

IV. Security, Building, and Parking Guidelines

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. It is suggested that you arrive at the CMS facility between 8:15 a.m and 8:30 a.m., E.S.T. so that you will be able to arrive promptly at the meeting by 9 a.m., E.S.T. 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 8:15 a.m., E.S.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, 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 demonstration.

V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide the information upon registering for the meeting. The deadline for such registrations is listed in the **DATES** section of this notice.

VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

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

Dated: February 18, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-4295 Filed 2-24-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1515-N]

Medicare Program; Public Meetings in Calendar Year 2011 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

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

ACTION: Notice.

SUMMARY: This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2011 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. The discussion will be focused on responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

DATES: Meeting Dates: The following are the 2011 HCPCS public meeting dates:

1. Tuesday, May 17, 2011, 9 a.m. to 5 p.m. eastern daylight time (e.d.t.) (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
2. Wednesday, May 18, 2011, 9 a.m. to 5 p.m. e.d.t. (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
3. Tuesday, May 24, 2011, 9 a.m. to 5 p.m. e.d.t. (Supplies and Other).
4. Wednesday, May 25, 2011, 9 a.m. to 5 p.m. e.d.t. (Supplies and Other).
5. Tuesday, June 7, 2011, 9 a.m. to 5 p.m. e.d.t. (Orthotics and Prosthetics).
6. Wednesday, June 8, 2011, 9 a.m. to 5 p.m. e.d.t. (Durable Medical Equipment (DME) and Accessories).

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 for the May 17, 2011 and May 18, 2011 public meetings.
- May 10, 2011 for the May 24, 2011 and May 25, 2011 public meetings.
- May 24, 2011 for the June 7, 2011 and June 8, 2011 public meetings.

Deadline 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 (as described in section IV. of this notice) 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 for the May 17, 2011 and May 18, 2011 public meetings.
- May 6, 2011 for the May 24, 2011 and May 25, 2011 public meetings.
- May 19, 2011 for the June 7, 2011 and June 8, 2011 public meetings.

Deadlines for all Other Attendees Registration: All other individuals who plan to enter the building to attend the public meeting 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 for the May 17, 2011 and May 18, 2011 public meeting dates.
- May 17, 2011 for the May 24, 2011 and May 25, 2011 public meeting dates.
- May 31, 2011 for the June 7, 2011 and June 8, 2011 public meeting dates.

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 for the May 17, 2011 and May 18, 2011 public meetings.
- May 10, 2011 for the May 24, 2011 and May 25, 2011 public meetings.
- May 24, 2011 for the June 7, 2011 and June 8, 2011 public meetings.

Deadline for Submission of Written Comments: Written comments must be received by the date of the meeting at which the code request is scheduled for discussion.

ADDRESSES: Meeting Location: The public meetings will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Submission of Written Comments: Written comments may either be e-mailed to HCPCS@cms.hhs.gov or sent via regular mail to Jennifer Carver or Sharon Ventura, HCPCS Public Meeting Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244-1850.

Registration and Special Accommodations: Individuals wishing to participate or who need special accommodations or both must register by completing the on-line registration located at <http://www.cms.hhs.gov/medhcpcsgeninfo> or by contacting one of the following persons: Jennifer Carver at (410) 786-6610 or Jennifer.Carver@cms.hhs.gov; or Sharon Ventura at (410)786-1985 or Sharon.Ventura@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Jennifer Carver at (410) 786-6610 or Jennifer.Carver@cms.hhs.gov; or Sharon Ventura at (410) 786-1985 or Sharon.Ventura@cms.hhs.gov.

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 durable medical equipment (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.

In the November 23, 2001 **Federal Register** (66 FR 58743), we published a notice providing information regarding the establishment of the public meeting process for DME. It is our intent to distribute any materials submitted to CMS to the Healthcare Common Procedure Coding System (HCPCS) workgroup members for their consideration. CMS and the HCPCS workgroup members require sufficient preparation time to review all relevant materials. Therefore, we are implementing a 10-page submission limit and firm deadlines for receipt of any presentation materials a meeting speaker wishes us to consider. For this reason, our HCPCS Public Meeting Coordinators will only accept and review presentation materials received by the deadline for each public meeting, as specified in the **DATES** section of this notice.

The public meeting process provides an opportunity for the public to become aware of coding changes under consideration, as well as an opportunity for CMS to gather public input.

II. Meeting Registration

A. Required Information for Registration

The following information must be provided when registering:

- Name.
- Company name and address.
- Direct-dial telephone and fax numbers.
- E-mail address.
- Special needs information.

A CMS staff member will confirm your registration by e-mail.

B. Registration Process

1. Primary Speakers

Individuals must also indicate whether they are the “primary speaker” for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. When registering, primary speakers must provide a brief written statement regarding the nature of the information they intend to provide, and advise the HCPCS Public Meeting Coordinator regarding needs for audio/visual support. 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 accept tapes and disk files that are received by the deadline for submissions for each public meeting as specified in the **DATES** section of this notice. The sum of all materials including the presentation may not exceed 10 pages (each side of a page counts as 1 page). An exception will be made to the 10-page limit for relevant studies published between the application deadline and the public meeting date, in which case, we would like a copy of the complete publication as soon as possible. This exception applies only to the page limit and not the deadline submission.

The materials may be e-mailed or delivered by regular mail to one of the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** section of this notice. The materials must be e-mailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to provide 35 copies if materials are delivered by mail.

2. 5-Minute Speakers

To afford the same opportunity to all attendees, 5-minute speakers are not required to register as primary speakers.

However, 5-minute speakers must still register as attendees by the deadline set forth under “Deadlines for all Other Attendees Registration” in the **DATES** section of this notice. Attendees can sign up only on the day of the meeting to do a 5-minute presentation. Individuals must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that they will address.

C. Additional Meeting/Registration Information

Public Meetings are scheduled far in advance of the influx of HCPCS applications each cycle. At the time they are scheduled we can only anticipate the number of applications that we receive in each category. As a result, we may not need the second day of Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents Public Meeting on Wednesday, May 18, 2011. We have scheduled this date tentatively. The Public Meeting Agendas published on CMS’ HCPCS Web site at <http://www.cms.hhs.gov/medhcpcsgeninfo> will serve as final notification regarding whether a meeting will be held on Wednesday, May 18, 2011.

The product category reported by the applicant may not be the same as that assigned by us. Prior to registering to attend a public meeting, all participants are advised to review the public meeting agendas at <http://www.cms.hhs.gov/medhcpcsgeninfo> which identify our category determinations, and the dates each item will be discussed. Draft agendas, including a summary of each request and our preliminary decision will be posted on our HCPCS Web site at <http://www.cms.hhs.gov/medhcpcsgeninfo> at least 4 weeks before each meeting.

Additional details regarding the public meeting process for all new public requests for revisions to the HCPCS, along with information on how to register and guidelines for an effective presentation, will be posted at least 4 weeks before the first meeting date on the official HCPCS Web site at <http://www.cms.hhs.gov/medhcpcsgeninfo>. The document titled “Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)” will be made available on the HCPCS Web site at least 4 weeks before the first public meeting in 2011 for all new public requests for revisions to the HCPCS. Individuals who intend to provide a presentation at a public meeting need to familiarize themselves

with the HCPCS Web site and the valuable information it provides to prospective registrants. The HCPCS Web site also contains a document titled "Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures," which is a description of the HCPCS coding process, including a detailed explanation of the procedures used to make coding determinations for all the products, supplies, and services that are coded in the HCPCS.

The HCPCS Web site also contains a document titled "HCPCS Decision Tree & Definitions" which illustrates, in flow diagram format, HCPCS coding standards as described in our Coding Procedures document.

A summary of each public meeting will be posted on the HCPCS Web site by the end of August 2011.

III. Presentations and Comment Format

We can only estimate the amount of meeting time that will be needed since it is difficult to anticipate the total number of speakers that will register for each meeting. Meeting participants should arrive early to allow time to clear security and sign-in. Each meeting is expected to begin promptly as scheduled. Meetings may end earlier than the stated ending time.

A. Oral Presentation Procedures

All primary speakers must register as provided under the section titled "Meeting Registration." Materials and writings that will be used in support of an oral presentation should be submitted to one of the HCPCS Public Meeting Coordinators.

The materials may be e-mailed or delivered by regular mail to one of the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** section of this notice. The materials must be e-mailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to include 35 copies if materials are delivered by mail.

B. Primary Speaker Presentations

The individual or entity requesting revisions to the HCPCS coding system for a particular agenda item may designate one "primary speaker" to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and the presentation must incorporate the demonstration, set-up, and distribution of material. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we 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.

Individuals designated to be the primary speaker must register to attend the meeting using the registration procedures described under the "Meeting Registration" section of this notice and contact one of the HCPCS Public Meeting Coordinators, specified in the **ADDRESSES** section. Primary speakers must also separately register as primary speakers by the date specified in the **DATES** section of this notice.

C. "5-Minute" Speaker Presentations

Meeting attendees can 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.

D. Speaker Declaration

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

Each primary speaker and 5-minute speaker must declare in their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

E. Written Comments From Meeting Attendees

Written comments will be accepted from the general public and meeting registrants anytime up to the date of the public meeting at which a request is discussed. Comments must be sent to the address listed in the **ADDRESSES** section of this notice.

Meeting attendees may also submit their written comments at the meeting. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

IV. Security, Building, and Parking Guidelines

The meetings are held within the CMS Complex which is not open to the

general public. 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. Participants will also be subject to a vehicular search before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on Federal Property include but are not limited to, 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). Once cleared for entry to the complex participants will be directed to parking by a security officer.

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. Participants are reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. 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.

Guest access to the complex 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. Also be mindful that 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. 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.

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 2 weeks

prior to each public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the 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 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

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** section 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.
- Dates of visits.
- Company Name.
- Position/Title.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh).

Dated: February 10, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011-3812 Filed 2-24-11; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Assistance Program Estimates: ORR-1	46	1	2	92
<i>Estimated Total Annual Burden Hours:</i>				92

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *E-mail address:* infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 22, 2011.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2011-4278 Filed 2-24-11; 8:45 am]

BILLING CODE 4184-01-P

Title: Refugee Assistance Program Estimates: CMA—ORR-1.

OMB No.: 0970-0030.

Description:

The Refugee Assistance Program Estimates: ORR-1 form is the application for funding for the Refugee Cash and Medical Assistance program. Applicants for funding provide estimates of costs of the different components of the program—Refugee Cash Assistance, Refugee Medical Assistance, Health Screening, Services to Unaccompanied Refugee Minors, Administrative Cost of the Services to Unaccompanied Refugee Minors program, and Administrative Costs of the State Refugee Coordinator. Applicants also submit a narrative justification for their estimates. Applicants submit the form annually on August 15 of the fiscal year prior to the fiscal year for which funds are being requested. The form may be submitted through an On-Line Data Collection system or hard copy format. The Office of Refugee Resettlement uses the cost estimate data from the ORR-1 in determining and allocating quarterly awards of funds and in projecting full year costs of this program.

Respondents:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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