

2019
GUIDELINES FOR PARTICIPATION IN PUBLIC MEETINGS
FOR ALL NEW PUBLIC REQUESTS FOR REVISIONS TO THE HEALTHCARE
COMMON PROCEDURE CODING SYSTEM (HCPCS)

The purpose of the 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 meeting also provides an opportunity to obtain public reaction to the CMS preliminary coding recommendations, as well as CMS' preliminary recommendations regarding Medicare payment methodology. Coding decisions related to the Medicare and Medicaid programs internal operating procedures are reviewed internally, and are not included in this forum.

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

The agendas for Public Meetings will consist of summaries of HCPCS coding requests for products, supplies and services submitted through the standard HCPCS coding review and recommendation process. The specific items on each public meeting agenda will be posted on the HCPCS Web site at: www.cms.gov/medhcpcsgeninfo. The public meetings are open to the public on a space-available basis. The meetings have typically been attended by representatives of drug, biological and medical equipment manufacturers and suppliers; government relations, regulatory and compliance specialist personnel from various provider organizations; industry consultants; and CMS 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.

The CMS' preliminary recommendations regarding coding requests and CMS' preliminary Medicare payment methodology recommendations are published in advance of the public meeting on CMS' HCPCS Web site at: www.cms.gov/medhcpcsgeninfo. After the public meetings, CMS reconsiders its preliminary coding recommendations in light of any new information presented at the public meetings, and written comments submitted timely. CMS also reconsiders its pricing recommendations in view of information presented at the public meetings. 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 Public Meetings are designed for all 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. Final HCPCS coding and Medicare payment decisions are made by CMS, in accordance with the Medicare Statute and regulations. The public meetings provide an opportunity for CMS to hear, and for the public to provide, comments regarding applications and specific comments in reaction to CMS published preliminary decisions. CMS reserves the right to change its preliminary decision following the public meeting. Final decisions may or may not model the preliminary decision.

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 for free at: www.cms.gov/medhcpcsgeninfo.

ADDITIONAL OPPORTUNITIES FOR PUBLIC INPUT

All public requests for HCPCS Level II codes that have been submitted and processed through the HCPCS coding review and recommendation process are listed in the Public Meeting agendas and published on CMS' HCPCS Web site at: www.cms.gov/medhcpcsgeninfo. Comments, recommendations and inquiries are welcomed, and may be submitted via e-mail to HCPCS@cms.hhs.gov or via regular mail to CMS, c/o Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-09-14, Baltimore, Maryland 21244. Comments and recommendations regarding these items may also be made in person or via remote participation at the Public Meetings. Written and oral comments will be considered if they are received by the end of the Public Meeting at which they are discussed. Remote participation in the public meeting is available to all.

FREEDOM OF INFORMATION ACT (FOIA)

All materials submitted to CMS are subject to FOIA rules, and may be released, in whole or in part, by CMS' FOIA Office, in response to a FOIA request.

MEETING LOCATION

Public Meetings are held in the Auditorium at the:

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Meeting participants attending in person are responsible for arranging and funding their own travel and lodging. Individuals who wish to participate via remote dial-in or WebEx must follow the "Remote Attendance and Participation" information in these Guidelines.

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

Notice of the Public Meetings for All New Public Request for Revisions to the HCPCS Coding and Payment Determinations was published on 3/1/2019 in the Federal Register at: www.federalregister.gov.

Public meeting dates, public meeting agendas, the application summaries, and related materials and registration information are published at www.cms.gov/medhcpcsgeninfo. The product category reported by the applicant may not be the same as that assigned by CMS.

All meeting participants are advised to review the public meeting agenda at www.cms.gov/medhcpcsgeninfo and the dates each item will be discussed. Draft agendas, including a summary of each application and CMS' preliminary recommendations, will be posted on our website prior to each public meeting.

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 and application to CMS Level II is the appropriate coding jurisdiction.

PUBLIC MEETING DATES AND TIMES, FOR CALENDAR YEAR 2019

Monday, May 13, 2019, 9 a.m. to 5 p.m., eastern daylight time (e.d.t), for

Drugs/Biologicals/ Radiopharmaceuticals/Radiologic Imaging Agents.

Tuesday, May 14, 2019, 9 a.m. to 5 p.m., e.d.t., for Drugs/Biologicals/

Radiopharmaceuticals/Radiologic Imaging Agents.

Wednesday, May 15, 2019, 9 a.m. to 5 p.m., e.d.t., for Drugs/Biologicals/

Radiopharmaceuticals/Radiologic Imaging Agents.

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.

Wednesday, June 12, 2019, 9 a.m. to 5 p.m., e.d.t., for Durable Medical Equipment

(DME) and Accessories, Orthotics and Prosthesis (O&P), Supplies, and Other.

Because it is impossible to anticipate whether all 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 and arrive no earlier than 45 minutes before the meeting start time, and plan on the meeting commencing promptly at the start time. Speakers are asked to arrive prepared and wait until it is their turn to speak.

For those who would like to view and listen only, CMS will broadcast the meeting live via Live Stream Webcast at <http://www.cms.gov/live/>. Note that technical support is not available for livestreaming. There is no registration requirement for viewing via Live

Stream. Remote participation for the public meetings via dial-in or WebEx is available. For more information, see “Remote Attendance and Participation” information in these Guidelines.

REGISTERING TO ATTEND A PUBLIC MEETING

Registration can be completed online up to approximately 3 weeks before each meeting date at <https://www.cms.gov/apps/events/upcomingevents.asp>. To register by telephone

or e-mail, please contact CMS National HCPCS Public Meeting Coordinators: Irina

Akelaitis, (410) 786-4602, or Irina.Akelaitis@cms.hhs.gov and Felicia Kyeremeh, (410)

786-1898 or Felicia.Kyeremeh@cms.hhs.gov

Individuals must register for each date they plan to attend and/or to provide a presentation. The following information must be provided when registering: the person’s name, company name and address, telephone numbers, e-mail address, and special needs information. A CMS staff member will confirm your registration by mail or e-mail.

Registration information is used to generate a list of attendees. The names of individuals who have registered to attend in person at CMS, will appear on the attendee list. This list is used by CMS Security guards to permit access into the building. It is also used to generate meeting sign-in sheets.

Deadlines for Primary Speaker Registration and Presentation Materials for In-person or Remote Participation:

The deadline for registering to be a primary speaker, and submitting material; writings that will be used in support of an oral presentation are as follows:

Monday, May 6, 2019 is the deadline for submission of materials and primary speaker registration for the May 13, 14, and 15th, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents, public meetings.

Deadline for Primary Speaker Registration for In-person or Remote Participation:

The deadline for registering to be a primary speaker or to attend the public meeting is midnight **Monday, June 3, 2019** for both the June 11 and June 12, 2019 Durable Medical Equipment (DME) and accessories, Orthotics and Prosthetics (O&P), Supplies, and Other, public meeting dates.

Deadline for Submission of Presentation Materials for In-person or Remote Participation:

The deadline for submitting materials; writings that will be used in support of an oral presentation is midnight **Wednesday, June 5, 2019** for both the June 11 and June 12,

2019 Durable Medical Equipment (DME) and accessories, Orthotics and Prosthetics (O&P), Supplies, and Other, public meeting dates.

Registration Deadlines for all Other Attendees (Non-Primary Speakers):

All individuals must register for each date or dates that they plan on attending. The registration deadlines are different for each meeting. Registration deadlines are as follows:

Monday, May 6, 2019 is the deadline for submission of materials and primary speaker registration for the May 13, 14, and 15th, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.

Monday, June 3, 2019 is the deadline for registration for all persons who plan to attend either or both the June 11 and June 12, 2019 Durable Medical Equipment (DME) and accessories, Orthotics and Prosthetics (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, May 6, 2019 for May 13, 14, and 15th, 2019 Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.

Monday, June 3, 2019 for the June 11 and June 12, 2019 Durable Medical Equipment (DME) and accessories, Orthotics and Prosthetics (O&P), Supplies, and Other, public meetings.

REMOTE ATTENDANCE AND PARTICIPATION INFORMATION

As part of our efforts to increase transparency and expand opportunities for public input, CMS has arranged a new option for remote participation in HCPCS public meetings in addition to in-person at CMS only. Participants may join the HCPCS public meeting via telephone or WebEx. The remote participation option is available to primary speakers, 5-minute speakers, and persons interested in listening only.

For all remote participation registration, please contact CMS National HCPCS Public

Meeting Coordinators: Irina Akelaitis, (410) 786-4602, or Irina.Akelaitis@cms.hhs.gov

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

Individuals **must register** for each date they plan to attend or to provide a presentation, or to be a “5-minute” speaker, in order to **receive invitation** to attend/participate remotely.

All Other Attendees (Non-Primary Speakers)

CMS will post the WebEx meeting link and the dial-in information one week before the meeting date at www.cms.gov/medhcpcsgeninfo.

FOREIGN NATIONALS REGISTERING TO ATTEND A PUBLIC MEETING

Foreign National Visitors are defined as Non-U.S. Citizens, and non-lawful permanent residents, non-residents aliens or non-green-card holders. CMS policy requires that every foreign national 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 are 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 below of this notice:

- A. Visitor's full name (as it appears on passport);
- B. Gender;
- C. Country of origin and citizenship;
- D. Biographical data and related information;
- E. Date of birth;
- F. Place of birth;
- G. Passport number;
- H. Passport issue date;
- I. Passport expiration date;
- J. Visa Type
- K. Dates of visits
- L. Company Name Position/Title

This information is necessary for security clearance.

Deadlines for Attendees that are Foreign Nationals Registration:

Attendees that are foreign nationals are required to identify themselves as such, and provide the necessary information for security clearance to the public meeting coordinator at least 12 business days in advance of the date of the public meeting. Therefore, the deadlines for attendees that are foreign nationals are as follows:

Wednesday, April 24, 2019, for the May 13, 14 and 15, 2019

Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents public meetings.

Tuesday, May 21, 2019, for the June 11 and 12, 2019 DME and Accessories, O&P

Supplies, and Other public meetings.

REGISTERING TO SPEAK AT A PUBLIC MEETING

Primary Speakers:

The applicant that requested the modification to the HCPCS coding system may speak or designate one primary speaker to represent the applicant's views on their application and CMS' preliminary coding recommendation for a maximum of 15 minutes. Primary speakers that are not the applicant may not register as a primary speaker until after the actual applicant has made this designation to CMS in writing. Applicants may not reassign any unused or forfeited time or assign time to speakers who are not specifically designated to speak on their behalf. Designation of a primary speaker may be made via email to CMS National HCPCS Public Meeting Coordinator: Irina Akelaitis, (410) 786-4602, or Irina.Akelaitis@cms.hhs.gov and Felicia Kyeremeh, (410) 786-1898 or Felicia.Kyeremeh@cms.hhs.gov

Fifteen minutes is the total time interval for the presentation, and must incorporate the demonstration, set-up, and distribution of materials. In establishing the Public Meeting agenda, CMS may group multiple, related requests under the same agenda item. In that case, CMS 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. In other words, the amount of time allotted to aggregate proposals might not be expanded exponentially by the number of requests.

Presentation materials page limit, deadline; and number of copies needed:

It is our intent to distribute any materials submitted to CMS for consideration. The CMS requires sufficient time, in advance of the public meetings, to review all submitted materials. For this reason, the HCPCS Public Meeting Coordinator will only accept presentation materials received by the submission deadline for each public meeting. For system security reasons, electronic presentations are considered final and may not be changed after the submission deadline. Submission deadlines for presentation materials are listed in the above section.

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 a copy of the entire study, as published, as soon as possible, but no later than 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.

Presentation materials may be delivered by regular mail (for receipt at CMS no later than the deadline date) or by e-mail to the CMS staff listed above. Individuals will need to provide 25 copies if materials are delivered by mail.

Primary Speaker Responsibilities:

In advance of the meeting:

- Register to be a Primary speaker by personally notifying the public meeting coordinators AND register on-line. You must do both, regardless of whether you plan to attend in person or participate remotely.
- Upon registering to be a Primary Speaker, indicate your needs for audio/visual support. CMS offers audio and visual support options.
- Please avoid using a dark or black background on your slides. If you include charts within your overhead slides, please make sure the font size is large enough so that audience can read the print.
- Please do not submit audio-visual materials to Dropbox as CMS security cannot accept this format.
- Due to additional security restrictions, CMS is no longer accepting presentations with imbedded video content. In addition, speakers may not connect their personal Laptop to CMS' Audio Visual system.
- Register on-line to attend the meeting (which is separate registration process from sending your presentation materials).
- Provide a brief, written statement to CMS' meeting coordinator regarding the nature of the information that will be presented at the meeting.

On the day of the meeting:

- Primary speakers may bring handout materials with them for the public audience, and the public meeting coordinator will distribute all handouts to CMS staff at the start of the meeting. Any materials distributed at the meeting should also have been forwarded electronically to CMS by the deadline for submission of written materials, for review by CMS. Equipment or samples intended for demonstration may not be shipped in advance of the meeting.

- Provide a written summary of your statement. State whether you support or disagree with the CMS preliminary recommendation and if you disagree, briefly summarize the reason(s) why.
- All speakers must declare in their oral presentation and in their written summary whether or not they have any financial involvement with the manufacturers or competitors of any items or services being discussed. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

“5-Minute” Speakers:

All 5-Minute speakers must register prior to the meeting as stated above, regardless of whether they are attending in-person or remotely. 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 number of minutes allotted should be reduced in order to accommodate more speakers. In order to offer the same opportunity to all attendees.

5-Minute speakers are required to submit, on the day of the meeting, a brief (one page) summary of their presentation. 5-Minute speakers will not have access to audio/visual support.

The actual speaking time for 5-minute speakers may be less than 5 minutes, depending on the number of 5-minute speakers that register and the time available, in order to accommodate all speakers within the meeting timeframe.

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:

All 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 your product is not adequately described by existing HCPCS code categories, and why your product fits the criteria for revising the HCPCS coding system, as described in a document entitled “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures” and in the (HCPCS Decision Tree) documents at: www.cms.gov/medhcpcsgeninfo. Describe who will and who will not benefit by the use of the specific product that is the subject of the application.

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 even 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.

It is inadvisable to expose at-risk patients to the public for the purpose of providing testimony.

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 why the recommendation is unsatisfactory, or how or why it should be changed.

The 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 all speakers as well as to the audience, the moderator will end all presentations precisely at the end of their allotted time. Therefore, it is helpful to rehearse and time your presentations so as to ensure that key points are made within the allotted time period.

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

WRITTEN COMMENTS FROM MEETING ATTENDEES

The CMS welcomes the written comments of other persons in attendance at the meeting, who did not have the opportunity to or did not care to make an oral presentation. These written comments should be submitted at the meeting, to the public meeting coordinator.

All speakers (Primary Speakers and 5-Minute Speakers) are required to submit, on the day of the meeting, a brief (one page) written summary of their presentation.

SPECIAL NEEDS

Persons attending the meeting who are hearing or visually impaired and have special requirements or a condition that requires special assistance or accommodations should make a notation to that effect on the registration form, or directly contact one of the assigned CMS meeting coordinators, as listed in this document, by the registration deadline. Advance notice is necessary in order for us to make arrangements to accommodate special needs.

SECURITY ON THE DAY OF THE PUBLIC MEETING

The meetings are held within the CMS Complex which is not open to the general public. In planning arrival time, CMS recommends allowing 15 minutes time to clear security. Persons, who are not registered in advance, will not be permitted access to the CMS Headquarters Facility and thus will be unable to attend the meeting. Persons attending the meeting will be required to show a U.S. Government-issued ID, preferably a driver's license, and are subject to a vehicle inspection prior to entering the complex. If proper identification is not provided, the visitor will be denied access. CMS is a tobacco-free campus and violators are subject to legal action.

Visitor Screening Procedures

Screening procedures will require visitors to empty pockets, remove belts, hats, outerwear (not suit jackets or sports coats), and large pieces of jewelry and place in provided bins for x-ray screening. Small and loose items (e.g., purses, laptop computers, cell phones) will be placed in bins and larger items (e.g. computer bags) may be placed directly onto the conveyer. All items being carried into the building will be screened via an x-ray machine.

After all items are placed on the conveyer, visitors will proceed through the walk-through metal detector. If the detector alarms, a security guard will use a wand to clear the alarm. If the cause of the alarm is identified and resolved, screening is complete and the visitor may enter the facility. In the event that the wand does not clear the alarm, the security guard will physically check the area of the body where screening equipment indicated the area of concern. Anytime there is an alarm over a sensitive area of a

person's body, the officer will use the back of his/her hands to clear the area. If footwear alarms, it will need to be removed and placed in a bin for x-ray screening. Disabled visitors using a mobility device (e.g. wheel chair, motorized scooter) that cannot pass through the walk-through metal detector will bypass the device and undergo screening by the officer using a wand and/or pat down.

Identity Verification

Beginning in October of 2015, photo IDs (such as a driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. As of February 5, 2018, the following states/territories are not compliant with the Real ID Act: American Samoa. This means CMS visitors from these states/territories will have to be escorted at all times while in CMS buildings. For up to date Real ID ACT States and Territories please reference <https://www.dhs.gov/real-id>

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.

Visitors who are in possession of prohibited items will be denied access to the complex. Prohibited items on Federal Property include, alcoholic beverages, illegal narcotics, dogs or other animals except Seeing Eye dogs and other dogs trained to assist the handicapped, explosives, firearms or other dangerous weapons (including pocket knives). Participants are reminded that photography on the CMS complex is prohibited.

No visitor is allowed to attach USB cables, USB flash drives, or any other equipment to any CMS information technology (IT) system or hardware for any purpose at any time. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

The public may not enter the building earlier than 45 minutes before the convening of the meeting each day. Visitor access is limited to the meeting area, the main lobby and the cafeteria with the exception of visitors from non-compliant states listed in the prior section. If a visitor is found outside of those areas without proper staff escort they may be escorted out of the facility.

During the meeting, there will be an opportunity for everyone to speak and CMS requests that everyone waits for the appropriate time to present their product and opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex.

In the event that the National Security level is elevated to "code red", please phone CMS at 410-786-6010. In the event the building is operating under a code red this means the building will be closed and the Public Meeting will be cancelled.

2 WEEKS ADVANCE APPROVAL IS REQUIRED FOR BRINGING IN EQUIPMENT/DEVICES

CMS 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 to support a presentation. For security reasons, special arrangements and approvals are required two weeks prior to each public meeting in order to bring in pieces of equipment and/or medical devices. These arrangements need to be made with the 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 two weeks is required for approvals and security procedures to bring in equipment and/or devices. Any request not submitted at least two weeks in advance of the public meeting will be denied. CMS asks presenters to consider the practicality of bringing in large equipment or multiple pieces of equipment, and whether other means of demonstration, such as video or pictures, may be useful, less distracting, and more easily managed.

MEETING SIGN-IN ONCE ON-SITE

On-site sign-in for visitors who have registered to attend the meeting will be held 30 minutes prior to the starting time of each meeting.

FAQs:

WHO MAY ATTEND THE PUBLIC MEETINGS?

The public is invited to attend CMS' Public Meetings. Entities who submit requests that are being discussed at the meeting and their competitors might attend. Attendance at the Public Meetings is voluntary and optional.

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

No. Attendance is completely voluntary, and attendees are not required to make a presentation. Whether or not the requesting entity is represented at the meeting, all 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 www.cms.gov/medhcpcsgeninfo), and public comments will be invited.

Remote participation is an option for the public to attend the meeting; see "Remote Attendance and Participation Information" section on remote participation for more information.

ARE DECISIONS MADE AT THE PUBLIC MEETINGS?

No. The CMS' 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 competing points of view. It is an opportunity for the general public and competitors to participate in a discussion of HCPCS coding for new requests.

Information provided at the CMS HCPCS Public Meetings is considered subsequently by the 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 impossible to anticipate whether all 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 arrive prepared at the meeting 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.