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A bill to be entitled

An act relating to freestanding diagnostic imaging facilities; creating pt. V of ch. 483, F.S., the Florida Freestanding Diagnostic Imaging Facilities Law; creating s. 483.95, F.S.; providing a popular name; creating s. 483.951, F.S.; declaring policy and purpose; creating s. 483.952, F.S.; providing exemptions from the act; creating s. 483.953, F.S.; providing definitions; creating s. 483.954, F.S.; granting rulemaking authority, powers, and duties to the Agency for Health Care Administration; providing standards, fees, and licensing requirements; creating s. 483.955, F.S.; providing for inspection of facilities; creating s. 483.956, F.S.; providing for licensing of facilities and requirements; providing for licensing denials and revocations; creating s. 483.9565, F.S.; providing for licensure application and application requirements; creating s. 483.957, F.S.; requiring a facility to have a medical director; providing requirements for the director; creating s. 483.958, F.S.; requiring facilities to display licenses; creating s. 483.959, F.S.; providing for disciplinary actions against facilities in specified circumstances; creating s. 483.9591, F.S.; providing administrative penalties; creating s. 483.9595, F.S.; providing for offenses; creating s. 483.95955, F.S.; providing criminal penalties; creating s. 483.9596, F.S.; authorizing injunctive actions to be brought against unlicensed facilities; prohibiting claims to be filed by unlicensed facilities; providing an effective date.



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

32
 33 Section 1. Part V of chapter 483, consisting of sections
 34 483.95, 483.951, 483.952, 483.953, 483.954, 483.955, 483.956,
 35 483.9565, 483.957, 483.958, 483.959, 483.9591, 483.9595,
 36 483.95955, and 483.9596, Florida Statutes, is created to read:

37 PART V

38 FREESTANDING DIAGNOSTIC IMAGING FACILITIES

39 483.95 Popular name.--This part may be known by the
 40 popular name "The Florida Freestanding Diagnostic Imaging
 41 Facilities Law."

42 483.951 Declaration of policy and statement of
 43 purpose.--The purpose of this part is to protect the health,
 44 safety, and welfare of the people of this state from the hazards
 45 of improper performance by freestanding diagnostic imaging
 46 facilities. Diagnostic imaging facilities provide, among other
 47 things, certain physician-ordered diagnostic imaging services,
 48 including computerized axial tomography (CAT scan), magnetic
 49 resonance imaging (MRI), ultrasound, and certain nuclear
 50 medicine procedures, which are performed at the facility by
 51 trained technicians under the supervision of physicians. Some
 52 facilities utilize equipment that is obsolete or poorly
 53 maintained. Images produced by such equipment lack sufficient
 54 resolution and detail to enable a physician to render a
 55 consistently reliable diagnosis or treatment decision. An
 56 inaccurate diagnosis or treatment decision may cause unnecessary
 57 anxiety, suffering, and additional financial expense for
 58 individuals and their insurers and other third-party payors, or
 59 may create a false and injudicious sense of security with
 60 respect to the state of an individual's health, and may even



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61 contribute directly to an individual's death. Improving the
62 quality of health care in the manner provided in this part will
63 have a positive effect upon the cost of professional liability
64 insurance for professionals and other providers. Therefore, the
65 Legislature finds and declares that the protection of the public
66 health requires the licensing of such facilities, the
67 establishment of certain minimum standards for the equipment and
68 professional staff used in such facilities, and other necessary
69 safeguards as authorized by this part.

70 483.952 Application of part; exemptions.--This part
71 applies to all freestanding diagnostic imaging facilities within
72 the state, but does not apply to:

73 (1) An entity operated by the United States Government,
74 the state, or any political subdivision of the state.

75 (2) An entity that limits screening to tests intended to
76 identify specific physical disorders or conditions and that
77 provides health services to the public free of charge or for a
78 donation to be used for charitable purposes.

79 (3) A hospital licensed under chapter 395.

80 (4) An ambulatory surgical facility licensed under chapter
81 395.

82 (5) A health maintenance organization certified under part
83 I of chapter 641.

84 (6) An office that is operated by a physician licensed
85 under chapter 458 or chapter 459.

86 483.953 Definitions.--As used in this part:

87 (1) "Agency" means the Agency for Health Care
88 Administration.

89 (2) "Computerized axial tomography" or "CAT scan" means a
90 series of X-ray images as slices of the human body that are



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91 integrated by computer to create a two-dimensional image of the
92 body and its internal structures along various axes.

93 (3) "Consumer freestanding diagnostic imaging facilities"
94 are freestanding diagnostic imaging facilities that are open to
95 the general public.

96 (4) "Facility personnel" includes persons employed by a
97 facility, but does not include persons employed to perform
98 clerical or other administrative responsibilities.

99 (5) "Freestanding diagnostic imaging facility" or
100 "facility" means any fixed or mobile facility where computerized
101 axial tomography technology, magnetic resonance imaging,
102 ultrasound, or nuclear medicine is used to make diagnostic
103 images.

104 (6) "Magnetic resonance imaging" or "MRI" means a
105 procedure that uses magnetic signals, as opposed to X rays, to
106 create image slices of soft tissues, blood vessels, and other
107 body structures that are integrated by computer to create highly
108 detailed two-dimensional images of the human body along various
109 axes.

110 (7) "Nuclear medicine" includes a variety of medical
111 procedures including bone scans, scans of various internal
112 organs, cardiac stress tests utilizing radiopharmaceuticals, and
113 positron emission tomography (PET) scanning. Each of these
114 procedures involves introduction into the human body of low-
115 level radioactive material that is absorbed by the specific body
116 structure or diseased tissue to be studied. Specialized scanners
117 are then used to collect data regarding the concentrations of
118 radioactive material absorbed by the specific body structure or
119 tissue being studied.



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120 (8) "Ultrasound" means a procedure that uses reflected
121 soundwaves, similar to sonar, transmitted and collected by a
122 transducer, which creates a real-time image of internal body
123 structures.

124 483.954 Powers and duties of the agency; rules.--The
125 agency shall adopt rules to implement this part, which rules
126 must include the following:

127 (1) LICENSING STANDARDS.--The agency shall license all
128 freestanding diagnostic imaging facilities meeting the
129 requirements of this part and shall prescribe standards
130 necessary for licensure.

131 (2) FEES.--The agency shall establish annual fees, which
132 shall be reasonable in amount, for licensing of facilities. The
133 fees must be sufficient in amount to cover the cost of licensing
134 and inspecting facilities.

135 (a) The annual licensure fee is due at the time of
136 application and is payable to the agency to be deposited in the
137 Health Care Trust Fund administered by the agency. The licensure
138 fee must be not less than \$300 nor more than \$1,000.

139 (b) The fee for the late filing of an application for
140 license renewal is \$200 and is in addition to the licensure fee
141 due for renewing the license.

142 (3) ANNUAL LICENSING.--The agency shall provide for annual
143 licensing of facilities. Any facility that fails to pay the
144 proper fee or otherwise fails to qualify by the date of
145 expiration of its license is delinquent, and its license is
146 automatically canceled without notice or further proceeding.
147 Upon cancellation of its license under this subsection, a
148 facility may have its license reinstated only upon application



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149 and qualification as provided for initial applicants and upon
150 payment of all delinquent fees.

151 (4) STANDARDS OF PERFORMANCE.--The agency shall prescribe
152 standards for the performance of freestanding diagnostic imaging
153 facilities.

154 (5) CONSTRUCTION OF FACILITIES.--The agency may adopt
155 rules to ensure that facilities comply with all local, county,
156 state, and federal standards for the construction, renovation,
157 maintenance, or repair of facilities, which standards must
158 ensure the conduct and operation of the facilities in a manner
159 that shall protect the public health.

160 (6) SAFETY AND SANITARY CONDITIONS WITHIN THE FACILITY AND
161 ITS SURROUNDINGS.--The agency shall establish standards relating
162 to safety and sanitary conditions within the facility and its
163 surroundings, including water supply, sewage, storage of
164 chemicals, workspace, fire safety, and general measures, which
165 standards must ensure the protection of the public health.

166 (7) EQUIPMENT.--The agency shall establish minimum
167 detailed quality-related standards for facility equipment
168 essential to the proper conduct and operation of the facility,
169 including the resolution of images generated by such equipment
170 and other requirements that recognize the importance of using
171 up-to-date technology. This may include requiring facilities to
172 use specified equipment and technology that is approved by the
173 FDA and is not obsolete.

174 (8) DIAGNOSTIC RECORDS.--The agency shall establish
175 minimum standards relating to the accuracy and retention of
176 medical records prepared and maintained by diagnostic imaging
177 facilities. This includes standards of review to determine
178 compliance.



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179 483.955 Inspection of facilities.--The agency shall, at
180 least annually, inspect the premises and operations of all
181 facilities subject to licensure under this part, without prior
182 notice to the facilities, for the purpose of studying and
183 evaluating the operation, supervision, and procedures of such
184 facilities to determine their compliance with agency standards
185 and to determine their effect upon the health and safety of the
186 people of this state. This inspection shall include an
187 evaluation to determine that the facility's equipment is meeting
188 specific standards of performance and is performing according to
189 the manufacturer's specifications and an evaluation of accuracy
190 and timeliness of the diagnostic reports prepared by such
191 facilities.

192 483.956 Licensing of facilities.--

193 (1) A person may not conduct, maintain, or operate a
194 freestanding diagnostic imaging facility in this state without
195 obtaining a freestanding diagnostic imaging facility license
196 from the agency. The license is valid only for the person or
197 persons to whom it is issued and may not be sold, assigned, or
198 transferred, voluntarily or involuntarily. A license is not
199 valid for any premises other than the facility for which it is
200 issued. However, a new license may be secured for the new
201 location for a fixed facility before the actual change, if the
202 change is in compliance with this part and the rules adopted
203 under this part. A facility must be relicensed if a change of
204 ownership occurs. Application for relicensure must be made 60
205 days before the change of ownership.

206 (2) Each applicant for licensure must comply with the
207 following requirements:



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208 (a) Upon receipt of a completed, signed, and dated
209 application, the agency shall require background screening, in
210 accordance with the level 2 standards for screening set forth in
211 chapter 435, of the managing employee, or other similarly titled
212 individual who is responsible for the daily operation of the
213 facility, and of the financial officer, or other similarly
214 titled individual who is responsible for the financial operation
215 of the facility, including billings for patient services. The
216 applicant must comply with the procedures for level 2 background
217 screening as set forth in chapter 435, as well as the
218 requirements of s. 435.03(3).

219 (b) The agency may require background screening of any
220 other individual who is an applicant if the agency has probable
221 cause to believe that he or she has been convicted of a crime or
222 has committed any other offense prohibited under the level 2
223 standards for screening set forth in chapter 435.

224 (c) Proof of compliance with the level 2 background
225 screening requirements of chapter 435 which has been submitted
226 within the previous 5 years in compliance with any other health
227 care licensure requirements of this state is acceptable in
228 fulfillment of the requirements of paragraph (a).

229 (d) A provisional license may be granted to an applicant
230 when each individual required by this section to undergo
231 background screening has met the standards for the Department of
232 Law Enforcement background check but the agency has not yet
233 received background screening results from the Federal Bureau of
234 Investigation, or a request for a disqualification exemption has
235 been submitted to the agency as set forth in chapter 435 but a
236 response has not yet been issued. A license may be granted to
237 the applicant upon the agency's receipt of a report of the



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238 results of the Federal Bureau of Investigation background
239 screening for each individual required by this section to
240 undergo background screening which confirms that all standards
241 have been met, or upon the granting of a disqualification
242 exemption by the agency as set forth in chapter 435. Any other
243 person who is required to undergo level 2 background screening
244 may serve in his or her capacity pending the agency's receipt of
245 the report from the Federal Bureau of Investigation. However,
246 such person may not continue to serve if the report indicates
247 any violation of background screening standards and a
248 disqualification exemption has not been requested of and granted
249 by the agency as set forth in chapter 435.

250 (e) Each applicant shall submit to the agency, with its
251 application, a description and explanation of any exclusions,
252 permanent suspensions, or terminations of the applicant from the
253 Medicare or Medicaid program. Proof of compliance with the
254 requirements for disclosure of ownership and control interests
255 under the Medicaid or Medicare program may be accepted in lieu
256 of this submission.

257 (f) Each applicant shall submit to the agency a
258 description and explanation of any conviction of an offense
259 prohibited under the level 2 standards of chapter 435 by a
260 member of the board of directors of the applicant, its officers,
261 or any individual owning 5 percent or more of the applicant.
262 This requirement does not apply to a director of a not-for-
263 profit corporation or organization if the director serves solely
264 in a voluntary capacity for the corporation or organization,
265 does not regularly take part in the day-to-day operational
266 decisions of the corporation or organization, receives no
267 remuneration for his or her services on the corporation or



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268 organization's board of directors, and has no financial interest
 269 and has no family members with a financial interest in the
 270 corporation or organization; provided that the director and the
 271 not-for-profit corporation or organization include in the
 272 application a statement affirming that the director's
 273 relationship to the corporation satisfies the requirements of
 274 this paragraph.

275 (g) A license may not be granted to an applicant if the
 276 applicant or managing employee has been found guilty of,
 277 regardless of adjudication, or has entered a plea of nolo
 278 contendere or guilty to, any offense prohibited under the level
 279 2 standards for screening set forth in chapter 435, unless an
 280 exemption from disqualification has been granted by the agency
 281 as set forth in chapter 435.

282 (h) The agency may deny or revoke licensure if the
 283 applicant:

284 1. Has falsely represented a material fact in the
 285 application required by paragraph (e) or paragraph (f), or has
 286 omitted any material fact from the application required by
 287 paragraph (e) or paragraph (f); or

288 2. Has had prior action taken against the applicant under
 289 the Medicaid or Medicare program as set forth in paragraph (e).

290 (i) An application for license renewal must contain the
 291 information required under paragraphs (e) and (f).

292 483.9565 Application for license.--

293 (1) Application for a license as required by s. 483.956
 294 must be made to the agency on forms furnished by it and must be
 295 accompanied by the appropriate license fee.

296 (2) The application shall contain:



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297 (a) A determination as to whether the facility will be
298 fixed or mobile and the location for a fixed facility.

299 (b) The name and address of the owner if an individual; if
300 the owner is a firm, partnership, or association, the name and
301 address of every member thereof; or if the owner is a
302 corporation, its name and address and the name and address of
303 its medical director, officers, and each person having at least
304 a 10 percent interest in the corporation.

305 (c) The name of any person whose name is required on the
306 application under the provisions of paragraph (b) and who owns
307 at least a 10 percent interest in any professional service,
308 firm, association, partnership, or corporation providing goods,
309 leases, or services to the facility for which the application is
310 made, and the name and address of the professional service,
311 firm, association, partnership, or corporation in which such
312 interest is held.

313 (d) The name by which the facility is to be known.

314 (e) The name, address, and Florida physician's license
315 number of the medical director.

316 483.957 Medical director of facility.--Each facility
317 licensed under this part shall employ a medical director who is
318 a physician licensed under chapter 458 or chapter 459 and who is
319 a board certified radiologist or nuclear medicine physician.

320 483.958 Display of license.--The license of a facility
321 must specify, on its face, the names and addresses of the owner
322 and the medical director, the period for which the license is
323 valid, and, in the case of fixed facilities, the location at
324 which procedures are performed. The license must be displayed at
325 all times in a prominent place at the facility, where it is
326 visible to the public.



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327 483.959 Grounds for disciplinary action against
328 facilities.--The following acts constitute grounds for which a
329 disciplinary action specified in s. 483.9591 may be taken
330 against a facility:

331 (1) Making a fraudulent statement on an application for a
332 license or on any other document required by the agency pursuant
333 to this part.

334 (2) Permitting unauthorized persons to operate a
335 freestanding diagnostic imaging center in violation of this
336 part.

337 (3) Rendering a report on the results of any test to a
338 person not authorized by law to receive such information.

339 (4) Knowingly having professional connection with, or
340 knowingly lending the use of the name of the licensed facility
341 or its medical director to, an unlicensed facility.

342 (5) Violating, or aiding and abetting in the violation of,
343 any provision of this part or the rules adopted hereunder.

344 (6) Failing to file any report required by the provisions
345 of this part or the rules adopted hereunder.

346 483.9591 Administrative penalties.--

347 (1)(a) The agency may deny, suspend, revoke, annul, limit,
348 or deny renewal of a license or impose an administrative fine,
349 not to exceed \$500 per violation, for the violation of any
350 provision of this part or rules adopted hereunder. Each day of
351 violation constitutes a separate violation and is subject to a
352 separate fine.

353 (b) In determining the amount of the fine to be levied for
354 a violation, as provided in paragraph (a), the following factors
355 shall be considered:



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356 1. The severity of the violation, including the
 357 probability that death or serious harm to the health or safety
 358 of any person will result or has resulted; the severity of the
 359 actual or potential harm; and the extent to which the provisions
 360 of this part were violated.

361 2. Actions taken by the licensee to correct the violation
 362 or to remedy complaints.

363 3. Any previous violation by the licensee.

364 4. The financial benefit to the licensee of committing or
 365 continuing the violation.

366 (c) All amounts collected under this subsection must be
 367 deposited into the Health Care Trust Fund administered by the
 368 agency.

369 (2) The agency may issue an emergency order immediately
 370 suspending, revoking, annulling, or limiting a license when it
 371 determines that any condition in the licensed facility presents
 372 a clear and present danger to public health and safety.

373 483.9595 Offenses.--It is unlawful for any person to:

374 (1) Operate, maintain, direct, or engage in the business
 375 of operating a freestanding diagnostic imaging facility unless
 376 the person has obtained a license for the facility.

377 (2) Conduct, maintain, or operate a facility unless the
 378 facility is under the direct and responsible supervision and
 379 direction of a medical director who meets the qualifications
 380 specified in s. 483.3957(1).

381 (3) Violate, or aid and abet in the violation of, any
 382 provision of this part or the rules adopted under this part.

383 483.95955 Criminal penalties.--



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384 (1) The performance of any of the acts specified in s.
385 483.3995 is a misdemeanor of the second degree, punishable as
386 provided in s. 775.082 or s. 775.083.

387 (2) Any use or attempted use of a forged license under
388 this part is a felony of the third degree, punishable as
389 provided in s. 775.082, s. 775.083, or s. 775.084.

390 483.9596 Unlicensed facilities.--

391 (1) INJUNCTION.--The operation or maintenance of an
392 unlicensed facility or the performance of any diagnostic imaging
393 procedures or operations in violation of this part is declared a
394 nuisance and inimical to the public health, welfare, and safety.
395 The agency, or any state attorney in the name of the people of
396 the state, may, in addition to other remedies provided in this
397 part, bring an action for an injunction to restrain such
398 violation, or to enjoin the future operation or maintenance of
399 any such facility or the performance of any health testing
400 procedures or operations in violation of this part, until
401 compliance with the provisions of this part or the rules adopted
402 under this part has been demonstrated to the satisfaction of the
403 agency.

404 (2) CLAIMS.--All charges or reimbursement claims made by
405 or on behalf of a facility that is required to be registered
406 under this section but that is not so registered are unlawful
407 charges and therefore are noncompensable and unenforceable.

408 Section 2. This act shall take effect upon becoming a law.