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FDA advances policy changes to modernize mammography

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Proposed rule would require breast density reporting

The U.S. Food and Drug Administration (FDA) has announced important new steps to modernize breast cancer screening and help empower patients with more information when they are considering important decisions regarding their breast health care.

For the first time in more than 20 years of regulating mammography facilities, the agency is proposing amendments to key regulations that would help improve the quality of mammography services for millions of Americans.

These actions would expand the information mammography facilities must provide to patients and health care professionals, allowing for more informed medical decision-making. It would also modernize mammography quality standards and better position the FDA to enforce regulations that apply to the safety and quality of mammography services.

Among the proposed amendments to improve communication and medical decision making is 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.

The FDA is proposing specific language that would explain how breast density can influence the accuracy of mammography and would recommend patients with dense breasts talk to their health care provider about high breast density and how it relates to breast cancer risk and their individual situation.