

determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the Annual Laboratory Public Meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our preliminary determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on the CMS website by early September 2018. This website can be accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Interested parties may submit written comments on the preliminary determinations for new and reconsidered codes by early October 2018, to the address specified in the **ADDRESSES** section of this notice or electronically to our CLFS dedicated email box, [CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov) (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2019 and reconsidered codes will be posted on the CMS website in November 2018, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

### III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS public meeting registration. Beginning April 4, 2018, and ending June 11, 2017, registration may be completed on-line at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. On this web

page, under the heading "Meeting Notice, Registration and Agenda," you will find a link entitled "Register for CLFS Annual Meeting". Click this link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone numbers.
- Email addresses.

When registering, individuals who want to make a presentation must also specify the new test codes on which they will be presenting comments. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the **DATES** section of this notice.

If not attending the Annual Laboratory Public Meeting in person, the public may view the meeting via webcast or listen by teleconference. During the public meeting, webcasting is accessible online at <http://cms.gov/live>. Teleconference dial-in information will appear on the final Annual Laboratory Public Meeting agenda, which will be posted on the CMS website when available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>.

### IV. Security, Building, and Parking Guidelines

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. We suggest that you arrive at the CMS facility between 7:00 a.m. and 8:00 a.m. E.D.T., so that you will be able to arrive promptly at the meeting by 8:00 a.m. E.D.T. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 7:15 a.m. E.D.T. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and

instructions will be issued after the vehicle inspection.

- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

### V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide that information upon registering for the meeting. The deadline for registration is listed in the **DATES** section of this notice.

### VI. 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.*).

Dated: March 20, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2018-06551 Filed 3-29-18; 8:45 am]

**BILLING CODE 4120-01-P**

## 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, email [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/LaboratoryPublicMeetings.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.*).

Dated: March 20, 2018.

**Seema Verma,**

*Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Formative Data Collections for ACF Research and Program Support.  
*OMB No.:* 0970-0356.

*Description:* The Office of Planning, Research, and Evaluation (OPRE), in the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) to renew a generic clearance to conduct a variety of formative data collections with more than nine respondents. The data collections will inform future research and program support but will not be highly systematic nor intended to be statistically representative.

ACF programs promote the economic and social well-being of families, children, individuals and communities. OPRE studies ACF programs, and the populations they serve, through rigorous research and evaluation projects. These include evaluations of existing programs, evaluations of innovative approaches to helping low income children and families, research syntheses and descriptive and exploratory studies. OPRE’s research serves to provide further understanding of current programs and service populations, explore options for program improvement, and assess alternative policy and program designs. OPRE anticipates undertaking a variety of new research projects related to welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, family and youth services, home visiting, child welfare, and other areas of interest to ACF. Many ACF program offices find a need to learn more about funded program services to inform internal decision-making and to provide adequate support. Some program offices conduct their own research and evaluation projects.

Under this generic clearance, ACF would engage in a variety of formative

data collections with researchers, practitioners, TA providers, service providers and program participants throughout the field to fulfill the following goals: (1) Inform the development of ACF research, (2) maintain a research agenda that is rigorous and relevant, (3) ensure that research products are as current and responsive to audience needs as possible and (4) inform the provision of technical assistance. ACF envisions using a variety of techniques including semi-structured discussions, focus groups, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Under this generic IC information will not be collected with the primary purpose of publication, but findings are meant to inform ACF activities and may be incorporated into documents or presentations that are made public. The following are some examples of ways in which we may disseminate information resulting from these data collections: Research design documents or reports; research or technical assistance plans; background materials for technical workgroups; concept maps, process maps, or conceptual frameworks; contextualization of research findings from a follow-up data collection that has full PRA approval; informational reports to stakeholders such as funders, grantees, local implementing agencies, and/or TA providers. In presenting findings, we will describe the study methods and limitations with regard to generalizability and as a basis for policy.

*Respondents:* Key stakeholder groups involved in ACF projects and programs, state or local government officials, service providers, participants in ACF programs or similar comparison groups; experts in fields pertaining to ACF research and programs, or others involved in conducting ACF research or evaluation projects.

**ANNUAL BURDEN ESTIMATES**

Instrument type	Estimated total number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours
Semi-Structured Discussions, Focus Groups .....	2,000	1	2	4,000
Interviews .....	1,000	1	1	1,000