4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the estimated reporting, recordkeeping, and third-party disclosure burden associated with the Mammography Quality Standards Act requirements.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0134 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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 (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		

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 (in dollars)	Total Operating and Maintenance Costs (in dollars)
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
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--FDA Form 3422	700	1	700	0.25	175		

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 (in dollars)	Total Operating and Maintenance Costs (in dollars)
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 (FFDM) 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		
Certification agency conflict of interest--900.22(a)	5	1	5	1	5		

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)
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	

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)
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	
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

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)

[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: June 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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