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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 1.--Estimated Annual Reporting Burden

Activity/21 CFR Section/FDA Form No.	No. of Respondents	No. 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		
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	No. of Recordkeepers	No. 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	No. of Respondents	No. 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
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.

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