IV. Collection of Information Requirements

This document does not impose information collection requirements, that is reporting, recordkeeping and 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. chapter 35).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** announcing the result of our evaluation.

Dated: June 11, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–13901 Filed 6–27–19; 8:45 am]

BILLING CODE 4120–01–P

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, Ph.D., Designated Federal Official (DFO), (410) 786–3434 or email 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, Ph.D. (Precision Diagnostics);
- Elaine Lyon, Ph.D. (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, Ph.D., 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.

[FR Doc. 2019–13900 Filed 6–27–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2452]

Endpoints for Drug Development in Heart Failure; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Endpoints for Drug Development in Heart Failure.'' The purpose of this public meeting is to bring the stakeholder community together to discuss clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. The workshop will focus on endpoints related to symptoms and physical function. In addition, there will be discussion of the need to assess mortality effects of drugs under development for heart failure.

DATES: The public workshop will be held on Friday, July 26, 2019, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Meg Pease-Fye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4115, Silver Spring, MD, 20993–0002, 301–796–1130, *Meg.PeaseFye@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding clinical endpoints for trials in heart failure that could be used to support FDA approval of drugs. FDA is convening this public workshop to discuss the Agency's current thinking with expert stakeholders and to consider public comments.

II. Topics for Discussion at the Public Workshop

FDA is interested in soliciting feedback on a number of topics:

1. Consider and discuss endpoints related to symptoms and physical function, *e.g.,* patient-reported outcome instruments, exercise tests, data from electronic monitors;
2. Consider the best ways to count multiple hospitalizations;
3. Discuss when the nature and clinical importance of a treatment effect for a particular endpoint may justify deferral or omission of outcomes studies;
4. In setting an upper bound for a mortality risk to be ruled out, discuss how the boundary may be influenced by a drug's demonstrated benefits and risks;
5. Discuss the advantages and disadvantages of all-cause vs. cardiovascular-specific endpoints, *e.g.,* hospitalizations and deaths;
6. Discuss the advantages and disadvantages of adjudicating causes of deaths and hospitalizations.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website *https://fdaheartfailureendpointsindrugdev.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public workshop must register by July 24, 2019, at 3 p.m., Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Meg Pease-Fye at 301–796–2240 no later than July 1, 2019.

Requests for Oral Comment: On the day of the meeting, a signup sheet will be made available for those who wish to speak during the public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their