



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1669-N]

Medicare Program; Rechartering, Membership, and Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on August 1, 2017

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

ACTION: Notice.

SUMMARY: This notice announces the rechartering of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel), designation of a new chairperson to the Panel, and the next public meeting date for the Panel on Tuesday, August 1, 2017. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on issues related to clinical diagnostic laboratory tests (CDLTs). The Panel will make recommendations to the Secretary and the Administrator regarding crosswalking and gapfilling for new and reconsidered laboratory codes that are discussed during the Public Meeting Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year (CY) 2018 (2017 CLFS Public Meeting), and provide input on other CY 2018 CLFS issues that are designated in the Panel's charter and specified on meeting agenda. The Secretary approved the rechartering of the Panel on April 25, 2017 for a 2-year period effective through April 25, 2019.

DATES: Meeting Date: The meeting of the Panel is scheduled for Tuesday, August 1, 2017, from 9:00 a.m. to 5:00 p.m., Eastern Daylight Savings Time (E.D.T.). We note that the Panel will also attend the 2017 CLFS Public Meeting and will gather information and ask questions to

presenters if they choose. Notice of the 2017 CLFS Public Meeting is published elsewhere in this issue of the **Federal Register**. As we also indicate in that notice, in the event the 2017 CLFS Public Meeting needs to extend to August 1, 2017, the 2017 CLFS Public Meeting will begin at 9:00 a.m., E.D.T. and the Panel Meeting will convene immediately following the conclusion of that meeting.

Meeting Registration: The public may attend the Panel Meeting in person, view via webcast, or listen via teleconference. Beginning Monday, June 19, 2017 and ending Friday, July 14, 2017 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 August 1, 2017 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 August 1, 2017 should not register. No registration is required for participants who plan to view the Panel Meeting via webcast or listen via teleconference. Participants planning to attend only the 2017 CLFS Public Meeting (on July 31, 2017), or both the 2017 CLFS Public Meeting and the Panel Meeting (on August 1, 2017), should register only once for the 2017 CLFS Public Meeting. We refer readers to the Public Meeting Regarding New and Reconsidered Clinical Diagnostic

Laboratory Test Codes for the CLFS for CY 2018 notice published elsewhere in this issue of the **Federal Register** for instructions on registering. Participants planning to attend only the Panel Meeting (August 1, 2017) must register using the above link and instructions. Comments and presentations on new and reconsidered CDLTs will be made during the 2017 CLFS Public Meeting (on July 31, 2017). We note that here because the Panel will address crosswalking and gapfilling for new and reconsidered laboratory codes that are discussed during 2017 CLFS Public Meeting and may wish to ask follow-up questions to presenters at the Panel Meeting (on August 1, 2017).

Issues concerning the CY 2018 CLFS that are designated in the Panel's charter and specified in the meeting agenda will be discussed at the Panel Meeting. The deadline to register to be a presenter and to submit written presentations for agenda items during the Panel Meeting (that is, presentations on issues other than payment for new and reconsidered CDLTs considered at the 2017 CLFS Public Meeting) is Friday, July 14, 2017. Issues to be discussed will be specified in the Panel Meeting agenda, to be published approximately 2 weeks before the meeting (a preliminary agenda is described in Section II. of this notice). Comments and presentations should not address issues not specified in the agenda for the Panel Meeting. If issues are added to the agenda, we would be interested in public comments or presentations related to those additional issues. Commenters and presenters may register via email to the designated CLFS-dedicated email box listed in the "**FOR FURTHER INFORMATION CONTACT**" section of this notice. Presentations should be sent via email to the same email address.

Meeting Location, Webcast, and Teleconference: The Panel Meeting will be held in the Auditorium of the CMS, Central Office, 7500 Security Boulevard, Baltimore, Maryland

21244-1850. Alternately, the public may view the Panel Meeting via a webcast or listen by teleconference. During the scheduled Panel Meeting, webcasting is accessible online at <http://cms.gov/live>. Teleconference dial-in information will appear on the final Panel Meeting agenda, which will be posted on the CMS website when available at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

Meeting Format: This Panel Meeting is open to the public. The on-site check-in for visitors will be held from 8:30 a.m. to 9:00 a.m. E.D.T. on Monday, July 31, 2017, preceding the 2017 CLFS Public Meeting, and again at 8:30 a.m. to 9:00 a.m. E.D.T. on August 1, 2017 for visitors attending only the Panel Meeting.

During the 2017 CLFS Public Meeting, the public, along with the Panel, will hear and pose questions to presenters concerning crosswalking and gapfilling for new and reconsidered CDLTs for calendar year CY 2018. Following the opening remarks of the Panel Meeting, the Panel will address any issues relating to the CY 2018 CLFS new and reconsidered laboratory codes, including making recommendations to the Secretary of HHS and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory codes discussed during the CLFS Public Meeting. The Panel will also provide input on other CY 2018 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda. The Panel will hear oral presentations from the public for a total time period of no more than 1 hour.

FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, Designated Federal Official (DFO), 410-786-5723, e-mail CDLTPanel@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690-6145. For additional information on the Panel, please refer to the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html> .

SUPPLEMENTARY INFORMATION:

I. Background

The Advisory Panel on Clinical Diagnostic Laboratory Tests 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. 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 Center 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; and
- 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**. Since the last meeting, the Secretary approved re-chartering of the Panel on April 25, 2017. The new charter is effective through April 25, 2019 and may be found on the CMS website at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. Karen Nakano, M.D. has been designated as the new Panel Chair after the retirement of the former Panel Chair.

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 CMS 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.

II. Agenda

The Agenda for the August 1, 2017, Panel Meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- CY 2018 CLFS new and reconsidered test codes, to be posted on June 16, 2017, on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.
- Other CY 2018 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>.

III. Meeting Attendance

The Panel's meeting on August 1, 2017 is open to the public. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the "Meeting Registration" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

IV. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification (ID) to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.

- All items brought into CMS including personal items, for example, laptops and cell phones, are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

V. Special Accommodations

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

VI. Panel Recommendations and Discussions

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

VIII. Copies of the Charter

The Secretary's Charter for the 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 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.

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Dated: June 2, 2017.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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