A bill to be entitled

An act relating to informed consent for mammograms; creating s. 381.934, F.S.; requiring certain facilities to provide each patient with an informed consent form before performing a mammogram; requiring that the form be signed by patients; requiring the facility to notify patients of the form at a specified time; requiring the facility to post the form on its website; providing requirements for the form; requiring the facility to include a certain statement on the summary of a patient's mammography report; requiring the Department of Health to develop the form; providing an effective date.

WHEREAS, breast cancer is the second leading cause of cancer-related deaths among women in the United States, and

WHEREAS, when detected and treated early, women diagnosed with breast cancer have been shown to have a 93 percent or higher survival rate in the first 5 years after diagnosis, and

WHEREAS, early detection and best practices for detecting breast cancer are key to increasing the chances for successful treatment, and

WHEREAS, each woman's breast tissue is unique and may appear similar to cancerous tissue and as normal breast tissue, and

WHEREAS, mammograms are the best primary tool for breast cancer screening, and

WHEREAS, the Florida Cancer Control and Research Advisory Council within the H. Lee Moffitt Cancer Center and Research Institute, Inc., created the 2020-2025 Florida Cancer Plan, which includes a goal to "reduce breast cancer mortality through early detection of breast cancer," and

WHEREAS, the Legislature finds that the early detection of breast cancer and establishing best practices for breast cancer screenings may reduce breast cancer mortality, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.934, Florida Statutes, is created to read:

381.934 Informed consent for mammograms.—

(1)(a) Before performing a mammogram, a facility, as defined in 21 C.F.R. s. 900.2(q), as that definition exists on the effective date of this act, shall provide each patient with an informed consent form that must be signed by the patient.

(b) The facility must notify a patient of the informed consent form at the time of scheduling the patient's appointment. The facility shall also post the form on its website in a location readily accessible to patients and designated for scheduling appointments.

(2) The informed consent form must include, but need not be limited to, all of the following:

(a) A statement explaining that in 2011, the United States Food and Drug Administration approved three-dimensional (3-D) advanced mammography devices that provide informative images of breast tissue and may be helpful in evaluating dense breast tissue.

(b) A statement explaining that, compared to two-dimensional (2-D) digital mammography, studies have shown that 3-D digital mammography has improved breast cancer detection rates and has reduced the number of patients who may be required to return to a facility for unnecessary followup tests.

(c) Information regarding the differences between a standard 2-D digital mammogram and a 3-D digital mammogram.

(d) A statement indicating whether a patient will be receiving a 2-D digital mammogram or a 3-D digital mammogram.

(e) A statement emphasizing the importance of receiving an annual mammogram, regardless of whether the patient receives a 2-D digital mammogram or a 3-D digital mammogram.

(f) A statement recommending a patient to follow the advice of his or her health care provider.

(3) A facility must also include a statement on the summary of a patient's mammography report sent in accordance with 21 C.F.R. s. 900.12(c) which indicates whether or not the patient's mammogram was interpreted by a fellowship-trained

breast imaging radiologist.

(4) The Department of Health shall develop the patient informed consent form required under this section.

Section 2. This act shall take effect July 1, 2022.