



UNITED STATES  
HOUSE OF REPRESENTATIVES

ROSA L. DELAURO  
3RD DISTRICT, CONNECTICUT

October 5, 2022

The Honorable Robert M. Califf  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

**Re: Mammography Quality Standards Act, Docket No. FDA-2013-N-0134**

Dear Commissioner Califf,

I write to you today regarding the Food and Drug Administration (FDA) pending Mammography Quality Standards Act (MQSA) Final Rule. In 2009, Connecticut became the first state to require letters be sent to patients following their mammogram with information about breast density. This effort was led by the late Dr. Nancy Cappello who, despite having received multiple mammograms, was not diagnosed with Stage 3c breast cancer until after a breast ultrasound was performed. Dr. Cappello had never been told she had dense breasts and thus was delayed in receiving the ultrasound and subsequent care.<sup>1</sup> Nearly half of all women over the age of forty have dense breasts, meaning they are at greater likelihood of having breast cancer.

Starting in 2011, I led Congressional efforts to require mammography facilities to include up-to-date information about breast density in both the written report of the results of a mammography examination provided to a patient's physician and the summary of that written report given to the patient. Ultimately the Consolidated Appropriations Act, 2019 (Public Law 116-6) included language from the Breast Density and Mammography Reporting Act. This report language stated the following:

“Breast Density. —The Committee recognizes the importance of patients receiving their own personal medical information and directs the Food and Drug Administration to ensure that mammography reports and summaries received by

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<sup>1</sup> Grady, Denise. “Nancy Cappello, Breast Cancer Activist, Is Dead at 66.” The New York Times, 28 Nov. 2018, [www.nytimes.com/2018/11/28/obituaries/nancy-cappello-dead.html](http://www.nytimes.com/2018/11/28/obituaries/nancy-cappello-dead.html).

patients and their providers include appropriate information about breast density specified by the Secretary, including:

- at a minimum, the effect of breast density in masking the presence of breast cancer on a mammogram,
- the qualitative assessment of the provider who interpreted the mammogram, and
- a reminder to patients that individuals with dense breast tissue should talk with their providers if they have any questions or concerns about their summary.”

On March 27, 2019, FDA announced its proposed amendments to the MQSA including the addition of breast density information to the “mammography lay summary letter provided to patients and to the medical report provided to their referring health care professionals.”<sup>2</sup> The Notice of Proposed Rule comment period ended on June 26, 2019,<sup>3</sup> and a final rule has yet to be issued more than three years later.

Researchers have found there were significant declines in screening mammography during the COVID-19 pandemic, and the resulting cases of delayed diagnosis could lead to nearly 2,500 excess breast cancer deaths according to one estimate.<sup>4</sup> It is imperative that as routine mammograms return to pre-pandemic levels, the nationwide breast density standard be implemented as soon as possible. Without this information, far too many will lack critical information about their dense breasts and subsequently face unnecessary suffering.

It is my understanding that the proposed rule is currently with FDA, is actively being worked on, and remains a priority for the agency. I recognize there are many updates to the MQSA in addition to this nationwide breast density reporting standard, but given the longstanding delay in addressing this issue I am requesting you provide my staff and I with the following:

1. An update on the expected timing for when the final rule will be issued;
2. A chronological account, beginning at enactment of Public Law 116-6 to date, of milestones and/or progress made on the breast density issue, including an explanation and/or rationale for the prolonged release of a final rule; and
3. Any additional information with respect to items 1 and 2 you may deem pertinent.

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<sup>2</sup> Commissioner, Office of the. “FDA Advances Landmark Policy Changes to Modernize Mammography Services and Improve Their Quality.” FDA, 24 Mar. 2020, [www.fda.gov/news-events/press-announcements/fda-advances-landmark-policy-changes-modernize-mammography-services-and-improve-their-quality](http://www.fda.gov/news-events/press-announcements/fda-advances-landmark-policy-changes-modernize-mammography-services-and-improve-their-quality). Accessed 5 Oct. 2022.

<sup>3</sup> <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AH04>

<sup>4</sup> Oguzhan Alagoz, PhD, Kathryn P Lowry, MD, Allison W Kurian, MD, MSc, Jeanne S Mandelblatt, MD, Mehmet A Ergun, PhD, Hui Huang, MS, Sandra J Lee, ScD, Clyde B Schechter, MD, Anna N A Tosteson, ScD, Diana L Miglioretti, PhD, Amy Trentham-Dietz, PhD, Sarah J Nyante, PhD, Karla Kerlikowske, MD, Brian L Sprague, PhD, Natasha K Stout, PhD, from the CISNET Breast Working Group, Impact of the COVID-19 Pandemic on Breast Cancer Mortality in the US: Estimates From Collaborative Simulation Modeling, *JNCI: Journal of the National Cancer Institute*, Volume 113, Issue 11, November 2021, Pages 1484–1494, <https://doi.org/10.1093/jnci/djab097>.

I am requesting you provide this information by Friday, October 14, 2022. Please contact Caitlin Peruccio, Legislative Counsel and Senior Policy Advisor, in my office with any questions. I appreciate your urgent attention to this matter. Women and their loved ones cannot wait any longer.

Sincerely,

A handwritten signature in black ink that reads "Rosa L. DeLauro". The signature is written in a cursive style with a large, looping initial "R".

Rosa L. DeLauro  
Member of Congress

CC: Jeff Shuren, M.D., J.D. Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration