collection reflects an overall increase of 22 hours. We attribute the increase to the correction of an inadvertent error in the reported hours for 21 CFR 300.200, which requires the submission of an annual report on Form FDA 5023 by sponsors and manufacturers who provide an ''*eligible investigational drug*'' under the Right to Try Act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04938 Filed 3–12–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4942]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Standards Quality 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: Submit written comments (including recommendations) on the collection of information by April 13, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0309.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, 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; standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. Implementing regulations are found in part 900 (21 CFR part 900). The regulations are intended 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.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) for the purposes of advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. 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 regularly meets or holds teleconferences with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. We also engage with the Conference of State Radiation Program Directors (CRCPD), a professional organization of 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.

In the **Federal Register** of December 9, 2025 (90 FR 57070), 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/FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PART 900, MAMMOGRAPHY					
Subpart A, Accreditation					
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
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)	338	1	338	7	2,366

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—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
AB reporting to FDA; facility [4]—900.4(h)	8,931	1	8,931	1	8,931
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
Total Subpart A					11,648
Subpart B, Quality and Standards Certification					
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
Total Subpart B					16
Subpart C, States as Certifiers					
Certification agency application—900.21(b)	0.33	1	0.33	320	106
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 (5 minutes)	83
Changes to standards—900.22(i)	2	1	2	30	60
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
Total Subpart C					285
Inspection fee exemption—FDA Form 3422	355	1	355	0.25 (15 minutes)	89
Total					12,038

[1] Numbers 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]
Part 900, MAMMOGRAPHY					
Subpart A, Accreditation					
AB transfer of facility records—900.3(f)(1)	0.1	1	0.1	1	1
Consumer complaints system; AB—900.4(g)	5	1	5	1	5
Total Subpart A					6
Subpart B, Quality and Standards Certification					
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(2).	89	1	89	8	712
Documentation of interpreting physician personnel requirements—900.12(a)(4)	8,931	4	35,724	1	35,724
Permanent medical record—900.12(c)(4)	8,931	1	8,931	1	8,931
Procedures for cleaning equipment—900.12(e)(13)	8,931	52	464,412	0.083 (5 minutes)	38,546
Audit program—900.12(f)	8,931	1	8,931	16	142,896
Consumer complaints system; facility—900.12(h)(2)	8,931	2	17,862	1	17,862
Total Subpart B					244,671
Subpart C, States as Certifiers					
Certification agency conflict of interest—900.22(a)	4	1	4	1	4
Processes for suspension and revocation of certificates—900.22(d)	4	1	4	1	4
Processes for appeals—900.22(e)	4	1	4	1	4
Processes for additional mammography review—900.22(f)	4	1	4	1	4
Processes for patient notifications—900.22(g)	3	1	3	1	3
Evaluation of certification agency—900.23	4	1	4	20	80
Appeals—900.25(b)	4	1	4	1	4
Total Subpart C					103
Total					244,774

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
PART 900, MAMMOGRAPHY					
Subpart A, Accreditation					
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2)	0.1	1	0.1	200	20
Clinical images; facility [2]—900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,955	1	2,955	1.44	4,255
Clinical images; AB [3]—900.4(c)	5	1	5	416	2,080
Phantom images; facility [2]—900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,955	1	2,955	0.72 (43 minutes)	2,128
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility [2]—900.4(e), 900.11(b)(1), and 900.11(b)(2).	8,931	1	8,931	1	8,931
Annual equipment evaluation and survey; AB [3]—900.4(e)	5	1	5	1,730	8,650
Total Subpart A					27,104
Subpart B, Quality Standards and Certification					
Provisional mammography facility certificate extension application—900.11(b)(3)	2	1	2	0.5 (30 minutes)	1
Mammography facility certificate reinstatement application—900.11(c)	288	1	288	5	1,440
Provision of personnel records to IPs—900.12(a)(4)	615	1	615	0.08 (5 minutes)	49
Transfer of personnel records by closing facilities—900.12(a)(4)	190	1	190	5	950
New assessment categories and breast density reporting in mammography report (one-time burden)—900.12(c)(1)(iv) to (vi).	8,931	1	8,931	23	205,413
Lay summary of examination—900.12(c)(2)	8,931	5,085	45,414,135	0.083 (5 minutes)	3,769,373
Breast density reporting in lay summary (one-time burden)—900.12(c)(2)	8,931	1	8,931	11	98,241
Lay summary of examination; patient refusal [4]—900.12(c)(2)	89	1	89	0.5 (30 minutes)	45
Transfer/provision of copies of mammograms and records upon patient's request—900.12(c)(4)(ii) and (iii).	8,931	520	4,644,120	0.08 (5 minutes)	371,530
Facility closure; notification and records access—900.12(c)(4)(v)	190	1	190	32	6,080
Report of unresolved serious complaints—900.12(h)(4)	20	1	20	1	20
Information regarding compromised quality; facility [2]—900.12(j)(1)	20	1	20	200	4,000
Information regarding compromised quality; AB [3]—900.12(j)(1)	20	1	20	320	6,400
Patient notification of serious risk—900.12(j)(2)	7	1	7	100	700
Reconsideration of accreditation—900.15(c)	5	1	5	2	10
Total Subpart B					4,464,252
Subpart C, States as Certifiers					
Notification of requirement to correct major deficiencies—900.24(a)	0.4	1	0.4	200	80
Notification of loss of approval; major deficiencies—900.24(a)(2)	0.15	1	0.15	100	15
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60
Notification of loss of approval; minor deficiencies—900.24(b)(3)	0.15	1	0.15	100	15
Total Subpart C					170
Total					4,491,526

[1] Total hours have been rounded.
[2] Refers to the facility component of the burden for this requirement.
[3] Refers to the AB component of the burden for this requirement.
[4] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Our estimated burden for the information collection reflects an overall decrease of 4,225,729 hours and a corresponding decrease of 321,202 responses. We attribute this adjustment due to the number of certified mammography facilities. The estimated number of respondents in the tables are based on the number (8,931) of certified mammography facilities as of October 1, 2024. Title 21 CFR part 900 Mammography, as amended, includes various reporting, recordkeeping, and third-party disclosure activities. In addition, there was a decrease in state certifiers from 5 to 4—Illinois, Iowa, South Carolina, and Texas.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4060]

Medical Devices With Indications Associated With Weight Loss—Premarket Considerations; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Medical Devices with Indications Associated with