correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services.

The Panel may use data collected or developed by entities and organizations other than DHHS and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review.

All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to represent either one or more agenda items. All 508 compliant presentations and comments will be placed on the CMS Web site. For guidance on making documents Section 508 compliant, we refer readers to *http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/508-Compliant-doc.html.* All non-508 compliant presentations and comments will be available to the public upon request. Those wishing to access such materials should contact the Designated Federal Official and her address, email and phone number are provided above in the section that provides contact information.

In order to consider presentations and/or comments, we will need to receive the following:

1. An *email copy* of the presentation or comments sent to the DFO mailbox, *APCPanel@cms.hhs.gov* or, if unable to submit by email, a hard copy sent to the Designated Federal Official at the address noted under **FOR FURTHER INFORMATION CONTACT**.

2. Form *CMS–20017* with complete contact information that includes name, address, phone number, and email addresses for all presenters and commenters and a contact person that can answer any questions and or provide revisions that are requested for the presentation. Presenters and commenters must clearly explain the actions that they are requesting CMS to take in the appropriate section of the form. A presenter's/commenter's relationship with the organization that they represent must also be clearly listed.

- The form is now available through the CMS Forms Web site. The Uniform Resource Locator (URL) for linking to this form is as follows: *http://www.cms.hhs.gov/cmsforms/downloads/cms20017.pdf*.
- We encourage presenters to make efforts to ensure that their presentations and comments are 508 compliant.

IV. Oral Comments

In addition to formal oral presentations, which are limited to 5 minutes total per presentation, there will be an opportunity during the meeting for public oral comments, which will be limited to 1 minute for each individual and a total of 3 minutes per organization.

V. Meeting Participation

This is a teleconference-only meeting. The Panel meeting format is teleconference, webcast, and webinar. There will not be an in-person meeting location for this public Panel meeting. In addition, no meeting registration is required to access the meeting.

VIII. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our Web site after the meeting.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: November 12, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–30315 Filed 11–27–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1634–N]

Medicare Program; Town Hall Meeting on the FY 2017 Applications 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 in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2017 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 2017 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES: *Meeting Date:* The Town Hall Meeting announced in this notice will be held on Tuesday, February 16, 2016. The Town Hall Meeting will begin at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

Deadline for Registration for Participants (not Presenting) at the Town Hall Meeting and Submitting Requests for Special Accommodations: The deadline to register to attend the Town Hall Meeting and submit requests for special accommodations is 5:00 p.m., e.s.t. on Tuesday, February 2, 2016.

Deadline for Registration of Presenters at the Town Hall Meeting: The deadline to register to present at the Town Hall Meeting is 5:00 p.m., e.s.t. on Monday, February 1, 2016.

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, including agenda items by presenters, must be received by 5:00 p.m. e.s.t. on Monday, February 1, 2016. In addition to materials submitted for discussion at the Town Hall Meeting, individuals may submit other written comments after the Town Hall Meeting, 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 5:00 p.m. e.s.t. on Friday, February 26, 2016, for consideration in the FY 2017 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 located at 7500 Security Boulevard, Baltimore, MD 21244–1850.

In addition, we are providing two alternatives to attending the meeting in person—(1) there will be an open toll-free phone line to call into the Town Hall Meeting; or (2) participants may

view and participate in the Town Hall Meeting via live stream technology or webinar. Information on these options is discussed in section II.B. of this notice.

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.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit agenda item(s) regarding whether a FY 2017 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*.

FOR FURTHER INFORMATION CONTACT: Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov*, or Noel Manlove, (410) 786–5161, *noel.manlove@cms.hhs.gov.*

Alternatively, you may forward your requests via email to *newtech@cms.hhs.gov.*

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 hospital inpatient 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 fiscal year (FY) 2002 IPPS 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 evaluated 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 presentations provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2017. 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 2017 IPPS proposed rule.

II. Town Hall Meeting and Conference Calling/Live Streaming 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 for each of the FY 2017 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

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) via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to *newtech@cms.hhs.gov* 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 via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

B. Conference Call, Live Streaming, and Webinar Information

For participants who cannot attend the Town Hall Meeting in person, an open toll-free phone line, (877) 267–1577, has been made available. The Meeting Place meeting ID is 998–698–471.

Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology or a webinar. Information on the option to participate via live streaming technology or a webinar will be provided through an upcoming listserv notice and posted on the New Technology Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the Web site for updates.

C. Disclaimer

We cannot guarantee reliability for live streaming technology or a webinar.

III. Registration Instructions

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

Registration may be completed on-line at the following Web address: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* 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 *newtech@cms.hhs.gov.* 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 this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by the date specified 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 Town Hall Meeting in person 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. The Real ID Act of 2005 (Pub. L. 109–13), establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state is in compliance with the Real ID Act. (For information regarding the states or territories that are not in compliance with the Real ID Act see *http://www.dhs.gov/real-id-enforcement-brief.*) If a state or territory is listed on the *http://www.dhs.gov/real-id-enforcement-brief* Web site as non-compliant, a photographic ID (such as a driver's license) issued by one of those states or territories will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a passport) to gain entrance into Baltimore-based CMS buildings.
- 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, 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 presentation or to support a presentation.

Note: *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 prior to the convening of the meeting.*

All visitors must be escorted in all areas other than the lower level lobby and cafeteria area and first floor auditorium and conference areas in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Pub. L. 108–173.

Dated: November 12, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–30314 Filed 11–27–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Psychopharmacologic 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: Psychopharmacologic 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 February 3, 2016, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the