

added by the ACA largely extends the transparency provisions set forth in section 1311(e)(3) to non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage. *Form Number:* CMS-10572 (OMB control number: 0938-1310); *Frequency:* Annually; *Affected Public:* Private Sector, Business, and Not-for Profits; *Number of Respondents:* 400; *Number of Responses:* 400; *Total Annual Hours:* 22,000. (For questions regarding this collection, contact Jack Reeves at 301-492-5152.)

**4. Type of Information Collection**  
*Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) the research complies with 45 CFR part 46 or equivalent Federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Non-Federal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS-10286 (OMB control number: 0938-1077); *Frequency:* On Occasion; *Affected Public:* Private Sector; State, Local or Tribal Governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total*

*Annual Hours:* 0.5. (For policy questions regarding this collection contact Erik Gomez at 667-414-0682.)

**5. Type of Information Collection**  
*Request:* Extension of a currently approved collection; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS-10377 (OMB control number: 0938-1157); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 46; *Total Annual Responses:* 1,237,980; *Total Annual Hours:* 46. (For policy questions regarding this collection contact Russell Tipps at (667) 290-9640.)

**6. Type of Information Collection**  
*Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Use:* Form CMS-460 is the agreement a physician, supplier, or their authorized official signs to become a participating provider in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term “supplier” means

certain other persons or entities, other than physicians, that may bill Medicare for Part B services (e.g., suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered “suppliers” for purposes of this agreement. *Form Number:* CMS-460 (OMB control number: 0938-0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 14,029; *Number of Responses:* 14,029; *Total Annual Hours:* 3,507. (For questions regarding this collection contact Mark G. Baldwin at 410-786-8139.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2025-06760 Filed 4-18-25; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1841-N]

#### Medicare Program: Meeting Announcement for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests, July 23–24, 2025

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the public meeting dates for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Wednesday, July 23, 2025, and Thursday, July 24, 2025. 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.

**DATES:**

*Meeting Date:* Wednesday, July 23, 2025, from 10:00 a.m. to 4:00 p.m. Eastern Daylight Time (E.D.T.) and Thursday, July 24, 2025, from 10:00 a.m. to 4:00 p.m. E.D.T. The Panel is also expected to participate virtually in the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for Calendar Year (CY) 2026 on Friday, June 27, 2025 to gather information and question presenters. Notice of the CLFS

Annual Public Meeting for CY 2026 is published elsewhere in this issue of the **Federal Register**.

*Deadline for Meeting Registration, Presentation and Comments:* May 30, 2025, 5:00 p.m. E.D.T.

*Deadline for Requesting Special Accommodations:* May 30, 2025, 5:00 p.m. E.D.T.

*In-Person Attendance:* If attending the meeting in person at the CMS Headquarters, registration is required and must be completed by May 30, 2025. For more information on how to register as an in-person attendee, see the "Registration Instructions" (section IV. of this notice).

*Virtual Attendee Only:* The public may also view this meeting via webinar or listen-only via teleconference. If attending the meeting via webinar, or listen-only via teleconference, registration is not required for non-speakers.

*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 II. of this notice.

**ADDRESSES:** The Panel meeting will be held *virtually* and *in-person* at 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](mailto:CDLTPanel@cms.hhs.gov); or Rasheeda Arthur, Ph.D. (410) 786–3434. The CMS Press Office, for press inquiries, (202) 690–6145.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLTs) (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, 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 clinical diagnostic laboratory tests, 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 clinical diagnostic laboratory tests.
- 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**.

##### **II. Agenda**

The Agenda for the July 23 and July 24, 2025, hybrid Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- Calendar Year (CY) 2026 Clinical Laboratory Fee Schedule (CLFS) new and reconsidered test codes, which will be posted on the CMS website at [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory\\_Public\\_Meetings.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html).
- Other CY 2026 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>. The Panel will make recommendations to

the Secretary and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory tests discussed during the CLFS Annual Public Meeting for CY 2026. The Panel will also provide input on other CY 2026 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

##### **III. Meeting Participation**

This meeting is open to the public. Stand-by speakers may participate in the meeting in-person via teleconference and webinar. A stand-by speaker is an individual 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 at the recent CLFS Annual Public Meeting for CY 2026 on June 27, 2025. The public may also attend the hybrid meeting in-person or view and/or listen-only to the meeting via teleconference and webinar. Please note that CMS reserves the right to shift the meeting format from hybrid to virtual-only, if for some reason, a hybrid format is not possible. If there is a need to shift to a virtual-only format, we will alert the public as soon as possible and post updated information on the CMS website at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel>.

##### **IV. Registration Instructions**

Beginning May 1, 2025 and ending May 30, 2025 at 5:00 p.m. E.D.T., registration may be completed by stand-by speakers and in-person attendees. Individuals who intend to view and/or listen to the meeting virtually do not need to register. Stand-by speakers and individuals who intend to attend the meeting at the CMS campus must register online at <https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel>. On this web page, under the heading "Meeting" there is a link entitled "Register for 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.
- Indicate if individual is registering as a "Stand-by speaker" or "In-Person Attendee."
- Organization or company name.
- Email addresses that will be used by the speaker to connect to the virtual meeting.

- Indicate if individual is a “Foreign National” visitor

- New or Reconsidered Code(s) for which the company or organization 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 permitted to enter the building (see section VI. of this notice).

After registering, a confirmation email will be sent upon receipt of the registration. The email will provide information to the attendee in preparation for the meeting. Registration is only required for stand-by speakers and members of the public attending the meeting at the CMS campus (address specified in the **ADDRESSES** section of this notice). 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 the Panel meeting via webinar or listen via teleconference.

#### V. 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>.

#### VI. Security, Building, and Parking Guidelines

The hybrid meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS campus and parking facilities between 9:00 a.m. and 10:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 10:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. We note that the public may not enter the CMS building

earlier than 9:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, 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 demonstration or to support a demonstration.

#### VII. Special Accommodations

Individuals attending, 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](mailto: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 CDLT’s 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 Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Stephanie Carlton 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–3470–N]

#### Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee

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

**ACTION:** Notice.

**SUMMARY:** This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, June 25, 2025.

#### **DATES:**

*Meeting Date:* The virtual meeting will be held on Wednesday, June 25, 2025, from 10:00 a.m. until 4:00 p.m., Eastern Daylight Time (EDT).

*Deadline for Submission of Written Comments:* Written comments must be received at the email address specified in the **ADDRESSES** section of this notice by 5:00 p.m., EDT, on Wednesday, May 21, 2025. Once submitted, all comments are final.

*Deadlines for Speaker Registration and Presentation Materials:* The deadline to register as a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation, is 5:00 p.m., EDT on Wednesday, May 21, 2025. Speakers may register via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the email address specified in the **ADDRESSES** section of this notice.

*Deadline for All Other Attendees Registration:* Individuals who want to join the meeting may register online at: <https://cms.zoomgov.com/meeting/register/vJIsfuiiqTooHSfrDZdYHzCLsztgUqyaxvo> until 10:00 a.m., EDT on Wednesday, June 25, 2025.

*Deadline for Submitting a Request for Special Accommodations:* Individuals viewing or listening to the meeting who