

By Senator Alexander

17-632-04

1 A bill to be entitled
2 An act relating to independent diagnostic
3 testing facilities; creating part XIV of ch.
4 400, F.S., entitled the Independent Diagnostic
5 Testing Facility Act; providing for definitions
6 and exclusions; providing for the licensure,
7 inspection, and regulation of independent
8 diagnostic testing facilities by the Agency for
9 Health Care Administration; requiring licensure
10 of facilities and background screening of
11 applicants for licensure; providing for
12 facility inspections; providing rulemaking
13 authority; providing licensure fees; providing
14 fines and penalties for operating an unlicensed
15 facility; providing for facility
16 responsibilities with respect to personnel and
17 operations; providing accreditation
18 requirements; providing for injunctive
19 proceedings and agency actions; providing
20 administrative penalties; providing an
21 effective date.

22
23 Be It Enacted by the Legislature of the State of Florida:

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25 Section 1. Part XIV of chapter 400, consisting of
26 sections 400.996, 400.9961, 400.9962, 400.9963, 400.9964,
27 400.9965, 400.9966, 400.9967, 400.9968, 400.9969, and 400.997,
28 Florida Statutes, is created to read:

29 400.996 Short title; legislative findings.--
30 (1) This part, consisting of ss. 400.996-400.997, may
31 be cited as the "Independent Diagnostic Testing Facility Act."

1 (2) The Legislature finds that the regulation of
2 independent diagnostic testing facilities must be improved to
3 prevent significant cost and harm to consumers. The purpose of
4 this part is to provide for the licensure of independent
5 diagnostic testing facilities and enforcement of basic
6 standards by the Agency for Health Care Administration.

7 400.9961 Definitions.--As used in this part, the term:

8 (1) "Agency" means the Agency for Health Care
9 Administration.

10 (2) "Applicant" means an individual owner,
11 corporation, partnership, firm, business, association, or
12 other entity that owns or controls, directly or indirectly, 5
13 percent or more of an interest in an independent diagnostic
14 testing facility and that applies for a facility license, or
15 the general partners, but not the limited partners, in a
16 limited liability partnership.

17 (3) "Independent diagnostic testing facility" or
18 "facility" means an entity that performs the technical
19 component of magnetic resonance imaging, static radiographs
20 (static X-ray), computer tomography, or position emission
21 tomography in a fixed facility, and:

22 (a) Is accredited by the Joint Commission on
23 Accreditation of Healthcare Organizations or the American
24 College of Radiology within 1 year after licensure;

25 (b) Does not accept patient referrals prohibited by s.
26 456.053(5);

27 (c) Does not provide therapy or treatment services to
28 patients who are provided diagnostic imaging services;

29 (d) Does not have an investor as defined in s.
30 456.053(3)(1);

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1 (e) Does not employ, contract with, or have as an
2 investor:

3 1. A person or entity that is directly or indirectly
4 an investor in a clinic as defined in s. 400.9905(3); or

5 2. A person or entity that directly or indirectly
6 provides services to a clinic if the services include the
7 referral as defined by s. 456.053(3)(0) of patients to any
8 provider of diagnostic imaging services; and

9 (f) Is not a clinic as defined in s. 400.9905(3).

10
11 The facility may provide the professional components of the
12 imaging services through an employee or independent
13 contractor.

14 400.9962 License requirements; background screenings;
15 prohibitions.--

16 (1) Each facility must be licensed and shall at all
17 times maintain a valid license with the agency. Each facility
18 location shall be licensed separately regardless of whether
19 the facility is operated under the same business name or
20 management as another facility.

21 (2) The initial facility license application shall be
22 filed with the agency by all facilities on or before March 1,
23 2005. A facility license must be renewed biennially.

24 (3) An applicant that submits an application on or
25 before March 1, 2005, which meets all requirements for initial
26 licensure as specified in this section shall receive a
27 temporary license until the completion of an initial
28 inspection verifying that the applicant meets all requirements
29 in rules authorized by s. 400.9965. However, a facility
30 engaged in magnetic resonance imaging services may not receive
31 a temporary license unless it presents evidence satisfactory

1 to the agency that the facility is making a good faith effort
2 and substantial progress in seeking accreditation required
3 under s. 400.9967.

4 (4) An application for an initial facility license or
5 for renewal of an existing license shall be notarized on a
6 form furnished by the agency and must be accompanied by the
7 appropriate license fee as provided in s. 400.9965. The agency
8 shall take final action on an initial license application
9 within 60 days after receipt of all required documentation.

10 (5) The application must contain information that
11 includes, but need not be limited to, information pertaining
12 to the name, residence and business address, phone number,
13 social security number, and license number of the facility
14 director, each licensed medical provider employed or under
15 contract with the facility, and each person who, directly or
16 indirectly, owns or controls 5 percent or more of an interest
17 in the facility, the general partners, in a limited liability
18 partnership.

19 (6) The applicant must file with the application
20 satisfactory proof that the facility is in compliance with
21 this part and applicable rules, including:

22 (a) A listing of services to be provided directly by
23 the applicant or through contractual arrangements with
24 existing providers;

25 (b) The number and discipline of each professional
26 staff member to be employed; and

27 (c) Proof of financial ability to operate. An
28 applicant must demonstrate financial ability to operate a
29 facility by submitting a balance sheet and an income and
30 expense statement for the first year of operation which
31 provide evidence of the applicant's having sufficient assets,

1 credit, and projected revenues to cover liabilities and
2 expenses. The applicant has demonstrated financial ability to
3 operate if the applicant's assets, credit, and projected
4 revenues meet or exceed projected liabilities and expenses.
5 All documents required under this subsection must be prepared
6 in accordance with generally accepted accounting principles,
7 may be in a compilation form, and the financial statement must
8 be signed by a certified public accountant. As an alternative
9 to submitting a balance sheet and an income and expense
10 statement for the first year of operation, the applicant may
11 file a surety bond of at least \$500,000, payable to the agency
12 which guarantees that the facility will act in full conformity
13 with all legal requirements for operating a facility. The
14 agency may adopt rules to specify related requirements for the
15 surety bond.

16 (7) Each applicant for licensure shall comply with the
17 requirements of this subsection.

18 (a) As used in this subsection, the term "applicant"
19 means individuals owning or controlling, directly or
20 indirectly, 5 percent or more of an interest in a facility;
21 the facility director, or a similarly titled person who is
22 responsible for the day-to-day operation of the licensed
23 facility; the financial officer or similarly titled individual
24 who is responsible for the financial operation of the
25 facility; and the licensed medical providers at the facility.

26 (b) Upon receipt of a completed, signed, and dated
27 application, the agency shall require background screening of
28 the applicant, in accordance with the level 2 standards for
29 screening set forth in chapter 435. Proof of compliance with
30 the level 2 background screening requirements of chapter 435
31 which has been submitted within the previous 5 years in

1 compliance with any other health care licensure requirements
2 of this state is acceptable in fulfillment of this paragraph.

3 (c) Each applicant must submit to the agency, with the
4 application, a description and explanation of any exclusions,
5 permanent suspensions, or terminations of an applicant from
6 the Medicare or Medicaid programs. Proof of compliance with
7 the requirements for disclosure of ownership and control
8 interest under the Medicaid or Medicare programs may be
9 accepted in lieu of this submission. The description and
10 explanation may indicate whether the exclusions, suspensions,
11 or terminations were voluntary or involuntary on the part of
12 the applicant.

13 (d) A license may not be granted to a facility if the
14 applicant has been found guilty of, regardless of
15 adjudication, or has entered a plea of nolo contendere or
16 guilty to, any offense prohibited under the level 2 standards
17 for screening set forth in chapter 435, or a violation of
18 insurance fraud under s. 817.234, within the past 5 years. If
19 the applicant has been convicted of an offense prohibited
20 under the level 2 standards or insurance fraud in any
21 jurisdiction, the applicant must show that his or her civil
22 rights have been restored prior to submitting an application.

23 (e) The agency may deny or revoke licensure if the
24 applicant has falsely represented any material fact or omitted
25 any material fact from the application required by this part.

26 (8) Requested information omitted from an application
27 for licensure, license renewal, or transfer of ownership must
28 be filed with the agency within 21 days after receipt of the
29 agency's request for omitted information, or the application
30 shall be deemed incomplete and shall be withdrawn from further
31 consideration.

1 (9) The failure to timely file a renewal application
2 shall result in a late fee charged to the facility in an
3 amount equal to 50 percent of the current license fee.

4 400.9963 Facility inspections; emergency suspension;
5 costs.--

6 (1) Any authorized officer or employee of the agency
7 shall make inspections of the facility as part of the initial
8 license application or renewal application. The application
9 for a facility license issued under this part or for a renewal
10 license constitutes permission for an appropriate agency
11 inspection to verify the information submitted on or in
12 connection with the application or renewal.

13 (2) An authorized officer or employee of the agency
14 may make unannounced inspections of facilities licensed under
15 this part as necessary to determine that the facility is in
16 compliance with this part and with applicable rules. A
17 licensed facility shall allow full and complete access to the
18 premises and to billing records or information to any
19 representative of the agency who makes an inspection to
20 determine compliance with this part and with applicable rules.

21 (3) Failure by a facility licensed under this part to
22 allow full and complete access to the premises and to billing
23 records or information to any representative of the agency who
24 makes a request to inspect the facility to determine
25 compliance with this part constitutes a ground for emergency
26 suspension of the license by the agency under s. 120.60(6).

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

30 400.9964 License renewal; transfer of ownership;
31 provisional license.--

1 (1) An application for license renewal must contain
2 information as required by the agency.

3 (2) Ninety days before the expiration date, an
4 application for renewal must be submitted to the agency.

5 (3) The facility must file with the renewal
6 application satisfactory proof that it is in compliance with
7 this part and applicable rules. If there is evidence of
8 financial instability, the facility must submit satisfactory
9 proof of its financial ability to comply with the requirements
10 of this part.

11 (4) When transferring the ownership of a facility, the
12 transferee must submit an application for a license at least
13 60 days before the effective date of the transfer. An
14 application for change of ownership of a facility is required
15 only when 45 percent or more of the ownership, voting shares,
16 or controlling interest of a facility is transferred or
17 assigned, including the final transfer or assignment of
18 multiple transfers or assignments over a 2-year period which
19 cumulatively total 45 percent or greater.

20 (5) The license may not be sold, leased, assigned, or
21 otherwise transferred, voluntarily or involuntarily, and is
22 valid only for the facility owners and location for which
23 originally issued.

24 (6) A facility against whom a revocation or suspension
25 proceeding is pending at the time of license renewal may be
26 issued a provisional license effective until final disposition
27 by the agency of the proceedings. If judicial relief is sought
28 from the final disposition, the agency that has jurisdiction
29 may issue a temporary permit for the duration of the judicial
30 proceeding.

31 400.9965 Rulemaking authority; license fees.--

1 (1) The agency shall adopt rules necessary to
2 administer the facility administration, regulation, and
3 licensure program, including rules establishing the specific
4 licensure requirements, procedures, forms, and fees. It shall
5 adopt rules establishing a procedure for the biennial renewal
6 of licenses. The agency may issue initial licenses for less
7 than the full 2-year period by charging a prorated licensure
8 fee and specifying a different renewal date than would
9 otherwise be required for biennial licensure. The rules shall
10 specify the expiration dates of licenses, the process of
11 tracking compliance with financial responsibility
12 requirements, and any other conditions of renewal required by
13 law or rule.

14 (2) License application and renewal fees must be
15 reasonably calculated by the agency to cover its costs in
16 carrying out its responsibilities under this part, including
17 the cost of licensure, inspection, and regulation of
18 facilities. The total fees collected may not exceed the cost
19 of administering and enforcing compliance with this part.
20 Facility licensure fees are nonrefundable and may not exceed
21 \$2,000. The agency shall adjust the license fee annually by
22 not more than the change in the Consumer Price Index based on
23 the 12 months immediately preceding the increase. All fees
24 collected under this part must be deposited in the Health Care
25 Trust Fund for the administration of this part.

26 400.9966 Unlicensed facilities; penalties; fines;
27 verification of licensure status.--

28 (1) A person may not own, operate, or maintain a
29 facility without obtaining a license under this part.

30 (2) Any person who owns, operates, or maintains an
31 unlicensed facility commits a felony of the third degree,

1 punishable as provided in s. 775.082, s. 775.083, or s.
2 775.084. Each day of continued operation is a separate
3 offense.

4 (3) Any person found guilty of violating subsection
5 (2) a second or subsequent time commits a felony of the second
6 degree, punishable as provided under s. 775.082, s. 775.083,
7 or s. 775.084. Each day of continued operation is a separate
8 offense.

9 (4) Any person who owns, operates, or maintains an
10 unlicensed facility due to a change in this part or a
11 modification in agency rules within 6 months after the
12 effective date of the change or modification and who, within
13 10 working days after receiving notification from the agency,
14 fails to cease operation or to apply for a license under this
15 part commits a felony of the third degree, punishable as
16 provided in s. 775.082, s. 775.083, or s. 775.084. Each day of
17 continued operation is a separate offense.

18 (5) Any facility that fails to cease operation after
19 agency notification may be fined for each day of noncompliance
20 under this part.

21 (6) When a person has an interest in more than one
22 facility and fails to obtain a license for any one of these
23 facilities, the agency may revoke the license, impose a
24 moratorium, or impose a fine under this part on any or all of
25 the licensed facilities until the unlicensed facility is
26 licensed or ceases operation.

27 (7) Any person aware of the operation of an unlicensed
28 facility must report that facility to the agency.

29 (8) Any health care provider who is aware of the
30 operation of an unlicensed facility shall report that facility
31 to the agency. Failure to report a facility that the provider

1 knows or has reasonable cause to suspect is unlicensed shall
2 be reported to the provider's licensing board.

3 (9) The agency may not issue a license to a facility
4 that has any unpaid fines assessed under this part.

5 400.9967 Facility responsibilities.--

6 (1) Each facility shall appoint a facility director
7 who shall agree in writing to accept legal responsibility for
8 the following activities on behalf of the facility. The
9 facility director shall:

10 (a) Have signs identifying the facility director
11 posted in a conspicuous location within the facility readily
12 visible to all patients.

13 (b) Ensure that all practitioners providing health
14 care services or supplies to patients maintain a current
15 active and unencumbered Florida license.

16 (c) Review any patient referral contracts or
17 agreements executed by the facility.

18 (d) Ensure that all health care practitioners at the
19 facility have active appropriate certification or licensure
20 for the level of care being provided.

21 (e) Serve as the facility records owner as defined in
22 s. 456.057.

23 (f) Ensure compliance with the recordkeeping, office
24 surgery, and adverse incident reporting requirements of
25 chapter 456, the respective practice acts, and rules adopted
26 under this part.

27 (g) Conduct systematic reviews of facility billings to
28 ensure that the billings are not fraudulent or unlawful. Upon
29 discovery of an unlawful charge, the facility director shall
30 take immediate corrective action.

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1 (2) Any business that becomes a facility after
2 commencing operations must, within 5 days after becoming a
3 facility, file a license application under this part and is
4 subject to all provisions of this part applicable to a
5 facility.

6 (3) All charges or reimbursement claims made by or on
7 behalf of a facility that is required to be licensed under
8 this part, but that is not so licensed, or that is otherwise
9 operating in violation of this part, are unlawful charges, and
10 are noncompensable and unenforceable.

11 (4) Any person establishing, operating, or managing an
12 unlicensed facility that is required to be licensed under this
13 part, or any person who knowingly files a false or misleading
14 license application or license renewal application, or false
15 or misleading information related to the application or
16 department rule, commits a felony of the third degree,
17 punishable as provided in s. 775.082, s. 775.083, or s.
18 775.084.

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

22 (6) The agency may fine, or suspend or revoke the
23 license of, any facility licensed under this part for
24 operating in violation of the requirements of this part or the
25 rules adopted by the agency.

26 (7) The agency shall investigate allegations of
27 noncompliance with this part and the rules adopted under this
28 part.

29 (8) Any person or entity providing health care
30 services which is not a facility may voluntarily apply for a
31 certificate of exemption from licensure under its exempt

1 status with the agency on a form that sets forth its name or
2 names and addresses, a statement of the reasons why it cannot
3 be defined as a facility, and other information deemed
4 necessary by the agency.

5 (9) The facility shall display its license in a
6 conspicuous location within the facility readily visible to
7 all patients.

8 (10)(a) Each facility engaged in magnetic resonance
9 imaging services must be accredited by the Joint Commission on
10 Accreditation of Healthcare Organizations, the American
11 College of Radiology, or the Accreditation Association for
12 Ambulatory Health Care, within 1 year after licensure.

13 However, a facility may request a single, 6-month extension if
14 it provides evidence to the agency establishing that, for good
15 cause shown, the facility cannot be accredited within 1 year
16 after licensure, and that the accreditation will be completed
17 within the 6-month extension. After obtaining accreditation as
18 required by this subsection, each facility must maintain
19 accreditation as a condition of renewal of its license.

20 (b) The agency may disallow the application of any
21 entity formed for the purpose of avoiding compliance with the
22 accreditation provisions of this subsection and whose
23 principals were previously principals of an entity that was
24 unable to meet the accreditation requirements within the
25 specified timeframes.

26 (c) The agency shall give full faith and credit
27 pertaining to any past variance and waiver granted to a
28 magnetic resonance imaging facility from rule 64-2002, Florida
29 Administrative Code, by the Department of Health, until
30 September 2006. After that date, the facility must request a
31 variance and waiver from the agency under s. 120.542.

1 400.9968 Injunctions.--

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

4 (a) Enforce the provisions of this part or any minimum
5 standard, rule, or order issued or entered into under this
6 part if the attempt by the agency to correct a violation
7 through administrative fines has failed; if the violation
8 materially affects the health, safety, or welfare of facility
9 patients; or if the violation involves any operation of an
10 unlicensed facility.

11 (b) Terminate the operation of a facility if a
12 violation of any provision of this part, or any rule adopted
13 under this part, materially affects the health, safety, or
14 welfare of facility patients.

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

17 (3) If action is necessary to protect facility
18 patients from life-threatening situations, the court may allow
19 a temporary injunction without bond upon proper proof being
20 made. If it appears by competent evidence or a sworn,
21 substantiated affidavit that a temporary injunction should be
22 issued, the court, pending the determination on final hearing,
23 shall enjoin operation of the facility.

24 400.9969 Agency actions.--Administrative proceedings
25 challenging agency licensure enforcement action shall be
26 reviewed on the basis of the facts and conditions that
27 resulted in the agency action.

28 400.997 Agency administrative penalties.--

29 (1) The agency may impose administrative penalties
30 against a facility of up to \$5,000 per violation for
31 violations of the requirements of this part. In determining if

1 a penalty is to be imposed and in fixing the amount of the
2 fine, the agency shall consider the following factors:

3 (a) The gravity of the violation, including the
4 probability that death or serious physical or emotional harm
5 to a patient will result or has resulted, the severity of the
6 action or potential harm, and the extent to which the
7 provisions of the applicable laws or rules were violated.

8 (b) Actions taken by the owner or the facility
9 director to correct violations.

10 (c) Any previous violations.

11 (d) The financial benefit to the facility of
12 committing or continuing the violation.

13 (2) Each day of continuing violation after the date
14 fixed for termination of the violation, as ordered by the
15 agency, constitutes an additional, separate, and distinct
16 violation.

17 (3) Any action taken to correct a violation shall be
18 documented in writing by the owner or facility director and
19 verified through followup visits by agency personnel. The
20 agency may impose a fine and, in the case of an owner-operated
21 facility, revoke or deny a facility's license when an owner or
22 facility director fraudulently misrepresents actions taken to
23 correct a violation.

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

28 (5) Any unlicensed facility that continues to operate
29 after agency notification is subject to a fine of \$1,000 per
30 day.

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1 (6) Any licensed facility whose owner or facility
2 director concurrently operates an unlicensed facility shall be
3 subject to an administrative fine of \$5,000 per day.

4 (7) Any facility whose owner fails to apply for a
5 change-of-ownership license in accordance with s. 400.9964 and
6 operates the facility under the new ownership is subject to a
7 fine of \$5,000.

8 (8) The agency, as an alternative to or in conjunction
9 with an administrative action against a facility for
10 violations of this part and adopted rules, shall make a
11 reasonable attempt to discuss each violation and recommended
12 corrective action with the owner or facility director prior to
13 written notification. The agency, instead of fixing a period
14 within which the facility shall enter into compliance with
15 standards, may request a plan of corrective action from the
16 facility which demonstrates a good faith effort to remedy each
17 violation by a specific date, subject to the approval of the
18 agency.

19 (9) Administrative fines paid by any facility under
20 this section shall be deposited into the Health Care Trust
21 Fund.

22 Section 2. This act shall take effect October 1, 2004.
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SENATE SUMMARY

Creates part XIV of ch. 400, F.S., entitled the Independent Diagnostic Testing Facility Act. Provides for definitions and exclusions. Provides for the licensure, inspection, and regulation of independent diagnostic testing facilities by the Agency for Health Care Administration. Requires licensure and background screening. Provides for facility inspections and rulemaking authority. Provides for licensure fees. Authorizes fines and penalties for operating an unlicensed facility. Directs facility responsibilities with respect to personnel and operations. Provides accreditation requirements. Provides for injunctive proceedings and agency actions. Authorizes administrative penalties.