bar to access the webcast.

FOR FURTHER INFORMATION CONTACT: For inquiries about the Panel, contact the DFO: Chuck Braver, 7500 Security Boulevard, Mail Stop: C4–05–17, Woodlawn, MD 21244–1850. Phone: (410) 786–3985. Email: *APCPanel@cms.hhs.gov*

Mail hardcopies and email copies to the following addresses: Chuck Braver, DFO, CMS, CM, HAPG, DOC—HOP Panel, 7500 Security Blvd. Mail Stop: C4–05–17, Woodlawn, MD 21244–1850 Email: *APCPanel@cms.hhs.gov*

Note: We recommend that you advise couriers of the following information: When delivering hardcopies of presentations to CMS, call (410) 786–4532 or (410) 786–6719 to ensure receipt of documents by appropriate staff.

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) 786–3985 (local).

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

You may also search information about the Panel and its membership in the Federal Advisory Committee Act (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) and section 222 of the Public Health Service Act (PHS Act) to consult with an expert outside advisory panel regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel (which was formerly known as the Advisory Panel on Ambulatory Payment Classification Groups) 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.

The 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 (OPPS).

II. Agenda

The agenda for the March 2013 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 the packaging of OPPS services and costs, including the methodology and the impact on APC groups and payment.
- Removing procedures from the inpatient 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 subject matter before the Panel will be limited to these and related topics. 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, hospital outpatient supervision of diagnostic services and the types of practitioners who 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 the DHHS and CMS in conducting its review. We recommend organizations submit data for the Panel's and CMS staff's review. The Agenda will be posted on the CMS Web site before the meeting.

III. 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.

IV. 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.

V. 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 valid 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.

VI. Special Accommodations

Individuals requiring sign-language interpretation or other special accommodations must include the request for these services during registration.

VII. 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 our Web site after the meeting.

VIII. 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)

Dated: November 14, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–28639 Filed 11–23–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2013 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 two lists of guidance documents that the Center for Devices and Radiological Health (CDRH) is intending to publish in Fiscal Year (FY) 2013. In addition, FDA has established a docket where stakeholders may provide comments and/or propose draft language for those topics, suggest new or different guidance documents, and comment on the priority of topics for guidance.

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

ADDRESSES: Submit electronic comments on the proposed 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.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–114), 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 a list of prioritized medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the ''A-list'') and a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the ''B-list''). In addition to posting lists of prioritized device guidance documents, FDA has committed to updating its Web site in a timely manner to reflect the Agency's review of previously published guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency. Fulfillment of this commitment will be reflected through the issuance of updated guidance on existing topics, removal of guidances that that no longer reflect FDA's current thinking on a particular topic, and annual updates to A-list and B-list announced in this notice.

This notice announces the Web site location of the two lists of guidance documents which CDRH is intending to publish during FY 2013. We note that the Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. The Agency is not precluded from issuing guidance documents that are not on either list.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current