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: 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.

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.)

We do not expect any respondents for § 900.3(c) because all four ABs are approved until April 2020.

In the Federal Register of June 8, 2016 (81 FR 36924), 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

Activity/21 CFR Section/Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]	Total Capital Costs (in dollars)	Total Operating and Maintenance Costs (in dollars)
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	10,000	
Application for approval as an AB; limited[3]--900.3(b)(3)	5	1	5	30	150		
AB renewal of approval--900.3(c)	0	1	0	15	1		
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		77,600
AB reporting to FDA; facility[4]--900.4(h)	8,654	1	8,654	1	8,654		4,327
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		208
Certification agency application deficiencies--900.21(c)(2)	0.1	1	0.1	30	3		
Certification electronic data transmission--900.22(h)	5	200	1000	0.083	83	30,000	
Changes to standards--900.22(i)	2	1	2	30	60		20

Table 1.--Estimated Annual Reporting Burden

Activity/21 CFR Section/Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]	Total Capital Costs (in dollars)	Total Operating and Maintenance Costs (in dollars)
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	175		
Total					11,777	40,000	82,155

[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 (in dollars)	Total Operating and Maintenance Costs (in dollars)
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	28,000	
Procedures for cleaning equipment--900.12(e)(13)	8,654	52	450,008	0.083	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		

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 (in dollars)	Total Operating and Maintenance Costs (in dollars)
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		30
Evaluation of certification agency--900.23	5	1	5	20	100		
Appeals--900.25(b)	5	1	5	1	5		
Total					237,223	28,000	30

[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 (in dollars)
Notification of facilities that AB relinquishes its accreditation--900.3(f)(2)	0.1	1	0.1	200	20	50
Clinical images; facility[3]--900.4(c), 900.11(b)(1) and (2)	2,885	1	2,885	1.44	4,154	
Clinical images; AB[4]--900.4(c)	5	1	5	416	2,080	230,773
Phantom images; facility[3]--900.4(d), 900.11(b)(1) and (2)	2,885	1	2,885	0.72	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 (2)	8,654	1	8,654	1	8,654	8,654
Annual equipment evaluation and survey; AB[4]--900.4(e)	5	1	5	1,730	8,650	

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 (in dollars)
Provisional mammography facility certificate extension application--900.11(b)(3)	0	1	0	0.5	1	
Mammography facility certificate reinstatement application--900.11(c)	312	1	312	5	1,560	24,000,000
Lay summary of examination--900.12(c)(2)	8,654	5,085	44,055,590	0.083	3,652,464	
Lay summary of examination; patient refusal[5]--900.12(c)(2)	87	1	87	0.5	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	300
Information regarding compromised quality; AB[4]--900.12(j)(1)	20	1	20	320	6,400	600
Patient notification of serious risk--900.12(j)(2)	5	1	5	100	500	19,375
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	68
Notification of loss of approval; major deficiencies--900.24(a)(2)	0.15	1	0.15	100	15	25.50
Notification of probationary status--900.24(b)(1)	0.3	1	0.3	200	60	51
Notification of loss of approval; minor deficiencies--900.24(b)(3)	0.15	1	0.15	100	15	25.50
Total					3,691,842	24,259,921

[1] There are no capital costs associated with this 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.

Dated: August 15, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

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