Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1700–N]

Medicare Program; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting

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

ACTION: Notice.

SUMMARY: This notice announces the next public meeting date for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on September 25, 2017. 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).

DATES: *Meeting date:* The meeting of the Panel is scheduled for September 25, 2017, from 9 a.m. to 4 p.m., eastern daylight time (E.D.T.).

Deadline for Submission of Presentations: All presenters must submit their presentations and comments electronically to our CLFS dedicated email mailbox, *CDLTPanel@cms.hhs.gov,* by September 21, 2017 at 5 p.m. E.D.T.

FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, Designated Federal Official (DFO), email *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 Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

SUPPLEMENTARY INFORMATION: The Panel will make recommendations to the Secretary and the Administrator regarding payment for CDLTS for which CMS received no applicable information to calculate Medicare payment rates. The Panel did not deliberate and provide recommendations regarding the payment for these CDLTs during the Public Meeting Regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year (CY) 2018 (2017 CLFS Public Meeting) and the Panel meeting on July 31 through August 1, 2017.

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 (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 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; and
- 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 Secretary approved rechartering of the Panel on April 25, 2017. The new charter is effective through April 25, 2019 and may be found on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.* A notice announcing the rechartering of the Panel was published in the June 16, 2017 **Federal Register** (82 FR 27705).

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.

Section 1834A of the Act requires revisions to the payment methodology for clinical diagnostic laboratory tests paid under the CLFS. We implemented the requirements of section 1834A of the Act in the CLFS final rule published in the June 23, 2016 **Federal Register** (81 FR 41036) entitled, ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System.'' Under the CLFS final rule, reporting entities are required to report to CMS applicable information for their component applicable laboratories. The applicable information includes, for each CDLT furnished during a data collection period, the specific HCPCS code associated with the test, each private payor rate for which final payment has been made, and the associated volume of tests performed corresponding to each private payor rate. In general, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payor rates determined for the test, based on the applicable information that is collected during a data collection period and reported to us during a data reporting period.

Under 42 CFR 414.507(g), payment for a clinical diagnostic laboratory test for which CMS receives no applicable information is based on the crosswalking or gapfilling methods described in § 414.508(b)(1) and (2). On August 4, 2017, CMS posted on the CLFS Web site a list of laboratory codes for which CMS received no applicable information to calculate Medicare payment rates based on the weighted median of private payor rates. During the 2017 CLFS Public Meeting and the Panel meeting on July 31 through August 1, 2017, CMS discussed these codes, however, the Panel did not deliberate and provide recommendations regarding the payment for these codes. During this meeting, the Panel will address any issues relating to this list of laboratory test codes, including making

recommendations to the Secretary of HHS and the Administrator of CMS regarding the following questions as it relates to these codes:

- Should the code be included on the CLFS?
- If the code should be included on the CLFS, what method of payment should be used to price the test codes (crosswalking or gapfilling, as required by 42 CFR 414.507(g))?
- If crosswalking, specify the crosswalk code(s).

The Panel will also provide input on other CY 2018 CLFS issues that are designated in the Panel's charter and specified on the meeting agenda.

II. Agenda

The Agenda for the September 25, 2017, Panel Meeting will provide for discussion and comment on the following topics as designated in the Panel's charter:

- CY 2018 CLFS laboratory test codes for which CMS received no applicable information to calculate a Medicare payment rate and was posted on August 4, 2017, on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.*
- Other CY 2018 CLFS issues designated in the Panel's charter and further described on our Agenda.
- CDLTs that will be discussed during this meeting is available on the CMS Web site, in the document entitled ''2017 Clinical Laboratory Test Codes with No Data,'' at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html.*

A detailed Agenda will be posted approximately 1 week before the meeting, on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

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.

V. Panel Recommendations and Discussions

The Panel's recommendations will be posted after the meeting on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

VI. Additional Information

A. 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 Web site approximately 1 week prior to the meeting at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

B. Meeting Registration

Registration is required to participate in this teleconference 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.

C. Deadline for Submission of Presentations

There will be an opportunity during the meeting for public presentations and oral comments. During the meeting, an individual will be limited to 1 minute of comments for each laboratory test code. All presenters for the meeting must register and submit their presentations and comments electronically to our CLFS dedicated email mailbox, *CDLTPanel@cms.hhs.gov,* by the date listed in the **DATES** section of this notice. Presenters should submit all presentations and comments using a standard PowerPoint template that is available on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html,* under the ''Panel Meetings'' heading.

VI. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site 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: September 8, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Refugee Data Submission System for Formula Funds Allocation—ORR–5.

OMB No.: 0970–0043.

Description: The information collection, Refugee Data Submission System for Formula Funds Allocations, (ORR–5) satisfies the statutory requirements of the Immigration and Nationality Act (INA). Section 412(a)(3) of the Act requires the Director of the Office of Refugee Resettlement (ORR) to make a periodic assessment, based on refugee population and other relevant factors, of the relative needs of refugees for assistance and services and the resources available to meet those needs. This includes compiling and maintaining data on the secondary migration of refugees within the United States after arrival. Further, INA 412(c)(1)(B) states that formula funds shall be allocated based on the total number of refugees, taking into account secondary migration.

Respondents: States or replacement designees.