

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10637]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 4, 2021.

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 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term "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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Marketplace Operations; *Use:* The data collections and third-party disclosure requirements will assist HHS in determining Exchange compliance with Federal standards and monitoring QHP issuers in FFEs for compliance with Federal QHP issuer standards. The data collection will also assist HHS in monitoring Web-brokers for compliance with Federal Web-broker standards. The data collected by health insurance issuers and Exchanges will help to inform HHS, Exchanges, and health insurance issuers as to the participation of individuals, employers, and employees in the individual Exchange, the SHOP, and the premium stabilization programs. *Form Number:* CMS-10637 (OMB control number 0938-1353); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 3,902; *Total Annual Responses:* 3,902; *Total Annual Hours:* 2,336,190. (For policy questions regarding this collection contact: Nikolas Berkobien at 301-492-4400.)

Dated: August 31, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2019-N-3402]

Advisory Committee; National Mammography Quality Assurance Advisory Committee; Renewal

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the National Mammography Quality Assurance Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the National Mammography Quality Assurance Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until July 7, 2023, expiration date.

DATES: Authority for the National Mammography Quality Assurance Advisory Committee will expire on July 7, 2023, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, 301-796-0400, email: aden.asefa@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the National Mammography Quality Assurance Advisory Committee (the Committee). The committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner.

The Commissioner is charged with the administration of the Federal Food, Drug and Cosmetic Act and various provisions of the Public Health Service Act. The Mammography Quality Standards Act of 1992 amends the Public Health Service Act to establish national uniform quality and safety standards for mammography facilities. The National Mammography Quality Assurance Advisory Committee advises the Secretary and, by delegation, the Commissioner or designee in discharging their responsibilities with

respect to establishing a mammography facilities certification program. The Committee shall advise the HHS Secretary and the Commissioner or designee on:

(A) Developing appropriate quality standards and regulations for mammography facilities;

(B) Developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;

(C) Developing regulations with respect to sanctions;

(D) Developing procedures for monitoring compliance with standards;

(E) Establishing a mechanism to investigate consumer complaints;

(F) Reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;

(G) Determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas;

(H) Determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and

(I) Determining the costs and benefits of compliance with these requirements.

The Committee shall consist of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Members will be invited to serve for overlapping terms of up to 4 years. Almost all members of this committee serve as Special Government Employees. The core of voting members shall include at least four individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least two practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include two nonvoting industry representative members who have expertise in mammography equipment. The Committee may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/NationalMammographyQualityAssuranceAdvisoryCommittee/>

[ucm520365.htm](https://www.fda.gov/ucm520365.htm) or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-19108 Filed 9-2-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0609]

Agency Information Collection Activities; Proposed Collection; Comment Request; Drug Supply Chain Security Act Implementation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection associated with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by November 2, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 2, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 2, 2021. Comments received by mail/hand delivery/courier (for written/paper

submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 do not wish 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-2014-D-0609 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Drug Supply Chain Security Act Implementation." Received comments, those filed in a timely manner (see **ADDRESSES**), 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