



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-1706-N]**

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

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the appointment of three new members to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) and the next public meeting for the Panel, which is scheduled on Monday, July 16, 2018 and Tuesday, July 17, 2018.

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 16, 2018 from 9:00 a.m. to 5:00 p.m., Eastern Daylight Savings Time (E.D.T.) and Tuesday, July 17, 2018, from 9:00 a.m. to 5:00 p.m., E.D.T. The Panel is also expected to participate in the 2018 Annual Laboratory Public Meeting on June 25, 2018 in order to gather information and ask questions to presenters if they choose. Notice of the 2018 Annual Laboratory Public Meeting is published elsewhere in this issue of the **Federal Register**.

Webinar, Webcast, and Teleconference Meeting Information: The Panel meeting will be conducted only via webinar, webcast or by teleconference. The meeting registration 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-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. A preliminary agenda is described in Section II. of this notice.

**Meeting Registration:** Registration is required to participate in this public meeting. Interested participants will be able to access the registration, teleconference, webcast, and webinar instructions, by following the instructions on the meeting agenda. There is no deadline for meeting registration.

**FOR FURTHER INFORMATION CONTACT:** Glenn C. McGuirk, Designated Federal Official (DFO), 410-786-5723, 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, 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 (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. 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.
- 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**.

The Panel’s charter provides that Panel meetings will be held up to 4 times annually and the Panel shall consist of up to 15 individuals appointed by the Secretary’s or the CMS Administrator's designee to serve a term of up to 3 years. Members may serve after the expiration of his or her term until a successor has been sworn in. A Panel member selected to replace another Panel member who has resigned before the end of his or her term, shall serve for the balance of the original Panel member’s term.

A notice requesting nominations to the Panel was published in the September 29, 2017 **Federal Register** (82 FR 45590 through 45592). In that notice, we indicated that nominations would be accepted on a continuous basis. As a result of that notice, the Secretary's designee approved the appointment of the following new Panel members:

- Aaron Bossler, M.D., Ph.D.
- Pranil Chandra, D.O.
- Kimberley Hanson, M.D., MHS, FIDSA

The three new Panel member appointments are for 3-year terms beginning July 1, 2018.

Current Panel members include:

- Geoffrey Baird, M.D., Ph.D.
- Vickie Baselski, Ph.D.
- William Clarke, Ph.D., M.B.A., DABCC, FACB
- Stanley R. Hamilton, M.D.
- Raju Kucherlapati, Ph.D.
- Bryan A. Loy, M.D., M.B.A.
- Gail Marcus, M.S.E., M.B.A.
- Carl Morrison, M.D., D.V.M.
- Michele M. Schoonmaker, Ph.D.
- Rebecca Sutphen, M.D.

Terms have expired (or will expire during calendar year 2018) for the following Panel members:

- Stephen Bauer, M.D.
- Judith Davis, M.S.

- Curtis Hanson, M.D.
- Kandice Kottke-Marchant M.D., Ph.D.
- Victoria Pratt, Ph.D.

## **II. Agenda**

The Agenda for the July 16 and 17, 2018 Panel Meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- CY 2019 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 2019 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/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. The Panel will make recommendations to the Secretary of the Department of Health and Services and the Administrator of CMS regarding crosswalking and gapfilling for new and reconsidered laboratory tests discussed during the 2018 Annual Laboratory Public Meeting. The Panel will also provide input on other CY 2019 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

## **III. Special Accommodations**

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

#### **IV. Meeting Participation**

This meeting is open to the public. As noted previously, the public may participate in the meeting via teleconference, webcast, and webinar. There will not be an in-person meeting location for this public Panel meeting. In addition, meeting registration is required to access the meeting; however, there is no deadline for registration.

#### **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. 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 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.

#### **VII. 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.).

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**Dated:** March 20, 2018.

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**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.

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