In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed.

Section 923 (d) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 officially established 1–800–MEDICARE as the primary source of general Medicare information and assistance. As part of the MMA, CMS must provide Part D eligibles (and their representatives) with the information they need to make informed decisions among the available choices for Part D coverage. As Part D sponsors can start marketing their programs on October 1, 2005 and since the initial enrollment period for the general population is from November 15–May 15, 2006, CMS needs to insure that the 1–800–MEDICARE is meeting the needs of its callers. Therefore, CMS needs to have the Customer Experience Questionnaire in the field by September to provide quick, continuous feedback on the 1–800–MEDICARE experience.

CMS is requesting OMB review and approval of this collection by August 15, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by August 8, 2005.

Type of Information Collection Request: New collection; *Title of Information Collection:* 1–800–MEDICARE Customer Experience Questionnaire; *Use:* The information collected through this survey of callers to 1–800–MEDICARE is to help insure that this critical information channel will be meeting the needs of its customers during the key fall 2005 Part D enrollment period; *Form Number:* CMS–10163 (OMB#: 0938–NEW); *Frequency:* One-time; Affected Public: Individuals or households; *Number of Respondents:* 31,200; *Total Annual Responses:* 31,200; *Total Annual Hours:* 4,940.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by August 8, 2005: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262, Attn: Melissa Musotto, CMS–10163; and, OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 1, 2005.

Michelle Shortt,

Acting Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–13414 Filed 7–7–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1288–N]

Medicare Program; Meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups—August 17, 18, and 19, 2005

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

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 biannual meeting of the APC Panel for 2005.

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 (HHS) and the Administrator of the Centers for Medicare and Medicaid Services (CMS) concerning the clinical integrity of the APC groups and their associated weights. The advice provided by the Panel will be considered as CMS prepares its annual updates of the hospital Outpatient Prospective Payment System (OPPS) through rulemaking.

DATES: *Meeting Dates:* The second biannual meeting for 2005 is scheduled for the following dates and times:

- Wednesday, August 17, 2005, 1 p.m. to 5 p.m. (e.d.t.)
- Thursday, August 18, 2005, 8 a.m. to 5 p.m. (e.d.t.)
- Friday, August 19, 2005, 8 a.m. to 12 noon (e.d.t.)

Deadlines:

Deadline for Hardcopy Comments/Suggested Agenda Topics—

- 5 p.m. (e.d.t.), Monday, August 1, 2005.

Deadline for Hardcopy Presentations—

- 5 p.m. (e.d.t.), Monday, August 1, 2005.

Deadline for Attendance Registration—

- 5 p.m. (e.d.t.), Monday, August 8, 2005.

Deadline for Special Accommodations—

- 5 p.m. (e.d.t.), Monday, August 8, 2005.

Submittal 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 will be accepted for placement in the meeting booklets. All hardcopy presentations *must be accompanied by Form CMS–20017.* The form is now available through the CMS Forms Web site. The URL for linking to this form is (*http://www.cms.hhs.gov/forms/cms20017.pdf.*)

We are also requiring electronic versions of the written comments and presentations (in addition to the hardcopies), to forward to the Panel members for their review prior to the meeting.

Consequently, you must send BOTH electronic and hardcopy versions of your presentations and written comments by the prescribed deadlines. (Electronic transmission must be sent to the e-mail address below, and hardcopies—accompanied by Form CMS–20017—must be mailed to the Designated Federal Officer [DFO], as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.)

ADDRESSES: The meeting will be held in the Multipurpose Room, 1st Floor, CMS Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: For inquiries regarding the meeting; meeting registration; and hardcopy submissions of oral presentations, agenda items, and comments, please contact the DFO: Shirl Ackerman-Ross, DFO, CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4–05–17, Baltimore, MD 21244–1850. Phone (410) 786–4474.

- E-mail address for comments, presentations, and registration requests is *APCPanel@cms.hhs.gov.*
- News media representatives must contact our Public Affairs Office at (202) 690–6145.

Advisory Committees' Information Lines: The CMS Advisory Committees' Information Line is 1–877–449–5659 (toll free) and (410) 786–9379 (local).

Web Sites:

- For additional information on the APC meeting agenda topics and updates to the Panel's activities, search our Web site at: *http://www.cms.hhs.gov/faca/apc/default.asp.*
- To obtain Charter copies, search our Web site at *http://www.cms.hhs.gov/faca* or e-mail the Panel DFO.

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (HHS) (the Secretary) is required by section 1833(t)(9)(A) of the Act, as amended and redesignated by sections 201(h) and 202(a)(2) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), respectively, to establish and consult with an expert, outside advisory panel on APC groups. The APC Panel meets up to three times annually to review the APC groups and to provide technical advice to the Secretary and the Administrator of the Centers for Medicare and Medicaid Services (CMS) (the Administrator) concerning the clinical integrity of the groups and their associated weights. All members must have technical expertise that will enable them to participate fully in the work of the Panel. The expertise encompasses hospital payment systems, hospital medical-care delivery systems, outpatient payment requirements, APCs, Physicians' Current Procedural Terminology Codes (CPTs), the use and payment of drugs and medical devices in the outpatient setting, and other forms of relevant expertise. It is not necessary that any one member be an expert in all areas.

We will consider the technical advice provided by the Panel as we prepare the final rule that updates the OPPS payment rates for the next calendar year. The Secretary recently re-chartered the Panel on November 8, 2004.

The Panel may consist of a Chair and up to 15 representatives who are full-time employees (not consultants) of Medicare providers, which are subject to the OPPS.

The Administrator selected the Panel membership based upon either self-nominations or nominations submitted by providers or interested organizations. The Panel presently consists of the following members and a Chair:

- Edith Hambrick, M.D., J.D., Chair.
- Marilyn Bedell, M.S., R.N., O.C.N.
- Albert Brooks Einstein, Jr., M.D.
- Sandra J. Metzler, M.B.A., R.H.I.A., C.P.H.Q.
- Frank G. Opelka, M.D., F.A.C.S.
- Louis Potters, M.D., F.A.C.R.
- Lou Ann Schraffenberger, M.B.A., R.H.I.A., C.C.S.–P.
- Judie S. Snipes, R.N., M.B.A., F.A.C.H.E.
- Lynn R. Tomascik, R.N., M.S.N., C.N.A.A.
- Timothy Gene Tyler, Pharm.D.

II. Agenda

The agenda for the August 2005 meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Reconfiguration of 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).
- Evaluation of APC weights.
- Packaging devices and drug costs into APCs: methodology, effect on APCs, and need for reconfiguring APCs based upon device and drug packaging.
- Removal of procedures from the inpatient list for payment under the OPPS.
- Use of single and multiple procedure claims data.
- Packaging of HCPCS codes.
- Other technical issues concerning APC structure.

III. Written Comments and Suggested Agenda Topics

Hardcopy written comments and suggested agenda topics must be sent to the DFO. Such items must be received by the DFO 5 p.m. (e.d.t.), Monday, August 8, 2005.

Additionally, the written comments and suggested agenda topics must fall within the subject categories outlined in the Panel's Charter listed in the Agenda section of this notice.

IV. Oral Presentations

Individuals or organizations wishing to make 5-minute oral presentations must contact the DFO. The DFO must receive hardcopy presentations by 5 p.m. (e.d.t.), on Monday, August 8, 2005, in order to be scheduled.

The number of oral presentations may be limited by the time available. Oral presentations must not exceed 5 minutes in length.

The Chair may further limit time allowed for presentations due to the number of oral presentations, if necessary.

V. Presenter and Presentation Criteria

The additional criteria below must be supplied to the DFO by the August 8, 2005, deadline (along with hardcopies of presentations).

- Required personal information regarding presenter(s):
  - Name of presenter(s);
  - Title(s);
  - Organizational affiliation;
  - Address;
  - E-mail address; and
  - Telephone number(s).
- All presentations must contain, at a minimum, the following supporting information and data:
  - Financial relationship(s) of presenter(s), if any, with any company whose products, services, or procedures that are under consideration;
  - Physicians' Current Procedural Terminology (CPT) codes involved;
  - APC(s) affected;
  - Description of the issue(s);
  - Clinical description of the service under discussion (with comparison

to other services within the APC);
- Recommendations and rationale for change;
- Expected outcome of change; and
- Potential consequences of not making the change(s).

VI. Oral Comments

In addition to formal oral presentations, there will be opportunity during the meeting for public oral comments that will be limited to 1 minute for each individual and a total of 5 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 call or e-mail the Panel DFO to register in advance no later than 5 p.m. (e.d.t.), Wednesday, August 10, 2005.

The following information must be e-mailed or telephoned 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

Persons attending the meeting must present photographic identification to the Federal Protective Service or Guard Service personnel before they will be allowed to enter the building.

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, palm pilots, are subject to physical inspection.

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 30–45 minutes prior to the convening of the meeting each day. (Please note that the meeting on Wednesday, August 17, 2005, does not convene until 1 p.m.)

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

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

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 10, 2005.

Authority: Section 1833(t) of the Act (42 U.S.C. 1395l(t)). The Panel is governed by the provisions of Pub. L. 92–463, as amended (5 U.S.C. Appendix 2).

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

Dated: June 21, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–13562 Filed 7–7–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Members Representing Industry Interests on Public Advisory Panels or Committees; Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health.

DATES: Industry organizations interested in participating in the selection of a nonvoting member to represent industry for the vacancies listed in this document must send a letter to FDA by August 8, 2005, stating their interest in one or more panels. Concurrently, nomination materials for prospective candidates should be sent to FDA by August 8, 2005. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative.

ADDRESSES: All letters of interest and nominations should be sent to Kathleen L. Walker (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0450, ext. 114, e-mail: *klw@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION: Section 520(f)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include one nonvoting member to represent the interests of the medical device manufacturing industry.

FDA is requesting nominations for nonvoting members representing industry interests for the vacancies listed in table 1 of this document.

TABLE 1.—MEDICAL DEVICE PANEL VACANCIES

Medical Devices Panels	Approximate Date Representative is Needed
Anesthesiology and Respiratory Therapy Devices Panel	December 1, 2005
Dental Products Panel	November 1, 2005
General Hospital and Personal Use Devices Panel	January 1, 2006
Immunology Devices Panel	Immediate
Ophthalmic Devices Panel	November 1, 2005

I. Functions

The medical device panels perform the following functions: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation, (2) advise the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of these devices into one of three regulatory categories, (3) advise on any possible risks to health associated with the use of devices, (4) advise on formulation of product development protocols, (5) review premarket approval applications for medical devices, (6) review guidelines and guidance documents, (7) recommend exemption to certain devices from the application of portions of the act, (8) advise on the necessity to ban a device, (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices, and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.