October 13, 2022

The Honorable Rosa DeLauro
U.S. House of Representatives
Washington, DC 20515

Dear Chair DeLauro:

Thank you for your letter of October 5, 2022, to the U.S. Food and Drug Administration (FDA) expressing interest in the proposed rule, *Mammography Quality Standards Act; Amendments to Part 900 Regulations*, including proposed regulations concerning the reporting of breast density.

As you know, FDA issued the proposed rule to amend regulations issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act on March 28, 2019. The comment period for the proposed rule closed on June 26, 2019, and since that date, FDA has analyzed the comments it received from stakeholders, including patients, physicians, public health organizations, trade associations, and industry, addressing over 350 distinct issues. FDA has considered those issues and comments, which in some cases include extensive attachments and references, in drafting its final rule. Finalizing this rule remains a priority for FDA.

In particular, as FDA noted in its proposed rule, FDA proposed to modernize and improve the regulations and information, including breast density information, provided by mammography facilities to patients and their healthcare providers. The proposed changes would require that the lay summary provided to patients identify whether the patient has one of two categories of density (whether the patient has low or high density breasts) and include a prescribed paragraph on the significance of breast density. The proposed regulations would also establish four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider. FDA's intent is to provide patients and healthcare providers with additional information about their mammography and the potential limitations of their mammogram results, so patients and their healthcare providers can make informed healthcare decisions.

FDA received many comments in support of the proposed rule and the breast density notification to patients. Other comments opposed the portions of the rule proposing breast density notification, for various reasons. As with all public comments to a proposed rulemaking, FDA considers all the comments it receives, and determines whether it would be appropriate to make any changes to its proposal.

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FDA acknowledges that the current date of anticipated publication of the final rule on the Unified Agenda (UA) is identified as September 2022, which has passed. However, we remain optimistic that the MQSA final rule will publish before the end of the 2022 calendar year or early 2023. In addition, we would be happy to provide a status update to your office when the draft has been accepted by the Office of Management and Budget for interagency review.

FDA remains committed to advancing our MQSA rulemaking and to ensuring that patients can access safer, more reliable mammography services, and that providers are supported by the current science in order to improve outcomes and reduce suffering. Thank you again for your interest in this important public health matter. Please do not hesitate to contact us should you have any additional concerns or questions, and we will continue to keep you updated as this rulemaking proceeds.

Sincerely,

Katherine Klimczak

Katherine Klimczak
Acting Legislative Director for
Appropriations