

By Senator Bradley

5-01164-22

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1                   A bill to be entitled  
2       An act relating to informed consent for mammograms;  
3       creating s. 381.934, F.S.; requiring certain  
4       facilities to provide each patient with an informed  
5       consent form before performing a mammogram; requiring  
6       the form to be signed by the patient; requiring  
7       facilities to notify patients of the form at a  
8       specified time; requiring facilities to post the form  
9       on their websites; providing requirements for the  
10      form; requiring the Department of Health to develop  
11      the form; providing an effective date.

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

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

19       WHEREAS, early detection and best practices for detecting  
20      breast cancer are keys to increasing the chances for successful  
21      treatment, and

22       WHEREAS, each woman's breast tissue is unique and may  
23      appear similar to both cancerous tissue as well as normal breast  
24      tissue, and

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

27       WHEREAS, the Florida Cancer Control and Research Advisory  
28      Council within the H. Lee Moffitt Cancer Center and Research  
29      Institute, Inc., created the 2020-2025 Florida Cancer Plan,

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30 which includes a goal to "reduce breast cancer mortality through  
31 early detection of breast cancer," and

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

35

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

37

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

40 381.934 Informed consent for mammograms.-

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

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

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

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

56 (b) A statement explaining that studies have shown that 3-D  
57 digital mammography has improved breast cancer detection rates  
58 and has reduced the number of patients who may be required to

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59 return to a facility for follow-up screenings.

60 (c) Information regarding the differences between a  
61 standard two-dimensional (2-D) digital mammogram and a 3-D  
62 digital mammogram.

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

65 (e) A statement recommending that a patient follow the  
66 advice of his or her primary care physician.

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

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