Relevant recommendations should include feedback on the integration of the imaging efficiency measures into the overall HOP QDRP program.

II. Listening Session Format

The listening session will be held on January 31, 2011. Measure developers, hospitals, medical specialty societies, medical professionals, and other interested stakeholders are invited to participate in person or by teleconference. The session will begin at 1 p.m. E.S.T. with an overview of objectives for the session. The remainder of the meeting will be devoted to receiving input on additional imaging efficiency measures and their integration into the overall HOP QDRP program. The meeting will conclude by 5 p.m. E.S.T.

Participants will be permitted to speak in the order in which they sign up. Participants are encouraged to provide references to the evidence base supporting their suggested measures. Comments from individuals not registered to speak will be heard after scheduled statements only if time permits.

III. Registration Instructions

For security reasons, any persons wishing to attend this meeting must register by the date listed in the **DATES** section of this notice. Persons interested in attending the meeting must register by completing the on-line registration via the designated Web site *http://www.cms.gov/apps/events/event.asp?id=622.*

The on-line registration system will generate a confirmation page to indicate the completion of your registration. Please print this page as your registration receipt.

Individuals may also participate in the listening session by teleconference. For individuals interested in participating via teleconference, registration is available via the Web site at *https://www.magnetmail.net/events?cf4db6967a514fb681832e700ee3e5b0a.* Registration is required as the number of call-in lines will be limited.

Background information on the listening session will be posted on the QualityNet Web site at *http://www.qualitynet.org* prior to the session. The information will be posted under the tab for "Hospitals Outpatient," then select "Imaging Efficiency Measures" from the drop-down menu. We anticipate posting an audio download and/or transcript of the listening session in the same location on *http://www.qualitynet.org* after completion of the listening session.

Individuals requiring sign language interpretation or other special accommodations must contact the staff via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. The on-site check-in for visitors will begin at 12 noon E.S.T. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical 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 a presentation.

We note that 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 60 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

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

Dated: November 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 2010–29995 Filed 11–26–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1342–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2012 Applications for Add-on Payments for New Medical Services and Technologies Under the Hospital Inpatient Prospective Payment System and Informational Workshop on the Application Process and Criteria for Add-on Payments for New Medical Services and Technologies Under the Inpatient and Outpatient Prospective Payment Systems

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2012 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 2012 new medical services and technologies applications meet the substantial clinical improvement criterion.

Additionally, we will hold an Informational Workshop for all interested parties on the application process and criteria for add-on payments for new medical services and technologies under the IPPS and the application processes for the outpatient prospective payment system (OPPS) transitional pass-through payment for drugs, biological, and devices and new technology ambulatory payment classification (APC) group assignments for new services.

DATES: *Meeting Date:* Both the Town Hall Meeting and Informational Workshop announced in this notice will be held on Wednesday, February 2, 2011. The Informational Workshop will begin at 9 a.m., and check-in will begin at 8:30 a.m. eastern standard time (e.s.t.). The Town Hall Meeting will begin at 1 p.m. e.s.t. and check-in will begin at 12:30 p.m. e.s.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 again for the Town Hall Meeting.

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 19, 2011.

Deadline for Registration of All Other Participants for the Town Hall Meeting and the Informational Workshop and Submitting Requests for Special Accommodations: All other participants must register by January 24, 2011. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on January 24, 2011.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the Town Hall Meeting must be received by January 19, 2011. In addition to materials submitted for discussion at the Town Hall Meeting, individuals may submit other written comments, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by February 16, 2011, for consideration before publication of the FY 2012 IPPS proposed rule.

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 and 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 2012 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via e-mail to *newtech@cms.hhs.gov* or sent via regular mail to:

Division of Acute Care, New Technology Team, Mailstop C4–08–06, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore Maryland 21244–1850, Attention: Michael Treitel or Celeste Beauregard.

FOR FURTHER INFORMATION CONTACT: Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov,* or Celeste Beauregard, (410) 786–8102, *celeste.beauregard@cms.hhs.gov.* Alternatively, you may forward your requests via e-mail to *newtech@cms.hhs.gov* or regular mail as specified in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

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). (See the FY 2002 proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

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 the clinical staff of CMS 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 2012. 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 2012 IPPS proposed rule.

II. Town Hall Meeting and Informational Workshop Formats and Conference Calling Information

A. Format of the Town Hall Meeting

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 meeting will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2012 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.*

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 our 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 diagnosis-related group (DRG) assignment and requesting new ICD–9–CM 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/.*

In addition, to facilitate the public's knowledge of the OPPS application processes for transitional pass-through status of drugs, biologicals, and devices and assignment of new services to new technology ambulatory payment classification (APC) groups, 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 and biologicals. 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.*

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 9897 through 59903). 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.* We plan to discuss all three of these OPPS application processes at the Informational Workshop that will be held on February 2, 2011.

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 below.

C. Conference Call Information

For participants who cannot come to CMS for the Informational Workshop or the Town Hall Meeting, an open toll-free phone line, (877) 267–1577, has been made available. The conference code is "0400."

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting 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 link at the bottom of the page "Register to Attend the New Technology Town Hall Meeting" or "Register to Attend the New Technology Informational Workshop". After completing the registration, on-line registrants should print the confirmation page(s) and bring it with them to the meeting(s).

If you are unable to register on-line, you may register by sending an e-mail to the contacts listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include your name, address, telephone number, e-mail 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 by 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.s.t. if you are

attending the Informational Workshop and no later than 12:30 p.m. e.s.t. 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 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 Pub. L. 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 18, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–29989 Filed 11–26–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3237–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—January 19, 2011

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

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, January 19, 2011. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the currently available evidence regarding the effects of Erythropoiesis Stimulating Agents (ESAs) on health outcomes in adult chronic kidney disease (CKD) patients (pre-dialysis and dialysis). This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting Date:* The public meeting will be held on Wednesday, January 19, 2011 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (EST).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m. EST, Monday, December 20, 2010. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit powerpoint presentation materials and writings that will be used in support of an oral presentation, is 5 p.m., EST on Monday, December 20, 2010. Speakers may register by phone or via e-mail by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3,* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. EST, Wednesday, January 12, 2011.

We will be broadcasting the meeting via Webinar. You must register for the Webinar portion of the meeting at *https://webinar.cms.hhs.gov/esamedcac119/event/registration.html* by 5 p.m. EST, Thursday, January 13, 2011.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., EST Friday, January 7, 2011.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via e-mail to *MedCACpresentations@cms.hhs.gov* or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410–786–0309) or via e-mail at *Maria.Ellis@cms.hhs.gov* .

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 **Federal Register** (63 FR 68780).) This notice announces the January 19, 2011, public meeting of the Committee. During this meeting, the Committee will discuss the evidence that is currently available regarding the effects of Erythropoiesis Stimulating Agents (ESAs) on health outcomes in adult chronic kidney disease (CKD) patients (pre-dialysis and dialysis). Background information about this topic, including panel materials, is available at *http://www.cms.hhs.gov/center/coverage.asp.*