

Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

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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.

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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