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 presentation or to support a presentation.

Note: 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 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

Dated: May 26, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–13085 Filed 6–2–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1666–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on July 18, 2016

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

ACTION: Notice.

SUMMARY: This notice announces the next public meeting date of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, July 18, 2016. 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) (the Administrator) on issues related to clinical diagnostic laboratory tests.

DATES: *Meeting Date:* The meeting of the Panel is scheduled for Monday, July 18, 2016 beginning at 9:00 a.m., Eastern Daylight Time (EDT). The morning session will be held jointly with the Public Meeting on New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule (CLFS) for Calendar Year (CY) 2017 (the 2016 Laboratory Public Meeting) (*see* 81 FR 29863, May 13, 2016 for notice of the 2016 Laboratory Public Meeting). During the afternoon session, the Panel will deliberate and make recommendations regarding the new and reconsidered laboratory codes for CY 2017. The Panel may also hear public presentations on additional issues concerning the CY 2017 CLFS that are designated in the Panel's charter and specified in the Panel meeting agenda for the afternoon session.

Meeting Registration: The public may attend the Panel meeting in-person, view via webcast, or listen via teleconference. Beginning Monday, June 6, 2016 and ending Friday, July 1, 2016 at 5:00 p.m. EDT, registration to attend the Panel 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.
- Address.
- Email addresses.

Note: Participants who do not plan to attend the Panel meeting in-person on July 18, 2016 should not register. No registration is required for participants who plan to view the Panel meeting via webcast or listen via teleconference. Participants planning to attend only the morning session which includes the 2016 Laboratory Public Meeting, or both the morning and afternoon sessions, should register only once, for the 2016 Laboratory Public Meeting (*see* instructions for registering for the 2016 Laboratory Public Meeting at 81 FR 29863). Participants planning to attend only the afternoon session of the Panel meeting must register using the above link and instructions.

Presenter Registration and Submission of Presentations and Comments: In the morning session only, we are interested in in-person presentations concerning the payment methodologies for new or reconsidered laboratory codes. The instructions for submitting such comments and presentations are also included in 2016 Laboratory Public Meeting notice (81 FR 29863). Although these comments and presentations will be made during the morning joint session of the 2016 Laboratory Public Meeting and Panel Meeting, the Panel may wish to ask follow-up questions to presenters at the afternoon session of the Panel Meeting.

As previously mentioned, additional issues concerning the calendar year (CY) 2017 clinical laboratory fee schedule (CLFS) that are designated in the Panel's charter and specified in the meeting agenda, may also be discussed at the afternoon session of the Panel meeting. Any such issues to be discussed will be specified in the Panel meeting agenda, to be published approximately 3 weeks before the meeting (A preliminary agenda is described in section II. of this notice.) Should issues be added to the agenda, we would be interested in public comments or presentations related to those issues. The comments and presentations should not address issues not specified in the agenda for the Panel meeting. The deadline to register to be a presenter and to submit written presentations for agenda items for the Panel's afternoon session (that is, presentations on issues other than payment for new and reconsidered laboratory codes for CY 2017) is 5:00 p.m. EDT July 1, 2016. Presenters may register by 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.

Meeting Location, Webcast, and Teleconference: The Panel meetings will be held in the Auditorium of the CMS, Central Office, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Alternately, the public may either view the Panel meetings via a webcast or listen by teleconference. During the scheduled Panel meeting, webcasting is accessible online at *http://cms.gov/live.* Teleconference dial-in information will appear on the final Panel 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 Panel meeting is open to the public. The on-site check-in for visitors will be held from 8:30 a.m. to 9:00 a.m. on Monday, July 18, 2016, preceding the morning session of the 2016 Laboratory Public Meeting, and again at 12:30 p.m. for visitors attending only the Panel meeting (afternoon session).

During the morning session, the Panel, along with the public, will hear and pose questions to presenters recommending crosswalks or gapfilling for new and reconsidered laboratory codes for calendar year (CY) 2017. During the afternoon session, the Panel will deliberate and make recommendations to the Secretary of HHS and the Acting Administrator of CMS regarding crosswalks or gapfilling for new and reconsidered laboratory codes discussed during the morning

session. The Panel may also hear public presentations (for a total time period of no more than one hour) and provide input on other CY 2017 CLFS issues that are designated in the Panel's charter and specified on meeting agenda. Both the morning and afternoon sessions are open to the public.

ADDRESSES: Web site: For additional information on the Panel, please refer to our Web site at *https://www.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 *CDLTPanel@cms.hhs.gov* or *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(a) 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 (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, 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 Acting 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 upcoming new payment system, to be based on private payor rates, 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.

The Panel charter provides that panel meetings will be held up to four times annually. The Panel consists of 15 individuals and a Chair. The Panel Chair facilitates the meeting and the Designated Federal Official (DFO) or DFO's designee must be present at all meetings.

II. Agenda

The Agenda for the July 18, 2016, Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- CY 2017 CLFS new and reconsidered test codes which were posted on May 12, 2016, on our Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Laboratory_Public_Meetings.html*
- Other CY 2017 CLFS issues designated in the Panel's charter and further described on our Agenda.

A detailed Agenda will be posted approximately 3 weeks before the meeting, on our Web site at *http://cms.gov/Regulations-andGuidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html.*

III. Meeting Attendance

The Panel's meeting on July 18, 2016, is open to the public. 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 after the meeting on our Web site at *http://cms.gov/Regulations-and Guidance/Guidance/FACA/Advisory PanelonClinicalDiagnosticLaboratory Tests.html.*

VIII. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on our Web site at *http://cms.gov/Regulations-and-Guidance/Guidance/FACA/Advisory PanelonClinicalDiagnosticLaboratory Tests.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.

IX. 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: May 25, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–13084 Filed 6–2–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Migrant and Seasonal Head Start Study.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing an information collection activity for the Migrant and Seasonal Head Start (MSHS) Study.

The MSHS Study will describe the characteristics and experiences of the children and families who enroll in MSHS and the practices and services of the MSHS programs that serve them. The findings will provide up-to-date information to the Office of Head Start, other federal government agencies, local MSHS programs, and the public. The study will be the first national MSHS study to include direct child assessments, which will provide information about MSHS children that programs can use to inform program, center and classroom practices.

Data collection will involve mail surveys to selected MSHS center directors and all MSHS program directors nationwide about operational characteristics, program- and center-level policies and practices, and services and resources offered to MSHS families. The study will also conduct on-site data collection with children, parents, teachers, and classrooms in a nationally-representative sample of MSHS centers. The on-site data collection will include classroom observations, teacher surveys, child reports and child assessments.

Respondents: MSHS program directors, center directors, teachers, assistant teachers, parents, and children.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Program Director survey	53	1	0.5	27
Center Director survey	253	1	0.5	127
Call script for Program Directors	24	1	1	24
Form for Program Directors to verify key information for selected centers	24	1	0.5	12
Call script for Center Directors	53	1	1	53
Call script for On Site Coordinators	53	1	1	53
Classroom sampling form	53	1	0.5	27
Child roster form	53	3	0.25	40
Teacher survey	159	1	0.5	80
Teacher child report	159	8	0.25	318
Assistant Teacher survey	159	1	0.25	40
Parent consent form	1,018	1	0.25	255
Child assessments (preschoolers and older toddlers only)	848	1	0.75	636
Parent interview (including Parent child report)	1,018	1	1	1,018

Estimated Total Annual Burden Hours: 2,710.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2016–13104 Filed 6–2–16; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0628]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.