



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1865-N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2028 Applications for New Technology Add-On Payments

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: This notice announces a town hall meeting in accordance with section 1886(d)(5)(K)(viii)(III) of the Social Security Act (the Act) to discuss fiscal year (FY) 2028 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 virtual meeting to present their comments, recommendations, and data regarding whether the FY 2028 applications for new technology add-on payments meet the substantial clinical improvement criterion.

DATES: *Meeting Dates:* The New Technology **Town Hall meeting** announced in this notice will be held virtually on Wednesday, December 9, 2026, and Thursday, December 10, 2026 (the number of presentations will determine if a second day for the meeting is necessary; see the **SUPPLEMENTARY INFORMATION** section for details regarding the second day of the meeting and the posting of the final schedule). The New Technology Town Hall meeting will begin each day at 9:00 a.m. Eastern Standard Time (EST) and online check-in will begin at 8:30 a.m. EST.

Deadline for Registration of Presenters at the New Technology Town Hall Meeting: The deadline to register to present at the New Technology Town Hall meeting is 5:00 p.m. EST on Monday, November 2, 2026.

Deadline for Submission of Agenda Item(s) or Written Remarks for the New Technology Town Hall Meeting: Written remarks and agenda items for discussion at the New Technology Town Hall meeting, including agenda items by presenters (presentation slide decks), must be received by 5:00 p.m. EST on Thursday, November 12, 2026.

Deadline for Requesting Special Accommodations: The deadline to submit requests for special accommodations is 5:00 p.m. EST on Thursday, November 12, 2026.

Deadline for Submission of Written Comments after the New Technology Town Hall Meeting for Consideration in the FY 2028 Inpatient Prospective Payment System/Long-Term Care Hospital PPS (IPPS/LTCH PPS) Proposed Rule: Individuals may submit written comments after the New Technology 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. EST on Monday, December 14, 2026, to ensure consideration in the FY 2028 IPPS/LTCH PPS proposed rule.

ADDRESSES: *Meeting Location:* The New Technology Town Hall meeting will be held virtually via live stream technology or webinar and listen-only via toll-free teleconference. Live stream or webinar and teleconference dial-in information will be provided through an upcoming listserv/email notice to registered presenters, and will appear on the final meeting agenda which will be posted on the New Technology website when available at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. Continue to check the website for updates.

Registration and Special Accommodations: Individuals wishing to present at the meeting must follow the instructions located in section III. of this notice. Individuals who need special accommodations should send an email to NTAP@cms.hhs.gov.

Submission of Agenda Item(s) or Written Remarks for the New Technology Town Hall Meeting: Each presenter must submit at least one agenda item for presentation regarding whether a FY 2028 application for new technology add-on payments meets the substantial

clinical improvement criterion. Agenda items must be submitted via email, by the previously specified deadline, to: NTAP@cms.hhs.gov.

Submission of Written Comments for the New Technology Town Hall Meeting: Written comments must be submitted via email, by the previously specified deadline, to: NTAP@cms.hhs.gov. Comments should be limited to information or material regarding whether the application(s) for new technology add-on payments meet the substantial clinical improvement criterion. Information and studies previously submitted in the application do not need to be resubmitted in Town Hall comments, even if they are cited within the comment.

FOR FURTHER INFORMATION CONTACT:

Drew Kasper, (410) 786-8926, drew.kasper@cms.hhs.gov and NTAP@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies under the IPPS

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 IPPS. For discussion on the new technology add-on payment criteria, we refer readers to the new technology add-on payment final rule (66 FR 46912, September 7, 2001), as well as the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

As finalized in the FY 2020 and FY 2021 IPPS/LTCH PPS final rules, and updated in the FY 2027 IPPS/LTCH PPS final rule, for applications submitted for new technology add-on payments for FYs 2021 through 2029, inclusive, the technologies that are eligible for the alternative pathway for certain transformative new devices or the alternative pathway for certain antimicrobial products do not need to meet the requirement under 42 CFR 412.87(b)(1) that the

technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. See the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), and the FY 2027 IPPS/LTCH PPS final rule (91 FR 49767 through 49789) for additional information.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42289 through 42292), we codified in our regulations at § 412.87 the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS to determine if a new technology meets the substantial clinical improvement criterion:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following--

- ++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

- ++ The new medical service or technology 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 and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient; or

- ++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following outcomes:

-- A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

-- A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

-- A decreased number of future hospitalizations or physician visits.

-- A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.

-- An improvement in one or more activities of daily living.

-- An improved quality of life.

-- A demonstrated greater medication adherence or compliance.

++ The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

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 substantial clinical improvement criterion for traditional pathway new technology add-on payment applications submitted for FY 2028.

II. New Technology Town Hall Meeting Format and Conference Call 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 criterion, which is evaluated for traditional pathway applications, for the FY 2028 applications for new technology add-on payments. 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](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html).

The majority of the meeting will be reserved for presentations from registered presenters. The time for each presentation will be 10 minutes, with additional time reserved for questions from CMS and interested parties. Individuals who would like to present must register and submit their agenda item(s) via email to NTAP@cms.hhs.gov by the dates specified in the **DATES** section of this notice.

Depending on the number of presentations, we will determine if a second meeting day is necessary. The final date(s) for the New Technology Town Hall meeting will be posted on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html> by November 27, 2026 to inform the public of the number of days of the meeting.

Written comments may be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the FY 2028 IPPS/LTCH PPS proposed rule, the comments must be received via email to NTAP@cms.hhs.gov by the date specified in the **DATES** section of this notice.

B. Conference Call and Webinar Information

As noted previously, the New Technology Town Hall meeting will be held virtually. There will be an option to participate in the New Technology Town Hall Meeting via webinar and a toll-free teleconference phone line. Information on the option to participate via webinar and a teleconference dial-in will be provided through an upcoming listserv/email notice to registered presenters and will appear on the final meeting agenda, which will be 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 a webinar.

III. Registration Instructions

The Division of New Technology in CMS is coordinating the meeting registration for the New Technology Town Hall meeting on substantial clinical improvement. While there is no registration fee, individuals planning to present at the New Technology Town Hall meeting must register to present.

Registration for presenters may be completed by sending an email to NTAP@cms.hhs.gov, by the date specified in the **DATES** section of this notice. Please include the name (with applicable title(s), as it should appear on the agenda) and email address of the presenter(s), as well as address, telephone number, and the name of the technology for which they will be presenting.

Registration for attendees not presenting at the meeting is not required.

IV. Collection of Information

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. chapter 35 *et seq*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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