

PROCEDURES FOR PUBLIC MEETINGS FOR NEW DURABLE MEDICAL EQUIPMENT (DME)

PURPOSE OF PUBLIC MEETINGS FOR NEW DME

The purpose of the DME 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 new DME. The meeting also provides an opportunity to obtain industry and public reaction to the preliminary coding recommendations of the CMS HCPCS Workgroup to the HCPCS National Panel, as well as CMS' preliminary recommendations regarding payment methodology for new DME items. Public meetings are required for new DME, under Section 531(b) of the Benefits Improvement and Protection Act 2002 (BIPA). Coding decision 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 NEW DME, RELATIVE TO THE OVERALL HCPCS CODING PROCESS

The agenda for DME Public Meetings will consist of HCPCS coding requests for new DME, as determined by CMS, that have been submitted through the HCPCS coding review and recommendation process. The specific items on each public meeting agenda will be posted on the HCPCS web site at <http://cms.hhs.gov/medicare/hcpcs/default.asp>.

The DME public meetings are open to the public, including the Press, 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. Entities who have an item on the public meeting agenda might attend, however their attendance is not mandatory.

The preliminary recommendations of the CMS HCPCS workgroup regarding coding requests, and CMS' preliminary payment methodology decisions, will be presented at the public meetings. After the public meeting, the CMS HCPCS workgroup will reconsider its preliminary coding recommendations, and CMS staff will reconsider its pricing recommendation, in view of information presented at the public meeting. The workgroup will formulate its recommendation to the HCPCS National Panel. No decisions are made at the DME Public Meetings. The National Panel is the entity that maintains the permanent HCPCS Level II codes, and is the final decision-making authority concerning requests for permanent HCPCS Level II codes. The DME Public Meetings are designed for DME 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, nor are they made by the HCPCS workgroup. Final payment decisions are made by CMS, in accordance with the Medicare Statute and regulations.

General information about the HCPCS coding process, the standard HCPCS code request form and instructions can be found on the official HCPCS web site at www.cms.hhs.gov/medicare/hcpcs/default.asp.

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/providers/pufdownload/anhcpcdl.asp

ADDITIONAL OPPORTUNITIES FOR PUBLIC INPUT

The National Panel Meeting Agenda, including all requests for permanent HCPCS Level II codes that have been submitted through the HCPCS coding review and recommendation process, are listed on the HCPCS web site at <http://cms.hhs.gov/medicare/hcpcs/default.asp>. Comments, recommendations and inquiries are welcomed, and may be submitted via e-mail to www.cms.hhs.gov/medicare/hcpcs or via regular mail to the HCPCS National Panel, c/o Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, Maryland 21244.

Comments and recommendations regarding items that appear on the Public Meeting Agenda for New DME may be made in person at the Public Meetings, and/or written comments may be provided at or prior to the meeting at the addresses noted above. Comments regarding Public meeting agenda items will be considered if they are received by the end of the meeting at which they are discussed.

MEETING LOCATION

DME 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 MEETING, CONTENT OF THE AGENDA, AND MEETING SUMMARIES

Notice of Public Meetings for New DME appears in the Federal Register at www.access.gpo.gov/nara/index.html.

Public Meeting Dates, agendas and related materials, registration information and meeting summaries are published at <http://cms.hhs.gov/medicare/hcpcs/default.asp>. The agenda will be posted 2 to 4 weeks prior to the meeting. A meeting summary will be posted within one month after the meeting.

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 for New DME.

SELECTING AGENDA ITEMS FOR PUBLIC MEETINGS FOR NEW DME

Items are placed on a Public Meeting for New DME if:

The application for the item was complete and submitted timely to the National HCPCS process AND the item is considered by CMS to be new DME.

If you have submitted an application for a modification to the HCPCS system for an item you believe is DME, and your request is not represented on the agenda for the Public Meeting for New DME, please contact Joel Kaiser at 410-786-4499.

MEETING DATES AND TIMES, CALENDAR YEAR 2004

Tuesday, June 29, 2004

Wednesday, June 30, 2004

Thursday, July 1, 2004

A meeting will only be held on July 1, 2004 if the number of agenda items cannot be managed in two meeting days. Each meeting day will begin at 9:00 a.m. and is scheduled to adjourn at 5:00 p.m., E.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., and speakers simply need to arrive prepared and wait until it is their turn to speak.

ON-LINE REGISTRATION CLOSES JUNE 18, 2004 FOR ALL PUBLIC MEETINGS IN CALENDAR YEAR 2004.

REGISTERING TO ATTEND A PUBLIC MEETING FOR NEW DME

Registration may be completed on-line at <http://cms.hhs.gov/medicare/hcpcs/default.asp>. If you do not have internet access you may contact the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610.

Upon completing on-line registration, you will automatically receive a confirmation. If you register by phone, a CMS staff member will confirm your registration by phone or fax. **Please bring your confirmation and photo identification with you to the meeting**, (refer to Security information below).

On-line registration will not be accessible after June 18, 2004. Individuals who do not have internet access, or who have missed the deadline for on-line registration, may register by phone by contacting Jennifer Carver. The deadline for phone registration is June 22, 2003. Due to heightened national security, only registered individuals will be allowed to enter the building.

Pre-registration information is used to generate a list of attendees. The names of individuals who have pre-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.

REGISTERING TO SPEAK AT A PUBLIC MEETING FOR NEW DME

Primary Speakers:

The entity 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. 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.

Primary Speaker Responsibilities:

- No later than 15 days in advance of the meeting:
 - Register to be a Primary speaker by personally notifying the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610.
- No later than 10 days in advance of the meeting:
 - Register on-line to attend the meeting.
- No later than 7 days in advance of the meeting:
 - Provide a brief, written statement to Jennifer Carver regarding the nature of the information that will be presented at the meeting.
 - In order to avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence in advance of the meeting. We will accommodate tapes and disk files that are received timely by the meeting coordinator.
 - Upon registering to be a Primary Speaker, indicate your needs for audio/video 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)

- 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 be provided for review by the CMS HCPCS workgroup and the HCPCS National Panel. For that purpose, we request that at least 35 additional copies be provided, on the day of the meeting. Handout and demonstration materials 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 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.

“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 to two-page) summary of their presentation.

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:

Begin with the preliminary recommendation itself, and comment on it. State your position. React specifically to the individual coding recommendation and either 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, prior to releasing it to the HCPCS National Panel. Blanket dismissal of coding recommendation(s) or simply reiterating the original request without responding directly, and thoughtfully, to each individual preliminary coding recommendation does not help the workgroup to understand why the recommendation is unsatisfactory, or how or why it ought to be changed.

The focus of your presentation should be to convince the audience that your product fits the criteria for modifying the HCPCS coding system, as described in a document entitled “HCPCS BACKGROUND INFORMATION” at <http://cms.hhs.gov/medicare/hcpcs/default.asp>.

Describe who will and who will not benefit by the use of the item.

Information that is not helpful:

Keep in mind that HCPCS codes identify unique categories of products. The assignment of a HCPCS code does not guarantee, or even imply, that a product or service is covered by Medicare or by any other insurer. HCPCS decisions and coverage determinations are completely separate processes. Medicare coverage determinations are not part of the HCPCS coding decision-making process or part of the DME Public Meeting forum. Therefore, testimonials and discussions about medical necessity or efficacy 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 for New DME are not directed to the attention of buyers of medical products. Therefore, promotional information, or a “sales pitch” that does not address uniqueness of the product category is inappropriate.

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 presentations so 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 at the meeting.

All speakers (Primary Speakers and 5-Minute Speakers) are required to submit, on the day of the meeting, a brief (one to two-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 the DME Public Meeting Coordinator, Jennifer Carver, by the registration deadline at (410) 786-6610. Advance notice is necessary in order for us to make arrangements to accommodate special needs.

SECURITY ON THE DAY OF THE MEETING

All meeting attendees should bring with them government issued photo identification, and a copy of their pre-registration confirmation. The DME Public meetings are held in a government building; therefore, security measures will be applicable. Photo identification must be presented upon entering the complex and again upon signing-in at the security desk. Security Officers may deny access to the building complex to persons without proper identification. Meeting attendees must also provide registration information (confirmation of meeting registration). Meeting attendees should allow approximately 15 minutes to clear security upon arrival.

Any items brought to the building for the purpose of being demonstrated at the meeting must clear security. CMS does not assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety or security clearance of any belongings or items used for demonstration, or for their timely arrival at the meeting. 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 much more easily managed.

In the event that the National Security level is elevated to code red please phone CMS at

410-786-6010. If the building is operating under a code red this means the building will be closed and the DME Public Meeting will be cancelled.

MEETING SIGN-IN ONCE ON-SITE

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

FAQ's

WHO MAY ATTEND DME PUBLIC MEETINGS?

The public, including the press, is invited to attend CMS' Public Meetings for New DME. 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 for DME is voluntary and optional.

IS ATTENDANCE MANDATORY FOR ENTITIES 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 by CMS staff, with a description of the request and the preliminary recommendation of the CMS HCPCS Workgroup (as published with the agenda on the web).

ARE DECISIONS MADE AT THE PUBLIC MEETINGS FOR NEW DME?

No. The Public Meetings for New DME are not CMS HCPCS Workgroup meetings, and they are not HCPCS National Panel Meetings. The CMS' Public Meeting forum for New DME provides an opportunity for a requester to speak to CMS and to the Public, and an opportunity for CMS to hear from requester and public, and balance competing points of view. It is an opportunity for general public and competitors to participate in a discussion of HCPCS coding for New DME items.

Information provided at the CMS Public Meetings for New DME is shared with members of the CMS HCPCS Workgroup at a subsequent workgroup meeting. The workgroup reconsiders its preliminary recommendation in light of any new information provided, and formulates its recommendation to the HCPCS National Panel. The recommendation made by the CMS HCPCS work group to the HCPCS National may or may not be the same as the preliminary recommendation shared at the public meeting. The HCPCS National Panel may or may not agree with the recommendation of CMS HCPCS workgroup. The HCPCS National Panel is the final decision making authority concerning requests for permanent HCPCS Level II codes.

THE AGENDA DOES NOT INCLUDE TIMES. HOW DO PARTICIPANTS KNOW 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 9:00 a.m, E.S.T., and simply wait until it is their turn to speak. Meetings are 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 than 5:00 p.m.