Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–21688 Filed 10–4–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delegation of Authority

Notice is hereby given that I have delegated to the Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), without authority to redelegate, the authority vested in the Director, CDC, under Section 2695, Title XXVI of the Public Health Service Act (42 U.S.C. 300ff–131), and the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87), as amended.

This delegation became effective on August 27, 2018. I hereby affirm and ratify any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: October 1, 2018.

Robert R. Redfield,

Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–21672 Filed 10–4–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1704–N]

Medicare Program; Town Hall Meeting on the FY 2020 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) 2020 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 2020 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, December 4, 2018. 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: The deadline to register to attend the Town Hall Meeting is 5:00 p.m., e.s.t. on Monday, November 26, 2018.

Deadline for Requesting Special Accommodations: The deadline to submit requests for special accommodations is 5:00 p.m., e.s.t. on Monday, November 19, 2018.

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, November 19, 2018.

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, November 19, 2018.

Deadline for Submission of Written Comments after the Town Hall Meeting for consideration in the FY 2020 IPPS proposed rule: Individuals may submit 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, December 14, 2018, for consideration in the FY 2020 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 & 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. These options are 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 an agenda item(s) regarding whether a FY 2020 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: Michelle Joshua, (410) 786–6050, *michelle.joshua@cms.hhs.gov;* or Michael Treitel, (410) 786–4552, *michael.treitel@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 1886(d)(5)(K)(viii) of the Act requires that as part of the process for evaluating new medical services and technology applications, the Secretary shall 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 2020. 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 2020 IPPS proposed rule.

II. Town Hall Meeting Format and Conference Call/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 2020 new medical services and technology add-on payment applications. Information regarding the applications can be found on our website 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. 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 FY 2020 IPPS 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 will be made available. Continue to check our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* for updated dial-in number and instructions.

Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology or webinar. Information on the option to participate via live streaming technology or webinar will be provided through an upcoming listserv notice and posted on the New Technology website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the website 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, online registrants should print the confirmation page(s) and bring it with them to the meeting.

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 the meeting must register by the date specified in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. If you are attending the Town Hall Meeting in person, we suggest that you arrive at 7500 Security Boulevard no later than 8:30 a.m. e.s.t. 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.

Note: The REAL ID Act established minimum security standards for license issuance and production and prohibits Federal agencies from accepting for certain purposes driver's licenses and identification cards from states not meeting the Act's minimum standards. We encourage the public to visit the DHS website at *https://www.dhs.gov/real-id* prior to the new technology town hall meeting for updated information.

• All Foreign National visitor requests must be submitted 12 business days prior to the scheduled visitor to allow for processing./non U.S. citizen.

• 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 to 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 in person. 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.

Updated Security Information for In-Person Attendees

Effective June 1, 2018, Federal Protective Services (FPS) has implemented new security screening procedures at all CMS Baltimore locations to align with national screening standards. Please allow extra time to clear security prior to the beginning of the meeting. Employees, contractors and visitors must place all items in bins for screening, including:

• Any items in your pockets.

• Belts, hats, jackets & coats (not suit jackets or sport coats).

• Purses, laptop computers & cell phones.

• Larger items (*e.g.* computer bags) can be placed directly onto the conveyer.

In the event the metal detector beeps when you walk through:

• A security guard will run a hand-held metal detector over you. If the metal detector doesn't alarm, you're cleared to enter.

• If the hand-held metal detector alarms, the guard will pat down the area of the body where the metal detector alarmed.

• If footwear alarms, it will need to be removed and placed in a bin for x-ray screening.

If you believe that you have a disability that will cause you to require reasonable accommodation to comply with the new process, please contact *reasonableaccommodationprogram@cms.hhs.gov* as soon as possible.

Authority: Section 1886(d)(5)(K)(viii) of the Social Security Act.

Dated: October 1, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–21753 Filed 10–4–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10680]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by December 4, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10680 Electronic Visit Verification Compliance Survey

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is