



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1725-N]

### Medicare Program; Meeting Announcement for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the next public meeting dates for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, July 22, 2019 and Tuesday, July 23, 2019. 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 Dates: The meeting of the Panel is scheduled for Monday, July 22, 2019 from 8:00 a.m. to 4:30 p.m., Eastern Daylight Time (E.D.T.) and Tuesday, July 23, 2019, from 8:00 a.m. to 4:30 p.m., E.D.T. The Panel is also expected to participate in the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for Calendar Year (CY) 2020 on June 24, 2019 in order to gather information and ask questions to presenters. Notice of the CLFS Annual Public Meeting for CY 2020 is published elsewhere in this issue of the **Federal Register**.

Deadline for Registration: The public may attend the Panel meeting in person, view via webcast or listen via teleconference. Beginning Monday, April 8, 2019 and ending Monday, July 1, 2019 at 5:00 p.m. E.D.T., registration to attend the Panel meeting in person may be completed online at <http://cms.gov/Regulations-and->

[Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html](https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html). On this webpage, under “Panel Meetings,” click the “Register for July 22 through 23, 2019 Panel Meeting” link and enter the required information. We refer readers to Section IV. of this notice for additional details related to meeting registration.

Webinar, Webcast, and Teleconference Information: Teleconference dial-in instructions, and related webcast and 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-](https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html)

[Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html](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 in the auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Rasheeda Arthur, PhD, (410)786-3434, e-mail [CDLTPanel@cms.hhs.gov](mailto:CDLTPanel@cms.hhs.gov). Press inquiries are handled through the CMS Press Office at (202) 690-6145. For additional information on the Panel, refer to the CMS website at [https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html)

[Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html](https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html).

## **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, 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 new 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 were also announced in the **Federal Register**.

## **II. Agenda**

The Agenda for the July 22 and 23, 2019 Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- Calendar Year (CY) 2020 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 2020 CLFS issues designated in the Panel's charter and further described on the Agenda.

A detailed Agenda will be posted approximately 2 weeks before the meeting, on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. 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 2020. The Panel will also provide input on other CY 2020 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. As noted previously, the public may participate in the meeting on-site, via teleconference, webcast, and webinar. The on-site check-in for visitors will be held from 7:30 a.m. to 8:00 a.m. E.D.T.

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

Beginning Monday, April 8, 2019 and ending Monday, July 1, 2019 at 5:00 p.m. E.D.T., registration to attend the Panel Meeting in person may be completed online at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. On this webpage, under “Panel Meetings,” click the “Register for July 22 through July 23, 2019 Panel Meeting” link and enter the required information. All of the following information must be submitted when registering:

- Name
- Company name
- Address
- E-mail addresses

Note: Participants who do not plan to attend the Panel meeting in person on July 22 or 23, 2019 should not register. No registration is required for participants who plan to view the Panel meeting via webcast or listen via teleconference.

## **V. Security, Building, and Parking Guidelines**

The 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 7:00 a.m. and 8:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 8:00 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 7:15 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.

## **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 requiring special accommodations must include the request for these services during registration.

## **VIII. Copies of the Charter**

The Secretary's Charter for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests 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.).

**Dated:** March 15, 2019.

**Seema Verma,**  
*Administrator,*  
*Centers for Medicare & Medicaid Services.*

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