services being discussed (or with their competitors).

After the public and CMS presentations, the Panel will deliberate openly on the topic. Interested persons may observe the deliberations, but the Panel will not hear further comments during this time except at the request of the chairperson. The Panel will also allow approximately a 30-minute open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Panel will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

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

Dated: November 14, 2001.

Jeffrey L. Kang,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 01–29210 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1190–NC]

Medicare Program; Establishment of Procedures That Permit Public Consultation Under the Existing Process for Making Coding and Payment Determinations for New Clinical Laboratory Tests and for New Durable Medical Equipment

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

ACTION: Notice of public meetings with comment period.

SUMMARY: This notice announces the addition of public meetings under our existing process for making coding and payment determinations for new clinical laboratory tests and new durable medical equipment (DME). Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000(BIPA) requires us to establish procedures that permit public consultation for coding and payment determinations for new clinical laboratory tests and for new DME in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD–9–CM).

In addition, this notice announces the dates and general details of public meetings to be held in 2002. We are requesting comments on our plan to fulfill the requirements of section 531(b) of BIPA.

DATES: *Laboratory Public Meeting:* The meeting regarding the assignment of payment rates for new laboratory tests to be included in Medicare's Clinical Laboratory Fee Schedule for calendar year 2003 is scheduled for Monday, August 5, 2002. The meeting will begin at 8:30 a.m. and end at 4:30 p.m., E.S.T. The development of the codes for clinical laboratory tests is largely performed by the Current Procedural Terminology (CPT) Editorial Panel and will not be further discussed at the CMS meeting.

DME Public Meeting Dates: There will be three meetings regarding coding and payment for new DME. The meetings are scheduled for March 11, 2002, May 13, 2002, and June 17, 2002. All three meetings will begin at 8 a.m. and end at 5 p.m., E.S.T.

Comment Date: We are requesting comments on the procedures in this notice for establishing public consultation on our existing coding and payment determinations for new clinical laboratory tests and new DME. Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 22, 2002.

ADDRESSES: *Meetings:* All four meetings in 2002 will be held at the Centers for Medicare & Medicaid Services, CMS Auditorium, 7500 Security Boulevard, Baltimore, MD 21244.

Website: For clinical laboratory tests, a summary of the August 2002 meeting will be posted on our website (*www.hcfa.gov/audience/planprov.htm*) within 1 month after the meeting.

For DME items, you may access up-to-date meeting information on the HCPCS website at: *http://www.hcfa.gov/medicare/hcpcs.htm.*

Comments: Mail an original and three copies of written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1190–NC, P.O. Box 8017, Baltimore, MD 21244–8017.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them. If you prefer, you may deliver an original and three copies of your written comments to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1190–NC. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anita Greenberg, (410) 786–4601 for clinical laboratory payment rates; Kaye Riley, (410) 786–5323 for HCPCS coding for DME items; Joel Kaiser, (410) 786–4499 for DME payment rates.

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 mandates that we establish, no later than 1 year after the date of enactment, procedures that permit public consultation for coding and payment determinations for new clinical diagnostic laboratory tests and new DME under Part B of title XVIII of the Social Security Act (the Act) in a manner consistent with the procedures established for implementing coding modifications for ICD–9–CM. The ICD–9–CM process involves holding regularly scheduled public meetings that are announced in the **Federal Register** 30 days before the meeting date. The ICD–9–CM meetings are open to the public and are held in the CMS auditorium. The agenda for each meeting is posted on the CMS website before each meeting under the heading for meetings and announcements. A preliminary ICD–9–CM coding determination for each agenda item is presented by CMS at the meeting.

The procedures and public meetings announced in this notice for new clinical laboratory tests and new DME are in response to the mandate of section 531(b) of BIPA. Also, our HCPCS website at *http//www.hcfa.gov/medicare/hcpcs.htm* includes a description of our existing HCPCS

coding process and the additional public consultation process. The website provides a detailed explanation of the procedures we use to make coding and payment determinations for DME and other items and services that are coded in the HCPCS. We may make modifications to our process in the future as a result of comments we receive or based on our experience in implementing these procedures in 2002 and subsequent years.

II. Public Meetings

Registration

Deadline for Registration: Individuals must register for the meetings by the following dates:

DME meeting dates	Registration dates
March 11, 2002	January 28, 2002.
May 13, 2002	April 1, 2002.
June 17, 2002	May 3, 2002.
Laboratory meeting date	**Registration date**
August 5, 2002	July 24, 2002.

Presentations

Laboratory Agenda Item: Individuals who want to make a presentation on the Laboratory agenda item must register by sending a fax to the attention of Anita Greenberg at (410) 786–0169, no later than July 24, 2002. Please provide name, company name, address, and telephone number.

DME Agenda Item: Individuals who want to make presentations on a DME agenda item must register by sending a fax to the attention of Joel Kaiser at (410) 786–0765, by the registration dates listed above. Please provide name, company name, address, telephone number, and agenda item you want to address.

The agenda will consist of HCPCS coding requests for new DME. Requests must be submitted through the HCPCS coding process to Kaye Riley; Center for Medicare Management; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C5–08–27; Baltimore, MD 21244. Requests must be received by April 1 of each year in order to be considered during the review cycle for the next annual HCPCS update. The annual HCPCS update is January 1 of each year. Requests will be reviewed by CMS's HCPCS Alpha-Numeric Workgroup, which will make CMS's preliminary recommendation on what action needs to be taken in response to the request. Once the Workgroup's preliminary recommendation has been developed, the request will be added to the agenda for the next available public meeting.

General Information

The meetings will be held in a government building; therefore, security measures will be applicable. Anyone without government identification will need to present photo identification, sign-in, and provide registration information.

Persons attending the meetings in Baltimore who are hearing or visually impaired and have special requirements or a condition that requires special assistance or accommodations, should notify the individuals listed below.

Laboratory Meeting: Anita Greenberg at fax number (410) 786–0169 or call (410) 786–4601.

DME Meetings: Joel Kaiser at fax number (410) 786–0765 or call (410) 786–4499.

Purpose of the Meetings

New Laboratory Tests: The introduction of new codes may call for us to determine the rates at which the new codes will be paid. The laboratory meeting is intended to provide us with expert input on the nature of new tests before rate determinations are made. Discussion will be limited to the codes listed on the CMS Internet website at *www.hcfa.gov/audience/planprov.htm* by June 26, 2002.

New DME: Beginning in March 2002, CMS plans to schedule three public meetings per year on coding and pricing of new DME that will allow interested parties the opportunity to make oral presentations and submit written comments regarding coding and pricing recommendations for new DME that have been submitted using the HCPCS coding modification process. These public meetings will be held during the months of March, May, and June. Each meeting will be a full day.

Before each public meeting, the HCPCS workgroup will meet to review the coding requests that will be on the agenda for the next public meeting. In advance of a meeting, the Workgroup will complete a fact sheet that will include the following information for each agenda item:

- The nature of the request for a coding modification.
- Background information pertinent to the request.
- The fact sheet will also include for each request on the agenda the HCPCS workgroup's preliminary recommendation, and the rationale for this recommendation.

In addition, the fact sheet will also include the Workgroup's preliminary recommendation regarding the applicable payment category and the methodology that will be used to set a payment amount, for example, supplier price lists, price of a comparable item, or reasonable charge data. The preliminary recommendations of the HCPCS workgroup regarding the coding requests and CMS's preliminary payment methodology decision will be presented at the public meetings for discussion. After a public meeting, the workgroup will reconsider its preliminary coding recommendations, and CMS staff will reconsider pricing recommendations in view of the information presented at the public meeting. After reconsidering its preliminary coding recommendations in light of the discussions at the public meeting, the workgroup will decide what recommendations it should make to the HCPCS National Alpha-Numeric Editorial Panel, the entity that maintains the permanent HCPCS level II codes and that is hereafter referred to as the National Panel. The HCPCS National Panel is comprised of the Health Insurance Association of America, the Blue Cross and Blue Shield Association, and CMS.

Format and Agenda

New Laboratory Tests: This meeting is open to the public. The on-site check-in for visitors who have registered to attend the meeting will be held from 8 a.m. to 8:30 a.m., followed by opening remarks. Registered persons from the public may present discussion and individual recommendations on payment determinations for specific new Current Procedural Terminology (CPT–4) codes for the 2003 Clinical Laboratory Fee Schedule, which are to become effective January 1, 2003. A newly created CPT–4 code can represent either a refinement or modification of existing test methods, or a substantially new test method. Decisions regarding payment levels or methods for determining them for the newly created CPT–4 codes will not be made at this meeting. However, the meeting will provide an opportunity for us to receive public input before we determine payments for the new codes. All presentations should be brief, and three written copies should be submitted to accompany any oral presentations. Information we find helpful for presenters to address includes the nature of the test method, applications, costs, and any recommendation the presenter may have regarding the method for establishing a payment rate (as discussed below). Due to time constraints, we may limit the number and duration of oral presentations to fit the time available. The specific codes that will be discussed at the meeting will be identified on the CMS Internet

website at *www.hcfa.gov/audience/planprov.htm* by June 26, 2002.

New DME: This meeting is open to the general public. The on-site check-in for visitors who have registered to attend the meeting will be held from 7:30 a.m. to 8 a.m., followed by opening remarks. The purpose of the open meeting is to allow the public an opportunity, in a public forum, to do the following:

- Present to CMS representatives information and recommendations regarding the coding requests listed on the agenda.
- Discuss with representatives of the HCPCS Workgroup its preliminary recommendation regarding these coding requests.
- Discuss preliminary recommendations of CMS regarding payment for new DME items.

For each item on the agenda, the discussion will begin with CMS's presenting an overview of the request and the factors we considered in reaching our preliminary recommendations. Following the CMS overview, the entity that requested the HCPCS coding change will be given a maximum of 15 minutes to make a public presentation concerning its coding change application and payment for the item. For a requestor to participate in the public meeting as a primary presenter, the requestor must be registered with the HCPCS Coordinator, Kaye Riley, (410) 786–5323. For purposes of registering as a primary presenter, you must, at least 15 days prior to the meeting, submit the following to the HCPCS coordinator:

- A brief statement, one to two pages, of the general nature of the information you plan to present.
- The names and addresses of the proposed presenters.
- An estimate of the time required to make the presentation.

Primary presenters will be given up to 15 minutes for their presentations. Other presenters will be permitted to sign up at the meeting on a first come basis to make 5-minute presentations on agenda items. Time constraints will determine how many presenters, besides the primary presenter, will be allowed to make a public presentation. Speakers following the primary presenters will also be required to submit on the day of the meeting a one to two-page summary of their presentation. Other persons in attendance, who do not have the opportunity to make a presentation, may, at the meeting, submit their comments in a written statement of one to two typed pages.

We will request that speakers declare at the meeting and in any written statements whether or not they have any financial involvement with manufacturers of any items or services being discussed (or with their competitors). This would include any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer. A summary of each meeting will be posted on the HCPCS website within 3 weeks following the meeting. The HCPCS website is *http://www.hcfa.gov/medicare/hcpcs.htm.*

The DME public meetings will be held in the main auditorium at CMS's Central Office, located at 7500 Security Boulevard, Baltimore, MD, 21244. The first meeting is scheduled for March 11, 2002. For the remainder of 2002, meetings are also scheduled for May 13 and June 17. The meetings will begin at 8 a.m., E.S.T. For a coding request to be included on the agenda for the May or June meeting, it must received by April 1. For a coding request to be included on the agenda for the March meeting, it must be received at least 45 days before the scheduled date of the March meeting. If a coding request does not meet this deadline, it will be placed on the agenda for the next meeting.

The agenda for an upcoming DME public meeting will be posted on the HCPCS website at least 30 days before the scheduled date for the meeting. Posted with the agenda, there will also be a fact sheet, as described above, for each coding request to be reviewed at the meeting.

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: November 19, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–29326 Filed 11–21–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 7, 2001, from 8 a.m. to 5 p.m.

Location: CDER Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776 or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long, from 9 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: On December 7, 2001, from 8 a.m. to 9 a.m., the meeting will open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 17, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 17, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the December 7, 2001, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Closed Committee Deliberations: On December 7, 2001, from 9 a.m. to 5 p.m., the meeting will be closed to permit