Dated: September 5, 2025.

Mamatha Pancholi,

Deputy Director.C

[FR Doc. 2025–17323 Filed 9–9–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1840–N]

Medicare Program; Town Hall Meeting on the Fiscal Year 2027 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) 2027 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 2027 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 10, 2025, and Thursday, December 11, 2025 (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 3, 2025.

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 13, 2025.

Deadline for Requesting Special Accommodations: The deadline to submit requests for special accommodations is 5:00 p.m. EST on Thursday, November 13, 2025.

Deadline for Submission of Written Comments after the New Technology Town Hall Meeting for Consideration in the FY 2027 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 15, 2025, to ensure consideration in the FY 2027 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 2027 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, 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) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) 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 2027.

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 2027 applications for new technology add-on payments. 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 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 25, 2025 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 2027 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).

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.

[FR Doc. 2025–17401 Filed 9–9–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Charter Amendments, Establishments, Reestablishments, Renewals, and Terminations; Novel and Exceptional Technology and Research Advisory Committee

Pursuant to Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), the Director, National Institutes of Health (NIH) announces the re-establishment of the Novel and Exceptional Technology and Research Advisory Committee as authorized by 42 U.S.C. 282(b)(16), section 402(b)(16) of the Public Health Service Act, as amended.

The Director, NIH, has determined that the current activities of the Novel and Exceptional Technology and Research Advisory Committee are in the public interest in connection with the performance of duties imposed on NIH by law, and that these duties can best be performed through the advice and counsel of the committee.

This committee provides advice and recommendations on matters related to the conduct and oversight of research involving emerging technologies in biomedical science (also referred to as emerging biotechnologies).

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Novel and Exceptional Technology and Research Advisory Committee.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting should notify the Contact Person listed below in advance of the meeting. The meeting will be accessible through the following link (*https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab4/*).

Name of Committee: Novel and Exceptional Technology and Research Advisory Committee.

Date: September 29, 2025.

Time: 1:00 p.m.–3:00 p.m. ET.

Agenda: The Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) meeting will include presentation, discussion, and possible finalization of the Draft Report of the Working Group on Engaging the Public as Partners in Clinical Research.

Place: National Institutes of Health, 6705 Rockledge Drive, Suite 630, Bethesda, MD 20892 (*https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab4/*).

Contact Person: Jessica Tucker, Ph.D., Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 630, Bethesda, MD 20892, 301–496–9838, *SciencePolicy@od.nih.gov*.

Any interested person may file written comments by forwarding the statement to the Contact Person listed on this notice at least two business days prior to the meeting date. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Other than name and contact information, please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your comments. Please note that any comments NIH receives may be posted unredacted to the Office of Science Policy website.

Information is also available on the NIH Office of Science Policy website: *https://osp.od.nih.gov/policies/novel-and-exceptional-technology-and-research-advisory-committee-nextrac#tab4,* where an agenda, link to the webcast meeting, and any additional information for the meeting will be posted when available. Materials for this meeting will be posted prior to the meeting. Please check this website for updates.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: September 4, 2025.

Jayantha Bhattacharya,

Director, National Institutes of Health.

[FR Doc. 2025–17380 Filed 9–9–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Basic Mechanisms of Diabetes and Metabolism Study Section.

Date: October 9–10, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.