

Dated: February 19, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1705-N]

Medicare Program; Public Meetings in Calendar Year 2019 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 2019 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 2019 HCPCS public meeting dates:

1. Monday, May 13, 2019, 9 a.m. to 5 p.m., eastern daylight time (e.d.t), for Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents.
2. Tuesday, May 14, 2019, 9 a.m. to 5 p.m., e.d.t, for Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents.
3. Wednesday, May 15, 2019, 9 a.m. to 5 p.m., e.d.t., for Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents.
4. Tuesday, June 11, 2019, 9 a.m. to 5 p.m., e.d.t., for Durable Medical Equipment (DME) and Accessories, Orthotics and Prosthetics (O&P) Supplies, and Other for DME and Accessories, O&P Supplies, and Other.
5. Wednesday, June 12, 2019, 9 a.m. to 5 p.m., e.d.t., for DME and Accessories, O&P Supplies, and Other.

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:

- Monday, April 29, 2019, for the May 13, 14 and 15, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.
- Tuesday, May 28, 2019, for the June 11 and 12, 2019 DME and Accessories, O&P Supplies, and Other public meetings.

Registration Deadline for Attendees that are Foreign Nationals: CMS' registration deadlines for attendees that are foreign nationals (including the deadlines for providing necessary information for security clearance) are as follows:

- Monday, April 22, 2019, for the May 13, 14 and 15, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.
- Tuesday, May 21, for the June 11 and 12, 2019 DME and Accessories, O&P Supplies, and Other public meetings.

Registration Deadlines for all Other Attendees: The registration deadlines are different for each meeting. Registration deadlines are as follows:

- Monday, April 29, 2019, for the May 13, 14 and 15, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.
- Tuesday, May 28, 2019, for the June 11 and 12, 2019 DME and Accessories, O&P Supplies, and Other public meetings.

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:

- Monday, April 29, 2019, for the May 13, 14 and 15, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.
- Tuesday, May 28, 2019, for the June 11 and 12, 2019 DME and Accessories, O&P Supplies, and Other public meetings.

Deadline for Submission of Written Comments: Written comments and other documentation in response to a preliminary coding or payment determination that are received by no later than the date of the public meeting at which the code request is scheduled

for discussion, will be considered in formulating a final coding decision.

ADDRESSES:

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

Submission of Written Comments: Written comments may either be emailed to HCPCS@cms.hhs.gov or sent via regular mail to Irina Akelaitis or Felicia Kyeremeh at the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-09-14, 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/medhcpcsgeninfo or by contacting the staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

FOR FURTHER INFORMATION CONTACT: Irina Akelaitis, (410) 786-4602, or Irina.Akelaitis@cms.hhs.gov; or Felicia Kyeremeh, (410) 786-1898 or Felicia.Kyeremeh@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). 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. The procedures and public meetings announced in that notice for new DME were in response to the mandate of section 531(b) of BIPA. As part of HCPCS reform, we expanded the public meeting forum to include all public requests as of the 2005-2006 coding cycle.

It is our intent to distribute any submitted materials to CMS' Healthcare Common Procedure Coding System (HCPCS) workgroup members for their consideration. CMS 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, CMS 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 and provide input regarding coding changes under consideration, as well as an opportunity for us to gather public input.

II. Meeting Registration

A. Required Information for Registration

The following information must be provided when registering on-line to attend:

- 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 CMS’ HCPCS staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice, 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. Late submissions and updates of electronic materials after our deadline cannot be accommodated.

Please note our page limit for primary speaker presentation materials. The sum of all presentation materials and additional supporting documentation may not exceed 10 pages (each side of a page counts as 1 page). An exception will be made to the 10-page limit only for relevant studies newly 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 CMS officials 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 25 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 “Registration Deadlines for all Other Attendees” 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

The product category reported in the HCPCS code application 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 website 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 website 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 website at least 4 weeks before the first public meeting in 2019 for all new public requests for revisions to the HCPCS. Individuals who intend to provide a presentation at a public meeting need to familiarize themselves with the HCPCS website and the valuable information it provides to prospective registrants. The HCPCS website 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 website also contains a document titled “HCPCS Decision Tree & Definitions,” which illustrates, in flow diagram format, HCPCS coding standards as described in our Coding Procedures document.

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 must 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.” All materials that will be used in support of an oral presentation must be submitted to the CMS staff specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

The materials may be emailed or delivered by regular mail to the CMS staff 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 25 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 any 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* by the date specified in the **DATES** section of this notice using the meeting registration procedures described in the section II. of this notice, “Meeting

Registration”. *Primary speakers must also separately register as primary speakers* as 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 presentations for up to 5 minutes 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 and whether the 5-minute time allocation would be reduced, to accommodate the number of speakers.

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 CMS’ HCPCS staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Every primary speaker and 5-minute speaker must declare at the beginning of 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 business on the date of the public meeting at which the request is discussed.

F. Remote Attendance and Participation

CMS’ HCPCS Public Meetings are, and have been live-streamed on U-Tube for viewing and listening only. CMS is considering steps for future coding cycles that would make our HCPCS

coding program even more transparent, and provide additional opportunities for public input, by expanding participation in HCPCS Public Meetings, and making participation easier. Specifically, we are examining the logistics and feasibility of arranging for oral presentations to be made from remote locations, as opposed to in-person at CMS only.

IV. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register no later than the date specified in the **DATES** section of this notice.

Attendees that are foreign nationals are required to identify themselves as such, and provide the necessary information for security clearance in advance of the date of the public meeting the individual plans to attend to CMS’ HCPCS staff listed in the **ADDRESSES** section of this notice.

All individuals who are not foreign nationals who plan to enter the building to attend the public meeting must register for each date that they plan on attending.

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle’s interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. 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 presentation or to support a presentation.

Note: 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 prior to the convening of the meeting.

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

Dated: February 19, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10415]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 30, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or