Chapter 400, Florida Statutes
PART X
HEALTH CARE CLINIC ACT

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400.990 Short title; legislative findings.--
(1) This part, consisting of ss. 400.990-400.995, may be cited as the "Health Care Clinic Act."
(2) The Legislature finds that the regulation of health care clinics must be strengthened to prevent significant cost and harm to consumers. The purpose of this part is to provide for the licensure, establishment, and enforcement of basic standards for health care clinics and to provide administrative oversight by the Agency for Health Care Administration.

History.--s. 4, ch. 2003-411.

400.9905 Definitions.--
(1) "Agency" means the Agency for Health Care Administration.
(2) "Applicant" means an individual owner, corporation, partnership, firm, business, association, or other entity that owns or controls, directly or indirectly, 5 percent or more of an interest in the clinic and that applies for a clinic license.
(3) "Chief financial officer" means an individual who has at least a minimum of a bachelor's degree from an accredited university in accounting or finance, or a related field, and who is the person responsible for the preparation of a clinic's billing.
(4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:
(a) Entities licensed or registered by the state under chapter 395; or entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.
(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; or entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; or entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

(f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.

(g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse,
parent, child, or sibling of a licensed health care practitioner, so long as one of the owners who is
a licensed health care practitioner is supervising the business activities and is legally responsible
for the entity's compliance with all federal and state laws. However, a health care practitioner
may not supervise services beyond the scope of the practitioner's license, except that, for the
purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services
authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s.
456.053(3)(b).

(h) Clinical facilities affiliated with an accredited medical school at which training is provided
for medical students, residents, or fellows.

(i) Entities that provide only oncology or radiation therapy services by physicians licensed under
chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by
physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose
shares are publicly traded on a recognized stock exchange.

(j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on
Chiropractic Education at which training is provided for chiropractic students.

(k) Entities that provide licensed practitioners to staff emergency departments or to deliver
anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of
their gross annual revenues from the provision of such services. Entities claiming an exemption
from licensure under this paragraph must provide documentation demonstrating compliance.

(l) Orthotic or prosthetic clinical facilities that are a publicly traded corporation or that are
wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph,
a publicly traded corporation is a corporation that issues securities traded on an exchange
registered with the United States Securities and Exchange Commission as a national securities
exchange.

(5) "Medical director" means a physician who is employed or under contract with a clinic and
who maintains a full and unencumbered physician license in accordance with chapter 458,
chapter 459, chapter 460, or chapter 461. However, if the clinic does not provide services
pursuant to the respective physician practices acts listed in this subsection, it may appoint a
Florida-licensed health care practitioner who does not provide services pursuant to the respective
physician practices acts listed in this subsection to serve as a clinic director who is responsible
for the clinic's activities. A health care practitioner may not serve as the clinic director if the
services provided at the clinic are beyond the scope of that practitioner's license, except that a
licensee specified in s. 456.053(3)(b) who provides only services authorized pursuant to s.
456.053(3)(b) may serve as clinic director of an entity providing services as specified in s.
456.053(3)(b).

(6) "Mobile clinic" means a movable or detached self-contained health care unit within or from
which direct health care services are provided to individuals and which otherwise meets the
definition of a clinic in subsection (4).

(7) "Portable equipment provider" means an entity that contracts with or employs persons to
provide portable equipment to multiple locations performing treatment or diagnostic testing of
individuals, that bills third-party payors for those services, and that otherwise meets the
definition of a clinic in subsection (4).

400.991 License requirements; background screenings; prohibitions.--

(1) (a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and to entities licensed by or applying for such licensure from the agency pursuant to this part. A license issued by the agency is required in order to operate a clinic in this state. Each clinic location shall be licensed separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(b) Each mobile clinic must obtain a separate health care clinic license and must provide to the agency, at least quarterly, its projected street location to enable the agency to locate and inspect such clinic. A portable equipment provider must obtain a health care clinic license for a single administrative office and is not required to submit quarterly projected street locations.

(2) The initial clinic license application shall be filed with the agency by all clinics, as defined in s. 400.9905, on or before July 1, 2004.

(3) The application shall contain information that includes, but need not be limited to, information pertaining to the name, residence and business address, phone number, social security number, and license number of the medical or clinic director of the licensed medical providers employed or under contract with the clinic.

(4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:

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

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

(c) Proof of financial ability to operate as required under s. 408.810(8). As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least $500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond.

(5) Each applicant for licensure shall comply with the following requirements:

(a) As used in this subsection, the term "applicant" means individuals owning or controlling, directly or indirectly, 5 percent or more of an interest in a clinic; the medical or clinic director, or a similarly titled person who is responsible for the day-to-day operation of the licensed clinic; the financial officer or similarly titled individual who is responsible for the financial operation of the clinic; and licensed health care practitioners at the clinic.

(b) Upon receipt of a completed, signed, and dated application, the agency shall require background screening of the applicant, in accordance with the level 2 standards for screening set forth in chapter 435. Proof of compliance with the level 2 background screening requirements of chapter 435 which has been submitted within the previous 5 years in compliance with any other health care licensure requirements of this state is acceptable in fulfillment of this paragraph.
Applicants who own less than 10 percent of a health care clinic are not required to submit fingerprints under this section.

(c) Each applicant must submit to the agency, with the application, a description and explanation of any exclusions, permanent suspensions, or terminations of an applicant from the Medicare or Medicaid programs. Proof of compliance with the requirements for disclosure of ownership and control interest under the Medicaid or Medicare programs may be accepted in lieu of this submission. The description and explanation may indicate whether such exclusions, suspensions, or terminations were voluntary or not voluntary on the part of the applicant.

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


400.9915 Emergency suspension; costs.--

(1) Failure by a clinic to employ a qualified medical director or clinic director constitutes a ground for emergency suspension of the license by the agency pursuant to s. 408.814.

(2) In addition to any administrative fines imposed pursuant to this part or part II of chapter 408, the agency may assess a fee equal to the cost of conducting a complaint investigation.

History.--s. 4, ch. 2003-411; s. 124, ch. 2007-230.

400.9925 Rulemaking authority; license fees.--

(1) The agency shall adopt rules necessary to administer the clinic administration, regulation, and licensure program, including rules pursuant to this part and part II of chapter 408, establishing the specific licensure requirements, procedures, forms, and fees. It shall adopt rules establishing a procedure for the biennial renewal of licenses. The agency may issue initial licenses for less than the full 2-year period by charging a prorated licensure fee and specifying a different renewal date than would otherwise be required for biennial licensure. The rules shall specify the expiration dates of licenses, the process of tracking compliance with financial responsibility requirements, and any other conditions of renewal required by law or rule.

(2) The agency shall adopt rules specifying limitations on the number of licensed clinics and licensees for which a medical director or a clinic director may assume responsibility for purposes of this part. In determining the quality of supervision a medical director or a clinic director can provide, the agency shall consider the number of clinic employees, the clinic location, and the health care services provided by the clinic.

(3) In accordance with s. 408.805, an applicant or a licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be established by rule and may not exceed $2,000.

History.--s. 4, ch. 2003-411; s. 126, ch. 2007-230.

400.993 Unlicensed clinics; reporting.--
(1) Any person who violates s. 408.812 regarding unlicensed activity commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

(2) Any person found guilty of violating s. 408.812 a second or subsequent time commits a felony of the second degree, punishable as provided under s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

(3) In addition to the requirements of part II of chapter 408, any health care provider who is aware of the operation of an unlicensed clinic shall report that facility to the agency. Failure to report a clinic that the provider knows or has reasonable cause to suspect is unlicensed shall be reported to the provider's licensing board.


400.9935 Clinic responsibilities.--

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(a) Have signs identifying the medical director or clinic director posted in a conspicuous location within the clinic readily visible to all patients.

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

(c) Review any patient referral contracts or agreements executed by the clinic.

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

(e) Serve as the clinic records owner as defined in s. 456.057.

(f) Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, the respective practice acts, and rules adopted under this part and part II of chapter 408.

(g) Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful. Upon discovery of an unlawful charge, the medical director or clinic director shall take immediate corrective action. If the clinic performs only the technical component of magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography, and provides the professional interpretation of such services, in a fixed facility that is accredited by the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care, and the American College of Radiology; and if, in the preceding quarter, the percentage of scans performed by that clinic which was billed to all personal injury protection insurance carriers was less than 15 percent, the chief financial officer of the clinic may, in a written acknowledgment provided to the agency, assume the responsibility for the conduct of the systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful.

(h) Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography. The term "refer a patient" means the referral of one or more patients of the medical or clinical director or a member of the medical or clinical director's group practice to the clinic for magnetic resonance imaging, static
radiographs, computed tomography, or positron emission tomography. A medical director who is found to violate this paragraph commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2) Any contract to serve as a medical director or a clinic director entered into or renewed by a physician or a licensed health care practitioner in violation of this part is void as contrary to public policy. This subsection shall apply to contracts entered into or renewed on or after March 1, 2004.

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

(4) In addition to the requirements of s. 408.812, any person establishing, operating, or managing an unlicensed clinic otherwise required to be licensed under this part or part II of chapter 408, or any person who knowingly files a false or misleading license application or license renewal application, or false or misleading information related to such application or department rule, commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

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

(6) Any person or entity providing health care services which is not a clinic, as defined under s. 400.9905, may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that sets forth its name or names and addresses, a statement of the reasons why it cannot be defined as a clinic, and other information deemed necessary by the agency. An exemption is not transferable. The agency may charge an applicant for a certificate of exemption in an amount equal to $100 or the actual cost of processing the certificate, whichever is less.

(7)(a) Each clinic engaged in magnetic resonance imaging services must be accredited by the Joint Commission on Accreditation of Healthcare Organizations, the American College of Radiology, or the Accreditation Association for Ambulatory Health Care, within 1 year after licensure. A clinic that is accredited by the American College of Radiology or is within the original 1-year period after licensure and replaces its core magnetic resonance imaging equipment shall be given 1 year after the date on which the equipment is replaced to attain accreditation. However, a clinic may request a single, 6-month extension if it provides evidence to the agency establishing that, for good cause shown, such clinic cannot be accredited within 1 year after licensure, and that such accreditation will be completed within the 6-month extension. After obtaining accreditation as required by this subsection, each such clinic must maintain accreditation as a condition of renewal of its license. A clinic that files a change of ownership application must comply with the original accreditation timeframe requirements of the transferor. The agency shall deny a change of ownership application if the clinic is not in compliance with the accreditation requirements. When a clinic adds, replaces, or modifies magnetic resonance imaging equipment and the accreditation agency requires new accreditation, the clinic must be accredited within 1 year after the date of the addition, replacement, or modification but may request a single, 6-month extension if the clinic provides evidence of good cause to the agency.

(b) The agency may deny the application or revoke the license of any entity formed for the purpose of avoiding compliance with the accreditation provisions of this subsection and whose
principals were previously principals of an entity that was unable to meet the accreditation requirements within the specified timeframes. The agency may adopt rules as to the accreditation of magnetic resonance imaging clinics.

(8) The agency shall give full faith and credit pertaining to any past variance and waiver granted to a magnetic resonance imaging clinic from rule 64-2002, Florida Administrative Code, by the Department of Health, until September 2004. After that date, such clinic must request a variance and waiver from the agency under s. 120.542.

(9) In addition to the requirements of part II of chapter 408, the clinic shall display a sign in a conspicuous location within the clinic readily visible to all patients indicating that, pursuant to s. 626.9892, the Department of Financial Services may pay rewards of up to $25,000 to persons providing information leading to the arrest and conviction of persons committing crimes investigated by the Division of Insurance Fraud arising from violations of s. 440.105, s. 624.15, s. 626.9541, s. 626.989, or s. 817.234. An authorized employee of the Division of Insurance Fraud may make unannounced inspections of a clinic licensed under this part as necessary to determine whether the clinic is in compliance with this subsection. A licensed clinic shall allow full and complete access to the premises to such authorized employee of the division who makes an inspection to determine compliance with this subsection.


400.995 Agency administrative penalties.--

(1) In addition to the requirements of part II of chapter 408, the agency may deny the application for a license renewal, revoke and suspend the license, and impose administrative fines of up to $5,000 per violation for violations of the requirements of this part or rules of the agency. In determining if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the following factors:

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

(b) Actions taken by the owner, medical director, or clinic director to correct violations.

(c) Any previous violations.

(d) The financial benefit to the clinic of committing or continuing the violation.

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

(3) Any action taken to correct a violation shall be documented in writing by the owner, medical director, or clinic director of the clinic and verified through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated clinic, revoke or deny a clinic's license when a clinic medical director or clinic director knowingly misrepresents actions taken to correct a violation.

(4) Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic shall be subject to an administrative fine of $5,000 per day.

(5) Any clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership is subject to a fine of $5,000.
(6) During an inspection, the agency shall make a reasonable attempt to discuss each violation with the owner, medical director, or clinic director of the clinic, prior to written notification.