



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1698-N]

### Medicare Program; Request for Nominations to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

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

**ACTION:** Notice.

**SUMMARY:** This notice requests nominations to fill vacancies on the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel). 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). As announced in the notice published in the **Federal Register** on June 16, 2017, entitled “Medicare Program; Rechartering, Membership, and Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on August 1, 2017” (82 FR 27705), the Secretary approved the rechartering of the Panel on April 25, 2017 for a 2-year period effective through April 25, 2019.

**DATES:** The agency will receive nominations on a continuous basis.

**ADDRESSES:** All nominations should be sent electronically to the following email address:

*CDLTPanel@cms.hhs.gov.*

Web site: For additional information on the Panel and updates to the Panel’s activities, we refer readers to our Web site at *http://cms.gov/Regulations-and-*

*Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

**FOR FURTHER INFORMATION CONTACT:** Persons wishing to nominate individuals to serve on the Panel or to obtain further information may submit an email to the following email address: *CDLTPanel@cms.hhs.gov*.

*News Media:* Representatives should contact 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(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93, enacted on April 1, 2014) (PAMA). 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 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**. As previously noted, the Secretary approved the rechartering of the Panel on April 25, 2017, for a 2-year period effective through April 25, 2019.

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 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. Request for Nominations; Criteria for Nominees**

We are requesting nominations for members to serve on the Panel. The Panel shall consist of up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include molecular pathologists, laboratory researchers, and individuals with expertise in laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests.

Panel members serve on a voluntary basis, without compensation, according to an

advance written agreement; however, for the meetings, we reimburse travel, meals, lodging, and related expenses in accordance with standard Government travel regulations.

Nominees must demonstrate personal experience with clinical diagnostic laboratory tests and services through a past or present history of direct employment with an organization that furnishes clinical diagnostic laboratory tests. (For purposes of this Panel, consultants or independent contractors shall not be representatives of clinical laboratories.)

We have special interest in ensuring, while taking into account the nominee pool, that the Panel membership is balanced under the FACA guidelines; therefore nominees will be evaluated based on expertise and factors needed to keep the balance of the Panel. These factors include, but are not limited to, geographic locations within the United States or territories; race; ethnicity; sex; disability; points of view; and area of expertise (for example, medical, scientific, financial, technical, administrative). Additionally, all nominees must have at least 5 years of experience with clinical diagnostic laboratory tests or genetic testing.

Based upon either self-nominations or nominations submitted by interested organizations, the Secretary, the CMS Administrator, or the Secretary's or CMS Administrator's designee, appoints new members to the Panel from among candidates determined to have the required expertise. Nominations will be considered as vacancies occur on the Panel. Nominations should be updated and resubmitted every 3 years to continue to be considered for Panel vacancies. New appointments are made in manner that ensures a balanced membership under FACA guidelines. Our appointment schedule will assure that we have the full complement of members for each Panel meeting.

It is not necessary for a nominee to possess expertise in all of the areas listed, but each must have a minimum of 5 years of experience and currently have full-time employment in his or her area of expertise. Generally, members of the Panel serve overlapping terms up to 3 years, based on the needs of the Panel and contingent upon the rechartering of the Panel. A member may serve after the expiration of his or her term until a successor has been sworn in. Any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term.

Any interested person or organization may nominate one or more qualified individuals.

Self-nominations will also be accepted. Each nomination must include the following:

- Letter of Nomination stating the reason why the nominee should be considered.
- Curriculum vitae or resume of the nominee that includes the following:
  - ++ Email address where the nominee can be contacted.
  - ++ Title and current position
  - ++ Professional affiliation
  - ++ Home and business address
  - ++ Home and business telephone and or fax numbers
  - ++ List of areas of expertise
- Written and signed statement from the nominee indicating that the nominee is willing to serve on the Panel under the conditions described in this notice and further specified in the Charter.
- Brief (1 page; double-spaced) biographical summary of the nominee's experience.

The top nominees will be contacted for interest and availability. Phone interviews of nominees may also be requested after review of the nominations. The Secretary, the CMS Administrator, or the Secretary's or CMS Administrator's designee will make the final decision

about who will serve on the committee. Formal letters of invitation to serve on the Panel will be extended by the CMS Administrator.

To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts.

### **III. Copies of the Charter**

To obtain a copy of the Panel's Charter, we refer readers to our Web site at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

### **IV. 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-1698-N**

**Dated:** September 22, 2017.

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**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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