DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Tumor Biomarkers.

Date: December 15, 2009.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Malaya Chatterjee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301–451–0131, *chatterm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cell Biology.

Date: December 15, 2009.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jonathan Arias, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 20, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–28396 Filed 11–25–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1513–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2011 Applications for New Medical Services and Technologies Add-on Payments and Informational Workshop on the Application Process and Criteria for New Medical Services and Technologies Add-on Payments

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to discuss fiscal year (FY) 2011 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2011 new medical services and technologies applications meet the substantial clinical improvement criterion.

Additionally, this notice announces an Informational Workshop for all interested parties on the application process and criteria for new medical services and technologies under the IPPS and on the outpatient prospective payment system (OPPS) transitional pass-through payment for drugs, biologicals, and devices and new technology Ambulatory Payment Classification (APC) assignment for new services application processes.

DATES: *Meeting Date:* The Town Hall meeting and the Informational Workshop announced in this notice will be held on Wednesday, February 10, 2010. The Informational Workshop will begin at 9 a.m., and check-in will begin at 8:30 a.m. eastern daylight time (e.d.t.). The Town Hall meeting will begin at 1 p.m. e.d.t. and check-in will begin at 12:30 p.m. e.d.t. Only one check-in is required to enter the building. Participants attending the Informational Workshop will be able to attend the Town Hall meeting without an additional check-in unless they exit the building. In this case, a participant will need to repeat the security procedures and check-in.

Deadline for Registration of Presenters of the Town Hall Meeting: All presenters for the Town Hall meeting, whether attending in person or by phone, must register and submit their agenda item(s) by January 26, 2010.

Deadline for Registration of All Other Participants for the Town Hall Meeting, Participants of the Informational Workshop, and Submitting Requests for Special Accommodations: All other participants for the Town Hall Meeting and participants of the Informational Workshop must register by February 2, 2010. Requests for special accommodations must be received no later than 5 p.m., e.d.t. on February 2, 2010.

ADDRESSES: *Meeting Location:* The Town Hall meeting and Informational Workshop will both be held in the main Auditorium in the central building of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located *in* section III. of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Registration information and special accommodation requests may also be mailed to the address listed in the **ADDRESSES** section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2010 application meets the substantial clinical improvement criterion. Agenda items or written comments, questions, or other statements must not exceed three single-spaced typed pages and must be sent to: Division of Acute Care, New Technology Team, Mailstop C4–07–08, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, Attention: Michael Treitel.

Agenda items or written comments may also be sent via e-mail to *newtech@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act

requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). (For a more detailed discussion, see the FY 2002 proposed and final rules (66 FR 22693, May 4, 2001) and the final rule (66 FR 46912, September 7, 2001) respectively.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluate a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

++ Reduced mortality rate with use of the device.

++ Reduced rate of device-related complications.

++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

++ Decreased number of future hospitalizations or physician visits.

++ More rapid beneficial resolution of the disease process treatment because of the use of the device.

++ Decreased pain, bleeding or other quantifiable symptoms.

++ Reduced recovery time.

In addition, we indicated that the requester is required to submit evidence that the technology meets one or more of these criteria.

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1886(d)(5)(K)(viii) of the Act to revise the process for evaluating new medical services and technology applications by requiring the Secretary to do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data to our clinical staff as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2011. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2011 IPPS proposed rule.

II. Town Hall Meeting and Informational Workshop Format

A. Town Hall Meeting Format

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial improvement. This will allow for a discussion of the substantial clinical improvement criteria as it relates to each of the FY 2011 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.*

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) to the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Comments from participants will be heard after scheduled statements if time permits. Once the agenda is completed, it will be posted on the CMS IPPS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.*

For presenters or participants unable to attend the CMS for the meeting, an open toll-free phone line, (800) 603–1774, is available. Persons who call in will be asked for the conference code by the conference operator. The conference code is ''New Tech.''

In addition, written comments will also be accepted and presented at the meeting if they are received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for CMS consideration. If the comments are to be considered before the publication of the proposed rule, the comments must be received at the address specified in the **ADDRESSES** section of this notice by the date specified in the **DATES** section of this notice.

B. Informational Workshop Format

In addition, to the statutorily-required Town Hall meeting on whether an IPPS new technology application meets the substantial clinical improvement criteria we will be holding an Informational Workshop on applying for special payment for new medical services and technologies under the IPPS and OPPS. Specifically, for new technology add-on payments under the IPPS, we will discuss each criterion in detail along with other information that will be helpful in guiding an applicant through the new technology add-on payment process. We will also discuss the processes of DRG assignment and requesting new ICD–9 codes under the IPPS. (Information on DRGs can be found on the IPPS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp#TopOfPage* and information on ICD–9–CM coding can be found on our Web site at (*http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/*)

To facilitate the public's knowledge of OPPS application processes for transitional pass-through status of

drugs, biologicals and devices and assignment of new services to New Technology Ambulatory Payment Classification (APCs), the Informational Workshop will also include information on several processes for applying for special payment under the OPPS. One topic concerns the process for applying for a new category of devices for pass-through payment and criteria for evaluation. Interested parties may apply for a new device category, in accordance with section 1833(t)(6) of the Act. As background information, we have posted application and process background information on our Web site at *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.*

Furthermore, under section 1833(t)(6) of the Act interested parties may also apply for transitional pass-through payment for certain new drugs, biological or radiopharmaceutical agents. As background information, we have posted application and process background information on our Web site, *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.* Finally, we provide the opportunity for the public to apply for new services to be placed in New Technology APC groups in the OPPS, in accordance with our criteria and discussion in our November 30, 2001 final rule (66 FR 59897). As background information, we have posted application and process background information on our Web site, *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.* We plan to discuss all three of these OPPS application processes at the Informational Workshop that will be held on February 10, 2010.

The Informational Workshop is open to all interested parties including organizations representing hospitals, physicians, and manufacturers. We encourage all interested parties to attend, especially those who are not familiar with these processes. Individuals who want to attend this Informational Workshop must register by the date specified in the **DATES** section of this notice. Registration information is available in section III. of this notice.

For participants who cannot come to CMS for the meeting, an open toll-free phone line, (800) 603–1774, has been made available. If you are calling in, the operator will ask you for the conference code. The conference code is ''New Tech.''

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial improvement. This will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2011 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.*

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For participants who cannot come to CMS for the meeting, an open toll-free phone line, (800) 603–1774, has been made available. If you are calling in, the operator will ask you for the conference code. The conference code is ''New Tech.''

III. Registration Instructions

The Division of Acute Care in CMS is coordinating registration for both the Town Hall meeting and the Informational Workshop. While there is no registration fee, individuals must register to attend the Town Hall meeting on substantial clinical improvement and for the Informational Workshop (two separate registrations).

Registration may be completed on-line at the following web address: *http://www.cms.hhs.gov/AcuteInpatientPPS/08_newtech.asp#TopOfPage.* Select the links at the bottom of the page ''Register to Attend the New Technology Town Hall meeting'' and ''Register to attend the New Technology Informational Workshop''. After completing the registration, on-line registrants should print the confirmation page and bring it with them to the meeting(s).

If you are unable to register on-line, you may register by sending an email to the contacts listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include your name, address, telephone number, email address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

IV. Security, Building, and Parking Guidelines

Because these meetings will be located on Federal property, for security reasons, any persons wishing to attend these meetings must register by close of business on the date listed in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 8:30 a.m., e.d.t. if you are attending the Informational Workshop and no later than 12:30 p.m. if you are attending the town hall meeting so that you will be able to arrive promptly at the appropriate meeting.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- 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.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meetings. The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting(s).

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Public Law 108–173.

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

Dated: November 12, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. E9–27971 Filed 11–25–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Cardiovascular and Renal Drugs 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). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

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 January 11, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Elaine Ferguson, 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: 301–827–6778, e-mail: *elaine.ferguson@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 11, 2010, the committee will discuss supplemental drug application (sNDA) 21–742, nebivolol tablets, Forest Laboratories, Inc., for the proposed indication (use) of treatment of chronic heart failure.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: 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 on or before December 24, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before December 16, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 17, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–28302 Filed 11–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5280–N–46]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

DATES: *Effective Date: November 27, 2009.*

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD