

By Senator Grimsley

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1 A bill to be entitled
2 An act relating to mammography; amending s. 404.031,
3 F.S.; defining the term "mammography"; amending s.
4 404.22, F.S.; conforming a change made by the act;
5 creating s. 402.221, F.S.; requiring facilities
6 performing mammography to include certain information
7 in a summary of the mammography report which must be
8 provided to each patient; providing an effective date.

9
10 Be It Enacted by the Legislature of the State of Florida:

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12 Section 1. Present subsections (10) through (20) of section
13 404.031, Florida Statutes, are redesignated as subsections (11)
14 through (21), respectively, and a new subsection (10) is added
15 to that section, to read:

16 404.031 Definitions.—As used in this chapter, unless the
17 context clearly indicates otherwise, the term:

18 (10) "Mammography" means radiography of the breast for the
19 purpose of enabling a physician to determine the presence, size,
20 location, and extent of cancerous or potentially cancerous
21 tissue in the breast.

22 Section 2. Subsection (6) of section 404.22, Florida
23 Statutes, is amended to read:

24 404.22 Radiation machines and components; inspection.—

25 ~~(6) (a) For purposes of this subsection, "mammography" means~~
26 ~~radiography of the breast for the purpose of enabling a~~
27 ~~physician to determine the presence, size, location, and extent~~
28 ~~of cancerous or potentially cancerous tissue in the breast.~~

29 ~~(b)~~ All radiation machines used for mammography shall meet

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30 the accreditation criteria of the American College of Radiology
31 or similar criteria established by the department.

32 (b)~~(e)~~ All radiation machines used for mammography shall be
33 specifically designed to perform mammography.

34 (c)~~(d)~~ All radiation machines used for mammography shall be
35 used exclusively to perform mammography.

36
37 The department shall adopt rules to implement ~~the provisions of~~
38 this subsection.

39 Section 3. Section 402.221, Florida Statutes, is created to
40 read:

41 402.221 Mammography reports.—Each facility that performs
42 mammography shall send a summary of a patient's mammography
43 report to each patient in accordance with 21 C.F.R. s.
44 900.12(c).

45 (1) The summary must include information describing the
46 Breast Imaging-Reporting and Data System (BI-RADS) categories
47 established by the American College of Radiology and the
48 patient's individual BI-RADS categorical score.

49 (2) If a facility determines that a patient has
50 heterogeneously or extremely dense breasts, the summary must
51 include the following notice:

52
53 "Your mammogram shows that your breast tissue is dense.
54 Dense breast tissue is relatively common and is found in 40
55 percent of women. The presence of dense breast tissue makes it
56 more difficult to evaluate the results of your mammogram and may
57 also be associated with an increased risk of breast cancer. This
58 information is given to you so that you will be informed when

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59 you discuss your dense breast tissue and other breast cancer
60 risk factors with your health care providers. Together, you can
61 decide which screening options are right for you. A report of
62 your results was sent to your primary physician."

63 Section 4. This act shall take effect July 1, 2018.