

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

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

13  
 14           Section 1. Subsections (10) through (20) of section  
 15           404.031, Florida Statutes, are renumbered 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"~~  
 28 | ~~means radiography of the breast for the purpose of enabling a~~  
 29 | ~~physician to determine the presence, size, location, and extent~~  
 30 | ~~of cancerous or potentially cancerous tissue in the breast.~~

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

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

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

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

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

42 | Section 3. Section 402.221, Florida Statutes, is created  
 43 | to read:

44 | 402.221 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  
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, standard of care,  
64 or other legal obligation beyond the duty to provide notice as  
65 set forth 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.