

Orthotics, Prosthetics, and Pedorthics, Inc.).

- The Compliance Team, Inc.

Authority: Section 1834(a)(20) of the Social Security Act (42 U.S.C. 1395m(a)(20)). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 17, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1322-N]

Medicare Program; Second Semi-Annual Meeting of the Advisory Panel on Ambulatory Payment Classification Groups—September 5, 6, and 7, 2007

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 2007. 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 2008.

DATES: Meeting Dates: We are scheduling the second semi-annual meeting in 2007 for the following dates and times:

- Wednesday, September 5, 2007, 1 p.m. to 5 p.m. (e.s.t.)¹
- Thursday, September 6, 2007, 8 a.m. to 5 p.m. (e.s.t.)¹
- Friday, September 7, 2007, 8 a.m. to 12 noon (e.s.t.)²

¹The 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, September 6, there will be no Friday meeting.

Deadlines: Deadline for Hardcopy Comments/Suggested Agenda Topics—

5 p.m. (e.s.t.), Thursday, August 9, 2007

Deadline for Hardcopy Presentations—
5 p.m. (e.s.t.), Thursday, August 9, 2007

Deadline for Attendance Registration—
5 p.m. (e.s.t.), Wednesday, August 29, 2007

Deadline for Special Accommodations—
5 p.m. (e.s.t.), Wednesday, August 29, 2007

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, to send electronically to the Panel members for their review prior to 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.

- 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:

- For further information, contact: Shirl Ackerman-Ross, DFO, CMS, CMM, HAPG, DOC, 7500 Security Boulevard, Mail Stop C4-05-17, Baltimore, MD 21244-1850. *Phone:* (410) 786-4474.

(Note: Please advise couriers of the following: When delivering hardcopies of presentations to CMS, if no one answers at the above phone number, please call (410) 786-4532.)

- E-mail address for comments, presentations, and registration requests is 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 search the CMS Web site at http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage in order 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, and
- 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 redesignated 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 OPSS.

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 OPSS. 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 CMS and FACA Web sites as listed above.

The Panel presently consists of the following members:

- E.L. Hambrick, M.D., J.D., Chair
- Marilyn Bedell, M.S., R.N., O.C.N.
- Gloryanne Bryant, B.S., R.H.I.A., R.H.I.T., C.C.S.
- Hazel Kimmel, R.N., C.C.S.
- Sandra J. Metzler, M.B.A., R.H.I.A., C.P.H.Q.
- Thomas M. Munger, M.D., F.A.C.C.
- James V. Rawson, M.D.
- 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.
- Timothy Gene Tyler, Pharm.D.
- Kim Allan Williams, M.D., F.A.C.C., F.A.B.C.
- Robert Matthew Zwolak, M.D., Ph.D., F.A.C.S.
- Patricia Spencer-Cisek, M.S., A.P.R.N.-B.C., A.O.C.N.
- Russ Ranallo, M.S.
- Michael A. Ross, M.D.
- Beverly Khnie Philip, M.D.

II. Agenda

The agenda for the September 2007 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 OPSS.
- 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 OPSS 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 urge 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.s.t.), Thursday, August 9, 2007. There will be no exceptions. We appreciate your cooperation on this matter.

The written comments and suggested agenda topics submitted for the September 2007 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.s.t.), Thursday, August 9, 2007, 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 Panel DFO to register in advance no later than 5 p.m. (e.s.t.), Wednesday, August 29, 2007. A confirmation will be sent to the requester(s) via 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

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.

- In addition, all persons entering the building must pass through a metal detector.

- All items brought into CMS—including personal items such as desktops, cell phones, palm pilots, etc.—are subject to physical inspection.

- The public may enter the building 30–45 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.

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.s.t.), Wednesday, August 29, 2007.

Authority: Section 1833(t)(9) of the Act (42 U.S.C. 13951(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: May 1, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1546–N]

Medicare Program; Public Meeting in Calendar Year 2007 for New Clinical Laboratory Tests Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting to discuss payment determinations for specific new Physicians' Current Procedural Terminology (CPT) codes for clinical laboratory tests. The meeting provides a forum for interested parties to make oral

presentations and submit written comments on the new codes that will be included in Medicare's Clinical Laboratory Fee Schedule for calendar year 2008, which will be effective on January 1, 2008. The meeting will address technical issues relating to payment determinations for a specified list of new clinical laboratory codes.

The development of the codes for clinical laboratory tests is performed by the CPT Editorial Panel and will not be discussed at the CMS meeting.

DATES: The public meeting is scheduled for Monday, July 16, 2007 from 10 a.m. to 2 p.m.

ADDRESSES: The public meeting will be held in the main auditorium of the central building of the Centers for Medicare & Medicaid Services (CMS) located at 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Anita Greenberg, (410) 786–4601.

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554, mandated procedures that permit public consultation for payment determinations for new clinical laboratory tests under Part B of title XVIII of the Social Security Act (the Act) in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD–9–CM). The procedures and public meeting announced in this notice for new clinical laboratory tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA. Also, section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173, added section 1833(h)(8)(B)(iii) of the Act, which required that we establish by regulation procedures for determining the basis for, and amount of, payment for new clinical laboratory tests. In the calendar year (CY) 2007 physician fee schedule final rule (71 FR 69701 through 69704), we adopted new 42 CFR subpart G regarding payment for new clinical diagnostic laboratory tests. Under 42 CFR 414.506, we annually convene a meeting that includes representatives of CMS officials involved in determining payment amounts to receive individual comments and recommendations (and data on which the recommendations are based).

A newly created CPT code can either represent a refinement or modification of existing test methods, or a substantially new test method. The newly created CPT codes for the calendar year 2007 will be listed at the web site <http://www.cms.hhs.gov/ClinicalLabFeeSched> on or after June 18, 2007.

The first method, called cross-walking, is used when a new test is determined to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amounts and resulting national limitation amount. The second method, called gap-filling, is used when no comparable, existing test is available. When using this method, instructions are provided to each Medicare carrier to determine a payment amount for its geographic area(s) for use in the first year, and the carrier-specific amounts are used to establish a national limitation amount for following years. For each new clinical laboratory test code, a determination must be made to either cross-walk or to gap-fill, and, if cross-walking is appropriate, to know which tests to cross-walk.

II. Meeting Format

This meeting is open to the public. The on-site check-in for visitors will be held from 9:30 to 10 a.m., followed by opening remarks. Registered individuals may discuss and recommend payment determinations for specific new CPT codes for the 2008 Clinical Laboratory Fee Schedule.

Oral presentations must be brief, and must be accompanied by three written copies. Presenters may also make copies available for approximately 50 meeting participants. Presenters should address the new test code(s) and descriptor, the test purpose and method, costs, charges, and make a recommendation with rationale for using one of two methods (cross-walking or gap-fill) for determining payment for new clinical laboratory codes. Presentations that do not address the six items may be considered incomplete and not considered by CMS when making a payment determination. We will request missing information following the meeting in order to prevent a recommendation from being considered incomplete.

A summary of the new codes and the payment recommendations that are presented during the public meeting will be posted on our Web site by September 7, 2007 and can be accessed at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. In addition, the