



**GUIDELINES FOR PARTICIPATION
IN VIRTUAL PUBLIC MEETINGS IN JULY 2021
FOR NEW REVISIONS TO THE HEALTHCARE COMMON PROCEDURE
CODING SYSTEM (HCPCS) CODE SET**

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 the Centers for Medicare & Medicaid Services (CMS) to obtain public reaction to 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. 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 website 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 HCPCS Level II 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 maintains the HCPCS Level II code set, and is the final decision-making authority concerning requests for 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 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, including the standard HCPCS code request format and detailed instructions can be found on CMS' official Level II HCPCS website at: www.cms.gov/medhpcpsgeninfo. 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>.

Meeting participants are advised to review the public meeting agendas at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>. Comments and inquiries are welcome, but will only be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov by 5:00 p.m., eastern daylight time (e.d.t.), 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: Wednesday, July 7, 2021, 9:00 a.m. to 5:00 p.m., e.d.t., Thursday, July 8, 2021, 9:00 a.m. to 5:00 p.m., e.d.t., and Friday, July 9, 2021, 9:00 a.m. to 5:00 p.m., e.d.t.

CMS notes that although we have announced that the virtual public meeting will be held over a period of three days, we have arranged the preliminary coding recommendations we intend to discuss over a period of two days; July 7 and 8. If we receive a greater number of speaker registrations than we believe we can reasonably accommodate over those two days, we reserve the right to shift some agenda items to a third day, July 9. In that eventuality, we would make every effort to notify all affected speakers as soon as possible, in addition to posting all updates on CMS' HCPCS website at: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings>.

Address: Virtual Meeting Location: The July 7-9, 2021 HCPCS public meetings will be held virtually and available for remote attendance only via Zoom. Detailed information pertaining to registering to participate via Zoom, 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 that will be used in support of an oral presentation is 5:00 p.m., e.d.t., Friday, June 25, 2021. All primary speakers must register by the registration deadline at:

https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w.

Deadline for 5-Minute Speakers Registration: The deadline for registering to be a 5-minute speaker is 5:00 p.m., e.d.t., Friday, June 25, 2021. All 5-minute speakers must register by the registration deadline at:

https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w.

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 are also required to register for the public meeting for the date that they plan to attend, using the link at: https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w.

In other words, registration is required for all who plan to attend the public meeting. A registration link for the public meeting is also 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 Special Accommodations: Individuals who plan to participate in the virtual public meetings and require assistance must request these services by 5:00 p.m., e.d.t., Friday, June 25, 2021.

Deadline for Submission of Written Comments: To be considered in formulating a final coding decision, written comments and other documentation must be received by 5:00 p.m., e.d.t., on the date of the virtual public meeting at which the applicable code request is scheduled for discussion.

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 through CMS’ HCPCS Level II application process in the current coding cycle, or as identified by CMS for public consideration.

A. Required Information for Registration

The following information must be provided when registering online to attend:

Direct-dial telephone

Email address

Any special accommodation requests

After registering, you will get confirmation with instructions on how to join the webinar.

B. Registration Process

1. Primary Speakers

Individuals must also indicate whether they are the "primary speaker" for an agenda item, and if they have a PowerPoint presentation. 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 regarding any needs for audio/visual support and email it to HCPCS_Level_II_Code_Applications@cms.hhs.gov. Speaker PowerPoint files are tested and arranged in speaker sequence well in advance of the meeting. We will accept emailed PowerPoint files that are received by the deadline for submissions of presentation materials as specified in the "DATES" section of this notice. Materials will only be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov. Due to the timeframe for planning and coordination of the HCPCS public meetings under CMS' shorter and more frequent coding cycles that started in 2020, late submissions and updates of materials after our deadline cannot be accommodated.

All presentation materials and additional supporting documentation should 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 virtual public meeting date, in which case, we request a copy of the complete publication be emailed as soon as possible to

HCPCS_Level_II_Code_Applications@cms.hhs.gov. This exception applies only to the page limit and not the submission deadline.

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

Every primary 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.

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

2. 5-Minute Speakers

The deadline for registering to be a 5-minute speaker is noted in the "DATES" section of this notice. Individuals must provide their name, company name and address, and contact information as specified in the instructions for remote participation, and identify the specific agenda item that they will address. Based on the number of items on the agenda and the progress of the meeting, a determination will be made 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.

Every 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.

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 PowerPoint presentation 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.

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.

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:

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 for how to correct it. Focus on factual information and supporting documentation. 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 agree or 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 reasons for 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/why it should be changed.

Timing of presentations:

Speakers may not take 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 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

CMS welcomes written comments from other persons participating in the meeting who did not have the opportunity to, or did not choose to make an oral presentation. As

part of CMS' response to the COVID-19 public health emergency, written comments from the general public and meeting registrants will **only** be accepted when emailed to HCPCS_Level_II_Code_Applications@cms.hhs.gov by 5:00 p.m., e.d.t., on the date of the virtual public meeting at which a request is discussed.

For Further Information, Contact:

Irina Akelaitis, Irina.Akelaitis@cms.hhs.gov;

Felicia Kyeremeh, Felicia.Kyeremeh@cms.hhs.gov;

Sundus Ashar, Sundus.Ashar1@cms.hhs.gov; or

Constantine Markos, Constantine.Markos@cms.hhs.gov; or

William Walker, William.Walker@cms.hhs.gov

FAQs:

Who may Attend the Public Meetings?

The general public is invited to attend CMS' virtual public meetings.

Is attendance mandatory for applicants who have an item on the agenda?

No. Attendance is voluntary, and attendees are not required to present.

Regardless of if an applicant attends the virtual public meeting, their agenda item(s) will be presented with a description of the request and the CMS preliminary recommendation (as published in 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. CMS' virtual public meeting forum provides an opportunity for a requester to speak to CMS and the public, as well as an opportunity for CMS to hear from the requester and interested stakeholders. It is an opportunity for the public and competitors

to participate in a discussion of new HCPCS coding requests, and to present their points of view.

Information provided at the virtual public meetings is considered by CMS when making its final decision.

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:

Virtual Public Meeting Zoom-link:

https://cms.zoomgov.com/webinar/register/WN_ukTCxcctSReHO2RJaD5O6w.

Please join meeting at least 10 minutes before the scheduled start time so you don'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.