

periods beginning on or after January 1, 2002. (On July 1, 2002, we published a correcting amendment to the final rule in the **Federal Register** (67 FR 44073). Any reference to the August 7, 2001 final rule in this proposed rule includes the provisions effective in the correcting amendment.)

Section 1886(j)(5) of the Act and § 412.628 of the regulations requires the Secretary to publish in the **Federal Register**, on or before August 1 of the preceding fiscal year, the classifications and weighting factors for the IRF case-mix groups (CMGs) and a description of the methodology and data used in computing the prospective payment rates for the upcoming fiscal year. On August 1, 2002, we published a notice in the **Federal Register** (67 FR 49928) to update the IRF Federal prospective payment rates from FY 2002 to FY 2003 using the methodology described in § 412.624 of the regulations. As stated in that notice, we used the same classifications and weighting factors for the IRF CMGs that were set forth in the August 7, 2001 final rule to update the IRF Federal prospective payment rates from FY 2002 to FY 2003. The FY 2003 Federal prospective payment rates are effective for discharges on or after October 1, 2002 and before October 1, 2003.

After implementing the IRF PPS on January 1, 2002 and through the first quarter of calendar year 2002, we held conference calls with the IRF industry. These conference calls were beneficial for our staff and the IRF industry to understand and address the issues and concerns of implementing this new PPS. Since the IRF PPS has been implemented for over one year, we believe that this town hall meeting will provide interested parties with the opportunity to discuss issues and concerns regarding the IRF PPS.

In the near future, we anticipate publishing a proposed rule to set forth proposed updated FY 2004 IRF prospective payment rates and to propose other changes to the IRF PPS. It is important to note that if the proposed rule is published before the IRF town hall meeting, statements and comments made or received during the town hall meeting will not be accepted and considered as official comments on the proposed rule. To be considered as official comments, the procedures described in the **DATES**, **ADDRESSES**, and **SUPPLEMENTARY INFORMATION** sections of the proposed rule must be followed.

II. Meeting Format

The meeting will begin with an overview of the goals of the meeting. The meeting moderator will be

introduced along with members of the CMS IRF PPS Panel. After a brief overview of the IRF PPS, the moderator will lead a discussion of the written statements received before the town hall meeting as described below. We have developed an agenda (to be posted on the CMS Web site discussed below) for the meeting consisting of the following aspects of the IRF PPS: (1) The IRF patient classification and payment systems; (2) the IRF patient assessment instrument; and (3) the requirements for a hospital or a unit of a hospital to be classified as an IRF.

Beginning on or about April 28, 2003, information about the IRF PPS town hall meeting will be posted at the following Web site address: www.cms.hhs.gov/providers/irfpps/default.asp. At this address, interested parties will find important information on the town hall meeting including an agenda for the meeting and handouts to be used during the discussions.

We will limit the time for participants to make formal statements according to the number of registered participants. Individuals who wish to make formal statements must contact August Nemec as soon as possible. Those individuals must subsequently submit their formal statement in writing so that it is received by CMS no later than 5 p.m., Monday, May 12, 2003. Send written submissions to: August Nemec, Division of Institutional Post Acute Care, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-06-27, Baltimore, Maryland 21244 or ANemec@cms.hhs.gov. If time permits, statements from individuals not registered to speak will be heard after individuals with scheduled statements.

III. Registration Instructions

The Division of Institutional Post Acute Care is coordinating meeting registration. While there is no registration fee, all individuals must register to attend. Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by writing or e-mailing the actual names of the attendees to August Nemec at least 72 hours in advance of the meeting date. Attendees must show photographic identification to the Federal Protective Service or Guard Service personnel before they will be permitted to enter the building. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting. The meeting is limited to registered persons, and seating capacity is limited to the first 250 registrants.

Individuals requiring sign language interpretation for the hearing impaired

or other special accommodations should contact August Nemec at least 10 days before the meeting.

Authority: Section 1886(j) of the Social Security Act (42 U.S.C. 1395ww(j)).

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

Dated: March 24, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1230-N]

Medicare Program; Public Meetings in Calendar Year 2003 for New Durable Medical Equipment Coding and Payment Determinations

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

ACTION: Notice of meetings.

SUMMARY: This notice announces the dates and location of public meetings to be held in calendar year 2003 to discuss our preliminary coding and payment determinations for new durable medical equipment. These meetings provide a forum for interested parties to make oral presentations and/or to submit written comments in response to preliminary coding and pricing recommendations for new durable medical equipment that have been submitted using the Healthcare Common Procedure Coding System coding modification process. Discussion is directed toward response to our specific preliminary recommendations, and will be limited to items on the new durable medical equipment public meeting agenda.

DATES: The public meetings are scheduled for Tuesday, June 24; Wednesday, June 25; and Thursday, June 26, 2003. Each meeting day will begin at 8 a.m. and end at 5 p.m., e.s.t. We have tentatively scheduled Friday, June 27, 2003 as an optional meeting date. A meeting will only be held on June 27 if the number of agenda items cannot be managed in three meeting days.

ADDRESSES: The public meetings will be held in the Centers for Medicare & Medicaid Services (CMS) Auditorium,

located at 7500 Security Boulevard, Baltimore, MD 21244.

Web site: Additional details regarding the public meeting process for new DME, along with information on how to register, and guidelines for an effective presentation will be posted at least one month before the first meeting date on the official HCPCS Web site, and can be accessed at <http://cms.hhs.gov/medicare/hcpcs/default.asp>.

Individuals who intend to provide a presentation at a public meeting for new DME should familiarize themselves with this information. This website 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 DME and other items and services that are coded in the HCPCS.

A summary of each public meeting for new DME will be posted on the above website within one month after the meeting.

FOR FURTHER INFORMATION CONTACT:
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 for new DME are in response to the mandate of section 531(b) of BIPA.

Information regarding the establishment of the public meeting process for new durable medical equipment was published in the **Federal Register** at 66 FR 58743 on November 23, 2001.

II. Registration

Registration Procedures: Registration may be completed on-line at <http://cms.hhs.gov/medicare/hcpcs/default.asp>, or you may contact the DME Public Meeting Coordinator, Jennifer Carver at 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. Registrants must also indicate whether they are the "Primary Speaker" for an agenda item, designated by the entity that submitted the HCPCS

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

Registration Deadline: Individuals must register for each date they plan to attend and/or provide a presentation. The deadline for registration for all of the meetings dates is Tuesday, June 10, 2003.

III. Presentations

Primary Speaker Presentations: The entity that submitted the HCPCS coding request for an item that appears on the Public Meeting agenda 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 website at least a month before the first public meeting in 2003 for new DME. Persons who have been designated to be a Primary Speaker must register to attend the meeting using the registration procedures described above and, at least 15 days before the meeting, contact the DME Public Meeting Coordinator, Jennifer Carver at 410-786-6610. 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 7 or more calendar days prior to the meeting. In addition, on the day of the meeting, Primary Speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

"5-Minute" Speaker Presentations: 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 at the meeting 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, there is no pre-registration for 5-Minute speakers. Attendees may sign-up only on the day of the meeting to do a 5-Minute presentation. They must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that

will be addressed. On the day of the meeting, 5-Minute speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

Speaker Declaration: The Primary Speakers and the 5-Minute 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.

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://www.cms.hhs.gov/medicare/hcpcs> or via regular mail to the HCPCS Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244.

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 your 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. 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 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, should provide such information upon registering for the meeting.

Each meeting day will begin at 8 a.m. and end at 5 p.m., e.s.t. Because it is impossible to anticipate, in advance of

the April 1, 2003 submission deadline, the nature and the number of coding requests that will be submitted for new DME, we can only estimate the amount of meeting time that will be needed, and we are unable to post a final agenda at this time. We may not need three full-day meetings. We will consider each meeting individually, and we may modify the meeting dates and times published in this notice. Final confirmation of meeting dates and times, and agenda items will be posted three weeks in advance of each scheduled meeting, on the official HCPCS Web site and can be accessed at <http://cms.hhs.gov/medicare/hcpcs/default.asp>.

Authority: Sections 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: March 17, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–7060 Filed 3–27–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0514]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the information collection provisions by April 28, 2003.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to sshapiro@omb.eop.gov or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under

the food additive premarket approval provisions of the act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To assure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by x-ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
179.25(e)	6	120	720	1	720

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of firms who process food using irradiation is extremely limited. FDA estimates that there are two irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: Two facilities devoting 100

percent of their business (or 600 hours for recordkeeping annually) to food irradiation; four facilities devoting 10 percent of their business or 120 hours (4 x 30 hours) for recordkeeping annually to food irradiation.

No burden has been estimated for the labeling requirements in §§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of

information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: March 14, 2003.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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