

2020 GUIDELINES FOR PARTICIPATION IN VIRTUAL PUBLIC MEETINGS FOR NEW PUBLIC REQUESTS FOR REVISIONS TO THE HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)

The purpose of the virtual public meetings is to provide a forum for the public to present information regarding specific Healthcare Common Procedural Coding System (HCPCS) coding requests for products, supplies and services. The virtual meeting also provides an opportunity for CMS to obtain public reaction to the CMS preliminary coding recommendations.

ROLE OF THE VIRTUAL PUBLIC MEETINGS FOR NEW REQUESTS, RELATIVE TO THE OVERALL HCPCS CODING PROCESS

The agenda for the virtual public meetings consists of summaries of HCPCS coding requests for products, supplies and services submitted through the standard HCPCS coding review and recommendation process. The CMS' preliminary recommendations regarding coding requests, including specific items on the virtual public meeting agenda can be viewed in advance of the virtual public meeting on CMS' HCPCS Web site at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

The virtual public meetings are open to the public. The meetings typically have been attended by representatives of medical equipment manufacturers and suppliers; government relations, regulatory and compliance specialist personnel from various provider organizations; industry consultants; and CMS and other federal government staff. Applicants who submitted a code request for a product that appears on the public meeting agenda are welcome to attend; however, their attendance is not mandatory. CMS may reconsider its preliminary coding recommendations in light of any new information presented at the public meetings, and written comments submitted by the deadline. CMS is the entity that maintains

the permanent HCPCS Level II codes. CMS is the final decision-making authority concerning requests for permanent HCPCS Level II codes.

The virtual public meetings are designed for applicants and others to present additional information, clarify issues, and offer supporting or opposing perspectives regarding CMS' preliminary recommendations. Final coding decisions are made by CMS; they are not made at the public meetings. CMS reserves the right to change its preliminary decision following the public meeting. Final decisions may or may not model the preliminary recommendations.

General information about the CMS' HCPCS coding process, the standard HCPCS code request format and detailed instructions can be found on CMS' official Level II HCPCS Web site at: www.cms.gov/medhcpcsgeninfo. The official update of the HCPCS code system is available as a Public Use File and can be downloaded at:

<https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS>.

The product category reported by the applicant may not be the same as that assigned by CMS. Meeting participants are advised to review the public meeting agenda at <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings> under the dates each item will be discussed.

Comments and inquiries are welcome, and will only be accepted when e-mailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov by 5:00 PM, ET on the date of the virtual public meeting at which the request that is the subject of the comment appears on the agenda for discussion.

DATES: Virtual Meeting Dates: Monday, December 21, 2020, 9:00 AM to 5:00 PM, Eastern Time (ET), and Tuesday, December 22, 2020, 9:00 AM to 5:00 PM, ET, for Medical non-drug and non-biological items.

ADDRESSES: Virtual Meeting Location: The December 21 and December 22, 2020 HCPCS Public meetings will be held virtually and available for remote attendance only via Zoom. Detailed information pertaining to registering to participate via Zoom, including dial-in information for all attendees is specified in the “DEADLINE FOR REGISTRATION” section below.

Deadline 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 is 5:00 PM, ET, Thursday, December 17, 2020. All registered primary speakers may join the virtual meeting on the date that they plan to attend, using the meeting link listed in the “JOIN THE MEETING INFORMATION” section of this notice. All registered primary speakers will be e-mailed a participant ID number for their individual use to join the meeting, in advance of the virtual meeting.

Deadline for 5-Minute Speakers Registration: The deadline for registering to be a 5-minute speaker is 5:00 PM, ET, Thursday, December 17, 2020. All registered 5-minute speakers may join the virtual meeting on the date that they plan to attend, using the meeting link listed in the “JOIN THE MEETING INFORMATION” section of this notice. All registered 5-minute speakers will be e-mailed a participant ID number for their individual use to join the meeting, in advance of the virtual meeting.

Deadline for Registration for all Other Attendees: All individuals who plan to attend the virtual public meetings to listen, but do not plan to offer prepared comments, may simply

join the virtual meeting on the date that they plan to attend, using the meeting link specified for that meeting date. In other words, registration is not required for participants who plan to listen, but not present. A meeting link for each public meeting date is listed in the “JOIN MEETING INFORMATION” section of this notice. A “raise your hand” feature will be available to ask questions or provide comments.

Deadline for Requesting Accommodations: Individuals who plan to participate in the virtual public meetings and require assistance must request these services by 5:00 PM, ET, Monday, December 14, 2020.

Deadline for Submission of Written Comments: Written comments and other documentation in response to a preliminary coding determination that are received by no later than the date of the virtual public meeting at which the code request is scheduled for discussion will be considered in formulating a final coding decision.

NOTIFICATION OF PUBLIC MEETINGS, CONTENT OF THE AGENDA, AND MEETING SUMMARIES

Notice of the Public Meetings for new Public Request for Revisions to the HCPCS Coding was published on September 28, 2020 in the Federal Register at:

<https://www.federalregister.gov/documents/2020/09/28/2020-21257/medicare-program-virtual-public-meetings-in-october-2020-for-new-public-requests-for-revisions-to>.

Virtual public meeting dates, public meeting agendas, including summaries of each application; and related materials and registration information are published at:

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

SELECTING AGENDA ITEMS FOR PUBLIC MEETINGS

Items are placed on a Public Meeting agenda for New Requests if the application for the item was complete and submitted timely to the standard National HCPCS process in the current coding cycle, or as identified by CMS for public consideration.

REGISTERING TO BE A SPEAKER

Registration should be completed by the registration deadline before each meeting at <https://www.cms.gov/apps/events/upcomingevents.asp>. Individuals must register for each date they plan to speak or provide a presentation.

A. Required Information for Registration

The following information must be provided when registering to attend the virtual meeting:

- Name
- Company name and address
- Direct-dial telephone
- E-mail address
- Accommodations information, if needed

A CMS staff member will confirm your registration by e-mail.

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. Primary speakers must provide a brief written statement regarding the nature of the information they intend to provide and advise CMS staff regarding PowerPoint presentation. Speaker PowerPoint files are tested and arranged in speaker sequence well in advance of the meeting. We will accept e-mailed PowerPoint

files that are received by the deadline for submissions of presentation materials as specified in the “DATES” section of this guideline. All materials will only be accepted when e-mailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov. Late submissions and updates of electronic materials after our deadline cannot be accommodated.

It is necessary for us to implement a **10-page limit** and firm deadlines for receipt of any materials and presentations that the meeting participant wishes CMS to consider. An exception will be made to this **10-page limit** only for relevant scientific studies published between the application deadline and the public meeting date, in which case, CMS would like an electronic copy of the entire study, as published, as soon as possible, but by no later than close of business on the public meeting date. Discussion or questions by CMS staff on any topic at the public meeting should not be construed as an extension of the deadline for materials submission.

Fifteen minutes is the total time interval for the presentation. In establishing the virtual 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 primary speaker.

2. “5-Minute Speakers”

Individuals must also indicate whether they are “5-minute speaker” for an agenda item. Five-minute speakers must register as such by the deadline set forth under “Deadline for “5-minute Registration” in the “DATES” section of this guideline. 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 allocation would be reduced to accommodate the number of speakers.

On the day of the virtual meeting, before the end of the meeting, all 5-minute speakers must email a brief written summary of their comments and conclusions to HCPCS_Level_II_Code_Applications@cms.hhs.gov.

Primary Speaker Responsibilities:

In advance of the meeting:

- Register to be a primary speaker on-line.
- Upon registering to be a primary speaker, indicate if you have a PowerPoint presentation.
- Please avoid using a dark or black background on your slides. If you include charts within your slides, please make sure the font size is large enough so that participants can read the print.
- Send your presentation material and a brief written statement regarding the nature of the information that will be presented at the meeting to HCPCS_Level_II_Code_Applications@cms.hhs.gov.

On the day of the meeting:

Speakers must declare at the beginning of the speaker's presentation at the meeting, as well as in the speaker's written summary, whether the speaker has 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.

Speakers must email a brief written summary of their comments and conclusions to HCPCS_Level_II_Code_Applications@cms.hhs.gov.

Because it is difficult to anticipate whether presentations will fill their allotted time period (e.g., 15 minutes for primary speakers; 5 minutes for "5-minute speakers"),

CMS cannot commit specific items to specific time frames, but can only estimate the amount of time that may be needed. As a result, meetings may end earlier than the designated time. Meeting participants should review the dates and times of the public meetings included in this announcement.

GUIDANCE TO SPEAKERS FOR AN EFFECTIVE PRESENTATION

Based on experience, CMS has established the following tips for an effective presentation:

Information that is helpful to CMS:

Speakers are required to state their name, relationship to the applicant and to the manufacturer, and declare any financial involvement with the manufacturer or competitors of any items being discussed. React specifically to the individual coding recommendation and state whether you support or refute it. If you disagree with the recommendation, provide substantiating information and explanation, and offer a recommendation as to how to correct it. Focus on factual information and objective, supporting documentation. Information that is in addition to that already provided in the application may help to make a point. CMS has evaluated the requests that appear on the public meeting agenda, arrived at and published its preliminary coding recommendations. The public meeting forum is an opportunity to provide additional information that may convince CMS to reconsider its preliminary recommendation.

The focus of your presentation should be to convince the audience as to the reasons why you disagree with CMS' preliminary recommendation, for example: if the preliminary recommendation is that the product that is the subject of your application is adequately described by existing HCPCS code categories, and you disagree, provide the

reason why you disagree along with substantiating information. It is also helpful to describe who would and would not benefit by the use of the product.

Information that is not beneficial to CMS:

Keep in mind that HCPCS codes identify categories of like products. The assignment of a HCPCS code does not guarantee or imply that a product or service is covered or separately payable by any insurer. HCPCS coding decisions and coverage determinations are completely separate processes. Coverage determinations are not part of the HCPCS coding decision-making process or part of the public meeting forum. Therefore, testimonials and discussions about medical necessity or efficacy intended to address coverage are not beneficial, and may detract from the purpose of the meeting.

Blanket dismissal of coding recommendation(s) or simply reiterating the original request without responding directly, and thoughtfully, to each individual preliminary coding recommendation and decision rationale does not help CMS to understand the reason why the recommendation is unsatisfactory, or how or why it should be changed.

The virtual public meetings are not directed to the attention of buyers of medical products. Therefore, promotional information that does not address the uniqueness of the product category is not helpful.

Timing of presentations:

Speakers may take less but not more than the amount of time allotted (15 minutes for primary speakers, 5 minutes for “5-minute” speakers). Speakers may not give away, assign or yield unused time. Unused time is automatically forfeited to the moderator. Only the moderator may call speakers. Speakers may not call other speakers. In fairness to speakers as well as to the other participants, the moderator will end all presentations

precisely at the end of their allotted time. Therefore, it is helpful to rehearse and time your presentations to ensure that key points are made within the allotted time.

The moderator reserves the right to interrupt a presentation in order to preserve the meeting for the benefit of all participants.

Written Comments from Meeting Attendees

The CMS welcomes the written comments of other persons participating in the meeting, who did not have the opportunity to or did not care to make an oral presentation. As part of CMS' response to the COVID-19 public health emergency, there is a limited presence at the CMS headquarters for receiving paper packages. Therefore, written comments from the general public and meeting registrants will **only** be accepted when e-mailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov by 5:00 PM up to the date of the virtual public meeting at which a request is discussed. With implementation of shorter and more frequent coding cycles and the resultant close timing of the virtual public meetings, subsequent agency reconsiderations, formulation of final decisions, and publication deadlines; we are able to consider only those written submissions received by the close of business on the date of the virtual public meeting at which the request is discussed.

FOR FURTHER INFORMATION, CONTACT:

Kimberlee Combs, (410) 786-6707, or Kimberlee.Combs@cms.hhs.gov;

Irina Akelaitis, (410) 786-4602, or Irina.Akelaitis@cms.hhs.gov;

Felicia Kyeremeh, (410) 786-1898, or Felicia.Kyeremeh@cms.hhs.gov;

Sundus Ashar, (410) 786-0750, or Sundus.Ashar1@cms.hhs.gov; or

Constantine Markos, (410) 786-0911, or Constantine.Markos@cms.hhs.gov.

FAQs:

WHO MAY ATTEND THE PUBLIC MEETINGS?

The public is invited to attend CMS' virtual public meetings. Entities who submit requests that are being discussed at the meeting and their competitors might attend.

Attendance at the virtual public meetings is voluntary.

IS ATTENDANCE MANDATORY FOR APPLICANTS WHO HAVE AN ITEM ON THE AGENDA?

No. Attendance is voluntary, and attendees are not required to make a presentation.

Whether or not the requesting entity is represented at the virtual meeting, agenda items will be presented with a description of the request and the CMS preliminary

recommendation (as published with the agenda on the official HCPCS website at

<https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>),

and public comments will be invited.

ARE DECISIONS MADE AT THE VIRTUAL PUBLIC MEETINGS?

No. The CMS' virtual public meeting forum provides an opportunity for a requester to speak to CMS and to the public, and an opportunity for CMS to hear from the requester and the public, and balance sometimes competing points of view. It is an opportunity for the public and competitors to participate in a discussion of HCPCS coding for new requests.

Information provided at the CMS HCPCS virtual public meetings is considered subsequently by CMS. CMS is the final decision-making authority concerning requests for Level II HCPCS codes.

THE AGENDA DOES NOT INCLUDE TIMES. HOW DO PARTICIPANTS KNOW EXACTLY WHEN SPECIFIC ITEMS WILL BE DISCUSSED?

It is not possible to anticipate with precision whether presentations will fill their allotted time period (e.g., 15 minutes for primary speakers; 5 minutes for “5-minute speakers”); therefore, CMS cannot commit specific items to specific time frames. CMS asks that speakers dial in to the meeting at least 10 minutes prior to the start time, plan on the meeting commencing promptly at the designated start time, and wait until it is their turn to speak. Meetings are typically scheduled to adjourn at a specified time; however, because CMS can only estimate the amount of meeting time that will be needed, meetings may adjourn earlier.

JOIN THE MEETING INFORMATION:

All registered and non-registered meeting attendees must use the Zoom-link and instructions below. Attendees have the capability to offer comments by using the “raise hand” or “via chat box” feature during question and comment portions for every agenda item throughout the meeting.

Event Address for Attendees of Virtual Public Meeting

When: Monday, December 21, 2020 9:00 AM- 5:00 PM Eastern Time.

Where: You are invited to a Zoom webinar.

Topic: Medicare & Medicaid Service (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting for DMEPOS

Please click the link below to join the webinar:

<https://cms.zoomgov.com/j/1610701817?pwd=R3hYaWtPaGVVREh2YVNMSkFQMThEQT09>

Password: 083822

Telephone: Dial US: +1 669 254 5252 or +1 646 828 7666

Webinar ID: 161 070 1817

Please join at least 10 minutes before the scheduled start time so you won't miss valuable information.

Event Address for Attendees of Virtual Public Meeting

When: Tuesday, December 22, 2020 9:00 AM- 5:00 PM Eastern Time.

Where: You are invited to a Zoom webinar.

Topic: Medicare & Medicaid Service (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting for DMEPOS

Please click the link below to join the webinar:

<https://cms.zoomgov.com/j/1610701817?pwd=R3hYaWtPaGVVREh2YVNMSkFQMThEQT09>

Password: 083822

Telephone: Dial US: +1 669 254 5252 or +1 646 828 7666

Webinar ID: 161 070 1817

Please join at least 10 minutes before the scheduled start time so you won't miss valuable information.

For assistance, you can contact Marvelyn Davis at:

Marvelyn.Davis1@cms.hhs.gov

IMPORTANT NOTICE: Please note that this Zoom Meetings service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you

do not consent to being recorded, discuss your concerns with the host or do not join the session.