

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 [oir\\_submission@omb.eop.gov](mailto:oir_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](mailto: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)

(21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to

obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or

Agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of April 22, 2016 (81 FR 23720), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity/Section of FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—section 801(e)(2) .....	38	1	38	3	114	\$9,500

<sup>1</sup> There are no capital costs associated with this collection of information.

Dated: August 15, 2016.

**Peter Lurie,**

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016-19807 Filed 8-18-16; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0134]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Quality Standards Act Requirements

**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 [oir@omb.eop.gov](mailto:oir@omb.eop.gov).

[submission@omb.eop.gov](mailto:submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0309. 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](mailto: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.

#### Mammography Quality Standards Act Requirements—21 CFR Part 900, OMB Control Number 0910-0309—Extension

The Mammography Quality Standards Act (Pub. L. 102-539) requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with

information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

The following sections of Title 21 of the Code of Federal Regulations (CFR) are not included in the burden tables because they are considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional burden: 21 CFR 900.12(c)(1) and (3) and 900.3(f)(1). Section 900.24(c) was also not included in the burden tables because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, there wouldn't be an additional reporting burden.

We have rounded numbers in the "Total Hours" column in all three burden tables. (Where the number was a portion of 1 hour, it has been rounded to 1 hour. All other "Total Hours" have been rounded to the nearest whole number.)