

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1438-N]

Medicare Program; Public Meetings in Calendar Year 2013 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2013 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. The discussion will be focused on responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

DATES: *Meeting Dates:* The following are the 2013 HCPCS public meeting dates:

1. Wednesday, May 8, 2013, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.) (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
2. Thursday, May 9, 2013, 9 a.m. to 5 p.m., e.d.t. (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
3. Wednesday, May 29, 2013, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).
4. Tuesday, June 4, 2013, 9 a.m. to 5 p.m., e.d.t. (Durable Medical Equipment (DME) and Accessories & (Orthotics and Prosthetics)).

Deadlines for Primary Speaker Registration and Presentation Materials: The deadline for registering to be a primary speaker and submitting materials and writings that will be used in support of an oral presentation are as follows:

- April 24, 2013 for the May 8, 2013 and May 9, 2013 public meetings.
- May 15, 2013 for the May 29, 2013 public meeting.
- May 22, 2013 for the June 4, 2013 public meeting.

Deadline for Attendees that are Foreign Nationals Registration: Attendees that are foreign nationals (as described in section IV. of this notice)

are required to identify themselves as such, and provide the necessary information for security clearance (as described in section IV. of this notice) to the public meeting coordinator at least 12 business days in advance of the date of the public meeting date the individual plans to attend. Therefore, the deadlines for attendees that are foreign nationals are as follows:

- April 22, 2013 for the May 8, 2013 and May 9, 2013 public meetings.
- May 10, 2013 for the May 29, 2013 public meeting.
- May 16, 2013 for the June 4, 2013 public meeting.

Deadlines for all Other Attendees

Registration: All other individuals who plan to enter the building to attend the public meeting must register for each date that they plan on attending. The registration deadlines are different for each meeting. Registration deadlines are as follows:

- May 1, 2013 for the May 8, 2013 and May 9, 2013 public meeting dates.
- May 22, 2013 for the May 29, 2013 public meeting date.
- May 29, 2013 for the June 4, 2013 public meeting date.

Deadlines for Requesting Special Accommodations: Individuals who plan to attend the public meetings and require sign-language interpretation or other special assistance must request these services by the following deadlines:

- April 24, 2013 for the May 8, 2013 and May 9, 2013 public meetings.
- May 15, 2013 for the May 29, 2013 public meeting.
- May 22, 2013 for the June 4, 2013 public meeting.

Deadline for Submission of Written Comments: Written comments must be received by the date of the meeting at which the code request is scheduled for discussion.

ADDRESSES: *Meeting Location:* The public meetings will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Submission of Written Comments: Written comments may either be emailed to HCPSC@cms.hhs.gov or sent via regular mail to Jennifer Carver or Kimberlee Combs Miller, HCPCS Public Meeting Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244-1850.

Registration and Special Accommodations: Individuals wishing to participate or who need special accommodations or both must register by completing the on-line registration

located at www.cms.hhs.gov/medhpcsgeninfo or by contacting one of the following persons: Jennifer Carver at (410) 786-6610 or Jennifer.Carver@cms.hhs.gov; or Kimberlee Combs Miller at (410) 786-6707 or Kimberlee.CombsMiller@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Jennifer Carver at (410) 786-6610 or Jennifer.Carver@cms.hhs.gov. Kimberlee Combs Miller at (410) 786-6707 or Kimberlee.CombsMiller@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554). Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new durable medical equipment (DME) under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice for new DME are in response to the mandate of section 531(b) of BIPA.

In the November 23, 2001 **Federal Register** (66 FR 58743), we published a notice providing information regarding the establishment of the public meeting process for DME. It is our intent to distribute any materials submitted to CMS to the Healthcare Common Procedure Coding System (HCPCS) workgroup members for their consideration. CMS and the HCPCS workgroup members require sufficient preparation time to review all relevant materials. Therefore, we are implementing a 10-page submission limit and firm deadlines for receipt of any presentation materials a meeting speaker wishes us to consider. For this reason, our HCPCS Public Meeting Coordinators will only accept and review presentation materials received by the deadline for each public meeting, as specified in the **DATES** section of this notice.

The public meeting process provides an opportunity for the public to become aware of coding changes under consideration, as well as an opportunity for CMS to gather public input.

II. Meeting Registration

A. Required Information for Registration

The following information must be provided when registering:

- Name.
- Company name and address.
- Direct-dial telephone and fax numbers.

- Email address.
- Special needs information.

A CMS staff member will confirm your registration by email.

B. Registration Process

1. Primary Speakers

Individuals must also indicate whether they are the “primary speaker” for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. When registering, primary speakers must provide a brief written statement regarding the nature of the information they intend to provide, and advise the HCPCS Public Meeting Coordinator regarding needs for audio/visual support. To avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accept tapes and disk files that are received by the deadline for submissions for each public meeting as specified in the **DATES** section of this notice. The sum of all materials including the presentation may not exceed 10 pages (each side of a page counts as 1 page). An exception will be made to the 10-page limit for relevant studies published between the application deadline and the public meeting date, in which case, we would like a copy of the complete publication as soon as possible. This exception applies only to the page limit and not the submission deadline.

The materials may be emailed or delivered by regular mail to one of the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** section of this notice. The materials must be emailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to provide 35 copies if materials are delivered by mail.

2. 5-Minute Speakers

To afford the same opportunity to all attendees, 5-minute speakers are not required to register as primary speakers. However, 5-minute speakers must still register as attendees by the deadline set forth under “Deadlines for all Other Attendees Registration” in the **DATES** section of this notice. Attendees can sign up only on the day of the meeting to do a 5-minute presentation. Individuals must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that they will address.

C. Additional Meeting/Registration Information

We were able this year to combine the Orthotics/Prosthetics and DME meeting into one public meeting date. That public meeting will be Tuesday, June 4, 2013.

The product category reported by the applicant may not be the same as that assigned by us. Prior to registering to attend a public meeting, all participants are advised to review the public meeting agendas at www.cms.hhs.gov/medhpcsgeninfo which identify our category determinations, and the dates each item will be discussed. Draft agendas, including a summary of each request and our preliminary decision will be posted on our HCPCS Web site at www.cms.hhs.gov/medhpcsgeninfo at least 4 weeks before each meeting.

Additional details regarding the public meeting process for all new public requests for revisions to the HCPCS, along with information on how to register and guidelines for an effective presentation, will be posted at least 4 weeks before the first meeting date on the official HCPCS Web site at www.cms.hhs.gov/medhpcsgeninfo. The document titled “Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)” will be made available on the HCPCS Web site at least 4 weeks before the first public meeting in 2013 for all new public requests for revisions to the HCPCS. Individuals who intend to provide a presentation at a public meeting will need to familiarize themselves with the HCPCS Web site and the valuable information it provides to prospective registrants. The HCPCS Web site also contains a document titled “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” which is a description of the HCPCS coding process, including a detailed explanation of the procedures used to make coding determinations for all the products, supplies, and services that are coded in the HCPCS.

The HCPCS Web site also contains a document titled “HCPCS Decision Tree & Definitions” which illustrates, in a flow diagram format, HCPCS coding standards as described in our Coding Procedures document.

A summary of each public meeting will be posted on the HCPCS Web site by the end of August 2013.

III. Presentations and Comment Format

We can only estimate the amount of meeting time that will be needed since it is difficult to anticipate the total number of speakers that will register for

each meeting. Meeting participants should arrive early to allow time to clear security and sign-in. Each meeting is expected to begin promptly as scheduled. Meetings may end earlier than the stated ending time.

A. Oral Presentation Procedures

All primary speakers must register as provided under the section titled “Meeting Registration.” Materials and writings that will be used in support of an oral presentation should be submitted to one of the HCPCS Public Meeting Coordinators.

The materials may be emailed or delivered by regular mail to one of the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** section of this notice. The materials must be emailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to include 35 copies if materials are delivered by mail.

B. Primary Speaker Presentations

The individual or entity requesting revisions to the HCPCS coding system for a particular agenda item may designate one “primary speaker” to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and the presentation must incorporate the demonstration, set-up, and distribution of material. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the speaker by increments of less than 15 minutes.

Individuals designated to be the primary speaker must register to attend the meeting using the registration procedures described under the “Meeting Registration” section of this notice and contact one of the HCPCS Public Meeting Coordinators, specified in the **ADDRESSES** section. Primary speakers must also separately register as primary speakers by the date specified in the **DATES** section of this notice.

C. “5-Minute” Speaker Presentations

Meeting attendees can sign up at the meeting, on a first-come, first-served basis, to make 5-minute presentations on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made at the meeting by the meeting coordinator and the meeting moderator regarding how many 5-minute speakers can be accommodated.

D. Speaker Declaration

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

Each primary speaker and 5-minute speaker must declare in their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

E. Written Comments From Meeting Attendees

Written comments will be accepted from the general public and meeting registrants anytime up to the date of the public meeting at which a request is discussed. Comments must be sent to the address listed in the **ADDRESSES** section of this notice.

Meeting attendees may also submit their written comments at the meeting. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

IV. Security, Building, and Parking Guidelines

The meetings are held within the CMS Complex which is not open to the general public. Visitors to the complex are required to show a valid U.S. Government issued photo identification, preferably a driver's license, at the time of entry. Participants will also be subject to a vehicular search before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on Federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocket knives), dogs or other animals except service animals. Once cleared for entry to the complex participants will be directed to parking by a security officer.

In order to ensure expedited entry into the building it is recommended that participants have their ID and a copy of their written meeting registration confirmation readily available and that they do not bring laptops or large/bulky items into the building. Participants are

reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. 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 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted out of the facility. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at anytime. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

CMS policy requires that every foreign national (as defined by the Department of Homeland Security is "an individual who is a citizen of any country other than the United States") is assigned a host (in accordance with the Department Foreign Visitor Management Policy, Appendix C, Guidelines for Hosts and Escorts). The host/hosting official is required to inform the Division of Critical Infrastructure Protection (DCIP) at least 12 business days in advance of any visit

by a foreign national. Foreign nationals will be required to produce a valid passport at the time of entry.

Attendees that are foreign nationals need to identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Visitor's full name (as it appears on passport).
- Gender.
- Country of origin and citizenship.
- Biographical data and related information.
- Date of birth.
- Place of birth.
- Passport number.
- Passport issue date.
- Passport expiration date.
- Dates of visits.
- Company Name.
- Position/Title.

Dated: February 8, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0145]

Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I; Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Accreditation and Reaccreditation Process for Firms Under the Third Party Review Program: Part I." The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), requires FDA to establish and publish criteria to reaccredit or deny reaccreditation to persons accredited by FDA under the FD&C Act to perform premarket review of medical devices. This draft guidance describes the accreditation, reaccreditation, and accreditation withdrawal processes, including criteria that will be considered to accredit, reaccredit, deny accreditation to, and deny reaccreditation to third party