On August 5, 2008 (73 FR 45454), FDA announced the availability of the draft version of this guidance. The public comment period closed on October 6, 2008. A number of comments were received, which the agency considered carefully as it finalized the guidance and made appropriate changes. Most of the changes to the guidance were made to clarify statements in the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on inclusion of recommended information to support applications for parametric release of human and veterinary drug products terminally sterilized by moist heat processes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information requested in the guidance is covered under FDA regulations at 21 CFR 314.50, 314.70, and 314.81(b)(2) for human drugs; 21 CFR 514.1, 514.8, 514.8(b)(4) and (c) for animal drugs; and 21 CFR 601.2 and 601.12 for biologics. The collection of information is approved under the following OMB control numbers: 0910–0001 for human drugs, 0910–0600 for animal drugs, and 0910–0338 for biologics.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or *http://www.regulations.gov*.

Dated: February 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3978 Filed 2–25–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI K99 Grant Applications.

Date: March 1, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel—Chevy Chase Pavilion Washington, DC 20015.

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Officer, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892, 301–451–2020, *kenshalod@nei.nih.gov*.

This Notice is late due to administrative procedures.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 17 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–3784 Filed 2–25–10; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1514–N]

Medicare Program; Public Meetings in Calendar Year 2010 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 2010 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. Discussion will be directed toward responses to our specific preliminary recommendations and will include all items on the public meeting agenda.

DATES: *Meeting Dates:* The following are the 2010 HCPCS public meeting dates:

1. Tuesday, May 4, 2010, 9 a.m. to 5 p.m., eastern daylight time (e.d.t.) (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
2. Wednesday, May 5, 2010, 9 a.m. to 5 p.m., e.d.t. (Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
3. Tuesday, May 25, 2010, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).
4. Wednesday, May 26, 2010, 9 a.m. to 5 p.m., e.d.t. (Supplies and Other).
5. Thursday, May 27, 2010, 9 a.m. to 5 p.m, e.d.t. (Orthotics and Prosthetics).
6. Tuesday, June 8, 2010, 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:

- April 20, 2010 for the May 4 and 5, 2010 public meetings.
- May 11, 2010 for the May 25, 26 and 27, 2010 public meetings.
- May 25, 2010 for the June 8, 2010 public meeting.

Deadline for Attendees that are Foreign Nationals (reside outside the

U.S.) Registration: Attendees that are Foreign Nationals (reside outside the U.S.) need 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 10 business days in advance of the public meeting date in which the individual plans to attend.

Deadlines for all Other Attendees Registration: 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:

- April 27, 2010 for the May 4 and 5, 2010 public meeting dates.
- May 18, 2010 for the May 25, 26 and 27, 2010 public meeting dates.
- June 1, 2010 for the June 8, 2010 public meeting date.

Deadlines for Requesting Special Accommodations:

- April 20, 2010 for the May 4 and 5, 2010 public meeting dates.
- May 11, 2010 for the May 25, 26 and 27, 2010 public meeting dates.
- May 25, 2010 for the June 8, 2010 public meeting.

Deadline for Submission of Written Comments: Written comments must be received by the date of meeting at which a 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 can be e-mailed to *HCPCS@cms.hhs.gov* or sent via regular mail to Jennifer Carver or Geneva Harkness, HCPCS Public Meeting Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–08–27, Baltimore, MD 21244.

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 Geneva Harkness at (410) 786–6951 or *Geneva.Harkness@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Carver at (410) 786–6610 or *Jennifer.Carver@cms.hhs.gov;* or Geneva Harkness at (410) 786–6951 or *Geneva.Harkness@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 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 the meeting participant wishes CMS 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.

These materials may be delivered by regular mail postmark date no later than the deadline date or by e-mail to one of the HCPCS Public Meeting Coordinators as specified in the **ADDRESSES** 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 Wednesday, May 5, 2010. 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 May 5, 2010.

The product category reported by the applicant may not be the same as that

assigned by CMS. 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 CMS' 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 HCPCS Web site at *http://www.cms.hhs.gov/medhcpcsgeninfo.* 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 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 2010.

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

Individuals who are planning to provide an oral presentation 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.

These materials may be delivered by regular mail (postmark date no later than the deadline date) or by e-mail to one of the HCPCS Public Meeting Coordinators specified in the **ADDRESSES** section. 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.

We will post "Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)" on the official HCPCS Web site at least 4 weeks before the first public meeting in 2010 for all new public requests for revisions to the HCPCS. 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 in a Federal government building; therefore, Federal security 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 government-issued photo identification and a copy of your written meeting registration confirmation. Persons without proper identification will be denied access.

CMS has had a long standing policy of established Visitor and Foreign National Visitor controls that effectively control access to sensitive facilities and restricted/controlled areas containing CMS information, information systems, and media libraries. Visitors shall be authenticated prior to being granted access to facilities or areas other than areas designated as publicly accessible. Government contractors and others with permanent authorization credentials are not considered visitors.

However, HHS policy requires us to ensure that a government employee, US citizen host/hosting official is assigned to every foreign national visitor visiting an HHS facility. As such, the host/hosting official is required to inform the Security and Emergency Management Group (SEMG) Division of Physical Security, at least 10 business days in advance of any visit by a foreign national visitor.

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.

Attendees that are Foreign Nationals (reside outside the U.S.) 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; and
- Dates of visits.

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.

Security measures will also include inspection of vehicles, inside and outside, at the entrance to the grounds and buildings. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS 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 arrangements and approvals are required in order to bring pieces of equipment or medical devices at least 2 weeks prior to each public meeting. 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.

Parking permits and instructions are issued upon arrival by the guards at the main entrance.

All visitors must be escorted by agency staff in order to enter areas other than the public areas on the lower and first-floor levels in the Central Building.

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

Dated: February 18, 2010.

Charlene Frizzera,

Acting Adminstrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–3722 Filed 2–25–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Maternal and Child Health in Poor Countries: Evidence from Randomized Evaluations.

Date: March 18, 2010.

Time: 11 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852.(Telephone Conference Call)

Contact Person: Carla T. Walls, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435–6898, *wallsc@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the closing of the Federal Government the week of February 7, 2010. The Federal Government was closed due to inclement weather conditions.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 19, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–4081 Filed 2–25–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.

Date: March 10, 2010.

Time: 8 a.m. to 4:30 p.m.

Agenda: Presentation and discussion will include updates from SMRB Working Groups; Deliberating Organization Change and Effectiveness; NIH Intramural Research Program; and Substance Use, Abuse, and Addiction. The Board will also discuss perspectives on organizational change. Time will be allotted on the agenda for public comment. Sign up for public comment will begin at approximately 7 a.m. and will be restricted to one sign in per person. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person address below.