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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1728-N]

Medicare Program; Rechartering and Appointment of New Members to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

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

ACTION: Notice.

SUMMARY: This notice announces the rechartering and appointment of seven new members to the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the CDLT Panel). The purpose of the CDLT 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:

Recharter Dates: The charter for the CDLT Panel will expire on April 26, 2021 (2 years from the date the charter was filed).

New CDLT Panel Member Appointment Dates: The term period for the new CDLT Panel members is July 1, 2019 through June 30, 2022.

FOR FURTHER INFORMATION CONTACT:

Rasheeda Arthur, PhD, Designated Federal Official (DFO), (410) 786-3434 or e-mail at CDLTPanel@cms.hhs.gov.

Press inquiries are handled through the CMS Press Office at (202) 690-6145.

For additional information on the CDLT Panel, please refer to the CMS website at

https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html .

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT 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 CDLT 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. Individuals may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.

The CDLT Panel will provide information 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 (CDLTs), including whether to use "cross walking" or "gap filling" processes to determine payment for a specific new test;
- The factors used in determining coverage and payment processes for new CDLTs; and
- Other aspects of the new payment system under section 1834A of the Act.

A notice announcing the establishment of the CDLT 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 CDLT Panel along with the first public meeting date for the CDLT Panel, which was held on August 26, 2015. Subsequent meetings of the CDLT Panel and membership appointments were also announced in the **Federal Register**.

The CDLT Panel charter provides that CDLT Panel meetings will be held up to 4 times annually and the CDLT Panel shall consist of up to 15 individuals appointed by the Secretary's or 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 CDLT Panel member selected to replace another CDLT Panel member who has resigned prior to the end of his or her term shall serve for the balance of the original CDLT Panel members' term.

II. Provisions of the Notice

A notice requesting nominations to the CDLT Panel was published in the September 29, 2017 **Federal Register** (82 FR 45590 through 45592). In that notice, we stated that nominations would be accepted on a continuous basis. Since the last CDLT Panel meeting, which was held July 16 through 17, 2018, the Secretary's designee approved membership (term period: July 1, 2019 through June 30, 2022) of the following new panel members (parenthetical denotes nomination source (s)):

- Maria Arcila, MD (Memorial Sloan Kettering Cancer Center);
- Karen Carroll, MD, FIDSA (Infectious Diseases Society of America);
- Lydia Contis, MD (University of Pittsburgh School of Medicine);
- Elizabeth Harris, MD (Humana, Inc.);

- Kevin Krock, PhD (Precision Diagnostics);
- Elaine Lyon, PhD (Association for Molecular Pathologists);
- Heather Shappell, MS, CGC (National Society of Genetic Counselors);

Current CDLT Panel members (parenthetical denotes nomination source(s):

- Vickie Baselski, Ph.D. (American Society of Microbiology);
- Aaron Bossler, M.D., Ph.D. (Association for Molecular Pathologists);
- Pranil Chandra, D.O. (Association for Molecular Pathologists);
- William Clarke, Ph.D., M.B.A., DABCC, FACB (American Association of Clinical Chemistry);
- Stanley R. Hamilton, M.D. (Alliance of Dedicated Cancer Centers; College of American Pathologists; National Association of Medical Examiners; MD Anderson Cancer Center);
- Kimberley Hanson, MD, MHS, FIDSA (Infectious Diseases Society of America);
- Michele M. Schoonmaker, Ph.D. (Advanced Medical Technology Association);

Terms have expired (or will expire during Calendar Year (CY) 2019) for the following CDLT Panel members (parenthetical denotes nomination source (s)):

- Geoffrey Baird, M.D., Ph.D. (Seattle Children's Hospital);
- Raju Kucherlapati, Ph.D. (Coalition of 21st Century Medicine);
- Bryan A. Loy, M.D., M.B.A. (Humana, Inc.);
- Gail Marcus, PhD., M.B.A., M.S.E. (Self-Nomination);
- Carl Morrison, M.D., D.V.M. (The United States Congress; Roswell Park Cancer Center);

- Rebecca Sutphen, M.D. (Self- Nomination; Informed Medical Decisions);

III. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on CDLTs is available on the CMS website at http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html. Also, copies of the charter can be obtained by submitting a request to the contact listed in the "For Further Information Contact" section of this notice.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, 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.) is not required.

Dated: June 11, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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