Medicare—Supplementary Medical Insurance Program)

Dated: October 18, 2011.

Patrick Conway,

CMS Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1431–N]

Medicare Program; Town Hall Meeting on FY 2013 Applications for New Medical Services and Technology Add-On Payments Under the Hospital Inpatient Prospective Payment System

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a town hall meeting in accordance with to discuss fiscal year (FY) 2013 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 2013 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES: *Meeting Date:* The town hall Meeting will be held on Tuesday, February 14, 2012. The town hall meeting will begin at 9 a.m. eastern standard time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

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 Monday, January 23, 2012.

Deadline for Registration of All Other Participants for the Town Hall Meeting and Submitting Requests for Special Accommodations: All other participants must register by Tuesday, January 24, 2012. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on Tuesday, January 31, 2012.

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 23, 2012. 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 March 6, 2012, for consideration before publication of the FY 2013 IPPS proposed rule.

ADDRESSES: *Meeting Location:* The town hall meeting will 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 2013 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 email 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 email 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 Hospital Inpatient Prospective Payment System (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 FY 2002 IPPS 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 2013. 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 2013 IPPS proposed rule.

II. Town Hall Meeting Format 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 clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2013 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. 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. Conference Call Information

For participants who cannot come to CMS for the Town Hall Meeting, an open toll-free phone line, (877) 267–1577, has been made available. The conference code is ''0638.''

III. Registration Instructions

The Division of Acute Care of CMS is coordinating the meeting registration for the Town Hall Meeting. While there is no registration fee, individuals must register to attend the Town Hall Meeting on substantial clinical improvement.

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''. 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 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 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 CMS complex no later than 8:30 a.m. e.s.t. if you are attending the Town Hall Meeting so that you will be able to arrive promptly for the 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 3, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

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