4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1863-N]

Medicare Program; Meeting Announcement for the Public and the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests – September 2026

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces meeting dates for a Clinical Laboratory Fee Schedule (CLFS) public meeting that includes the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Tuesday, September 15, 2026 and Wednesday, September 16, 2026. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on issues related to clinical diagnostic laboratory tests (CDLTs). During the meeting, the public will have an opportunity to present recommendations (including data on which recommendations are based) on the appropriate basis for establishing payment amounts for CDLTs (crosswalking or gapfilling) for which CMS received no applicable information during the data reporting period from May 1, 2026 through July 31, 2026 to calculate Medicare payment rates. After the public provides this input, the Panel will provide its recommendations to the Secretary and the Administrator on payment recommendations for these CDLTs.

DATES:

Meeting Date: Tuesday, September 15, 2026 and Wednesday, September 16, 2026, from 10:00 a.m. to 4:00 p.m. Eastern Daylight Time (E.D.T.).

Deadline for Meeting Registration, Presentation and Comments: August 21, 2026, 5:00 p.m. E.D.T. The public meeting will be conducted virtually and will not occur on-site at the CMS

Central Building. This meeting is still open to the public. Registration is only required for those interested in presenting public comments or speaking during the meeting.

Deadline for *Requesting Special Accommodations*: August 21, 2026, 5:00 p.m. E.D.T.

Webinar and Teleconference Meeting Information: Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website approximately 2 weeks prior to the meeting at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

A preliminary agenda is described in section III. of this notice.

ADDRESSES: This meeting for the public and the Panel will be held *virtually* only and broadcasted from the campus of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT: The CLFS Policy Team via email, *CDLTPanel@cms.hhs.gov*; or Rasheeda Arthur, PhD (410) 786-3434.

The CMS Press Office, for press inquiry, (202) 690-6145.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m-1), as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93), enacted on April 1, 2014. The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (the Secretary) to consult with an expert outside advisory panel established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests (CDLTs), which may include the development, validation,

performance, and application of such tests. Such individuals may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following:

- The establishment of payment rates under section 1834A of the Act for new CDLTs, including whether to use "crosswalking" or "gapfilling" processes to determine payment for a specific new test.
- The factors used in determining coverage and payment processes for new CDLTs.
- Other aspects of the payment system under section 1834A of the Act.

A notice announcing the establishment of the Panel and soliciting nominations for members was published in the October 27, 2014 **Federal Register** (79 FR 63919 through 63920). In the August 7, 2015 **Federal Register** (80 FR 47491), we announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015. Subsequent meetings of the Panel and membership appointments were also announced in the **Federal Register**. The Secretary approved rechartering of the Panel on April 24, 2025. The new charter is effective through April 24, 2027 and may be found on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

The Panel charter provides that Panel meetings will be held up to 4 times annually and the Panel Chair will serve for a period of 3 years, which may be extended at the discretion of the Administrator or his or her duly appointed designee. Additionally, the Panel Chair facilitates the meeting and the Designated Federal Official (DFO) or DFO's designee must be present at all meetings.

Section 1834A of the Act requires revisions to the payment methodology for CDLTs paid under the Clinical Laboratory Fee Schedule (CLFS). We implemented the requirements of

section 1834A of the Act in the CLFS final rule that appeared in the June 23, 2016 **Federal Register** (81 FR 41036) entitled, "Medicare Program; Medicare Clinical Diagnostic Laboratory Tests (CDLT) Payment System." Under the CLFS final rule, "reporting entities" must report to CMS during a "data reporting period" "applicable information" collected during a "data collection period" for their component "applicable laboratories." In general, the payment amount for a CDLT furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to us during a data reporting period. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not advanced diagnostic laboratory tests (ADLTs), the data collection period, data reporting period, and payment rate update were to occur every 3 years.

The first data collection period occurred from January 1, 2016, through June 30, 2016 and the first data reporting period occurred from January 1, 2017, through March 31, 2017.[1] The second data collection period for CDLTs that are not ADLTs was originally scheduled to be January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021. However, beginning in 2019, Congress passed a series of legislation that delayed the next data reporting period under the CLFS for CDLTs that are not ADLTs. Most recently, section 6226 of the Consolidated Appropriations Act, 2026 established that the next data reporting period for such tests is May 1, 2026 through July 31, 2026 and based on a data collection period of January 1, 2025 through June 30, 2025.

1 On March 30, 2017, we announced a 60-day period of enforcement discretion with respect to the initial data reporting period. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.

Under our existing regulations at 42 CFR 414.507(f), payment for a CDLT for which CMS receives no applicable information is based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2). Consistent with this process and to support transparency in payment determinations, in early August 2026, CMS will post on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html a list of laboratory codes for which CMS received no applicable information to calculate Medicare payment rates based on the weighted median of private payor rates. During this meeting on September 15 and 16, 2026, members of the public will have an opportunity to present recommendations for the basis of payment—specifically crosswalking or gapfilling—and respond to any questions from the Panel regarding those recommendations. The Panel will consider this input and provide recommendations to the Secretary of HHS and the Administrator of CMS regarding the following questions regarding these codes:

- What method of payment should be used to set rates for these test codes (crosswalking or gapfilling), as required by 42 CFR 414.507(f))?
- If crosswalking, specify the crosswalk code(s).

II. Format

This virtual meeting will be conducted in two parts. During Part I, registered public participants may discuss and make recommendations regarding the basis of payment (that is, crosswalking or gapfilling) for CDLTs for which CMS received no applicable information to calculate Medicare payment rates. During Part II, the Panel will ask questions of the registered public participants and discuss the information presented in Part I and make recommendations for the establishment of payment rates for the test.

In Part I, due to time constraints, presentations must be brief, lasting no longer than 5 minutes. Written presentations must be electronically submitted to CMS on or before August 21, 2026. Presentation slots will generally be assigned based upon chronological order of receipt of

presentation materials. In the event there is not enough time for presentations by everyone who is interested in presenting, we will only accept written presentations from those who submitted written presentations within the submission window and were unable to present due to time constraints. Presentations must be sent via email to our CLFS dedicated email box, *CDLTPanel@cms.hhs.gov.* In addition, a video recording of the meeting will be provided (once available) on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html after the meeting has concluded.

Presenters should submit all presentations using a standard PowerPoint template. In addition to the standard PowerPoint template available, presenters may also provide the same information from the PowerPoint presentation in a provided Excel worksheet template. Submitting the same information that is requested for the PowerPoint presentation in the Excel worksheet template will aid with triaging and reviewing recommendation information during the meeting and after the meeting, during the code review process. The standard PowerPoint presentation and Excel worksheet templates are available on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.htmls under the "Meeting" heading.

Presenters should address all of the following items (where applicable):

- Code(s) with the most current code descriptor.
- A recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for the test code.
- Test costs.
- Charges.

Additionally, presenters should provide the data on which their recommendations are based. Presentations that do not address the previous four items (where applicable) may be

considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

In Part II of the meeting, the Panel will make recommendations to the Secretary and the Administrator of CMS regarding crosswalking and gapfilling for the codes discussed during Part I, the CDLTs for which CMS received no applicable information during the data reporting period to calculate Medicare payment rates.

Taking into account the comments and recommendations (and accompanying data) received at this meeting from the public and the Panel, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each test code along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on our website in late September 2026. This website can be accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.htmls. Interested parties may submit written comments on the proposed determinations for codes in October 2026, electronically to our CLFS dedicated email box, CLFS_Annual_Public_Meeting@cms.hhs.gov (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2027, reconsidered codes, and test codes that received no applicable information, will be posted on our website in November 2026, along with the rationale for each determination, the data on which the determinations were based, and responses to comments and recommendations received from the public and the Panel.

III. Agenda

The Agenda for the September 15 and 16, 2026, virtual-only meeting with the public and the Panel will provide for discussion and comment on the following topics:

- CY 2027 CDLT codes for which CMS received no applicable information to calculate a Medicare payment rate, which will be posted on the CMS website at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel.
- Other CY 2027 CLFS issues designated in the Panel's charter and further described on our Agenda.

A detailed Agenda will be posted approximately 2 weeks before the meeting, on the CMS website at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel.

IV. Meeting Participation

This meeting is open to the public. Speakers may participate in the meeting via teleconference and webinar. A speaker is an individual who submitted a presentation or who will speak on behalf of a company or organization if the Panel has any questions during the meeting about technical information described in the public comments or presentation previously submitted or presented by the organization or company.

V. Registration Instructions

Beginning August 3, 2026 and ending August 21, 2026 at 5:00 p.m. E.D.T., registration may be completed by presenters. Individuals who intend to view and/or listen to the meeting virtually do not need to register. Speakers must register online at https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel. On this webpage, under the heading "Meeting" there is a link entitled "Register for September Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting." Click this link and enter the required information. All of the following information must be submitted when registering:

- Name.
- Confirm Presentation.
- Organization or company name.
- E-mail addresses that will be used by the speaker to connect to the virtual meeting.
- Code(s) for which the company or organization the individual is representing submitted a comment or presentation, if applicable.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the "DATES" section of this notice. Additionally, registration information must reflect individual level content and not reflect an organization name. Also, we request organizations register all individuals at the same time. That is, one individual may register multiple individuals at the same time. Individuals who are not registered in advance will not be able to speak during the meeting.

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the speaker in preparation for the meeting. Registration is only required for speakers. All registration must be submitted by the deadline specified in the "DATES" section of this notice. Note: No registration is required for participants who plan to view this meeting via webinar or listen via teleconference.

VI. Panel Recommendations and Discussions

The Panel's recommendations will be posted approximately 2 weeks after the meeting on the CMS website at https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

VII. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, must send an email to

the resource box (*CDLTPanel@cms.hhs.gov*). The deadline for submitting this request is listed in the "DATES" section of this notice.

VIII. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on CDLTs is available on the CMS website at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html or you may obtain a copy of the charter by submitting a request to the contact listed in the "FOR FURTHER INFORMATION CONTACT" section of this notice.

IX. Collection of Information Requirements

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. 3501 *et seq.).*

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

Vanessa Garcia,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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