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1 A bill to be entitled

2 An act relating to independent diagnostic testing
3 facilities; creating part XIV of chapter 400, F.S.;
4 providing a popular name; providing legislative findings;
5 providing definitions; providing licensing requirements;
6 providing application requirements and deadlines;
7 providing for temporary licensure; requiring background
8 screening of all applicants; restricting the issuance of
9 licenses under certain circumstances; providing for fees;
10 providing for inspections of facilities by the Agency for
11 Health Care Administration; providing for emergency
12 suspension of licenses; providing for administrative fines
13 and investigation fees; requiring license renewal and
14 providing requirements thereof; requiring application for
15 change of ownership under certain circumstances and
16 providing requirements thereof; restricting transfers of
17 licenses; providing for provisional licenses in certain
18 circumstances; requiring the agency to adopt rules;
19 requiring the agency to calculate certain fees; providing
20 requirements; providing for deposit of collected fees in
21 the Health Care Trust Fund; providing that it is unlawful
22 to own, operate, or maintain a facility without a license;
23 providing criminal penalties; providing for fines;
24 providing penalties for health care providers who fail to
25 report unlicensed facilities under certain circumstances;
26 requiring the president, director, medical director, or
27 chief executive officer of each independent diagnostic
28 testing facility to accept certain responsibilities;
29 requiring new independent diagnostic testing facilities to

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30 apply for licensure within a certain timeframe;
 31 restricting eligibility of certain claims; providing
 32 penalties for unlicensed activity; providing penalties for
 33 health care providers in violation; providing authority to
 34 the agency to suspend or revoke licenses issued; providing
 35 for investigations for compliance; providing for exemption
 36 from licensure under certain circumstances; requiring
 37 independent diagnostic testing facilities to display
 38 licenses; requiring accreditation for licensure; granting
 39 full faith and credit to magnetic resonance imaging
 40 independent diagnostic testing facilities under certain
 41 circumstances; authorizing the agency to pursue injunctive
 42 relief under certain circumstances; providing criteria;
 43 providing for a standard of review for agency actions;
 44 authorizing administrative penalties and providing
 45 criteria thereof; providing for procedures to correct
 46 violations; providing for interest on administrative
 47 fines; providing fines; providing for plans of corrective
 48 action in certain circumstances; providing for deposit of
 49 administrative fines in the Health Care Trust Fund;
 50 providing an effective date.

51

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

53

54 Section 1. Part XIV of chapter 400, Florida Statutes,
 55 consisting of sections 400.9970, 400.9971, 400.9972, 400.9973,
 56 400.9974, 400.9975, 400.9976, 400.9977, 400.9978, 400.9979, and
 57 400.9980, Florida Statutes, is created to read:

58 400.9970 Popular name; legislative findings.--

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59 (1) This part may be referred to by the popular name the
60 "Independent Diagnostic Testing Facility Act."

61 (2) The Legislature finds that the regulation of
62 independent diagnostic testing facilities must be strengthened
63 to prevent significant cost and harm to consumers. The purpose
64 of this part is to provide for the licensure, establishment, and
65 enforcement of basic standards for independent diagnostic
66 testing facilities and to provide for the administrative
67 oversight of such testing facilities by the Agency for Health
68 Care Administration.

69 400.9971 Definitions.--As used in this part:

70 (1) "Agency" means the Agency for Health Care
71 Administration.

72 (2) "Applicant" means an individual, partnership,
73 corporation, or other business entity that owns or controls 5
74 percent or more of an interest in the independent diagnostic
75 testing facility, but does not include the limited partners in
76 limited liability partnerships or an individual who is
77 responsible for the day-to-day operation or financial operation
78 of the independent diagnostic testing facility.

79 (3) "Independent diagnostic testing facility" means an
80 individual, partnership, corporation, or other business entity
81 that performs the technical components of magnetic resonance
82 imaging, static radiographs, computer tomography, and position
83 emission tomography, and provides the professional components of
84 such services, in a fixed facility that is accredited by the
85 Joint Commission on Accreditation of Healthcare Organizations
86 and the American College of Radiology within 1 year after
87 licensure and:

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88 (a) Does not accept patient referrals prohibited by s.
 89 456.053(5).

90 (b) Does not directly or indirectly provide therapy or
 91 treatment services to patients for whom it also provides
 92 diagnostic imaging services.

93 (c) Does not include any entity which has an investor as
 94 defined by s. 456.053(3) or include any one of the following:

95 1. Any individual or entity that is directly or indirectly
 96 an investor in a clinic; or

97 2. Any individual or entity that directly or indirectly
 98 provides services to a clinic if such services include the
 99 referral of patients to any provider of diagnostic imaging
 100 services as defined in s. 456.053(3).

101 (d) Is not a clinic as defined in s. 400.9905.

102 400.9972 License requirements; background screenings;
 103 prohibitions.--

104 (1) Each independent diagnostic testing facility shall be
 105 licensed and maintain a valid license with the agency. Each
 106 independent diagnostic testing facility location shall be
 107 licensed separately even if the independent diagnostic testing
 108 facility is operated under the same business name or management
 109 as another independent diagnostic testing facility.

110 (2) The initial independent diagnostic testing facility
 111 license application shall be filed with the agency by all
 112 independent diagnostic testing facilities on or before March 1,
 113 2005. An independent diagnostic testing facility license shall
 114 be renewed biennially.

115 (3) Applicants that submit an application on or before
 116 March 1, 2005, which meets all requirements for initial

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117 licensure shall receive a temporary license until the completion
118 of an initial inspection verifying that the applicant meets all
119 requirements in the rules authorized by s. 400.9975. However, a
120 clinic engaged in magnetic resonance imaging services may not
121 receive a temporary license unless it presents evidence
122 satisfactory to the agency that such clinic is making a good
123 faith effort and substantial progress in seeking accreditation
124 required under s. 400.9935.

125 (4) Application for an initial independent diagnostic
126 testing facility license or for renewal of an existing license
127 shall be notarized on forms furnished by the agency and shall be
128 accompanied by the appropriate license fee as specified in s.
129 400.9975. The agency shall take final action on an initial
130 license application within 60 days after receipt of all required
131 documentation.

132 (5) The application shall contain information that
133 includes, but need not be limited to, the name, residence and
134 business addresses, phone numbers, social security number, and
135 license number of each applicant and each licensed medical
136 provider employed or under contract with the independent
137 diagnostic testing facility.

138 (6) The application shall include satisfactory proof that
139 the independent diagnostic testing facility is in compliance
140 with this part and applicable rules, including the number and
141 discipline of each professional staff member to be employed.

142 (7) Upon receipt of a completed, signed, and dated
143 application, the agency shall require background screening of
144 the applicant, in accordance with the level 2 standards for
145 screening set forth in chapter 435. Proof of compliance with the

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146 level 2 background screening requirements of chapter 435 which
 147 has been submitted within the previous 5 years in compliance
 148 with any other health care licensure requirements of this state
 149 is acceptable in fulfillment of this subsection.

150 (8) Each applicant shall submit with the application a
 151 description and explanation of any exclusions, permanent
 152 suspensions, or terminations of an applicant from the Medicare
 153 or Medicaid program. Proof of compliance with the requirements
 154 for disclosure of ownership and control interest under the
 155 Medicaid or Medicare program may be accepted in lieu of this
 156 submission. The description and explanation may indicate whether
 157 such exclusions, suspensions, or terminations were voluntary or
 158 involuntary on the part of the applicant.

159 (9) A license may not be granted to an independent
 160 diagnostic testing facility if the applicant has been found
 161 guilty of, or has entered a plea of nolo contendere or guilty
 162 to, any offense prohibited under the level 2 standards for
 163 screening set forth in chapter 435, or a violation of insurance
 164 fraud under s. 817.234, within the past 5 years. If the
 165 applicant has been convicted of an offense prohibited under the
 166 level 2 standards or insurance fraud in any jurisdiction, the
 167 applicant shall show that his or her civil rights have been
 168 restored prior to submitting an application.

169 (10) The agency may deny or revoke licensure if the
 170 applicant has falsely represented any material fact or omitted
 171 any material fact from the application required by this part.

172 (11) Requested information omitted from an application for
 173 licensure, license renewal, or transfer of ownership shall be
 174 filed with the agency within 21 days after receipt of the

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175 agency's request for omitted information or the application
 176 shall be deemed incomplete and withdrawn from further
 177 consideration.

178 (12) The failure to file a timely renewal application
 179 shall result in a late fee charged to the independent diagnostic
 180 testing facility in an amount equal to 50 percent of the current
 181 license fee.

182 400.9973 Independent diagnostic testing facility
 183 inspections; emergency suspension; costs.--

184 (1) An authorized officer or employee of the agency shall
 185 make inspections of the independent diagnostic testing facility
 186 as part of the initial license application or renewal
 187 application. The application for an independent diagnostic
 188 testing facility license or renewal issued under this part
 189 constitutes permission for an appropriate agency inspection to
 190 verify the information submitted in connection with the
 191 application or renewal.

192 (2) An authorized officer or employee of the agency may
 193 make unannounced inspections of independent diagnostic testing
 194 facilities licensed pursuant to this part as are necessary to
 195 determine that such facilities are in compliance with this part
 196 and with applicable rules. A licensed independent diagnostic
 197 testing facility shall allow full and complete access to the
 198 premises and to billing records or information to any
 199 representative of the agency who makes an inspection to
 200 determine compliance with this part and with applicable rules.

201 (3) Failure by an independent diagnostic testing facility
 202 licensed under this part to allow full and complete access to
 203 the premises and to billing records or information to any

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204 representative of the agency who makes a request to inspect the
 205 independent diagnostic testing facility to determine compliance
 206 with this part constitutes grounds for emergency suspension of
 207 the license by the agency pursuant to s. 120.60(6).

208 (4) In addition to any administrative fines imposed, the
 209 agency may assess a fee equal to the cost of conducting a
 210 complaint investigation.

211 400.9974 License renewal; transfer of ownership;
 212 provisional license.--

213 (1) An application for license renewal shall contain
 214 information as required by the agency.

215 (2) An application for license renewal shall be submitted
 216 to the agency 90 days before the expiration date of the license.

217 (3) The independent diagnostic testing facility shall file
 218 with the license renewal application satisfactory proof that it
 219 is in compliance with this part and applicable rules.

220 (4) When transferring the ownership of an independent
 221 diagnostic testing facility, the transferee shall submit an
 222 application for a license at least 60 days before the effective
 223 date of the transfer. An application for change of ownership of
 224 an independent diagnostic testing facility is required only when
 225 45 percent or more of the ownership, voting shares, or
 226 controlling interest of an independent diagnostic testing
 227 facility is transferred or assigned, including the final
 228 transfer or assignment of multiple transfers or assignments over
 229 a 2-year period that cumulatively total 45 percent or more.

230 (5) The license may not be sold, leased, assigned, or
 231 otherwise transferred and is valid only for the independent
 232 diagnostic testing facility owners and location for which

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233 originally issued.

234 (6) An independent diagnostic testing facility against
 235 whom a revocation or suspension proceeding is pending at the
 236 time of license renewal may be issued a provisional license
 237 until final disposition by the agency of such proceedings. If
 238 judicial relief is sought from the final disposition, the agency
 239 may issue a temporary license for the duration of the judicial
 240 proceeding.

241 400.9975 Rulemaking authority; license fees.--

242 (1) The agency shall adopt rules necessary to administer
 243 the independent diagnostic testing facility administration,
 244 regulation, and licensure program, including rules establishing
 245 the specific licensure requirements, procedures, forms, and
 246 fees. The agency shall adopt rules establishing a procedure for
 247 the biennial renewal of licenses. The agency may issue initial
 248 licenses for less than the full 2-year period by charging a
 249 prorated licensure fee and specifying a different renewal date
 250 than would otherwise be required for biennial licensure. The
 251 rules shall specify the expiration dates of licenses and any
 252 other conditions of renewal.

253 (2) License application and renewal fees shall be
 254 reasonably calculated by the agency to cover the agency's costs
 255 in carrying out the agency's responsibilities under this part,
 256 including the cost of licensure, inspection, and regulation of
 257 independent diagnostic testing facilities, and shall be of such
 258 amount that the total fees collected do not exceed the cost of
 259 administering and enforcing compliance with this part.
 260 Independent diagnostic testing facility licensure fees are
 261 nonrefundable and may not exceed \$2,000. The agency shall adjust

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262 the license fee annually by not more than the change in the
 263 Consumer Price Index based on the 12 months immediately
 264 preceding the increase. All fees collected under this part shall
 265 be deposited in the Health Care Trust Fund for the
 266 administration of this part.

267 400.9976 Unlicensed independent diagnostic testing
 268 facilities; penalties; fines; verification of licensure
 269 status.--

270 (1) It is unlawful to own, operate, or maintain an
 271 independent diagnostic testing facility without obtaining a
 272 license under this part.

273 (2) Any person who owns, operates, or maintains an
 274 unlicensed independent diagnostic testing facility commits a
 275 felony of the third degree, punishable as provided in s.
 276 775.082, s. 775.083, or s. 775.084. Each day of continued
 277 operation is a separate offense.

278 (3) Any person who violates subsection (2) a second or
 279 subsequent time commits a felony of the second degree,
 280 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
 281 Each day of continued operation is a separate offense.

282 (4) Any person who owns, operates, or maintains an
 283 unlicensed independent diagnostic testing facility due to a
 284 change in this part or a modification in agency rules within 6
 285 months after the effective date of such change or modification
 286 and who, within 10 working days after receiving notification
 287 from the agency, fails to cease operation or apply for a license
 288 under this part commits a felony of the third degree, punishable
 289 as provided in s. 775.082, s. 775.083, or s. 775.084. Each day
 290 of continued operation is a separate offense.

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291 (5) Any independent diagnostic testing facility that fails
 292 to cease operation after agency notification may be fined for
 293 each day of noncompliance pursuant to this part.

294 (6) Any person aware of the operation of an unlicensed
 295 independent diagnostic testing facility shall report that
 296 facility to the agency.

297 (7) Any health care provider who is aware of the operation
 298 of an unlicensed independent diagnostic testing facility shall
 299 report that facility to the agency. Failure to report an
 300 independent diagnostic testing facility that the provider knows
 301 or has reasonable cause to suspect is unlicensed shall be
 302 reported to the provider's licensing board.

303 (8) The agency may not issue a license to an independent
 304 diagnostic testing facility that has any unpaid fines assessed
 305 under this part.

306 400.9977 Independent diagnostic testing facility
 307 responsibilities.--

308 (1) The president, director, medical director, or chief
 309 executive officer of each independent diagnostic testing
 310 facility shall agree in writing to accept legal responsibility
 311 for the following activities on behalf of the independent
 312 diagnostic testing facility:

313 (a) Ensuring that all practitioners providing health care
 314 services or supplies to patients maintain a current active and
 315 unencumbered Florida license.

316 (b) Reviewing any patient referral contracts or agreements
 317 executed by the independent diagnostic testing facility.

318 (c) Ensuring that all health care practitioners at the
 319 independent diagnostic testing facility have active, appropriate

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320 certification or licensure for the level of care being provided.

321 (d) Serving as the independent diagnostic testing facility
 322 records owner as defined in s. 456.057.

323 (e) Ensuring compliance with the recordkeeping, office
 324 surgery, and adverse incident reporting requirements of chapter
 325 456, the respective practice acts, and rules adopted under this
 326 part.

327 (f) Conducting systematic reviews of independent
 328 diagnostic testing facility billings to ensure that the billings
 329 are not fraudulent or unlawful. Upon discovery of an unlawful
 330 charge, the medical director or independent diagnostic testing
 331 facility director shall take immediate corrective action.

332 (2) Any business that becomes an independent diagnostic
 333 testing facility after commencing operations shall, within 5
 334 days after becoming an independent diagnostic testing facility,
 335 file a license application under this part and shall be subject
 336 to all provisions of this part applicable to an independent
 337 diagnostic testing facility.

338 (3) All charges or reimbursement claims made by or on
 339 behalf of an independent diagnostic testing facility that is
 340 required to be licensed under this part but that is not so
 341 licensed, or that is otherwise operating in violation of this
 342 part, are unlawful charges and therefore are noncompensable and
 343 unenforceable.

344 (4) Any person establishing, operating, or managing an
 345 unlicensed independent diagnostic testing facility otherwise
 346 required to be licensed under this part, or any person who
 347 knowingly files a false or misleading license application or
 348 license renewal application, or false or misleading information

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349 related to such application or department rule, commits a felony
 350 of the third degree, punishable as provided in s. 775.082, s.
 351 775.083, or s. 775.084.

352 (5) Any licensed health care provider who violates this
 353 part is subject to discipline in accordance with this chapter
 354 and his or her respective practice act.

355 (6) The agency may fine, or suspend or revoke the license
 356 of, any independent diagnostic testing facility licensed under
 357 this part for operating in violation of the requirements of this
 358 part or the rules adopted by the agency.

359 (7) The agency shall investigate allegations of
 360 noncompliance with this part and the rules adopted under this
 361 part.

362 (8) Any person or entity providing health care services
 363 which is not an independent diagnostic testing facility may
 364 voluntarily apply for a certificate of exemption from licensure
 365 under its exempt status with the agency on a form that sets
 366 forth its name, or names and addresses, a statement of the
 367 reasons it cannot be defined as an independent diagnostic
 368 testing facility, and other information deemed necessary by the
 369 agency.

370 (9) The independent diagnostic testing facility shall
 371 display its license in a conspicuous location within the
 372 independent diagnostic testing facility readily visible to all
 373 patients.

374 (10)(a) In order to remain licensed, an independent
 375 diagnostic testing facility shall be accredited by the Joint
 376 Commission on Accreditation of Healthcare Organizations and the
 377 American College of Radiology within 1 year after licensure.

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378 However, an independent diagnostic testing facility may request
 379 a single, 6-month extension if it provides evidence to the
 380 agency establishing that, for good cause shown, such independent
 381 diagnostic testing facility cannot be accredited within 1 year
 382 after licensure and that such accreditation will be completed
 383 within the 6-month extension. After obtaining accreditation as
 384 required by this paragraph, each such independent diagnostic
 385 testing facility shall maintain accreditation as a condition of
 386 renewal of its license.

387 (b) The agency may disallow the application of any entity
 388 formed for the purpose of avoiding compliance with the
 389 accreditation provisions of this subsection and whose principals
 390 were previously principals of an entity that was unable to meet
 391 the accreditation requirements within the specified timeframes.
 392 The agency may adopt rules as to the accreditation of magnetic
 393 resonance imaging independent diagnostic testing facilities.

394 (11) The agency shall give full faith and credit
 395 pertaining to any past variance and waiver granted to a magnetic
 396 resonance imaging independent diagnostic testing facility from
 397 Rule 64-2002, Florida Administrative Code, by the Department of
 398 Health, until September 1, 2004. After that date, such
 399 independent diagnostic testing facility shall request a variance
 400 and waiver from the agency under s. 120.542.

401 400.9978 Injunctions.--

402 (1) The agency may institute injunctive proceedings in a
 403 court of competent jurisdiction in order to:

404 (a) Enforce the provisions of this part or any minimum
 405 standard, rule, or order issued or entered into pursuant to this
 406 part if the attempt by the agency to correct a violation through

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407 administrative fines has failed; if the violation materially
 408 affects the health, safety, or welfare of independent diagnostic
 409 testing facility patients; or if the violation involves any
 410 operation of an unlicensed independent diagnostic testing
 411 facility.

412 (b) Terminate the operation of an independent diagnostic
 413 testing facility if a violation of any provision of this part,
 414 or any rule adopted pursuant to this part, materially affects
 415 the health, safety, or welfare of independent diagnostic testing
 416 facility patients.

417 (2) Such injunctive relief may be temporary or permanent.

418 (3) If action is necessary to protect independent
 419 diagnostic testing facility patients from life-threatening
 420 situations, the court may allow a temporary injunction without
 421 bond upon proper proof being made. If it appears by competent
 422 evidence or a sworn, substantiated affidavit that a temporary
 423 injunction should be issued, the court, pending the
 424 determination on final hearing, shall enjoin operation of the
 425 independent diagnostic testing facility.

426 400.9979 Agency actions.--Administrative proceedings
 427 challenging agency licensure enforcement action shall be
 428 reviewed on the basis of the facts and conditions that resulted
 429 in the agency action.

430 400.9980 Agency administrative penalties.--

431 (1) The agency may impose administrative penalties against
 432 independent diagnostic testing facilities of up to \$5,000 per
 433 violation for violations of the requirements of this part. In
 434 determining whether a penalty is to be imposed and in fixing the
 435 amount of the fine, the agency shall consider the following

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436 factors:

437 (a) The gravity of the violation, including the
438 probability that death or serious physical or emotional harm to
439 a patient will result or has resulted, the severity of the
440 action or potential harm, and the extent to which the provisions
441 of the applicable laws or rules were violated.

442 (b) Actions taken by the owner, medical director, or
443 independent diagnostic testing facility director to correct
444 violations.

445 (c) Any previous violations.

446 (d) The financial benefit to the independent diagnostic
447 testing facility of committing or continuing the violation.

448 (2) Each day of continuing violation after the date fixed
449 for termination of the violation, as ordered by the agency,
450 constitutes an additional, separate, and distinct violation.

451 (3) Any action taken to correct a violation shall be
452 documented in writing by the owner, medical director, or
453 independent diagnostic testing facility director and verified
454 through followup visits by agency personnel. The agency may
455 impose a fine and, in the case of an owner-operated independent
456 diagnostic testing facility, revoke or deny an independent
457 diagnostic testing facility's license when an independent
458 diagnostic testing facility medical director or independent
459 diagnostic testing facility director fraudulently misrepresents
460 actions taken to correct a violation.

461 (4) For fines that are upheld following administrative or
462 judicial review, the violator shall pay the fine, plus interest
463 at the rate as specified in s. 55.03, for each day beyond the
464 date set by the agency for payment of the fine.

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465 (5) Any unlicensed independent diagnostic testing facility
466 that continues to operate after agency notification is subject
467 to a \$1,000 fine per day.

468 (6) Any independent diagnostic testing facility whose
469 owner fails to apply for a change-of-ownership license in
470 accordance with s. 400.9974 and operates the independent
471 diagnostic testing facility under the new ownership is subject
472 to a fine of \$5,000.

473 (7) The agency, as an alternative to or in conjunction
474 with an administrative action against an independent diagnostic
475 testing facility for violations of this part and adopted rules,
476 shall, prior to written notification, make a reasonable attempt
477 to discuss each violation and recommended corrective action with
478 the owner, director, or medical director of the independent
479 diagnostic testing facility. The agency, instead of fixing a
480 period within which the independent diagnostic testing facility
481 shall enter into compliance with standards, may request a plan
482 of corrective action from the independent diagnostic testing
483 facility which demonstrates a good faith effort to remedy each
484 violation by a specific date, subject to the approval of the
485 agency.

486 (8) Administrative fines paid by any independent
487 diagnostic testing facility under this section shall be
488 deposited into the Health Care Trust Fund.

489 Section 2. This act shall take effect July 1, 2004.