Appendix A

FEE SCHEDULE FOR EACH VESSEL SIZE

Vessel size (GRT [1])	Inspection fee
Extra Small (<3,000 GRT)	US$1,495
Small (3,001–15,000 GRT) ..	2,990
Medium (15,001–30,000 GRT)	5,980
Large (30,001–60,000 GRT)	8,970
Extra Large (60,001–120,000 GRT)	11,960
Mega (>120,001 GRT)	17,940

[1] Gross register tonnage in cubic feet, as shown in Lloyd's Register of Shipping.

[FR Doc. 2016–19785 Filed 8–18–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1680–N]

Medicare Program; Announcement of the Advisory Panel on Clinical Diagnostic Laboratory Tests Meeting on September 12, 2016

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

ACTION: Notice.

SUMMARY: This notice announces the next meeting date of the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, September 12, 2016. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (HHS) (the Secretary) and the Acting Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Acting Administrator) on issues related to clinical diagnostic laboratory tests. The Panel will address Clinical Laboratory Fee Schedule issues relevant to the June 23, 2016 final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System'' (81 FR 41035 through 41101), which are designated in the Panel's charter and outlined in the agenda.

DATES: *Meeting Date:* The meeting of the Panel is scheduled to take place at CMS's headquarters in Baltimore, Maryland on Monday, September 12, 2016 beginning at 9:00 a.m. and ending at 4:30 p.m., Eastern Daylight Time (e.d.t.). The times listed in this notice are Eastern Daylight Time (EDT) and are approximate times except that the meeting will not begin before the posted time.

Meeting Registration: The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, August 19, 2016 and ending Friday, September 2, 2016 at 5:00 p.m. e.d.t., registration to attend the meeting in-person may be completed on-line 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 meeting in-person on September 12, 2016 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-person presentations at the meeting concerning the issues described in the **SUPPLEMENTARY INFORMATION** section of this notice and clarified in the agenda to be published approximately 2 weeks before the meeting. The comments and presentations should not address issues not before the Panel. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 p.m. e.d.t., Friday, September 2, 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.

ADDRESSES: *Meeting Location and Webcast:* The meeting will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244–1850. Alternately, the public may either view the meeting via a webcast at *http://cms.gov/live.*

Web site and Teleconference: For teleconference dial-in information, the final meeting agenda, and 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 *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 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 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 the 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, 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. Subsequent public meetings for the Panel were held on October 19, 2015 (80 FR 59782) and July 18, 2016 (81 FR 35772). Recommendations from Panel meetings are posted on the CMS Web site listed in the **ADDRESSES** section of this notice.

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. Meeting Format and Agenda

This 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, September 12, 2016. Following the opening remarks, the Panel will hear oral presentations from the public for no more than 1 hour during each of two sessions, one session in the morning and one session in the afternoon. During session one, registered persons from the public may present recommendations on payment options for routine chemistry tests that are currently paid as Automated Test Panels (ATPs) following implementation of the new payment system for clinical diagnostic laboratory tests on January 1, 2018. During session two, registered persons from the public may present recommendations on the application process for Advanced Diagnostic Laboratory Tests (ADLTs).

The agenda for the September 12, 2016, meeting will provide for discussion and comment on specified CLFS issues relevant to the final rule, CMS–1621–F entitled, ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' which are designated in the Panel's charter. Specifically, the Panel will discuss the following issues:

- Payment for routine chemistry tests that are currently paid as ATPs following implementation of the new payment system for clinical diagnostic laboratory tests on January 1, 2018.
- The application process for ADLTs.

A detailed agenda will be posted approximately 2 weeks before the meeting, on the CMS Web site listed in the **ADDRESSES** section of this notice.

III. Meeting Attendance

The Panel's meeting on September 12, 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 **DATES** section of this notice under ''Meeting Registration.'' 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 as specified in the **ADDRESSES** section of this notice.

VIII. Copies of the Charter

The Secretary's Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site as specified in the **ADDRESSES** section of this notice 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: August 4, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–19848 Filed 8–18–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0370]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

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.

DATES: Fax written comments on the collection of information by September 19, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0264. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export of Medical Devices; Foreign Letters of Approval—OMB Control Number 0910–0264—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)