

FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the

Internet from January 1, 2010, through March 31, 2010. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2010, THROUGH MARCH 31, 2010

PMA No. Docket No.	Applicant	Trade Name	Approval Date
P010047 FDA-2010-M-0068	Neomend, Inc.	PROGEL PLEURAL AIR LEAK SEALANT	January 14, 2010
P060040/S005 FDA-2010-M-0078	Thoratec Corp.	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	January 20, 2010
H080002 FDA-2010-M-0063	Medtronic, Inc.	MEDTRONIC MELODY TRANSCATHETER PULMONARY VALVE (MODEL PB10) AND MEDTRONIC ENSEMBLE TRANSCATHETER VALVE DELIVERY SYSTEM (NU10)	January 25, 2010
P090003 FDA-2010-M-0135	Boston Scientific Corp.	EXPRESS LD LLIAC PREMOUNTED STENT SYSTEM	March 5, 2010
P090006 FDA-2010-M-0158	Medtronic Vascular	COMPLETE SE VASCULAR STENT SYSTEM	March 17, 2010

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: June 28, 2010.

**Nancy Stade,**

*Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.*

[FR Doc. 2010-16139 Filed 7-1-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel ZAA1 HH01—AA3 Member Conflicts.

*Date:* July 30, 2010.

*Time:* 11 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

*Contact Person:* Lorraine Gunzerath, PhD, MBA, Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, Office of Extramural Activities, Extramural Project Officer, 5635 Fishers Lane, Room 2121, Bethesda, MD 20892-9304, 301-443-2369.

(Catalogue of Federal Domestic Assistance Program Nos.)

Dated: June 25, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-16037 Filed 7-1-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1571-N]

#### Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—August 23 & 24, 2010

**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 2010. 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 2011.

**DATES:** *Meeting Dates:* We are scheduling the second semi-annual

meeting in 2010 for the following dates and times:

- Monday, August 23, 2010, 1 p.m. to 5 p.m. eastern standard time (e.d.t.).<sup>1</sup>
- Tuesday, August 24, 2010, 8 a.m. to 5 p.m. (e.d.t.).<sup>1</sup>

#### Deadlines

*Deadline for Hardcopy Comments (including the comment in electronic format)/Suggested Agenda Topics*—5 p.m. (e.d.t.), Monday, August 2, 2010.

*Deadline for Hardcopy Presentations*, including the required electronic documents as discussed below—5 p.m. (e.d.t.), Monday, August 2, 2010.

*Deadline for Attendance Registration*—5 p.m. (e.d.t.), Wednesday, August 16, 2010.

*Deadline for Special Accommodations*—5 p.m. (e.d.t.), Wednesday, August 16, 2010.

#### 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.

**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.

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 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 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:** For further information, contact: Shirl Ackerman-Ross, Designated Federal Official (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, please call (410) 786-4532 or (410) 786-9316.

The e-mail address for comments, presentations, and registration requests is [CMSAPCPanel@cms.hhs.gov](mailto:CMSAPCPanel@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:** Please access the CMS Web site at: [http://www.cms.hhs.gov/FACA/05\\_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage](http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage) to obtain the following information:

**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) to consult with an expert, outside advisory panel on the clinical integrity of the APC groups and weights established under the Medicare 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. 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. Such expertise encompasses hospital payment systems; hospital medical care delivery systems; provider billing systems; APC groups; Current Procedural Terminology codes; and alpha-numeric Health Care Common Procedure Coding System 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:

- E.L. Hambrick, M.D., J.D., Chair, CMS Medical Officer.
- Ruth L. Bush, M.D., M.P.H.
- Dawn L. Francis, M.D., M.H.S.
- Patrick A. Grusenmeyer, Sc.D., F.A.C.H.E.
- Kathleen Graham, R.N., M.S.H.A., C.P.H.Q., A.C.M.
- David Halsey, M.D.
- Judith T. Kelly, B.S.H.A., R.H.I.T., R.H.I.A., C.C.S.
- Michael D. Mills, Ph.D.
- Agatha L. Nolen, D.Ph., M.S., F.A.S.H.P.
- Randall A. Oyer, M.D.
- Beverly Khnie Philip, 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.
- Russ Ranallo, M.S., B.S.
- Michael A. Ross, M.D., F.A.C.E.P.
- Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.

<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.

## II. Agenda

The agenda for the August 2010 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.

**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 the Department of Health and Human Services (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

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.d.t.), Monday, August 2, 2010. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the August 2010 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 2, 2010, 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. 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 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. Collection of Information Requirements

This document does not impose any 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).

## VII. 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.

## VIII. 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 16, 2010. 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).
- Telephone number(s).

## IX. Security, Building, and Parking Guidelines

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.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, such as laptops, cell phones, and palm pilots, 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.

## X. 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.), Monday, August 16, 2010.

## XI. 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 prior to final adjournment.

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

Dated: June 18, 2010.

**Marilyn Tavenner,**

*Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-16163 Filed 6-30-10; 4:15 pm]

**BILLING CODE 4120-01-P**