Board of Governors of the Federal Reserve System, August 4, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1641–N]

Medicare, Medicaid, and Children's Health Insurance Programs; 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 15 membership appointments to the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) and the first meeting date for the Panel. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on issues related to clinical diagnostic laboratory tests. The membership appointments are for 3 years. This notice also announces the first meeting date of the Panel on Wednesday, August 26, 2015.

DATES: *Meeting Date:* The first meeting of the Panel is scheduled to take place at CMS's headquarters in Baltimore, MD on Wednesday, August 26, 2015 beginning at 9:00 a.m., Eastern Daylight Time (EDT). The Panel will specifically recommend crosswalks for new laboratory codes, recommend an appropriate coding structure for drugs of abuse testing, and recommend crosswalks for such drugs of abuse testing.

Meeting Registration

The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, August 7, 2015 and ending Friday, August 14, 2015 at 5:00 p.m. EDT, registration to attend the meeting in-person may be completed online at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.* On this Web page, under ''Related Links,'' double-click the ''Clinical Diagnostic Laboratory Tests FACA Panel Meeting Registration'' link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Postal address.
- Email address.

Note: Participants who do not plan to attend the meeting in-person on August 26, 2015, should not register. No registration is required for participants who plan to view the meeting via webcast or listen via teleconference.

Presenter Registration and Submission of Presentations and Comments

We are interested in submitted comments or in presentations at the meeting concerning the issues described in the **SUMMARY** section of this notice. The comments and presentations should not duplicate those that were provided at the Annual Clinical Laboratory Public Meeting on July 16, 2015, or submitted through the comment process provided subsequent to the Annual Clinical Laboratory Public Meeting. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 p.m. EDT, Monday, August 17, 2015. Presenters may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentations should be sent via email to the same person's email address.

For reconsidered and new test codes, presenters should address all of the following items:

- Reconsidered or new test code(s) and descriptor.
- Test purpose and method.
- Costs.
- Charges.
- A recommendation with rationale for one of the two methods (crosswalking or gapfilling) for determining payment for new tests, or a recommendation with rationale for changing the basis or payment amount, as applicable, for reconsidered tests.

Additionally, the presenters should provide the data on which their recommendations are based.

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

Meeting Location, Webcast, and Teleconference

The meetings will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view the meetings via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at *http://cms.gov/live.* Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

Meeting Format

This meeting is open to the public. The onsite check-in for visitors will be held from 8:30 a.m. to 9:00 a.m. EDT on Wednesday, August 26, 2015, followed by opening remarks. Following the opening remarks, the Panel will hear oral presentations from the public for no more than 1 hour during two sessions. During the first session, registered persons from the public may present recommendations for crosswalks for new laboratory codes for the CY 2016 CLFS. During the second session, registered persons from the public may present recommendations for drugs of abuse testing and crosswalks. Time allotted for each presentation may be limited. If the number of registrants requesting to present is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. We will accept written presentations from those who were unable to present due to time constraints.

ADDRESSES: *Web site:* For additional information on the Panel, please refer to our Web site at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

FOR FURTHER INFORMATION CONTACT: Glenn C. McGuirk, Designated Federal Official (DFO), Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security Boulevard, Mail Stop C4–01–26, Baltimore, MD 21244, 410–786–5723, email *Glenn.McGuirk@cms.hhs.gov.* Press inquiries are handled through 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 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted 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 (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 representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator, Centers 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; and
- Other aspects of the new payment system under section 1834A of the Act.

The Panel charter provides that panel meetings will be held up to four times annually. The Panel will consist of up to 15 individuals and a Chair. The Panel Chair will facilitate meetings and the DFO or DFO's designee must be present at all meetings. Meetings will be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Sunshine Act of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings will be published in the **Federal Register** as required by applicable laws and Departmental regulations. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

In order to conduct the business of the Panel, a quorum is required. A quorum exists when a majority of currently appointed members is present at full Panel or subcommittee meetings or is participating in conference calls.

II. Provisions of This Notice

We published a notice in the **Federal Register** on October 27, 2014, entitled ''Medicare, Medicaid, and Children's Health Insurance Programs; Advisory Panel on Clinical Diagnostic Laboratory Tests and Request for Nominations'' (79 FR 63919 through 63920). The notice solicited nominations for up to 15 members and a Chair to serve on this Panel. This notice announces 16 new members to the Panel. Their appointments are for 3-year terms beginning July 1, 2015.

The Panel will consist of the following members and a Chair:

- Steve Phurrough M.D., Panel Chair, CMS Medical Officer
- Geoffrey Baird, M.D., Ph.D.
- Vickie Baselski, Ph.D.
- Stephen N. Bauer, M.D.
- William Clarke, Ph.D., M.B.A., DABCC, FACB
- Judith Davis, M.S.
- Stanley R. Hamilton, M.D.
- Curtis A. Hanson, M.D.
- Kandice Kottke-Marchant, M.D., Ph.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.
- Victoria M. Pratt, Ph.D., FACMG
- Michele M. Schoonmaker, Ph.D.
- Rebecca Sutphen, M.D.

III. Meeting Attendance

The first meeting (August 26, 2015) is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the ''Meeting Registration'' section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

IV. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building.
- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

V. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

VI. Panel Recommendations and Discussions

The Panel's recommendations will be posted to our Web site after the meeting.

VII. 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.

VIII. 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: August 3, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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