

CHAMBER ACTION

1 The Judiciary Committee recommends the following:

2
3 **Council/Committee Substitute**

4 Remove the entire bill and insert:

5 A bill to be entitled

6 An act relating to mammography; providing legislative
7 findings and intent; amending s. 456.077, F.S.;
8 authorizing the Board of Medicine and the Board of
9 Osteopathic Medicine to issue citations and to require
10 additional education in certain circumstances; creating s.
11 766.119, F.S.; providing for informed consent prior to the
12 performance of a mammogram; creating a presumption that a
13 physician is operating within the appropriate standard of
14 care when obtaining informed consent; providing an
15 exception; providing limitations; providing a limitation
16 on the use of subsequent mammograms as evidence in certain
17 negligence actions; providing for severability; providing
18 applicability; providing an effective date.

19
20 WHEREAS, breast cancer is the second leading cause of
21 cancer deaths in women, and

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22 WHEREAS, breast cancer affects all of us through our
23 spouses, mothers, daughters, sisters, aunts, nieces, friends,
24 and neighbors, and

25 WHEREAS, there are three main tools available to detect
26 breast cancer: breast examinations by a health care
27 practitioner, breast self-examinations, and screening
28 mammograms, and

29 WHEREAS, although mammography is an imperfect screening
30 tool, it is still the best method available to detect breast
31 cancer, and

32 WHEREAS, early detection of breast cancer decreases
33 mortality by 30 percent, and

34 WHEREAS, screening mammograms need to be widely available
35 to all women at risk regardless of geographic location, race,
36 type of or nonexistence of insurance, or socioeconomic status,
37 and

38 WHEREAS, the Workgroup on Mammography Accessibility created
39 by the Legislature under Senate Bill 2306 in the 2004 Regular
40 Session found that population growth combined with a growing
41 shortage of interpreting radiologists will have an adverse
42 effect on the future availability of mammography services, and

43 WHEREAS, radiologists are reluctant to provide screening
44 mammography services because of the high cost of obtaining
45 professional liability insurance in comparison to the low
46 reimbursements received and the fear of a medical malpractice
47 lawsuit being brought against a radiologist who is not able to
48 detect every single instance of a cancerous or precancerous
49 condition, and

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50 WHEREAS, in 2004, the Legislature directed the Office of
51 Program Policy Analysis and Government Accountability to study
52 issues relating to mammography services in the state, and

53 WHEREAS, the Office of Program Policy Analysis and
54 Government Accountability found that one of the factors limiting
55 access to mammography services in the state is the fear of
56 medical malpractice lawsuits which is causing some radiologists
57 to limit the number of mammograms they interpret, and

58 WHEREAS, the Department of Health conducted a survey and
59 found that 17 percent of the facilities surveyed had appointment
60 wait times exceeding 28 days for screening mammograms, and

61 WHEREAS, the Workgroup on Mammography Accessibility found
62 that mammography facilities in the state have high-quality
63 personnel and equipment and a high level of compliance with
64 safety and other standards of care, as demonstrated by the
65 results of inspections by the United States Food and Drug
66 Administration, and

67 WHEREAS, the Workgroup on Mammography Accessibility found
68 that national data show that most defendants in alleged medical
69 malpractice claims involving breast cancer are radiologists and
70 that only claims for neurologically impaired newborns are more
71 expensive than breast cancer in terms of indemnity dollars, and

72 WHEREAS, the Legislature has previously recognized that two
73 other medical specialists, obstetricians and emergency room
74 physicians, have such a high risk of liability claims that
75 access to these services is in jeopardy without statutory
76 protection limiting the damages available to patients and their
77 families, and

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78 WHEREAS, funds from professional liability insurance are
79 not an appropriate or adequate substitute for health insurance,
80 disability insurance, or life insurance, and

81 WHEREAS, breast cancer is not caused by physicians, and

82 WHEREAS, the Legislature must take action to protect the
83 advancements made in the diagnosis, treatment, and awareness of
84 breast cancer through the tireless efforts of groups such as the
85 Susan B. Komen Foundation, the American Cancer Society, the
86 American College of Radiology, and others, and

87 WHEREAS, the Workgroup on Mammography Accessibility made
88 eight recommendations to the Legislature to ensure that
89 mammography will continue to be available to women in Florida,
90 that there are enough radiologists available to interpret
91 mammograms, that the fear of lawsuits or high medical liability
92 insurance premiums does not deter physicians from entering the
93 field of radiology and the interpretation of mammograms, and
94 that utilization of mammography is increased in medically
95 underserved populations, NOW, THEREFORE,

96

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

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99 Section 1. Legislative findings.--

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

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

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

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

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

119 (6) The Legislature finds that the cost of medical
 120 malpractice insurance has increased dramatically during the past
 121 decade and both the increase and the current cost are
 122 substantially higher than the national average.

123 (7) The Legislature finds that the increase in medical
 124 malpractice liability insurance rates is forcing physicians,
 125 including radiologists, to practice medicine without
 126 professional liability insurance, to leave the state, to not
 127 perform high-risk procedures such as mammograms, or to retire
 128 early from the practice of medicine.

129 (8) The Legislature finds that the 2003 Governor's Select
 130 Task Force on Healthcare Professional Liability Insurance has
 131 established that a medical malpractice crisis exists in the

132 state which can be alleviated by the adoption of legislatively
 133 enacted comprehensive reforms.

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

137 (10) The Legislature finds that ensuring that physicians
 138 continue to practice radiology in the state is an overwhelming
 139 public necessity.

140 (11) The Legislature finds that ensuring the availability
 141 of affordable professional liability insurance for physicians is
 142 an overwhelming public necessity.

143 (12) The Legislature finds that, based upon the findings
 144 and recommendations of the Workgroup on Mammography
 145 Accessibility, the Governor's Select Task Force on Healthcare
 146 Professional Liability Insurance, the Office of Program Policy
 147 Analysis and Government Accountability, and the various study
 148 groups throughout the nation and based on the experience of
 149 other states, the overwhelming public necessity of making
 150 quality health care, including mammography services, available
 151 to the citizens of the state, ensuring that physicians continue
 152 to practice radiology in the state, and ensuring that those
 153 physicians have the opportunity to purchase affordable
 154 professional liability insurance cannot be met unless
 155 limitations on medical malpractice lawsuits are imposed.

156 (13) The Legislature finds that the high cost of medical
 157 malpractice claims can be substantially alleviated by imposing
 158 limitations on medical malpractice lawsuits relating to
 159 mammography services.

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160 (14) The Legislature further finds that there is no
 161 alternative measure for alleviating the high cost of medical
 162 malpractice claims without imposing even greater limits upon the
 163 ability of persons to recover damages for medical malpractice.

164 (15) The Legislature finds that the provisions of this act
 165 are naturally and logically connected to each other and to the
 166 purpose of making quality mammography services available to the
 167 women of the state.

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

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

173 456.077 Authority to issue citations.--

174 (7) The Board of Medicine and the Board of Osteopathic
 175 Medicine may issue a citation in lieu of disciplinary action for
 176 the first allegation brought against a physician alleging a
 177 failure to diagnose breast cancer through the interpretation of
 178 a mammogram. The board, in issuing the citation, may impose up
 179 to 10 additional hours of continuing education in mammography
 180 interpretation.

181 Section 3. Section 766.119, Florida Statutes, is created
 182 to read:

183 766.119 Actions relating to mammograms.--

184 (1) This section applies to any civil action brought
 185 pursuant to this chapter against a physician licensed in this
 186 state pursuant to chapter 458 or chapter 459 for any action or
 187 omission arising from the performance of his or her duties

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188 relating to mammograms and to any facility that provides
189 mammography services.

190 (2)(a) Prior to the performance of any radiologic test for
191 the screening of breast cancer, a physician or entity may
192 request that the patient read and execute a form giving written
193 informed consent to the physician and facility to administer the
194 screening. The written informed consent shall include a fair
195 explanation of the screening, including its purpose and
196 limitations, shall be evidenced in writing, and shall be validly
197 signed by the patient or another legally authorized person. A
198 valid signature is one which is given by a person who under all
199 the surrounding circumstances is mentally and physically
200 competent to give consent.

201 (b) A physician or entity is presumed to have acted within
202 the appropriate standard of care in the interpretation of a
203 mammogram if the physician or entity obtains informed consent
204 from a patient as provided in this section, unless the physician
205 or entity interpreting the mammogram fails to detect an
206 abnormality that is clear and obvious to a reasonable physician
207 with the same level of mammography training and experience who
208 is provided the same information about the patient's medical
209 history and condition known at the time of the mammogram by the
210 interpreting physician who is alleged to have failed to detect
211 the abnormality.

212 (c) The written informed consent used under this section
213 shall include the following language in at least 10-point type:
214 "Mammography is a screening tool, not a test, used to detect
215 some breast cancers. While not perfect, it is the best tool

216 available for the early detection of breast cancer. Knowing that
 217 not all breast cancers are detected by mammography, it is
 218 essential that you also perform a monthly breast self-
 219 examination and have your breasts examined yearly by a
 220 physician."

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

227 (e) In no event shall a physician's or entity's
 228 noncompliance with the provisions of this section create a
 229 presumption of negligence on the part of the physician or entity
 230 for any action or omission arising from the performance any duty
 231 relating to mammograms.

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

234 (a) The mammography is performed in concordance with the
 235 Mammography Quality Standards Act regulations in a facility that
 236 has an active and valid certificate issued by the United States
 237 Food and Drug Administration, meets the quality standards
 238 required by the United States Food and Drug Administration, and
 239 is accredited by an approved accreditation body or other entity
 240 as designated by the United States Food and Drug Administration.

241 (b) The interpreting physician has a minimum of 60 hours
 242 of documented medical education in mammography, which shall
 243 include instruction in the interpretation of mammograms and

244 education in basic breast anatomy, pathology, physiology,
 245 technical aspects of mammography, and quality assurance and
 246 quality control in mammography.

247 (c) The mammography equipment used meets the Mammography
 248 Quality Standards Act final rule as published by the United
 249 States Food and Drug Administration and is specifically designed
 250 for mammography and is certified pursuant to s. 1010.2 of the
 251 Federal Register as meeting the applicable requirements of ss.
 252 1020.30 and 1020.31 of the Federal Register in effect at the
 253 date of manufacture. Radiographic equipment designed for general
 254 purpose or special nonmammography procedures, including systems
 255 that have been modified or equipped with special attachments for
 256 mammography, shall not be used for mammography.

257 (d) The radiographic equipment used for mammography is
 258 specifically designed for mammography and is certified pursuant
 259 to s. 1010.2 of the Federal Register as meeting the applicable
 260 requirements of ss. 1020.30 and 1020.31 of the Federal Register
 261 in effect at the date of manufacture.

262 (e) The facility performing the mammography screening
 263 conducts daily, weekly, monthly, quarterly, and annual quality
 264 control tests as required by the United States Food and Drug
 265 Administration.

266 (f) The facility performing the mammography screening has
 267 established and maintained a quality assurance program to ensure
 268 the safety, reliability, clarity, and accuracy of mammography
 269 services performed at the facility.

270 (g) The facility performing the mammography screening has
 271 established and maintained a mammography medical outcomes audit

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272 program to ensure the reliability, clarity, and accuracy of the
 273 interpretation of mammograms.

274 (4) A subsequent mammogram may not be used by an expert
 275 witness or a finder of fact in determining the failure to
 276 diagnose breast cancer when the subsequent mammogram was
 277 performed more than 3 months after the mammogram that is alleged
 278 to have been incorrectly interpreted.

279 Section 4. If any provision of this act or its application
 280 to any person or circumstance is held invalid, the invalidity
 281 does not affect other provisions or applications of the act
 282 which can be given effect without the invalid provision or
 283 application, and to this end the provisions of this act are
 284 severable.

285 Section 5. It is the intent of the Legislature to apply
 286 the provisions of this act to prior medical incidents, to the
 287 extent such application is not prohibited by the State
 288 Constitution or the United States Constitution, except that the
 289 changes to chapter 766, Florida Statutes, shall apply only to
 290 any medical incident for which a notice of intent to initiate
 291 litigation is mailed on or after the effective date of this act.

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