security check procedures will be performed. For parking and security information, please refer to *www.fda.gov/publicmeetinginfo.*

FOR FURTHER INFORMATION CONTACT: Rokhsareh Shahidzadeh, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2383, Silver Spring, MD 20993, 301–796–8740, *FDASciProDev@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Science Forum is held biennially to share with the public the unique scientific research and collaborative efforts of our 11,000 scientists and researchers. These scientists and researchers use novel science and technologies to inform FDA's regulatory decision-making—and drive innovation. FDA scientific experts and nationally renowned scientists will speak on the eight topics of the upcoming FDA Science Forum, *Transforming Health: Innovation in FDA Science.* FDA's Science Forum welcomes the public, industry, academia, patient advocates, sister Agencies, and current and potential collaborators, to learn about the Agency's regulatory science—the type of science that is rarely undertaken by industry or academia, but that makes critical contributions to product quality and safety.

II. Topics for Discussion at the Public Workshop

Sessions in the two-day forum will highlight such areas as FDA research into new predictive tools for developing and evaluating therapeutics, advancing artificial intelligence, evaluating digital health devices, and novel methods of tackling critical public health challenges such as addiction.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/scienceforum.*

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by September 6, 2019, at 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Rokhsareh Shahidzadeh (see **FOR FURTHER INFORMATION CONTACT**) no later than September 4, 2019, by 5 p.m. Eastern Time.

Streaming Webcast of the public workshop: This public workshop will also be webcast. To register, please visit the following website: *https://www.fda.gov/scienceforum.* Participants interested in viewing via webcast must register by September 6, 2019, at 5 p.m. Eastern Time.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: August 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17703 Filed 8–16–19; 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 18, 2019.

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 0910–0309. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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). 21 CFR 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.)

In the **Federal Register** of May 1, 2019 (84 FR 18548), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that expressed general concern regarding the cost and quality of mammography equipment. However, the comment did not refer to any particular provision of the regulations or the information collection burden estimate. We note that in the **Federal Register** of March 28, 2019 (84 FR 11669), FDA published a proposed rule to update the mammography regulations. As part of the proposed rule, FDA prepared a Preliminary Economic Analysis of Impacts. Comments received on the proposed rule are currently being considered.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) annually. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. It is charged with advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC also discusses and comments on all guidances before they are made final. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also meets or holds teleconferences several times a year with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. The Agency has also long enjoyed a good relationship with the Conference of State Radiation Program Directors (CRCPD), which is the professional organization of the State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section/FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]	Total capital costs	Total operating and maintenance costs
Notification of intent to become an AB—900.3(b)(1).	0.33	1	0.33	1	1		
Application for approval as an AB; full [2]—900.3(b)(3).	0.33	1	0.33	320	106	$10,776	
Application for approval as an AB; limited [3]—900.3(b)(3).	5	1	5	30	150		
AB renewal of approval—900.3(c)	1	1	1	15	15		
AB application deficiencies—900.3(d)(2).	0.1	1	0.1	30	3		
AB resubmission of denied applications—900.3(d)(5).	0.1	1	0.1	30	3		
Letter of intent to relinquish accreditation authority—900.3(e).	0.1	1	0.1	1	1		
Summary report describing all facility assessments—900.4(f).	330	1	330	7	2,310		$83,618
AB reporting to FDA; facility [4]—900.4(h).	8,654	1	8,654	1	8,654		4,663
AB reporting to FDA; AB [5]—900.4(h).	5	1	5	10	50		
AB financial records—900.4(i)(2)	1	1	1	16	16		
Former AB new application—900.6(c)(1).	0.1	1	0.1	60	6		
Reconsideration of accreditation following appeal—900.15(d)(3)(ii).	1	1	1	2	2		
Application for alternative standard—900.18(c).	2	1	2	2	4		
Alternative standard amendment—900.18(e).	10	1	10	1	10		
Certification agency application—900.21(b).	0.33	1	0.33	320	106	32,327	224
Certification agency application deficiencies—900.21(c)(2).	0.1	1	0.1	30	3		
Certification electronic data transmission—900.22(h).	5	200	1,000	0.083 (5 minutes)	83		
Changes to standards—900.22(i)	2	1	2	30	60		22
Certification agency minor deficiencies—900.24(b).	1	1	1	30	30		
Appeal of adverse action taken by FDA—900.25(a).	0.2	1	0.2	16	3		
Inspection fee exemption—Form FDA 3422.	700	1	700	0.25 (15 minutes)	175		

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section/FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]	Total capital costs	Total operating and maintenance costs
Total					11,791	43,103	88,527

[1] Total hours have been rounded.
[2] One-time burden.
[3] Refers to accreditation bodies applying to accredit specific full-field digital mammography units.
[4] Refers to the facility component of the burden for this requirement.
[5] Refers to the AB component of the burden for this requirement.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]	Total capital costs	Total operating and maintenance costs
AB transfer of facility records—900.3(f)(1).	0.1	1	0.1	0	1		
Consumer complaints system; AB—900.4(g).	5	1	5	1	5		
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(*2*).	87	1	87	8	696		
Documentation of interpreting physician personnel requirements—900.12(a)(4).	8,654	4	34,616	1	34,616		
Permanent medical record—900.12(c)(4).	8,654	1	8,654	1	8,654	$30,171	
Procedures for cleaning equipment—900.12(e)(13).	8,654	52	450,008	0.083 (5 minutes)	37,351		
Audit program—900.12(f)	8,654	1	8,654	16	138,464		
Consumer complaints system; facility—900.12(h)(2).	8,654	2	17,308	1	17,308		
Certification agency conflict of interest—900.22(a).	5	1	5	1	5		
Processes for suspension and revocation of certificates—900.22(d).	5	1	5	1	5		
Processes for appeals—900.22(e)	5	1	5	1	5		
Processes for additional mammography review—900.22(f).	5	1	5	1	5		
Processes for patient notifications—900.22(g).	3	1	3	1	3		$32
Evaluation of certification agency—900.23.	5	1	5	20	100		
Appeals—900.25(b)	5	1	5	1	5		
Total					237,223	30,171	32

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating and maintenance costs
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2).	0.1	1	0.1	200	20	$54
Clinical images; facility [3]—900.4(c), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	1.44	4,154	248,670
Clinical images; AB [4]—900.4(c)	5	1	5	416	2,080	
Phantom images; facility [3]—900.4(d), 900.11(b)(1), and 900.11(b)(2).	2,885	1	2,885	0.72 (43 minutes)	2,077	
Phantom images; AB [4]—900.4(d)	5	1	5	208	1,040	
Annual equipment evaluation and survey; facility [3]—900.4(e), 900.11(b)(1), and 900.11(b)(2).	8,654	1	8,654	1	8,654	9,325
Annual equipment evaluation and survey; AB [4]—900.4(e).	5	1	5	1,730	8,650	
Provisional mammography facility certificate extension application—900.11(b)(3).	0	1	0	0.5 (30 minutes)	1	
Mammography facility certificate reinstatement application—900.11(c).	312	1	312	5	1,560	
Lay summary of examination—900.12(c)(2)	8,654	5,085	44,055,590	0.083 (5 minutes)	3,652,464	25,861,265
Lay summary of examination; patient refusal [5]—900.12(c)(2).	87	1	87	0.5 (30 minutes)	44	
Report of unresolved serious complaints—900.12(h)(4).	20	1	20	1	20	
Information regarding compromised quality; facility [3]—900.12(j)(1).	20	1	20	200	4,000	324

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating and maintenance costs
Information regarding compromised quality; AB [4]—900.12(j)(1).	20	1	20	320	6,400	646
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500	20,878
Reconsideration of accreditation—900.15(c)	5	1	5	2	10	
Notification of requirement to correct major deficiencies—900.24(a).	0.4	1	0.4	200	80	73
Notification of loss of approval; major deficiencies—900.24(a)(2).	0.15	1	0.15	100	15	27
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60	55
Notification of loss of approval; minor deficiencies—900.24(b)(3).	0.15	1	0.15	100	15	27
Total					3,691,842	26,141,344

[1] There are no capital costs associated with the collection of information.
[2] Total hours have been rounded.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the AB component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

FDA has adjusted the number of respondents for § 900.3(c) ''AB renewal of approval'' to one. This adjustment resulted in a 14-hour increase to the hour-burden estimate. Additionally, we updated the capital costs and operating and maintenance costs by adjusting them for inflation since the last update to those estimates. This adjustment resulted in a $1,893,071 increase to the estimated capital and operating and maintenance costs ($24,410,106 previously; $26,303,177 current extension request).

Dated: August 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17734 Filed 8–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public. For this meeting, the Working Group will receive updates from the eight subcommittees formed at the June 4, 2019, meeting and continue to focus on plans to develop the next report to the HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 report. The 2020 report will address a wide range of federal activities and research related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify gaps in tick-borne disease research; and provide recommendations to the HHS Secretary regarding changes or improvements to such activities and research. In developing the report, the TBDWG will solicit stakeholder input.

DATES: The meeting will be online via webcast and will be held on September 12, 2019, from 8:30 a.m. to 5 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the TBDWG at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html* when this information becomes available.

ADDRESSES: Members of the public may also attend the meeting via webcast. Instructions for attending the virtual meeting will be posted one week prior to the meeting at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html.*

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Email: *tickbornedisease@hhs.gov;* Phone: 202–795–7697.

SUPPLEMENTARY INFORMATION: The public will have an opportunity to present their views to the TBDWG during the meeting's public comment session or by submitting their views in writing. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html* and respond by midnight Wednesday, September 4, 2019, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the TBDWG members and public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the *21st Century Cures Act,* and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to tick-borne diseases to help ensure interagency coordination and minimize overlap, examine research priorities, and identify and address unmet needs. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: August 6, 2019.

James Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Senior Advisor for Blood and Tissue Policy, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2019–17689 Filed 8–16–19; 8:45 am]

BILLING CODE 4150–28–P