authorization request (and, upon request, to the beneficiary if he or she was not the original submitter). If a subsequent prior authorization request is submitted after a non-affirmative decision on an initial prior authorization request, the MACs will make every effort to conduct a review and postmark the notification of their decision on the request within 20 business days.

A facility or beneficiary may request an expedited review when the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. If the MAC agrees that the standard review timeframe would put the beneficiary at risk, the MAC will make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable, Medicare-required documentation. As this model is for a non-emergent service only, we expect requests for expedited reviews to be extremely rare.

The following describes examples of various prior authorization scenarios:

- Scenario 1: When a facility or beneficiary submits a prior authorization request to the MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the HBO therapy, the MAC will send a provisional affirmative prior authorization decision to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter). When the claim is submitted to the MAC, it is linked to the prior authorization via the claims processing system and the claim is paid so long as all Medicare coding, billing, and coverage requirements are met. However, after submission, the claim could be denied for technical reasons, such as the claim being a duplicate claim or being for a date of service after a beneficiary's death.
- Scenario 2: When a facility or beneficiary submits a prior authorization request but all relevant Medicare coverage requirements are not met, the MAC will send a non-affirmative prior authorization decision to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter), advising them that Medicare will not pay for the service. The facility or beneficiary may then resubmit the request with documentation showing that Medicare requirements have been met. Alternatively, a facility could render the service, and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The facility or the beneficiary would then have the Medicare denial for secondary insurance purposes and would have the opportunity to submit an appeal of the claim denial if they believe Medicare coverage was denied inappropriately.
- Scenario 3: When a facility or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter) with an explanation of what information is missing. The facility or beneficiary can rectify the situation and resubmit the prior authorization request with appropriate documentation.
- Scenario 4: When a facility renders a service that is subject to the prior authorization process to a beneficiary, and submits the claim to the MAC for payment without requesting a prior authorization, the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be not medically necessary or to be insufficiently documented, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The facility and/or beneficiary can appeal the claim denial if they believe the denial was inappropriate.

++ If the claim is determined to be payable, it will be paid.

Under the model, we will work to limit any adverse impact on beneficiaries and to educate beneficiaries about the process. If a prior authorization request is not affirmed, and the claim is still submitted by the facility, the claim will be denied in full, but beneficiaries will continue to have all applicable administrative appeal rights.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial facility cannot complete the total number of HBO treatments (for example, the initial facility closes or the beneficiary moves out of the area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required documentation in the submission. If multiple facilities are providing HBO treatments to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the facility indicated in the provisionally affirmed prior authorization request. Any facility submitting claims for which no prior authorization request is recorded will be subject to 100 percent pre-payment medical review of those claims.

Additional information is available on the CMS Web site at *http://go.cms.gov/PAHBO.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act, states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 1115A of the Social Security Act.

Dated: October 8, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27578 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1464–N]

Medicare Program; Town Hall Meeting on FY 2016 Applications for New Medical Services and Technology 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) 2016 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment systems (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2016 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 3, 2015. 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: Registration to attend the Town Hall Meeting and requests for special accommodations must be received no later than 5:00 p.m. Tuesday, January 20, 2015.

Deadline for Registration of Presenters at the Town Hall Meeting: Registration to present at the Town Hall Meeting must be received no later than 5:00 p.m. e.s.t. on Monday, January 19, 2015.

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 no later than 5:00 p.m. e.s.t. Monday, January 19, 2015. 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 no later than 5:00 p.m. e.s.t on Tuesday, February 24, 2015, for consideration in the FY 2016 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 and/or webinar. Information on these options is provided 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 an agenda item(s) regarding whether a FY 2016 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 Celeste Beauregard, (410) 786–8102, *celeste.beauregard@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 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 recommendations provided during this meeting will assist us as we evaluate the new medical services and technology applications for fiscal year (FY) 2016. 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 2016 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 2016 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 993 601 192.

Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology and/or a webinar. Information on the option to participate via live streaming technology and/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.

Disclaimer: We cannot guarantee the reliability of live streaming technology and/or a webinar.

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting for the FY 2016 Applications for New Medical Services and Technology Add-On Payments 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.

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 meeting in person. 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.

Dated: October 28, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27579 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB No.: 0970–0401.

Description: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that the Administration for Children and Families' programs are effective and meet our customers' needs we use a generic clearance process to collect qualitative feedback on our service delivery. This collection of information is necessary to enable ACF to garner customer and stakeholder feedback in an efficient timely manner, in accord with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient and satisfying experience with the programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service,