

By the Committees on Rules; and Health Policy; and Senator Grimsley

595-03283-18

2018164c2

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. 404.221, 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 applicability;
9 providing for future repeal; providing an effective
10 date.

11
12 Be It Enacted by the Legislature of the State of Florida:

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

18 404.031 Definitions.—As used in this chapter, unless the
19 context clearly indicates otherwise, the term:

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

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

26 404.22 Radiation machines and components; inspection.—
27 ~~(6)(a) For purposes of this subsection, "mammography" means~~
28 ~~radiography of the breast for the purpose of enabling a~~
29 ~~physician to determine the presence, size, location, and extent~~

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30 ~~of cancerous or potentially cancerous tissue in the breast.~~

31 ~~(b)~~ All radiation machines used for mammography must:

32 (a) ~~shall~~ Meet the accreditation criteria of the American
33 College of Radiology or similar criteria established by the
34 department.

35 (b) ~~(e)~~ All radiation machines used for mammography shall Be
36 specifically designed to perform mammography.

37 (c) ~~(d)~~ All radiation machines used for mammography shall Be
38 used exclusively to perform mammography.

39
40 The department shall adopt rules to implement ~~the provisions of~~
41 this subsection.

42 Section 3. Section 404.221, Florida Statutes, is created to
43 read:

44 404.221 Mammography reports.—Each facility that performs
45 mammography shall send a summary of a patient's mammography
46 report to each patient in accordance with 21 C.F.R. s.
47 900.12(c). If a facility determines that a patient has
48 heterogeneously or extremely dense breasts, the summary must
49 include the following notice:

50
51 "Your mammogram shows that your breast tissue is dense.
52 Dense breast tissue is relatively common and is found in
53 approximately 50 percent of women. The presence of dense breast
54 tissue can make it more difficult to detect some abnormalities
55 in the breast and may also be associated with an increased risk
56 of breast cancer. This information about the results of your
57 mammogram is given to you to raise your awareness. A report of
58 your results was sent to your health care provider. Further

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59 recommendations may be added at the discretion of the
60 interpreting radiologist. Please be aware that additional
61 screening studies may not be covered by your insurance."

62
63 (1) This section does not create a duty, a standard of
64 care, or another legal obligation beyond the duty to provide
65 notice as required in this section.

66 (2) This section does not require a notice that is
67 inconsistent with the federal Mammography Quality Standards Act
68 or any regulation promulgated pursuant to that act.

69 (3) This section is repealed June 30, 2023.

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