DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1657-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on October 19, 2015

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting date of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, October 19, 2015. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on issues related to clinical diagnostic laboratory tests.

DATES: Meeting Date: The meeting of the Panel is scheduled to take place at CMS's headquarters in Baltimore, MD on Monday, October 19, 2015. beginning at 9:00 a.m., Eastern Daylight Time (EDT). The Panel will address issues relating to the CY 2016 clinical laboratory fee schedule (CLFS) preliminary determinations of new and reconsidered test codes, as well as provide input on other CY2016 CLFS issues that are designated in the Panel's charter.

Meeting Registration:

The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and ending Tuesday, October 13, 2015 at 5:00 p.m. EDT, registration to attend the

meeting in-person may be completed on-line at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html. On this webpage, under "Related Links," double-click the "Clinical Diagnostic Laboratory Tests FACA Panel Meeting Registration" link and enter the required information. All the following information must be submitted when registering:

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

Note: Participants who do not plan to attend the meeting in-person on October 19, 2015 should not register. No registration is required for participants who plan to view the meeting via webcast or listen via teleconference.

Presenter Registration and Submission of Presentations and Comments:

We are interested in submitted comments or in person presentations at the meeting concerning the issues described in the **SUPPLEMENTARY INFORMATION** section of this notice and clarified in the agenda to be published approximately 2 weeks before the meeting. The comments and presentations should not address issues not before the Panel. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 pm EDT, Tuesday, October 13, 2015. Presenters may register by email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentations should be sent via email to the same person's email address.

Meeting Location, Webcast, and Teleconference:

The meetings will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244-1850. Alternately, the public may either view the meetings via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at http://cms.gov/live. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

Meeting Format:

This 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. on Monday, October 19, 2015. Following the opening remarks, the Panel will address any issues relating to the CY 2016 CLFS preliminary determinations of new and reconsidered test codes, as well as provide input on other CY 2016 CLFS issues that are designated in the Panel's charter. The Panel will hear oral presentations from the public for no more than 1 hour during each of two sessions. During session one, registered persons from the public may present recommendations on preliminary determinations of new and reconsidered codes for the CY 2016 CLFS. During session two, registered persons from the public may present recommendations on CLFS issues that are designated in the Panel's charter and outlined in the Agenda.

ADDRESSES: Web site: For additional information on the Panel**,** please refer to our Web site at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html. .

FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, Designated Federal Official (DFO), Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security

Boulevard, Mail Stop C4-01-26, Baltimore, MD 21244, 410-786-5723, e-mail CDLTPanel@cms.hhs.gov or Glenn.McGuirk@cms.hhs.gov. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

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 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93, enacted 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 (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, clinical laboratory 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; and

- 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), CMS announced membership appointments to the Panel along with the first public meeting date for the Panel, which was held on August 26, 2015.

The Panel charter provides that panel meetings will be held up to four times annually. The Panel consists of 15 individuals and a Chair. The Panel Chair facilitates the meeting and the DFO or DFO's designee must be present at all meetings.

II. Agenda

The Agenda for the October 19, 2015, meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- CY 2016 CLFS preliminary determinations of new and reconsidered test codes which were posted on September 25, 2015 on our Web site at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.

- Other CY 2016 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 Web site at http://cms.gov/Regulations-and Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.

III. Meeting Attendance

The Panel's meeting on October 19, 2015, is open to the public; however, attendance is

limited to space available. 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 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 our Web site at http://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 Web site 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.).

CMS-1657-N

Dated: September 29, 2015.

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Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

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