

Act provides that nominations for Council membership must be made to the Secretary by medical organizations representing physicians.

The Council held its first meeting on May 11, 1992. The current members are: Jose Azocar, M.D.; James Bergeron, M.D.; Ronald Castellanos, M.D.; Rebecca Gaughan, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Michael T. Rapp, M.D. (Chairperson); Anthony Senagore, M.D.; and Robert L. Urata, M.D.

The meeting will commence with a status report and our response to recommendations made by the Council at the May 17, 2004 meeting and prior meeting recommendations.

Additionally, updates will be provided on the Physician Fee Schedule, Evaluation and Management (E & M) Documentation Guidelines, Medical Economics Index and Proxy Indicators, 2005 Medicare Modernization Act issues and activities, Average Sales Price, and Physician Regulatory Issues Team. In accordance with the Council charter we are requesting assistance with the following agenda topics:

- Enrollment and Pecos.
- Chronic Care Improvement Program.

• Efforts to Improve the Accuracy of Call Center Information.

For additional information and clarification on these topics, contact the Executive Director, listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must contact the Executive Director by 12 noon, August 17, 2004, to be scheduled. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to John Lanigan, Designated Federal Official, no later than 12 noon, August 17, 2004, for distribution to Council members for review prior to the meeting. Physicians and medical organizations not scheduled to speak may also submit written comments to the Designated Federal Officer for distribution. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodations: Individuals requiring sign language interpretation or other special accommodation must contact John Lanigan by e-mail at Jlanigan@cms.hhs.gov or by telephone

at (410) 786-2312 at least 10 days before the meeting.

This notice also serves as an invitation to all organizations representing physicians to submit nominees for membership on the Council. Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit an evaluation of possible sources of conflicts of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts. Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Council members are expected to participate in all meetings. Section 1868(a)(3) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, we provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of the Council's membership.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92-463 (5 U.S.C. App. 2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 15, 2004.

Mark McClellan,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1334-N]

Medicare Program; Public Meeting in Calendar Year 2004 for Coding and Payment Determinations for Power Wheelchairs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to be held on September 1, 2004 to discuss coding and payment for power wheelchairs. This meeting provides a forum for interested parties to hear various proposals presented to us regarding changes to wheelchair coding. This meeting will provide an opportunity for the public to make oral presentations or to submit written comments in response to preliminary coding and pricing recommendations presented by CMS at this meeting. Discussion will be directed toward response to alternative coding recommendations, and will be limited to discussions of the proposed recommendations presented at the meeting on coding and payment of power wheelchairs.

DATES: This public meeting is scheduled for Wednesday, September 1, 2004 from 1 p.m. to 5 p.m. e.d.t.

ADDRESSES: This public meeting will be held in the Centers for Medicare & Medicaid Services Auditorium, located at 7500 Security Boulevard, Baltimore, MD 21244.

Web site: Additional details regarding the public meeting process and details on the public meeting on the power wheelchair coding and payment proposals will be posted at least two weeks before the date of the meeting on the official Healthcare Common Procedure Coding System (HCPCS) Web site, and can be accessed at <http://cms.hhs.gov/medicare/hcpcs/default.asp>.

Individuals who intend to provide a presentation at the public meeting for coding and payment of power wheelchairs need to familiarize themselves with this information. This Web site also includes a description of the HCPCS coding process, along with a detailed explanation of the procedures used to make coding and payment determinations for Durable Medical Equipment (DME) and other items and services that are coded in the HCPCS.

A summary of each public meeting for DME will be posted on the Web site

listed in this section within one month after the meeting.

FOR FURTHER INFORMATION CONTACT: Lorrie Ballantine, (410) 786-7543 or Jennifer Carver, (410) 786-6610.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice are in response to the mandate of section 531(b) of BIPA.

As part of "Operation Wheeler Dealer", we stated in testimony before the Senate Finance Committee that we will work to make changes to the HCPCS coding for power wheelchairs that better describe the power wheelchairs currently on the market and thus assure that wheelchair payments are accurate.

We published a notice in the **Federal Register** (66 FR 58743) on November 23, 2001 with information regarding the establishment of the public meeting process for DME.

II. Registration

Registration Procedures: Registration may be completed online at <http://cms.hhs.gov/medicare/hcpcs/default.asp>, or you may contact the Power Wheelchair Public Meeting Coordinator, Lorrie Ballantine, (410) 786-7543, or Jennifer Carver, (410) 786-6610, to register by phone. 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.

Registration Deadline: Individuals must register by August 20, 2004.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that has requested to speak at the Public Meeting may designate one person to be the "Primary Speaker" and make a presentation at the meeting. We will post guidelines regarding the amount of time allotted to the speaker, as well as other presentation guidelines, on the official HCPCS Web site by August 27, 2004. Persons designated to be a Primary Speaker must register to attend the meeting using the registration

procedures described in section II of this notice by August 20, 2004, contact the DME Public Meeting Coordinator, Lorrie Ballantine or Jennifer Carver.

At the time of registration, Primary Speakers must provide a brief, written statement regarding the nature of the information they intend to provide, and advise the meeting coordinator regarding needs for audio/visual support. 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 well in advance of the meeting. We will accommodate tapes and disk files that are received by the DME Public Meeting Coordinator by August 27, 2004. In addition, on the day of the meeting, Primary Speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

B. Speaker Declaration

The Primary Speakers must declare, at the meeting as well as in their written summary, whether or not they have any financial involvement with the manufacturers, suppliers or competitors of power wheelchairs. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

C. Written Comments From Meeting Attendees

We welcome written comments from persons in attendance at a public meeting, whether or not they had the opportunity to make an oral presentation. Written comments may be submitted at the meeting, or prior to the meeting via e-mail to <http://cms.hhs.gov/medicare/hcpcs/default.asp> or by regular mail to Lorrie Ballantine, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244.

IV. General Information

The meetings are held in a Federal government building; therefore, Federal measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of their confirmation of pre-registration for the meeting. Access may be denied to persons without proper identification.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items

brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. 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 Accommodations: Persons attending a meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information upon registering for the meeting.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 15, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0269]

Agency Information Collection Activities; Proposed Collection; Comment Request; Radioactive Drugs for Certain Uses Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to radioactive drugs used in research.

DATES: Submit written or electronic comments on the collection of information by September 21, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/>