

Bill No. SB 2470

Barcode 550682

CHAMBER ACTION

Senate

House

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The Committee on Health Care (Pruitt) recommended the following amendment:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

Section 1. Legislative findings.--

(1) The Legislature finds that it is of the utmost public importance that quality mammography services and other diagnostic tools remain available to detect and treat breast cancer.

(2) The Legislature finds that the current litigious environment and low reimbursement rates threaten the availability of mammography services for all women in the state.

(3) The Legislature finds that the rapidly growing population and the changing demographics of the state make it imperative that medical students continue to choose this state as the place they will receive their medical educations, complete their residency requirements, and practice radiology.

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1 (4) The Legislature finds that radiologists providing
2 mammography services are in a unique class of physicians who
3 have little or no direct patient contact and generally have no
4 established physician-patient relationship.

5 (5) The Legislature finds that the State of Florida is
6 among the states with the highest medical malpractice
7 insurance premiums in the nation.

8 (6) The Legislature finds that the cost of medical
9 malpractice insurance has increased dramatically during the
10 past decade and both the increase and the current cost are
11 substantially higher than the national average.

12 (7) The Legislature finds that the increase in medical
13 malpractice liability insurance rates is forcing physicians,
14 including radiologists, to practice medicine without
15 professional liability insurance, to leave the state, to not
16 perform high-risk procedures such as mammograms, or to retire
17 early from the practice of medicine.

18 (8) The Legislature finds that the 2003 Governor's
19 Select Task Force on Healthcare Professional Liability
20 Insurance has established that a medical malpractice crisis
21 exists in the state which can be alleviated by the adoption of
22 legislatively enacted comprehensive reforms.

23 (9) The Legislature finds that making high-quality
24 health care, including mammography services, available to the
25 citizens of the state is an overwhelming public necessity.

26 (10) The Legislature finds that ensuring that
27 physicians continue to practice radiology in the state is an
28 overwhelming public necessity.

29 (11) The Legislature finds that ensuring the
30 availability of affordable professional liability insurance
31 for physicians is an overwhelming public necessity.

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1 (12) The Legislature finds that, based upon the
2 findings and recommendations of the Workgroup on Mammography
3 Accessibility, the Governor's Select Task Force on Healthcare
4 Professional Liability Insurance, the Office of Program Policy
5 Analysis and Government Accountability, and the various study
6 groups throughout the nation and based on the experience of
7 other states, the overwhelming public necessity of making
8 quality health care, including mammography services, available
9 to the citizens of the state, ensuring that physicians
10 continue to practice radiology in the state, and ensuring that
11 those physicians have the opportunity to purchase affordable
12 professional liability insurance cannot be met unless
13 limitations on medical malpractice lawsuits are imposed.

14 (13) The Legislature finds that the high cost of
15 medical malpractice claims can be substantially alleviated by
16 imposing limitations on medical malpractice lawsuits relating
17 to mammography services.

18 (14) The Legislature further finds that there is no
19 alternative measure for alleviating the high cost of medical
20 malpractice claims without imposing even greater limits upon
21 the ability of persons to recover damages for medical
22 malpractice.

23 (15) The Legislature finds that the provisions of this
24 act are naturally and logically connected to each other and to
25 the purpose of making quality mammography services available
26 to the women of the state.

27 (16) The Legislature finds that each provision of this
28 act is necessary to alleviate the crisis relating to
29 mammography accessibility in the state.

30 Section 2. Subsection (7) is added to section 456.077,
31 Florida Statutes, to read:

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1 456.077 Authority to issue citations.--

2 (7) The Board of Medicine and the Board of Osteopathic
3 Medicine may issue a citation in lieu of disciplinary action
4 for the first allegation brought against a physician alleging
5 a failure to diagnose breast cancer through the interpretation
6 of a mammogram. The board, in issuing the citation, may impose
7 up to 10 additional hours of continuing education in
8 mammography interpretation. This paragraph does not prohibit
9 the Board of Medicine or the Board of Osteopathic Medicine
10 from proceeding with a disciplinary investigation and
11 prosecution if aggravating circumstances exist.

12 Section 3. Section 766.119, Florida Statutes, is
13 created to read:

14 766.119 Actions relating to mammograms.--

15 (1) This section applies to any civil action brought
16 pursuant to this chapter against a physician licensed in this
17 state pursuant to chapter 458 or chapter 459 for any action or
18 omission arising from the performance of his or her duties
19 relating to mammograms and to any facility that provides
20 mammography services.

21 (2)(a) Prior to the performance of any radiologic test
22 for the screening of breast cancer, a physician or entity may
23 request that the patient read and execute a form giving
24 written informed consent to the physician and facility to
25 administer the screening. The written informed consent shall
26 include an explanation of the screening, including its purpose
27 and limitations, shall be evidenced in writing, and shall be
28 validly signed by the patient or another legally authorized
29 person. A valid signature is one which is given by a person
30 who under all the surrounding circumstances is mentally and
31 physically competent to give consent.

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1 (b) A physician or entity is presumed to have acted
2 within the appropriate standard of care in the interpretation
3 of a mammogram if the physician or entity obtains informed
4 consent from a patient as provided in this section, unless the
5 physician or entity interpreting the mammogram fails to detect
6 an abnormality that is clear and obvious to a reasonable
7 physician with the same level of mammography training and
8 experience who is provided the same information about the
9 patient's medical history and condition known at the time of
10 the mammogram by the interpreting physician who is alleged to
11 have failed to detect the abnormality.

12 (c) The written informed consent used under this
13 section shall include the following language in at least
14 10-point type: "Mammography is a screening tool, not a test,
15 used to detect some breast cancers. While not perfect, it is
16 the best tool available for the early detection of breast
17 cancer. Knowing that not all breast cancers are detected by
18 mammography, it is essential that you also perform a monthly
19 breast self-examination and have your breasts examined yearly
20 by a physician."

21 (d) The written informed consent used under this
22 section shall include the following language in at least
23 10-point type at the end of the document but before the
24 signature line: "I have read this information about detecting
25 breast cancer and while I understand that a normal mammogram
26 is reassuring, I also realize that not all cancers may be
27 detected by mammography."

28 (e) In no event shall a physician's or entity's
29 noncompliance with the provisions of this section create a
30 presumption of negligence on the part of the physician or
31 entity for any action or omission arising from the performance

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1 any duty relating to mammograms.

2 (3) The protections and limitations provided by this
3 section apply only if:

4 (a) The mammography is performed in concordance with
5 the Mammography Quality Standards Act regulations in a
6 facility that has an active and valid certificate issued by
7 the United States Food and Drug Administration, meets the
8 quality standards required by the United States Food and Drug
9 Administration, and is accredited by an approved accreditation
10 body or other entity as designated by the United States Food
11 and Drug Administration.

12 (b) The interpreting physician has a minimum of 60
13 hours of documented medical education in mammography, which
14 shall include instruction in the interpretation of mammograms
15 and education in basic breast anatomy, pathology, physiology,
16 technical aspects of mammography, and quality assurance and
17 quality control in mammography.

18 (c) The mammography equipment used meets the
19 Mammography Quality Standards Act final rule as published by
20 the United States Food and Drug Administration and is
21 specifically designed for mammography and is certified
22 pursuant to s. 1010.2 of the Federal Register as meeting the
23 applicable requirements of ss. 1020.30 and 1020.31 of the
24 Federal Register in effect at the date of manufacture.
25 Radiographic equipment designed for general purpose or special
26 nonmammography procedures, including systems that have been
27 modified or equipped with special attachments for mammography,
28 shall not be used for mammography.

29 (d) The radiographic equipment used for mammography is
30 specifically designed for mammography and is certified
31 pursuant to s. 1010.2 of the Federal Register as meeting the

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1 applicable requirements of ss. 1020.30 and 1020.31 of the
2 Federal Register in effect at the date of manufacture.

3 (e) The facility performing the mammography screening
4 conducts daily, weekly, monthly, quarterly, and annual quality
5 control tests as required by the United States Food and Drug
6 Administration.

7 (f) The facility performing the mammography screening
8 has established and maintained a quality assurance program to
9 ensure the safety, reliability, clarity, and accuracy of
10 mammography services performed at the facility.

11 (g) The facility performing the mammography screening
12 has established and maintained a mammography medical outcomes
13 audit program to ensure the reliability, clarity, and accuracy
14 of the interpretation of mammograms.

15 (4) A subsequent mammogram may not be used by an
16 expert witness or a finder of fact in determining the failure
17 to diagnose breast cancer.

18 Section 4. If any provision of this act or its
19 application to any person or circumstance is held invalid, the
20 invalidity does not affect other provisions or applications of
21 the act which can be given effect without the invalid
22 provision or application, and to this end the provisions of
23 this act are severable.

24 Section 5. It is the intent of the Legislature to
25 apply the provisions of this act to prior medical incidents,
26 to the extent such application is not prohibited by the State
27 Constitution or the United States Constitution, except that
28 the changes to chapter 766, Florida Statutes, shall apply only
29 to any medical incident for which a notice of intent to
30 initiate litigation is mailed on or after the effective date
31 of this act.

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1 Section 6. This act shall take effect July 1, 2005.

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4 ===== T I T L E A M E N D M E N T =====

5 And the title is amended as follows:

6 Delete everything before the enacting clause

7

8 and insert:

9 A bill to be entitled

10 An act relating to mammography; providing
 11 legislative findings and intent; amending s.
 12 456.077, F.S.; authorizing the Board of
 13 Medicine and the Board of Osteopathic Medicine
 14 to issue citations and to require additional
 15 education in certain circumstances; providing
 16 that either board may nevertheless proceed with
 17 a disciplinary investigation and prosecution if
 18 there are aggravating circumstances; creating
 19 s. 766.119, F.S.; providing for informed
 20 consent prior to the performance of a
 21 mammogram; creating a presumption that a
 22 physician is operating within the appropriate
 23 standard of care when obtaining informed
 24 consent; providing an exception; providing
 25 limitations; providing a limitation on the use
 26 of subsequent mammograms as evidence in certain
 27 negligence actions; providing for severability;
 28 providing applicability; providing an effective
 29 date.

30

31 WHEREAS, breast cancer is the second leading cause of

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1 cancer deaths in women, and

2 WHEREAS, breast cancer affects all of us through our
3 spouses, mothers, daughters, sisters, aunts, nieces, friends,
4 and neighbors, and

5 WHEREAS, there are three main tools available to detect
6 breast cancer: breast examinations by a health care
7 practitioner, breast self-examinations, and screening
8 mammograms, and

9 WHEREAS, although mammography is an imperfect screening
10 tool, it is still the best method available to detect breast
11 cancer, and

12 WHEREAS, early detection of breast cancer decreases
13 mortality by 30 percent, and

14 WHEREAS, screening mammograms need to be widely
15 available to all women at risk regardless of geographic
16 location, race, type of or nonexistence of insurance, or
17 socioeconomic status, and

18 WHEREAS, the Workgroup on Mammography Accessibility
19 created by the Legislature under Senate Bill 2306 in the 2004
20 Regular Session found that population growth combined with a
21 growing shortage of interpreting radiologists will have an
22 adverse effect on the future availability of mammography
23 services, and

24 WHEREAS, radiologists are reluctant to provide
25 screening mammography services because of the high cost of
26 obtaining professional liability insurance in comparison to
27 the low reimbursements received and the fear of a medical
28 malpractice lawsuit being brought against a radiologist who is
29 not able to detect every single instance of a cancerous or
30 precancerous condition, and

31 WHEREAS, in 2004, the Legislature directed the Office

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1 of Program Policy Analysis and Government Accountability to
2 study issues relating to mammography services in the state,
3 and

4 WHEREAS, the Office of Program Policy Analysis and
5 Government Accountability found that one of the factors
6 limiting access to mammography services in the state is the
7 fear of medical malpractice lawsuits which is causing some
8 radiologists to limit the number of mammograms they interpret,
9 and

10 WHEREAS, the Department of Health conducted a survey
11 and found that 17 percent of the facilities surveyed had
12 appointment wait times exceeding 28 days for screening
13 mammograms, and

14 WHEREAS, the Workgroup on Mammography Accessibility
15 found that mammography facilities in the state have
16 high-quality personnel and equipment and a high level of
17 compliance with safety and other standards of care, as
18 demonstrated by the results of inspections by the United
19 States Food and Drug Administration, and

20 WHEREAS, the Workgroup on Mammography Accessibility
21 found that national data show that most defendants in alleged
22 medical malpractice claims involving breast cancer are
23 radiologists and that only claims for neurologically impaired
24 newborns are more expensive than breast cancer in terms of
25 indemnity dollars, and

26 WHEREAS, the Legislature has previously recognized that
27 two other medical specialists, obstetricians and emergency
28 room physicians, have such a high risk of liability claims
29 that access to these services is in jeopardy without statutory
30 protection limiting the damages available to patients and
31 their families, and

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1 WHEREAS, funds from professional liability insurance
2 are not an appropriate or adequate substitute for health
3 insurance, disability insurance, or life insurance, and
4 WHEREAS, breast cancer is not caused by physicians, and
5 WHEREAS, the Legislature must take action to protect
6 the advancements made in the diagnosis, treatment, and
7 awareness of breast cancer through the tireless efforts of
8 groups such as the Susan B. Komen Foundation, the American
9 Cancer Society, the American College of Radiology, and others,
10 and
11 WHEREAS, the Workgroup on Mammography Accessibility
12 made eight recommendations to the Legislature to ensure that
13 mammography will continue to be available to women in Florida,
14 that there are enough radiologists available to interpret
15 mammograms, that the fear of lawsuits or high medical
16 liability insurance premiums does not deter physicians from
17 entering the field of radiology and the interpretation of
18 mammograms, and that utilization of mammography is increased
19 in medically underserved populations, NOW, THEREFORE,
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