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.

[FR Doc. 2026–04939 Filed 3–12–26; 8:45 am]

BILLING CODE 4164–01–P

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

Weight Loss—Premarket Considerations.'' This guidance document provides recommendations regarding non-clinical testing and clinical study design for medical devices with indications for use associated with weight loss to support premarket submissions. The guidance also includes discussion on how FDA considers the benefit-risk analysis to support such indications.

DATES: The announcement of the guidance is published in the **Federal Register** on March 13, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–N–4060 for ''Medical Devices with Indications Associated with Weight Loss—Premarket Considerations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Medical Devices with Indications Associated with Weight Loss—Premarket Considerations'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations regarding non-clinical testing and clinical study design for medical devices with indications for use associated with weight loss to support premarket submissions. The guidance also includes discussion on how FDA considers the benefit-risk analysis to support such indications. Examples of indications associated with weight loss include indications for weight loss, weight reduction, weight management, or obesity treatment in patients who are overweight or have obesity. The recommendations reflect current review practices of premarket submissions for these devices and are intended to promote consistency and facilitate efficient review of these submissions.

Prior to issuing this guidance, FDA requested public comment on a concept for balancing the benefit of weight loss with the risks of adverse events in a discussion paper (September 2019, Docket No. FDA–2019–N–4060). FDA considered public comments and incorporated the feedback as appropriate in developing the draft guidance, ''Medical Devices with Indications Associated with Weight Loss—Clinical Study and Benefit-Risk Considerations.''

A notice of availability of the draft guidances ''Medical Devices with Indications Associated with Weight Loss—Clinical Study and Benefit-Risk Considerations'' and ''Medical Devices with Indications Associated with Weight Loss—Non-Clinical Recommendations'' appeared in the **Federal Register** of September 15, 2023 (88 FR 63589). FDA combined the two draft guidances into one final guidance document for ease of use, since the scope of the draft guidances included the same device area. FDA also considered comments received and revised the language as appropriate in response to the comments. Edits to the final guidance include clarification on the use of sham controls, discussion of

statistical analysis using modified intent-to-treat populations, inclusion of patient-reported outcomes as a factor to be considered as part of the benefit-risk evaluation, provision of additional reference citations, and addition of references to FDA's Q-Submission Program, which can be used to request feedback on aspects of a proposed clinical study design.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Medical Devices with Indications Associated with Weight Loss—Premarket Considerations''. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA considered the applicability of Executive Order 14192, per Office of Management and Budget (OMB) guidance in M–25–20, and finds this action to be neither an E.O. 14192 regulatory nor an E.O. 14192 deregulatory action.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Medical Devices with Indications Associated with Weight Loss—Premarket Considerations'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019046 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part or Guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04918 Filed 3–12–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 13, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017—Revision

Abstract: This request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. The MIECHV Program is administered by the Maternal and Child Health Bureau within HRSA in partnership with the Administration for Children and Families, and provides support to all 56 states and jurisdictions, as well as tribes and tribal organizations. Through a needs assessment, states, jurisdictions, tribes, and tribal organizations identify target populations and select the home visiting service delivery model(s) that