

2011 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 general 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 preliminary coding recommendations of the CMS HCPCS Workgroup, as well as CMS' preliminary recommendations regarding 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 HCPCS coding requests for products, supplies and services that have been 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.hhs.gov/medhcpcsgeninfo. The public meetings are open to the public on a space-available basis. The meetings have typically 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 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 preliminary recommendations of the CMS HCPCS workgroup regarding coding requests and CMS' preliminary payment methodology decisions are published approximately 4 weeks in advance of the public meeting on CMS' HCPCS Web site at: www.cms.hhs.gov/medhcpcsgeninfo. After the public meetings, the CMS HCPCS workgroup will reconvene to reconsider its preliminary coding recommendations in light of any new information presented at the public meetings. CMS staff will also reconsider its pricing recommendation in view of information presented at the public meeting. The HCPCS Workgroup 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 manufacturers and others to present additional information, clarify issues, and offer supporting or opposing perspectives regarding CMS' preliminary decisions. Final coding decisions are not made at the public meetings. Final 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 decision following the public meeting. Final decisions may or may not model the preliminary decision.

General information about the HCPCS coding process, the standard HCPCS code request format and detailed instructions can be found on the official HCPCS Web site at: www.cms.hhs.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.hhs.gov/medhcpcsgeninfo.

ADDITIONAL OPPORTUNITIES FOR PUBLIC INPUT

All public requests for HCPCS Level II codes that have been submitted 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.hhs.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' HCPCS Workgroup, c/o Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, Maryland 21244.

Comments and recommendations regarding these items may also be made in person at the Public Meetings. Comments will be considered if they are received by the end of the Public Meeting at which they are discussed.

FOIA (FREEDOM OF INFORMATION ACT)

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 are responsible for arranging and funding their own travel and lodging.

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

Notice of Public Meetings for All New Public Request for Revisions to the HCPCS Coding and Payment Determinations appears in the Federal Register at:
www.gpoaccess.gov/nara/index.html.

Public Meeting dates, agendas including the meeting summaries and related materials and registration information are published at www.cms.hhs.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.hhs.gov/medhcpcsgeninfo which identifies CMS' product category determinations and the dates each item will be discussed. Draft agendas including a summary of each request and CMS' preliminary decision will be posted on our website approximately 4 weeks prior to each meeting. A meeting summary will be posted by the end of August 2011. It is

the responsibility of the applicant and the general public to monitor the appropriate web sites for announcements and other information related to the Public Meetings.

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.

PUBLIC MEETING DATES AND TIMES, CALENDAR YEAR 2011

Tuesday, May 17, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents)

Wednesday, May 18, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents)

Tuesday, May 24, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Supplies and Other)

Wednesday, May 25, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Supplies and Other)

Tuesday, June 7, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Orthotics and Prosthetics)

Wednesday, June 8, 2011, 9 a.m. to 5 p.m., E.D.S.T.
(Durable Medical Equipment (DME) and Accessories)

Each meeting day is scheduled to begin at 9 a.m. and end at 5 p.m., E.D.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; 5 minutes or “5-Minute Speakers”), we cannot commit specific items to specific time frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m. Speakers are asked to arrive prepared and wait until it is their turn to speak.

REGISTERING TO ATTEND A PUBLIC MEETING

Registration Procedures/Deadlines: Registration can be completed online at www.cms.hhs.gov/medhcpcsgeninfo. To register by telephone or e-mail, please contact a public meeting coordinator Jennifer Carver at Jennifer.Carver@cms.hhs.gov or 410-786-6610 or Sharon Ventura at Sharon.Ventura@cms.hhs.gov or 410-786-1985. Individuals must register for each date they plan either to attend or to provide a presentation. The following information must be provided when registering: name, company name and address, telephone and fax numbers, e-mail address, and special

needs information. A CMS staff member will confirm your registration by mail, e-mail, or fax.

CMS policy requires that every foreign visitor is assigned a host. 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 visitor. Foreign National visitors 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** below 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; and
- Dates of visits

- Company Name
- Position/Title

This information is necessary for security clearance.

Registration information is used to generate a list of attendees. The names of individuals who have registered will appear on the attendee list. This list is used by 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:

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:

- May 3, 2011 is the deadline for submission of materials and primary speaker registration for the May 17, 2011 and May 18, 2011 public meetings.
- May 10, 2011 is the deadline for submission of materials and primary speaker registration for the May 24, 2011 and May 25, 2011 public meetings.
- May 24, 2011 is the deadline for submission of materials and primary speaker registration for the June 7, 2011 and June 8, 2011 public meetings.

**Deadlines for Attendees that are Foreign Nationals (reside outside the U.S.)
Registration:**

Attendees that are Foreign Nationals (reside outside the U.S.) 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 date the individual plans to attend. Therefore, the deadlines for attendees that are Foreign Nationals are as follows:

- April 29, 2011 is the registration deadline for Foreign Nationals for the May 17, 2011 and May 18, 2011 public meetings.
- May 6, 2011 is the registration deadline for Foreign Nationals for the May 24, 2011 and May 25, 2011 public meetings.
- May 19, 2011 is the registration deadline for Foreign Nationals for the June 7, 2011 and June 8, 2011 public meetings.

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

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

- May 10, 2011 is the registration deadline for Non-Primary Speakers for the May 17, 2011 and May 18, 2011 public meetings.
- May 17, 2011 is the registration deadline for Non-Primary Speakers for the May 24, 2011 and May 25, 2011 public meetings.
- May 31, 2011 is the registration deadline for Non-Primary Speakers for the June 7, 2011 and June 8, 2011 public meeting.

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:

- May 3, 2011 is the request deadline for Special Accommodations for the May 17, 2011 and May 18, 2011 public meetings.
- May 10, 2011 is the request deadline for Special Accommodations for the May 24, 2011 and May 25, 2011 public meetings.
- May 24, 2011 is the request deadline for Special Accommodations for the June 7, 2011 and June 8, 2011 public meetings.

REGISTERING TO SPEAK AT A PUBLIC MEETING**Primary Speakers:**

The applicant that requested the modification to the HCPCS coding system for a particular agenda item may designate one “primary speaker” to make a presentation of a maximum of 15 minutes. Primary speakers that are not the applicant may not register to speak until after the actual applicant has made this designation to CMS in writing. This can be handled via email to the meeting coordinator. 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. Applicants may speak or designate a speaker to represent the applicant’s views on their application and our preliminary coding recommendation. Applicants may not reassign any unused or forfeited time or assign time to speakers who are not specifically designated to speak on their behalf.

It is our intent to distribute any materials submitted to CMS to the HCPCS workgroup members for their consideration. The HCPCS workgroup members require sufficient time, in advance of the public meetings, to review all submitted materials. For this reason, our HCPCS Public Meeting Coordinators 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. The submission deadline is listed in the chart above. In addition, it is necessary for us to implement a 10-page submission limit and firm deadlines for receipt of any materials and presentations the meeting participant wishes CMS to consider. An exception will be made to this 10-page limit for relevant scientific studies published between the application deadline and the public meeting date, in which case,

we would like a copy of the entire study, as published, as soon as possible, but no later than the public meeting date.

These materials may be delivered by regular mail (postmark date no later than deadline date) or by e-mail to the public meeting coordinator listed in the chart above. Individuals will need to provide 35 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 appropriate public meeting coordinator AND register on-line. You must do both.
- Upon registering to be a Primary Speaker, indicate your needs for audio/visual support. We offer an extensive array of audio and visual support options, (see below).

AV Options:

Audio Cassette Tape Playback

Assisted Listening Device

Video Tape playback (standard VHS or SVHS)

DVD playback

35mm slides (we can display slides through the projection system by use of a slide to video converter that is housed in the control room. Slides should be preloaded in Kodak-style carousel trays)

Computer Display (compatible with CMS standard programs - check in advance with the meeting coordinator)

Computer Interface (we can interface the video projection system with most laptop computers equipped with a standard VGA output connector)

Document and/or overhead projector (overheads or hard copy pages can be projected from the control room)

- Register on-line to attend the meeting.
- Provide a brief, written statement to the public meeting coordinator regarding the nature of the information that will be presented at the meeting.
- Provide to the public meeting coordinator any tape or disk file you intend to use at the meeting. In order to ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence in advance of the meeting. We are only able to accommodate tapes and disk files that are received timely by the meeting coordinator. All materials are due by the submission deadline for the individual meeting, as listed in the chart (above). For systems security reasons, electronic presentations are considered final and may not be changed after the submission deadline.

On the day of the meeting:

- Primary speakers may bring handout materials with them, and distribute them at the meeting. Any materials distributed at the meeting should also have been forwarded electronically to CMS in advance of the meeting, for review by the CMS HCPCS workgroup. 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 preliminary recommendation of the CMS HCPCS Workgroup 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:

Meeting attendees will be permitted to 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 by the meeting coordinator and the meeting moderator, regarding how many 5-Minute speakers can be accommodated. In order to offer the same opportunity to all attendees, 5-Minute speakers may only register the day of the meeting, and not in advance of the meeting.

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.

All speakers must declare at the meeting as well as 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.

GUIDANCE TO SPEAKERS FOR AN EFFECTIVE PRESENTATION

We have established, based on experience, the following tips for an effective presentation:

Information that is helpful:

State your 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. The CMS HCPCS Workgroup has evaluated the requests that appear on the Public Meeting agenda, arrived at and published its preliminary coding recommendation. The Public Meeting forum is an opportunity to provide additional information that may convince the CMS HCPCS Workgroup to reconsider its preliminary recommendation. 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 the workgroup to understand why the recommendation is unsatisfactory, or how or why it should be changed.

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.hhs.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:

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 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 for the purpose of providing testimony.

The Public Meetings are not directed to the attention of buyers of medical products. Therefore, promotional information, or a “sales pitch” 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.

The moderator reserves the right to interrupt to preserve the order of the meeting for the benefit of the audience.

WRITTEN COMMENTS FROM MEETING ATTENDEES

We welcome 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 to the meeting coordinator at the meeting.

All speakers (Primary Speakers and 5-Minute Speakers) are required to submit, on the day of the meeting, a brief (one page) 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 Public Meeting Coordinators, as listed in the chart, 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 MEETING

The meetings are held within the CMS Complex which is not open to the general public. In planning arrival time, we recommend allowing 15 minutes time to clear security. 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 to the grounds and to the building. Visitors not in possession of a valid will be denied access to the complex. Additional security clearance requirements apply to Visitors who are Foreign Nationals (reside outside the U.S.). Refer to the information is located on page 4 of this document.

Visitors are subject to a vehicular search before access to the complex is granted. This includes inspection of vehicles inside and outside, at the entrance to the grounds. Once cleared for entry to the complex, participants will be directed to parking by a security officer.

All persons entering the building must pass through a metal detector. All items brought to CMS are subject to inspection. 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, 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.

CMS has also been declared a tobacco free campus and violators are subject to legal action. 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.

Visitor access 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.

During the meeting, 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.

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.

ADVANCE APPROVAL IS REQUIRED FOR BRINGING IN EQUIPMENT/DEVICES

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 two weeks prior to each public meeting in order to bring in pieces of equipment or medical devices. These arrangements need to be made with the appropriate 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 two weeks is required for approvals and security procedures. Any request not submitted at least two weeks in advance of the public meeting will be denied. We ask 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.

FAQ's:

WHO MAY ATTEND THE PUBLIC MEETINGS?

The public is invited to attend CMS' Public Meetings. Members of the CMS HCPCS Workgroup and CMS staff who have a special program interest in a topic may attend, based on their availability. 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. 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 preliminary recommendation of the CMS HCPCS Workgroup (as published with the agenda on the official HCPCS website at www.cms.hhs.gov/medhcpcsgeninfo), and public comments will be invited.

ARE DECISIONS MADE AT THE PUBLIC MEETINGS?

No. The Public Meetings are not CMS HCPCS Workgroup meetings. 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 by the CMS HCPCS Workgroup at a subsequent workgroup meeting. The workgroup reconvenes after the public meetings, and reconsiders its preliminary recommendation in light of any new information provided, and formulates its final coding decisions. CMS is the final decision-making authority concerning requests for permanent HCPCS Level II 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 we cannot commit specific items to specific time frames. We ask that speakers arrive prepared, plan on the meeting commencing promptly at 9:00a.m, E.D.S.T., and wait until it is their turn to speak. Meetings are typically scheduled to adjourn at 5:00 p.m.; however, because we can only estimate the amount of meeting time that will be needed, meetings may adjourn earlier.