Florida Senate - 2006

 ${\bf By}$ the Committees on Criminal Justice; and Banking and Insurance

591-2319-06

2An act relating to health care clinics;3amending s. 400.990, F.S.; providing additional4legislative findings; amending s. 400.9905,5F.S.; redefining the term "clinic" for purposes6of the Health Care Clinic Act to include7certain additional providers; excluding certain8facilities owned by publicly traded9corporations; defining the terms "specialty10clinic," "infusion therapy," and "fraud";11amending s. 400.991, F.S.; requiring specialty12clinics to be subject to licensure13requirements; requiring additional persons to14be subject to background screening; revising15certain requirements for applying for licensure16as a health care clinic; creating additional17requirements for applying for licensure as a18specialty clinic; providing additional grounds19under which an applicant may be denied20licensure due to a finding of guilt for21committing a felony; providing specialty clinics23s. 400.9915, F.S.; including specialty clinics24within clinic inspection requirements; amending25s. 400.992, F.S.; including specialty clinics26within requirements for license renewal,27transfer of ownership, and provisional28licensure; amending s. 400.9925, F.S.;29providing the agency with rulemaking authority30regarding specialty clinics; stating that the31licensure fee	1	A bill to be entitled
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31 licensure fee for a specialty clinic is	30	regarding specialty clinics; stating that the
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1	nonrefundable and may not exceed \$2,000;
2	amending s. 400.993, F.S.; including specialty
3	clinics within provisions regarding unlicensed
4	clinics; providing penalties for unlicensed
5	operation of a specialty clinic; including
б	specialty clinics within provisions regarding
7	verification of licensure; amending s.
8	400.9935, F.S.; including specialty clinics
9	within provisions regarding clinic
10	responsibilities; revising the responsibilities
11	of the medical director and the clinical
12	director; requiring all persons providing
13	health care services to individuals in a clinic
14	to comply with the licensure laws and rules
15	under which that person is licensed; providing
16	for a certificate of exemption from licensure
17	as a clinic to expire within a specified
18	period; providing for renewal of the
19	certificate of exemption; revising the
20	application procedures for a certificate of
21	exemption; providing grounds for the denial,
22	withdrawal, or emergency suspension of a
23	certificate of exemption by the Agency for
24	Health Care Administration; providing that it
25	is a third-degree felony for an applicant to
26	submit fraudulent or material and misleading
27	information to the agency; requiring a
28	specialty clinic to file an audited report with
29	the agency no less frequently than annually;
30	requiring a specialty clinic to maintain
31	compliance with part XIII of ch. 400, F.S.;
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1	requiring health care clinics and specialty
2	clinics to display signs containing certain
3	information relating to insurance fraud;
4	authorizing compliance inspections by the
5	Division of Insurance Fraud; requiring clinics
6	to allow inspection access; amending s.
7	400.994, F.S.; granting the agency authority to
8	institute injunctive proceedings against a
9	<pre>specialty clinic; amending s. 400.995, F.S.;</pre>
10	granting the agency authority to impose
11	administrative penalties against a specialty
12	clinic; creating s. 400.996, F.S.; creating a
13	process whereby the agency receives, documents,
14	and processes complaints about specialty
15	clinics; requiring the agency to request that
16	complaints regarding billing fraud by a
17	specialty clinic be made by sworn affidavit;
18	requiring the agency to refer to the Department
19	of Financial Services, Office of Fiscal
20	Integrity, any sworn affidavit asserting
21	billing fraud by a specialty clinic; requiring
22	the department to report findings regarding
23	billing fraud by a specialty clinic to the
24	agency; requiring the department to refer an
25	investigation to prosecutorial authorities and
26	provide investigative assistance under certain
27	circumstances; providing that it is a
28	first-degree misdemeanor to submit an affidavit
29	asserting billing fraud by a specialty clinic
30	which is without any factual basis; allowing
31	the department to conduct unannounced reviews,
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1	investigations, analyses, and audits to
2	investigate complaints of billing fraud by a
3	specialty clinic; authorizing the department to
4	enter upon the premises of a specialty clinic
5	and immediately secure copies of certain
б	documents; requiring a specialty clinic to
7	allow full and immediate access to the premises
8	and records of the clinic to a department
9	officer or employee under s. 400.996, F.S.;
10	providing that failure to provide such access
11	is a ground for emergency suspension of the
12	license of the specialty clinic; permitting the
13	agency to assess a fee against a specialty
14	clinic equal to the cost of conducting a
15	review, investigation, analysis, or audit
16	performed by the agency or the department;
17	providing that all investigators designated by
18	the Chief Financial Officer to perform duties
19	under part XIII of ch. 400, F.S., and certified
20	under s. 943.1395, F.S., are law enforcement
21	officers of the state; amending s. 456.072,
22	F.S.; providing that intentionally placing
23	false information in an application for a
24	certificate of exemption from clinic licensure
25	constitutes grounds for which disciplinary
26	action may be taken; providing an effective
27	date.
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29	Be It Enacted by the Legislature of the State of Florida:
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1 Section 1. Section 400.990, Florida Statutes, is 2 amended to read: 400.990 Short title; legislative findings.--3 (1) This part, consisting of <u>ss. 400.990-400.996</u> ss. 4 400.990 400.995, may be cited as the "Health Care Clinic Act." 5 6 (2) The Legislature finds that the regulation of 7 health care clinics must be strengthened to prevent 8 significant cost and harm to consumers. (3) The Legislature further finds the additional 9 10 regulation of specialty health care clinics is necessary to prevent significant fraudulent practices in the provision of 11 12 infusion therapy services in this state. 13 (4) The purpose of this part is to provide for the licensure, establishment, and enforcement of basic standards 14 for health care clinics and to provide administrative 15 oversight by the Agency for Health Care Administration. 16 17 Section 2. Subsection (4) of section 400.9905, Florida 18 Statutes, is amended, and subsections (8), (9), and (10) are added to that section, to read: 19 400.9905 Definitions.--20 21 (4) "Clinic" means an entity at which health care 22 services are provided to individuals and which tenders charges 23 for reimbursement for such services, including a mobile clinic and a portable equipment provider. For purposes of this part, 2.4 the term does not include and the licensure requirements of 25 this part do not apply to: 26 27 (a) Entities licensed or registered by the state under 2.8 chapter 395; or entities licensed or registered by the state 29 and providing only health care services within the scope of services authorized under their respective licenses granted 30 under ss. 383.30-383.335, chapter 390, chapter 394, chapter 31 5

1 397, this chapter except part XIII, chapter 463, chapter 465, 2 chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized 3 under 42 C.F.R. part 405, subpart U; or providers certified 4 under 42 C.F.R. part 485, subpart B or subpart H; or any 5 6 entity that provides neonatal or pediatric hospital-based 7 health care services by licensed practitioners solely within a 8 hospital licensed under chapter 395. (b) Entities that own, directly or indirectly, 9 10 entities licensed or registered by the state pursuant to chapter 395; or entities that own, directly or indirectly, 11 12 entities licensed or registered by the state and providing 13 only health care services within the scope of services authorized pursuant to their respective licenses granted under 14 ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, 15 this chapter except part XIII, chapter 463, chapter 465, 16 17 chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal disease providers authorized 18 under 42 C.F.R. part 405, subpart U; or providers certified 19 under 42 C.F.R. part 485, subpart B or subpart H; or any 20 21 entity that provides neonatal or pediatric hospital-based 22 health care services by licensed practitioners solely within a 23 hospital licensed under chapter 395. (c) Entities that are owned, directly or indirectly, 2.4 by an entity licensed or registered by the state pursuant to 25 chapter 395; or entities that are owned, directly or 26 27 indirectly, by an entity licensed or registered by the state 2.8 and providing only health care services within the scope of 29 services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, 30 chapter 397, this chapter except part XIII, chapter 463, 31

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1 chapter 465, chapter 466, chapter 478, part I of chapter 483, 2 chapter 484, or chapter 651; end-stage renal disease providers 3 authorized under 42 C.F.R. part 405, subpart U; or providers 4 certified under 42 C.F.R. part 485, subpart B or subpart H; or 5 any entity that provides neonatal or pediatric hospital-based 6 health care services by licensed practitioners solely within a 7 hospital under chapter 395.

8 (d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the 9 state pursuant to chapter 395; or entities that are under 10 common ownership, directly or indirectly, with an entity 11 12 licensed or registered by the state and providing only health 13 care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, 14 chapter 390, chapter 394, chapter 397, this chapter except 15 part XIII, chapter 463, chapter 465, chapter 466, chapter 478, 16 17 part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, 18 subpart U; or providers certified under 42 C.F.R. part 485, 19 subpart B or subpart H; or any entity that provides neonatal 20 21 or pediatric hospital-based health care services by licensed 22 practitioners solely within a hospital licensed under chapter 23 395.

(e) An entity that is exempt from federal taxation under 26 U.S.C. s. 501(c)(3) or s. 501(c)(4), any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

29 (f) A sole proprietorship, group practice, 30 partnership, or corporation<u>, or other legal entity</u> that 31 provides health care services by <u>licensed health care</u>

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1 practitioners licensed under chapter 458, chapter 459, chapter 2 460, chapter 461, or chapter 466 physicians covered by s. 627.419, that is directly supervised by one or more of such 3 physicians, and that is wholly owned by one or more of those 4 5 physicians or by a physician and the spouse, parent, child, or 6 sibling of that physician. 7 (g) A sole proprietorship, group practice, 8 partnership, or corporation, or other legal entity that provides health care services by licensed health care 9 10 practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 11 12 466, chapter 467, chapter 480, chapter 484, chapter 486, 13 chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which 14 entities are wholly owned by one or more licensed health care 15 practitioners, or the licensed health care practitioners set 16 17 forth in this paragraph and the spouse, parent, child, or 18 sibling of a licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is 19 supervising the <u>health care services</u> business activities and 20 21 is legally responsible for the entity's compliance with all 22 federal and state laws. However, a health care services 23 provided may not exceed the scope of the licensed owner's health care practitioner may not supervise services beyond the 2.4 scope of the practitioner's license, except that, for the 25 26 purposes of this part, a clinic owned by a licensee in s. 27 456.053(3)(b) that provides only services authorized pursuant 2.8 to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b). 29 30 31

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1	(h) Clinical facilities affiliated with an accredited
2	medical school at which training is provided for medical
3	students, residents, or fellows.
4	(i) Entities that provide only oncology or radiation
5	therapy services by physicians licensed under chapter 458 or
6	chapter 459 which are owned by a corporation whose shares are
7	publicly traded on a registered stock exchange.
8	(j) Clinical facilities affiliated with a college of
9	chiropractic accredited by the Council on Chiropractic
10	Education at which training is provided for chiropractic
11	students.
12	(k) Clinical facilities that are wholly owned,
13	directly or indirectly, by a publicly traded corporation. As
14	used in this paragraph, a "publicly traded corporation" is a
15	corporation that issues securities traded on an exchange
16	registered with the United States Securities and Exchange
17	Commission as a national securities exchange.
18	(8) "Specialty clinic" means a clinic not licensed as
19	a home health agency which provides infusion therapy services
20	either to outpatients who remain less than 24 hours at the
21	facility or to patients who receive such services where they
22	reside. The term does not include:
23	<u>(a) Entities licensed under part II, part III, or part</u>
24	IV; or
25	(b) Entities licensed under chapter 395.
26	(9) "Infusion therapy" includes, but is not limited
27	to, the therapeutic infusion of substances into, or injection
28	of substances through, the venous peripheral system,
29	consisting of activity that includes: observing, initiating,
30	monitoring, discontinuing, maintaining, regulating, adjusting,
31	documenting, planning, intervening, and evaluating. This

1 definition embraces administration of nutrition, antibiotic therapy, and fluid and electrolyte repletion. 2 (10) "Fraud" means deception or misrepresentation made 3 4 by a person or business entity with the intent that the 5 deception will likely result in an unauthorized benefit to 6 herself or himself or to another person. The term includes any 7 act that constitutes fraud under applicable federal or state 8 <u>law.</u> 9 Section 3. Section 400.991, Florida Statutes, is 10 amended to read: 400.991 License requirements; background screenings; 11 12 prohibitions.--13 (1)(a) Each clinic and specialty clinic, as defined in s. 400.9905, must be licensed and shall at all times maintain 14 a valid license with the agency. Each clinic and specialty 15 clinic location shall be licensed separately regardless of 16 17 whether the clinic or specialty clinic is operated under the 18 same business name or management as another clinic. 19 (b) Each mobile clinic and specialty clinic must obtain a separate health care clinic license and must provide 20 21 to the agency, at least quarterly, its projected street 2.2 location to enable the agency to locate and inspect such 23 clinic and specialty clinic. A portable equipment provider must obtain a health care clinic license for a single 2.4 administrative office and is not required to submit quarterly 25 26 projected street locations. 27 (c) A specialty clinic operating without a specialty 2.8 clinic license at the time of the effective date of this act shall be given a reasonable time, not to exceed 6 months from 29 the effective date of this act, to obtain a specialty clinic 30 31 <u>license.</u>

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1 (2) The initial clinic license application shall be 2 filed with the agency by all clinics, as defined in s. 400.9905, on or before July 1, 2004. A clinic license and 3 specialty clinic license must be renewed biennially. 4 5 (3) Applicants that submit an application on or before б July 1, 2004, which meets all requirements for initial 7 licensure as specified in this section shall receive a 8 temporary license until the completion of an initial inspection verifying that the applicant meets all requirements 9 in rules authorized in s. 400.9925. However, a clinic engaged 10 in magnetic resonance imaging services may not receive a 11 12 temporary license unless it presents evidence satisfactory to 13 the agency that such clinic is making a good faith effort and substantial progress in seeking accreditation required under 14 s. 400.9935. 15 (4) Application for an initial clinic or specialty 16 17 clinic license or for renewal of an existing license shall be notarized on forms furnished by the agency and must be 18 accompanied by the appropriate license fee as provided in s. 19 400.9925. The agency shall take final action on an initial 20 21 license application within 60 days after receipt of all 22 required documentation. 23 (5)(a) The application shall contain information that includes, but need not be limited to, information pertaining 2.4 to the name, residence and business address, phone number, 25 26 social security number, and license number of the medical or 27 clinic director, of the licensed medical providers employed or 2.8 under contract with the clinic, and of each person who, directly or indirectly, owns or controls 5 percent or more of 29 an interest in the clinic, or general partners in limited 30 liability partnerships. 31

11

1	(b) Any person or entity that has a pecuniary interest
2	<u>in a clinic who may or may not own stock or an equivalent</u>
3	interest in the clinic, but nonetheless has control over or
4	the authority to approve, directly or indirectly, clinic
5	billing, policy, business activities, or personnel decisions,
б	including, but not limited to, contracted or employed
7	third-party billing persons or entities, managers, and
8	management companies, and persons and entities, directly or
9	indirectly, which lend, give, or gift money of any
10	denomination or any thing of value exceeding an aggregate of
11	\$5,000, for clinic use, with or without an expectation of a
12	return of the money or thing of value, and regardless of
13	profit motive, are subject to background screening
14	requirements under this part.
15	(c) The agency may adopt rules to administer this
16	subsection.
17	(6) An application for a specialty clinic shall
18	contain, in addition to the information required in subsection
19	<u>(5):</u>
20	(a) The correct business name of each business entity
21	and full name of each individual holding any ownership
22	interest of 5 percent or more, or any pecuniary interest of
23	\$5,000 or more, in any legal entity that owns or operates any
24	specialty clinic seeking licensure, whether such ownership or
25	pecuniary interest arose out of a contract, loan, gift,
26	investment, inheritance, or any other source. Individual
27	possession of an ownership or pecuniary interest in any
28	subject specialty clinic includes, but is not limited to, a
29	direct or indirect interest in:
30	1. The business operation, equipment, or legend
31	pharmaceuticals used in the clinic;

1 The premises in which the clinic provides its 2 services; or 3 3. Any legal entity that owns any such interest, 4 directly or indirectly, in the business operation of the clinic; the equipment used in providing infusion therapy 5 6 services at the clinic; the legend pharmaceuticals used at the 7 clinic; or the premises in which the clinic provides its 8 <u>services.</u> 9 (b) In the case of an incorporated business entity 10 that holds any ownership interest of 5 percent or more, or any pecuniary interest of \$5,000 or more, in the specialty clinic, 11 copies of the articles of incorporation and bylaws, and the 12 13 names and addresses of all officers and directors of the 14 corporation. (c) On a form furnished by the agency, a sworn 15 notarized statement by each business entity and individual 16 17 that holds any ownership interest of 5 percent or more, or any pecuniary interest of \$5,000 or more, in the subject specialty 18 clinic which discloses the nature and degree of each such 19 ownership or pecuniary interest, and that discloses the source 2.0 21 of funds which gave rise to each such ownership or pecuniary 2.2 interest. 23 (d) On a form furnished by the agency, a sworn notarized statement by each individual and business entity 2.4 that holds any ownership interest of 5 percent or more, or any 25 pecuniary interest of \$5,000 or more, in the subject specialty 26 27 clinic which discloses whether he or she has been an owner or 2.8 part owner, individually or through any business entity, of any business entity whose health care license has been revoked 29 30 or suspended in any jurisdiction. 31

13

1 (e) On a form furnished by the agency, an estimate of 2 the costs for establishing the specialty clinic and the source of funds for payment of those costs and for sustaining the 3 4 operation of the clinic until its operation produces a positive cash flow. 5 б 7 For purposes of this subsection, the term "ownership or pecuniary interest does not include any individual whose 8 interest in a specialty clinic arises only out of his or her 9 interest in a lending company, insurance company, or banking 10 institution licensed by this state or any other state of the 11 12 United States; a company regularly trading on a national stock exchange of the United States; or a governmental entity in the 13 United States. 14 (7) (6) The applicant must file with the application 15 satisfactory proof that the clinic or specialty clinic is in 16 17 compliance with this part and applicable rules, including: (a) A listing of services to be provided either 18 directly by the applicant or through contractual arrangements 19 with existing providers; 20 21 (b) The number and discipline of each professional 22 staff member to be employed; and 23 (c) Proof of financial ability to operate. An applicant must demonstrate financial ability to operate a 2.4 clinic or specialty clinic by submitting a balance sheet and 25 an income and expense statement for the first year of 26 27 operation which provide evidence of the applicant's having 2.8 sufficient assets, credit, and projected revenues to cover liabilities and expenses. The applicant shall have 29 demonstrated financial ability to operate if the applicant's 30 assets, credit, and projected revenues meet or exceed 31

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1 projected liabilities and expenses. All documents required 2 under this subsection must be prepared in accordance with generally accepted accounting principles, may be in a 3 compilation form, and the financial statement must be signed 4 by a certified public accountant. As an alternative to 5 6 submitting a balance sheet and an income and expense statement 7 for the first year of operation, the applicant may file a surety bond of at least \$500,000 which guarantees that the 8 clinic will act in full conformity with all legal requirements 9 for operating a clinic, payable to the agency. The agency may 10 adopt rules to specify related requirements for such surety 11 12 bond. 13 (8)(7) Each applicant for licensure shall comply with 14 the following requirements: (a) As used in this subsection, the term "applicant" 15 16 means an individual individuals owning or controlling, 17 directly or indirectly, 5 percent or more of an interest in a clinic or an individual owning or controlling, directly or 18 indirectly, any interest in a specialty clinic; the medical or 19 clinic director, or a similarly titled person who is 20 21 responsible for the day-to-day operation of the licensed 22 clinic; the financial officer or similarly titled individual 23 who is responsible for the financial operation of the clinic; and licensed health care practitioners at the clinic. 2.4 (b) Upon receipt of a completed, signed, and dated 25 application, the agency shall require background screening of 26 27 the applicant, in accordance with the level 2 standards for 2.8 screening set forth in paragraph (d) chapter 435. Proof of compliance with the level 2 background screening requirements 29 of paragraph (d) chapter 435 which has been submitted within 30 the previous 5 years in compliance with the any other health 31

1 care clinic licensure requirements of this part state is 2 acceptable in fulfillment of this paragraph. Applicants who own less than 10 percent of a health care clinic are not 3 required to submit fingerprints under this section. 4 5 (c) Each applicant must submit to the agency, with the б application, a description and explanation of any exclusions, 7 permanent suspensions, or terminations of an applicant from 8 the Medicare or Medicaid programs. Proof of compliance with 9 the requirements for disclosure of ownership and control 10 interest under the Medicaid or Medicare programs may be accepted in lieu of this submission. The description and 11 12 explanation may indicate whether such exclusions, suspensions, 13 or terminations were voluntary or not voluntary on the part of the applicant. The agency may deny or revoke licensure based 14 on information received under this paragraph. 15 (d) A license may not be granted to a clinic if the 16 17 applicant, or a person or entity identified in paragraph 18 (5)(b), has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to, any 19 offense prohibited under the level 2 standards for screening 20 21 set forth in chapter 435; any felony under chapter 400, 22 chapter 408, chapter 409, chapter 440, chapter 624, chapter 23 626, chapter 627, chapter 812, chapter 817, chapter 831, chapter 837, chapter 838, chapter 895, or chapter 896; or any 2.4 substantially comparable offense or crime of another state or 25 of the United States, if a felony in that jurisdiction, within 26 27 the past 10 years. Each person required to provide background 2.8 screening shall disclose to the agency any arrest for any crime for which any court disposition other than dismissal has 29 been made within the past 10 years. Failure to provide such 30 information shall be considered a material omission in the 31

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1 application process., or a violation of insurance fraud under 2 s. 817.234, within the past 5 years. If the applicant has been convicted of an offense prohibited under the level 2 standards 3 4 insurance fraud in any jurisdiction, the applicant must 5 show that his or her civil rights have been restored prior to 6 submitting an application. 7 (e) The agency may deny or revoke licensure or 8 exemption if the applicant has falsely represented any material fact or omitted any material fact from the 9 10 application which is permitted or required by this part. (f) Each applicant that performs the technical 11 12 component of magnetic resonance imaging, static radiographs, 13 computed tomography, or positron emission tomography, and also provides the professional components of such services through 14 an employee or independent contractor must provide to the 15 agency on a form provided by the agency, the name and address 16 17 of the clinic, the serial or operating number of each magnetic 18 resonance imaging, static radiograph, computed tomography, and positron emission tomography machine, the name of the 19 manufacturer of the machine, and such other information as 20 21 required by the agency to identify the machine. The 2.2 information must be provided to the agency upon renewal of the 23 clinic's licensure and within 30 days after a clinic begins using a machine for which it has not provided the information 2.4 25 to the agency. (g) The agency shall deny or revoke a specialty clinic 26 27 license if an applicant has been found quilty of, regardless 2.8 of adjudication, or entered a plea of nolo contendere or guilty to, any felony involving dishonesty or making a false 29 30 statement in any jurisdiction within the preceding 10 years. 31

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1	(h) The agency shall deny a specialty clinic license
2	application when any business entity or individual possessing
3	an ownership or pecuniary interest in the specialty clinic
4	also possessed an ownership or pecuniary interest,
5	individually or through any business entity, in any health
б	care facility whose license was revoked in any jurisdiction
7	during the pendency of that interest.
8	(i) The agency may not issue a specialty clinic
9	license to any applicant to whom the agency has sent notice
10	that there is a pending question as to whether one or more of
11	the individuals with an ownership of 5 percent or more or with
12	a pecuniary interest of \$5,000 or more in the clinic has a
13	disqualifying criminal record. The agency notice shall request
14	the applicant to submit any additional information necessary
15	to resolve the pending criminal background question within 21
16	days after receipt of the notice. The agency shall deny a
17	specialty clinic license application when the applicant has
18	failed to resolve a criminal background screening issue
19	pertaining to an individual who is required to meet criminal
20	background screening requirements of this part and the agency
21	raised such background screening issue by notice as set forth
22	in this part.
23	(9)(8) Requested information omitted from an
24	application for licensure, license renewal, or transfer of
25	ownership must be filed with the agency within 21 days after
26	receipt of the agency's request for omitted information, or
27	the application shall be deemed incomplete and shall be
28	withdrawn from further consideration.
29	(10)(9) The failure to file a timely renewal
30	application shall result in a late fee charged to the facility
31	in an amount equal to 50 percent of the current license fee.
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1 Section 4. Section 400.9915, Florida Statutes, is 2 amended to read: 3 400.9915 Clinic inspections; emergency suspension; 4 costs.--5 (1) Any authorized officer or employee of the agency 6 shall make inspections of the clinic or specialty clinic as 7 part of the initial license application or renewal application. The application for a clinic or specialty clinic 8 license issued under this part or for a renewal license 9 constitutes permission for an appropriate agency inspection to 10 verify the information submitted on or in connection with the 11 12 application or renewal. 13 (2) An authorized officer or employee of the agency may make unannounced inspections of clinics and specialty 14 clinics licensed pursuant to this part as are necessary to 15 determine that the clinic or specialty clinic is in compliance 16 17 with this part and with applicable rules. A licensed clinic or specialty clinic 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 21 determine compliance with this part and with applicable rules. 22 (3) Failure by a clinic or specialty clinic licensed 23 under this part to allow full and complete access to the premises and to billing records or information to any 2.4 representative of the agency who makes a request to inspect 25 the clinic or specialty clinic to determine compliance with 26 27 this part or failure by a clinic or specialty clinic to employ 2.8 a qualified medical director or clinic director constitutes a 29 ground for emergency suspension of the license by the agency 30 pursuant to s. 120.60(6). 31

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1 (4) In addition to any administrative fines imposed, 2 the agency may assess a fee equal to the cost of conducting a complaint investigation. 3 Section 5. Section 400.992, Florida Statutes, is 4 amended to read: 5 б 400.992 License renewal; transfer of ownership; 7 provisional license.--(1) An application for license renewal must contain 8 information as required by the agency. 9 10 (2) Ninety days before the expiration date, an application for renewal must be submitted to the agency. 11 12 (3) The clinic or specialty clinic must file with the 13 renewal application satisfactory proof that it is in compliance with this part and applicable rules. If there is 14 evidence of financial instability, the clinic or specialty 15 clinic must submit satisfactory proof of its financial ability 16 17 to comply with the requirements of this part. (4) When transferring the ownership of a clinic or 18 specialty clinic, the transferee must submit an application 19 for a license at least 60 days before the effective date of 20 21 the transfer. An application for change of ownership of a 22 clinic or specialty clinic is required only when 45 percent or 23 more of the ownership, voting shares, or controlling interest of a clinic or specialty clinic is transferred or assigned, 2.4 including the final transfer or assignment of multiple 25 transfers or assignments over a 2-year period that 26 27 cumulatively total 45 percent or greater. 28 (5) The license may not be sold, leased, assigned, or otherwise transferred, voluntarily or involuntarily, and is 29 valid only for the clinic or specialty clinic owners and 30 location for which originally issued. 31 20

1 (6) A clinic or specialty clinic against whom a 2 revocation or suspension proceeding is pending at the time of license renewal may be issued a provisional license effective 3 until final disposition by the agency of such proceedings. If 4 judicial relief is sought from the final disposition, the 5 6 agency that has jurisdiction may issue a temporary permit for 7 the duration of the judicial proceeding. Section 6. Section 400.9925, Florida Statutes, is 8 amended to read: 9 10 400.9925 Rulemaking authority; license fees.--(1) The agency shall adopt rules necessary to 11 12 administer the clinic and specialty clinic administration, 13 regulation, and licensure program, including rules establishing the specific licensure requirements, procedures, 14 forms, and fees. It shall adopt rules establishing a procedure 15 for the biennial renewal of licenses. The agency may issue 16 17 initial licenses for less than the full 2-year period by charging a prorated licensure fee and specifying a different 18 renewal date than would otherwise be required for biennial 19 licensure. The rules shall specify the expiration dates of 20 21 licenses, the process of tracking compliance with financial 22 responsibility requirements, and any other conditions of 23 renewal required by law or rule. (2) The agency shall adopt rules specifying 2.4 25 limitations on the number of licensed clinics and specialty <u>clinics</u> and licensees for which a medical director or a clinic 26 27 director may assume responsibility for purposes of this part. 2.8 In determining the quality of supervision a medical director or a clinic director can provide, the agency shall consider 29 30 the number of clinic or specialty clinic employees, the clinic 31

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1 or specialty clinic location, and the health care services 2 provided by the clinic or specialty clinic. (3) License application and renewal fees must be 3 4 reasonably calculated by the agency to cover its costs in carrying out its responsibilities under this part, including 5 6 the cost of licensure, inspection, and regulation of clinics 7 and specialty clinics, and must be of such amount that the total fees collected do not exceed the cost of administering 8 and enforcing compliance with this part. Clinic and specialty 9 clinic licensure fees are nonrefundable and may not exceed 10 \$2,000. The agency shall adjust the license fee annually by 11 12 not more than the change in the Consumer Price Index based on 13 the 12 months immediately preceding the increase. All fees collected under this part must be deposited in the Health Care 14 Trust Fund for the administration of this part. 15 16 Section 7. Section 400.993, Florida Statutes, is 17 amended to read: 400.993 Unlicensed clinics; penalties; fines; 18 verification of licensure status.--19 (1) It is unlawful to own, operate, or maintain a 20 21 clinic or specialty clinic without obtaining a license under 22 this part. 23 (2) Any person who owns, operates, or maintains an unlicensed clinic or specialty clinic commits a felony of the 2.4 third degree, punishable as provided in s. 775.082, s. 25 26 775.083, or s. 775.084. Each day of continued operation is a 27 separate offense. 2.8 (3) Any person found guilty of violating subsection 29 (2) a second or subsequent time commits a felony of the second degree, punishable as provided under s. 775.082, s. 775.083, 30 31

1 or s. 775.084. Each day of continued operation is a separate 2 offense. 3 (4) Any person who owns, operates, or maintains an unlicensed clinic or specialty clinic due to a change in this 4 part or a modification in agency rules within 6 months after 5 6 the effective date of such change or modification and who, 7 within 10 working days after receiving notification from the 8 agency, fails to cease operation or apply for a license under this part commits a felony of the third degree, punishable as 9 provided in s. 775.082, s. 775.083, or s. 775.084. Each day of 10 continued operation is a separate offense. 11 12 (5) Any clinic or specialty clinic that fails to cease 13 operation after agency notification may be fined for each day of noncompliance pursuant to this part. 14 (6) When a person has an interest in more than one 15 clinic or specialty clinic, and fails to obtain a license for 16 17 any one of these clinics, the agency may revoke the license, impose a moratorium, or impose a fine pursuant to this part on 18 any or all of the licensed clinics or specialty clinics until 19 such time as the unlicensed clinic or specialty clinic is 20 21 licensed or ceases operation. 22 (7) Any person aware of the operation of an unlicensed 23 clinic or specialty clinic must report that facility to the 2.4 agency. (8) Any health care provider who is aware of the 25 operation of an unlicensed clinic or specialty clinic shall 26 27 report that facility to the agency. Failure to report a clinic 2.8 or specialty clinic that the provider knows or has reasonable cause to suspect is unlicensed shall be reported to the 29 provider's licensing board. 30 31

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1 (9) The agency may not issue a license to a clinic or 2 specialty clinic that has any unpaid fines assessed under this 3 part. 4 Section 8. Section 400.9935, Florida Statutes, is amended to read: 5 б 400.9935 Clinic responsibilities.--7 (1) Each clinic and specialty clinic shall appoint a medical director or clinic director who shall agree in writing 8 to accept legal responsibility for the following activities on 9 behalf of the clinic. The medical director or the clinic 10 director shall: 11 12 (a) Have signs identifying the medical director or 13 clinic director posted in a conspicuous location within the clinic readily visible to all patients. 14 (b) Ensure that all practitioners providing health 15 care services or supplies to patients maintain a current 16 17 active and unencumbered Florida license. 18 (c) Review any patient referral contracts or agreements executed by the clinic. 19 (d) Ensure that all health care practitioners at the 20 21 clinic have active appropriate certification or licensure for 22 the level of care being provided. 23 (e) Ensure that all health care practitioners at the clinic provide health care services in accordance with the 2.4 requirements of subsection (6). 25 (f)(e) Serve as the clinic records owner as defined in 26 27 s. 456.057. 2.8 (g)(f) Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of 29 chapter 456, the respective practice acts, and rules adopted 30 under this part. 31

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1	<u>(h)(g)</u> Conduct systematic reviews of clinic billings
2	to ensure that the billings are not fraudulent or unlawful.
3	Upon discovery of an unlawful charge, the medical director or
4	clinic director shall take immediate corrective action. If the
5	clinic performs only the technical component of magnetic
6	resonance imaging, static radiographs, computed tomography, or
7	positron emission tomography, and provides the professional
8	interpretation of such services, in a fixed facility that is
9	accredited by the Joint Commission on Accreditation of
10	Healthcare Organizations or the Accreditation Association for
11	Ambulatory Health Care, and the American College of Radiology;
12	and if, in the preceding quarter, the percentage of scans
13	performed by that clinic which was billed to all personal
14	injury protection insurance carriers was less than 15 percent,
15	the chief financial officer of the clinic may, in a written
16	acknowledgment provided to the agency, assume the
17	responsibility for the conduct of the systematic reviews of
18	clinic billings to ensure that the billings are not fraudulent
19	or unlawful.
20	(i) Serve in that capacity for no more than a maximum
21	of five health care clinics that have a cumulative total of no
22	more than 200 employees and persons under contract with the
23	health care clinic at a given time. A medical or clinic
24	director may not supervise a health care clinic more than 200
25	miles away from any other health care clinic supervised by the
26	same medical or clinic director. The agency may allow for
27	waivers to the limitations of this paragraph upon a showing of
28	good cause and a determination by the agency that the medical
29	director will be able to adequately perform the requirements
30	of this subsection.
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1 (2) Any business that becomes a clinic or specialty 2 clinic after commencing operations must, within 5 days after becoming a clinic or specialty clinic, file a license 3 application under this part and shall be subject to all 4 provisions of this part applicable to a clinic or specialty 5 6 clinic. 7 (3) Any contract to serve as a medical director or a 8 clinic director entered into or renewed by a physician or a licensed health care practitioner in violation of this part is 9 void as contrary to public policy. This subsection shall apply 10 to contracts entered into or renewed on or after March 1, 11 12 2004. 13 (4) All charges or reimbursement claims made by or on behalf of a clinic or specialty clinic that is required to be 14 licensed under this part, but that is not so licensed, or that 15 is otherwise operating in violation of this part, are unlawful 16 17 charges, and therefore are noncompensable and unenforceable. 18 (5) Any person establishing, operating, or managing an unlicensed clinic or specialty clinic otherwise required to be 19 licensed under this part, or any person who knowingly files a 20 21 false or misleading license application or license renewal 22 application, or false or misleading information related to 23 such application or department rule, commits a felony of the third degree, punishable as provided in s. 775.082, s. 2.4 775.083, or s. 775.084. 25 (6) All persons providing health care services to 26 27 individuals must comply with the licensure laws and rules 2.8 under which that person is licensed to provide such services or as otherwise provided by law. 29 30 31

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1 (7) (6) Any licensed health care provider who violates 2 this part is subject to discipline in accordance with this chapter and his or her respective practice act. 3 4 (8)(7) The agency may fine, or suspend or revoke the license of, any clinic or specialty clinic licensed under this 5 6 part for operating in violation of the requirements of this 7 part or the rules adopted by the agency. 8 (9)(8) The agency shall investigate allegations of noncompliance with this part and the rules adopted under this 9 10 part. (10)(9) Any person or entity providing health care 11 12 services which is not a clinic or specialty clinic, as defined 13 under s. 400.9905, may voluntarily apply for a certificate of exemption from licensure under its exempt status. Certificates 14 of exemption shall expire in 2 years and may be renewed. with 15 the agency on a form that sets forth its name or names and 16 17 addresses, a statement of the reasons why it cannot be defined 18 a clinic, and other information deemed necessary by the 19 agency. An exemption is not transferable. The agency may 20 charge an applicant for a certificate of exemption in an 21 amount equal to \$100 or the actual cost of processing the certificate, whichever is less. 22 23 (a) The agency shall provide a form that requires the name or names and addresses, a statement of the reasons why 2.4 the applicant is exempt from licensure as a health care clinic 25 or specialty clinic, and other information deemed necessary by 26 27 the agency. The signature on an application for a certificate 2.8 of exemption must be notarized and signed by persons having knowledge of the truth of its contents. An exemption is not 29 transferable and is valid only for the reasons, location, 30 persons, and entity set forth on the application form. A 31

1 person or entity claiming an exemption under this part or 2 issued a current certificate of exemption must be exempt from the licensing provisions of this part at all times, or such 3 4 claim or certificate shall be invalid from the date that such person or entity is not exempt. 5 б (b) The agency shall charge an applicant for a 7 certificate of exemption a fee of \$100 to cover the cost of 8 processing the certificate or the actual cost of processing the certificate, whichever is less. 9 10 (c) An application for the renewal of a certificate of exemption must be submitted to the agency prior to the 11 12 expiration of the certificate of exemption. The agency may 13 investigate any applicant, person, or entity claiming an exemption for purposes of determining compliance when a 14 certificate of exemption is sought. Authorized personnel of 15 the agency shall have access to the premises of any 16 17 certificateholder, applicant, or specialty clinic for the sole 18 purpose of determining compliance with an exemption under this part. The agency shall have access to all billings and records 19 indicated in s. 400.9915(2) and agency rules. The agency may 2.0 21 deny or withdraw a certificate of exemption when a person or 2.2 entity does not qualify under this part. 23 (d) A certificate of exemption is considered withdrawn when the agency determines that an exempt status cannot be 2.4 confirmed. The provisions applicable to the unlicensed 25 operation of a health care clinic or specialty clinic apply to 26 27 any health care provider that self-determines or claims an 2.8 exemption or that is issued a certificate of exemption if, in fact, such clinic does not meet the exemption claimed. 29 30 (e) Any person or entity that submits an application for a certificate of exemption which contains fraudulent or 31

1 material and misleading information commits a felony of the 2 third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. 3 4 (f) A response to a request in writing for additional information or clarification must be filed with the agency no 5 6 later than 21 days after receipt of the request or the 7 application shall be denied. (g) The agency shall grant or deny an application for 8 a certificate of exemption in accordance with s. 120.60(1). 9 10 (h) A person or entity that qualifies as a health care clinic or specialty clinic and has been denied a certificate 11 12 of exemption must file an initial application and pay the fee. 13 A certificate of exemption is valid only when issued and 14 current. (i) The agency shall issue an emergency order of 15 suspension of a certificate of exemption when the agency finds 16 17 that the applicant has provided false or misleading material 18 information or omitted any material fact from the application for a certificate of exemption which is permitted or required 19 by this part, or has submitted false or misleading information 2.0 21 to the agency when self-determining an exempt status and 2.2 materially misleading the agency as to such status. 23 (11)(10) The clinic or specialty clinic shall display its license in a conspicuous location within the clinic 2.4 readily visible to all patients. 25 (12)(11)(a) Each clinic engaged in magnetic resonance 26 27 imaging services must be accredited by the Joint Commission on 2.8 Accreditation of Healthcare Organizations, the American College of Radiology, or the Accreditation Association for 29 Ambulatory Health Care, within 1 year after licensure. 30 However, a clinic may request a single, 6-month extension if 31

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1 it provides evidence to the agency establishing that, for good 2 cause shown, such clinic can not be accredited within 1 year after licensure, and that such accreditation will be completed 3 within the 6-month extension. After obtaining accreditation as 4 required by this subsection, each such clinic must maintain 5 6 accreditation as a condition of renewal of its license. 7 (b) The agency may deny the application or revoke the 8 license of any entity formed for the purpose of avoiding compliance with the accreditation provisions of this 9 10 subsection and whose principals were previously principals of an entity that was unable to meet the accreditation 11 12 requirements within the specified timeframes. The agency may 13 adopt rules as to the accreditation of magnetic resonance imaging clinics. 14 (13)(12) The agency shall give full faith and credit 15 pertaining to any past variance and waiver granted to a 16 17 magnetic resonance imaging clinic from rule 64-2002, Florida 18 Administrative Code, by the Department of Health, until September 2004. After that date, such clinic must request a 19 variance and waiver from the agency under s. 120.542. 20 21 (14) Every licensed specialty clinic shall file with 2.2 the agency no less frequently than annually, including 23 concurrently with the filing of any change of ownership application, upon forms to be furnished by the agency, an 2.4 audited report showing the following information: 25 (a) The number of patients served by the specialty 26 clinic during the previous 12-month period, which report may 27 2.8 exclude any partial month for the month when the report was 29 <u>prepared;</u> 30 (b) Total specialty clinic operating expenses; 31

1	(c) Gross patient charges by payor category, including
2	Medicare, Medicaid, county indigent programs, any other
3	governmental programs, private insurance, self-paying
4	patients, nonpaying patients and other payees;
5	(d) The cost of operation of the specialty clinic
6	during the previous 12-month period, excluding any partial
7	month during which time the report was prepared;
8	(e) Unless the specialty clinic can demonstrate that
9	the clinic already has furnished the required information
10	regarding a particular subject individual, the full name of
11	any individual who became an owner or became possessed of any
12	pecuniary interest in the subject clinic since the last report
13	to the agency, along with the disclosure of the information
14	required by s. 400.9961(2) as to such individual; and
15	(f) A current statement of the source of funds for
16	payment of the costs of establishing the specialty clinic and
17	for sustaining the operation of the specialty clinic until its
18	operation produces a positive cash flow.
19	(15) Every licensee of a specialty clinic has a
20	continuing obligation to comply with this part and to report
21	to the agency any change of circumstance related to the
22	clinic's continuing compliance with this part. Such change of
23	circumstance includes, but is not limited to, any change in
24	the ownership of the specialty clinic, the addition of any
25	individual or business entity possessing a pecuniary interest
26	in the specialty clinic, the employment of any individual as a
27	member of the specialty clinic's staff who would be required
28	to undergo a criminal background screening if such individual
29	had been an employee at the time of the initial licensure, and
30	any change in the medical or clinic director. The clinic shall
31	furnish the information required about and of such individuals
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1 under this part and s. 400.991 within 30 days of the occurrence of such change of circumstance. 2 (16) The clinic or specialty clinic shall display a 3 4 sign in a conspicuous location within the clinic readily 5 visible to all patients indicating that, pursuant to s. 6 626.9892, the Department of Financial Services may pay rewards 7 of up to \$25,000 to persons providing information leading to 8 the arrest and conviction of persons committing crimes investigated by the Division of Insurance Fraud arising from 9 violations of s. 440.105, s. 624.15, s. 626.9541, s. 626.989, 10 or s. 817.234. An authorized employee of the Division of 11 12 Insurance Fraud may make unannounced inspections of a clinic or specialty clinic licensed under this part as necessary to 13 determine whether the clinic is in compliance with this 14 subsection. A licensed clinic or specialty clinic shall allow 15 full and complete access to the premises to such authorized 16 17 employee of the division who makes an inspection to determine 18 compliance with this subsection. Section 9. Section 400.994, Florida Statutes, is 19 amended to read: 20 21 400.994 Injunctions.--(1) The agency may institute injunctive proceedings in 22 23 a court of competent jurisdiction in order to: (a) Enforce the provisions of this part or any minimum 2.4 standard, rule, or order issued or entered into pursuant to 25 this part if the attempt by the agency to correct a violation 26 27 through administrative fines has failed; if the violation 2.8 materially affects the health, safety, or welfare of clinic or specialty clinic patients; or if the violation involves any 29 30 operation of an unlicensed clinic or specialty clinic. 31

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1 (b) Terminate the operation of a clinic or specialty 2 clinic if a violation of any provision of this part, or any rule adopted pursuant to this part, materially affects the 3 health, safety, or welfare of clinic or specialty clinic 4 5 patients. б (2) Such injunctive relief may be temporary or 7 permanent. 8 (3) If action is necessary to protect clinic or specialty clinic patients from life-threatening situations, 9 10 the court may allow a temporary injunction without bond upon proper proof being made. If it appears by competent evidence 11 12 or a sworn, substantiated affidavit that a temporary 13 injunction should issue, the court, pending the determination on final hearing, shall enjoin operation of the clinic or 14 15 specialty clinic. Section 10. Section 400.995, Florida Statutes, is 16 17 amended to read: 400.995 Agency administrative penalties .--18 19 (1) The agency may deny the application for a license renewal, revoke or suspend the license, and impose 20 21 administrative fines of up to \$5,000 per violation for 22 violations of the requirements of this part or rules of the 23 agency. In determining if a penalty is to be imposed and in fixing the amount of the fine, the agency shall consider the 2.4 following factors: 25 (a) The gravity of the violation, including the 26 27 probability that death or serious physical or emotional harm 2.8 to a patient will result or has resulted, the severity of the action or potential harm, and the extent to which the 29 30 provisions of the applicable laws or rules were violated. 31

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1 (b) Actions taken by the owner, medical director, or 2 clinic director to correct violations. 3 (c) Any previous violations. 4 (d) The financial benefit to the clinic or specialty clinic of committing or continuing the violation. 5 б (2) Each day of continuing violation after the date 7 fixed for termination of the violation, as ordered by the 8 agency, constitutes an additional, separate, and distinct violation. 9 10 (3) Any action taken to correct a violation shall be documented in writing by the owner, medical director, or 11 12 clinic director of the clinic or specialty clinic and verified 13 through followup visits by agency personnel. The agency may impose a fine and, in the case of an owner-operated clinic or 14 specialty clinic, revoke or deny a clinic's license when a 15 clinic medical director or clinic director knowingly 16 17 misrepresents actions taken to correct a violation. (4) For fines that are upheld following administrative 18 or judicial review, the violator shall pay the fine, plus 19 interest at the rate as specified in s. 55.03, for each day 20 21 beyond the date set by the agency for payment of the fine. 22 (5) Any unlicensed clinic or specialty clinic that 23 continues to operate after agency notification is subject to a \$1,000 fine per day. 2.4 (6) Any licensed clinic or specialty clinic whose 25 owner, medical director, or clinic director concurrently 26 27 operates an unlicensed clinic or specialty clinic shall be 2.8 subject to an administrative fine of \$5,000 per day. (7) Any clinic or specialty clinic whose owner fails 29 30 to apply for a change-of-ownership license in accordance with 31

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s. 400.992 and operates the clinic or specialty clinic under 1 2 the new ownership is subject to a fine of \$5,000. (8) The agency, as an alternative to or in conjunction 3 4 with an administrative action against a clinic or specialty clinic for violations of this part and adopted rules, shall 5 6 make a reasonable attempt to discuss each violation and 7 recommended corrective action with the owner, medical 8 director, or clinic director of the clinic or specialty clinic, prior to written notification. The agency, instead of 9 fixing a period within which the clinic or specialty clinic 10 shall enter into compliance with standards, may request a plan 11 12 of corrective action from the clinic or specialty clinic which 13 demonstrates a good faith effort to remedy each violation by a specific date, subject to the approval of the agency. 14 (9) Administrative fines paid by any clinic or 15 specialty clinic under this section shall be deposited into 16 17 the Health Care Trust Fund. 18 (10) If the agency issues a notice of intent to deny a license application after a temporary license has been issued 19 pursuant to s. 400.991(3), the temporary license shall expire 20 21 on the date of the notice and may not be extended during any 22 proceeding for administrative or judicial review pursuant to 23 chapter 120. Section 11. Section 400.996, Florida Statutes, is 2.4 created to read: 25 400.996 Specialty clinics; complaints; audits; 26 27 referrals.--2.8 (1) The agency shall receive, document, and process complaints about specialty clinics. Upon receipt of any 29 complaint that asserts the existence of facts evidencing 30 possible billing fraud by a specialty clinic or by any 31

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1 employee of a specialty clinic, the agency shall request the 2 complainant to make such assertions by sworn affidavit. (2) Upon receipt of any sworn affidavit that asserts 3 4 the existence of facts evidencing possible billing fraud by a 5 specialty clinic or any of its employees, the agency shall 6 refer the complaint to the Office of Fiscal Integrity within 7 the Department of Financial Services. (3) The Department of Financial Services shall report 8 findings to the agency for any appropriate licensure action. 9 10 Such report shall include a statement of facts as determined by the Department of Financial Services to exist, specifically 11 12 with regard to the possible violations of licensure 13 requirements. If during an investigation the department has reason to believe that any criminal law of this state has or 14 may have been violated, the department shall refer such 15 investigation to appropriate prosecutorial agencies and shall 16 17 provide investigative assistance to those agencies as 18 <u>required.</u> 19 (4) The investigating authority and the agency shall cooperate with each other with respect to preparing a record 2.0 21 and sharing information from which the agency may determine if 2.2 any action for sanctions under this part by the agency is 23 warranted. 2.4 (5) Any person submitting a sworn complaint that initiates a complaint investigation pursuant to this section, 25 which sworn complaint is determined to be totally without any 26 27 factual basis to support the assertions made in the complaint 2.8 that facts existed evidencing possible fraudulent practices by a specialty clinic or any of its employees, shall be quilty of 29 a misdemeanor of the first degree, punishable as provided in 30 s. 775.082 or s. 775.083. 31

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1	(6) The Office of Fiscal Integrity within the
2	Department of Financial Services shall conduct unannounced
3	reviews, investigations, analyses, and audits to investigate
4	complaints and, as necessary, to determine whether specialty
5	clinic billings are fraudulent or unlawful. The Department of
б	Financial Services is expressly authorized to enter upon the
7	premises of the clinic during regular business hours and
8	demand and immediately secure copies of billing and other
9	records of the clinic that will enable the Department of
10	Financial Services to investigate complaints or determine
11	whether specialty clinic billings are fraudulent or unlawful.
12	(7) A licensed specialty clinic shall allow full,
13	complete, and immediate access to the premises and to billing
14	records or information to any such officer or employee who
15	conducts a review, investigation, analysis, or audit to
16	determine compliance with this part and with applicable rules.
17	Failure to allow full, complete, and immediate access to the
18	premises and to billing records or information to any
19	representative of the agency or Department of Financial
20	Services who attempts to conduct a review, investigation,
21	analysis, or audit to determine compliance with this part
22	constitutes a ground for emergency suspension of the license
23	by the agency pursuant to s. 120.60(6).
24	(8) In addition to any administrative fines imposed,
25	the agency may assess a fee equal to the cost of conducting
26	any review, investigation, analysis, or audit performed by the
27	agency or the department.
28	(9) All investigators designated by the Chief
29	Financial Officer to perform duties under this part and who
30	are certified under s. 943.1395 are law enforcement officers
31	of the state. Such investigators have the authority to conduct
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criminal investigations, bear arms, make arrests, and apply for, serve, and execute search warrants, arrest warrants, capias, and other process throughout the state pertaining to fraud investigations under this section. Section 12. Paragraph (hh) is added to subsection (1) of section 456.072, Florida Statutes, to read: 456.072 Grounds for discipline; penalties; enforcement.--(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken: (hh) Intentionally providing false information on an application for a certificate of exemption from clinic licensure under part XIII of chapter 400. Section 13. This act shall take effect January 1, 2007.

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CS for CS for SB 2112

1		STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
2		COMMITTEE SUBSTITUTE FOR <u>CS/SB 2112</u>
3		
4	-	Provides for a legislative finding regarding additional regulation of specialty health care clinics, and defines
5		the terms "specialty clinic," "infusion therapy," and
6	_	Requires that each specialty clinic be licensed and
7		maintain a valid license with the Agency for Health Care Administration (AHCA or agency), that the clinic location
8	 8 be licensed separately regardless of whether the oris operated under the same business name or manage 9 another clinic, and that the clinic obtain a separate health care clinic license and provide to the AHC 	be licensed separately regardless of whether the clinic is operated under the same business name or management as
-		another clinic, and that the clinic obtain a separate health care clinic license and provide to the AHCA, at
10		least quarterly, its projected street location.
11	-	Provides that a specialty clinic operating without a specialty clinic license at the time of the effective
12		date of the bill must be given a reasonable time to obtain this license.
13	_	Requires biannual renewal of a specialty clinic license.
14	_	Requires notarization of an application for a specialty
15		clinic license or for renewal of an existing license on
16	6 specified license fee, and also specifies info	forms furnished by the AHCA and must be accompanied by a specified license fee, and also specifies information that must be included in the application in addition to
17		information currently required under the Health Care Clinic Act.
18	_	Provides that the requirements for an applicant for
19		clinic licensure, including the background screening of the applicant, pertain to an individual owning or
20	20 controlling, directly or indirectly, any interest specialty clinic.	controlling, directly or indirectly, any interest in a
21	_	Requires the AHCA to deny or revoke a specialty clinic
22		license if: an applicant has been found guilty of, regardless of adjudication, or entered a plea of nolo
23	23 contendere or guilty to, a specified offense; or	contendere or guilty to, a specified offense; or any business entity or individual possessing an ownership or
24 pecuniary interest in the specialty of	pecuniary interest in the specialty clinic also possessed an ownership or pecuniary interest, individually or	
25		through any business entity, in any health care facility whose license was revoked in any jurisdiction during the
26		pendency of that interest.
27	-	Provides that the AHCA may not issue a specialty clinic license to any applicant to whom the agency has sent
28		notice that there is a pending question as to whether one or more of the individuals with an ownership of 5 percent
29	or more or with a pecuniary interest of \$5,000 or mo	or more or with a pecuniary interest of \$5,000 or more in the clinic has a disqualifying criminal record.
30		
31	-	Requires the AHCA to deny a specialty clinic license application when the applicant has failed to resolve a criminal background screening issue. 39

1	-	Provides that specialty clinics will be subject to
2		requirements applicable to health care clinics regarding AHCA inspections as part of the initial license
3		application or renewal application and unannounced AHCA inspections to determine compliance with licensure laws
4		and rules, and provides for emergency suspension of the clinic's license when it does not allow the AHCA access
5		to the clinic premises and billing or other specified records as part of an inspection or the clinic fails to
6		employ a qualified medical director.
7	-	Provides that specialty clinics are also subject to provisions requiring the filing of satisfactory proof of
8		compliance with licensure laws and rules and financial ability to comply; specifying what is necessary for an
9		application for transfer or change of ownership; restricting the selling, leasing, assignment, or
10		otherwise, transfer of a license and limiting its validity to the clinic owners and location for which
11		originally issued; and directing when a provisional license or temporary permit may be issued.
12	-	Authorizing the AHCA to enact rules relevant to: the administration of the clinic administration, regulation,
13		and licensure program, including specific licensure requirements, procedures, forms, and fees; limitations on
14		the number of licensed clinics and licensees; and other matters.
15	_	Provides that it is a third degree felony for any person
16		to own, operate, or maintain a specialty clinic without obtaining a license, and a second or subsequent violation
17		is a second degree felony, and also provides for other third degree felony penalties relating to unlawful acts
18		involving a specialty clinic and fines, revocations of licenses, and other sanctions regarding non-compliance
19		with certain requirements relating to specialty clinics.
20	-	Requires the medical or clinic director of a specialty clinic to ensure that all health care practitioners at
21 22		the clinic provide health care services in accordance with law.
22	-	Requires any business that becomes a specialty clinic
23		after commencing operations, within 5 days after becoming a specialty clinic, to file a license application, and
24		provide the clinic is subject to all provisions of law applicable to a specialty clinic.
25	-	Provides that all charges or reimbursement claims made by
26		or on behalf of a specialty clinic that is required to be licensed, but that is not so licensed, or that is
27		otherwise operating in violation of the law, are unlawful charges, and therefore are noncompensable and
28		unenforceable.
29	-	Provides that any person establishing, operating, or managing an unlicensed specialty clinic otherwise
30		required to be licensed, or any person who knowingly files a false or misleading license application or
31		license renewal application, or false or misleading information relating to such application or department 40

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1		rule, commits a third degree felony.
2 3	-	Provides that the AHCA may fine, or suspend or revoke the license of, any licensed specialty clinic for operating in violation of the law.
4	-	Provides that any person or entity providing health care
5 certificate of exemption from	services which is not a specialty clinic may apply for a certificate of exemption from licensure under its exempt status, and that a certificate of exemption expires in 2 years and may be renewed.	
7	_	Requires the AHCA to provide a form and require certain
8		information of an applicant for exemption from licensure as a specialty clinic, and requires a person or entity
9		that qualifies as a specialty clinic and has been denied a certificate of exemption to file an initial application and pay a fee.
10		
11	-	Requires a specialty clinic to display its license in a conspicuous location within the clinic readily visible to all patients, and also display an antifraud sign as
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13	-	Requires each licensed specialty clinic to file with the AHCA an audited report showing specified information.
14	_	Authorizes the AHCA to institute injunctive proceedings
15		in a court of competent jurisdiction if a violation of the provisions of the Health Care Clinic Act or any
16		minimum standard, rule, or order issued or entered into pursuant to the Act materially affects the health,
17		safety, or welfare of specialty clinic patients or if the violation involves any operation of an unlicensed
18		specialty clinic, and also to terminate the operation of a specialty clinic based on such violation.
19	-	Provides that if action is necessary to protect specialty
20 21		clinic patients from life-threatening situations, the court may allow a temporary injunction without bond upon proper proof being made.
22	is	Provides, in regard to administrative penalties the AHCA is authorized to impose for a violation, that the AHCA
	must consider the financial benefit to the specialty clinic of committing or continuing the violation.	
24	_	Provides that an action taken to correct a violation must
25		be documented in writing by the owner, medical director, or clinic director of the specialty clinic and verified
26	6 through follo	through follow-up visits by AHCA personnel.
27		Authorizes the AHCA to impose a fine and, in the case of an owner-operated specialty clinic, revoke or deny a
28		clinic's license, when a clinic medical director or clinic director knowingly misrepresents actions taken to
29		correct a violation, and also impose an administrative fine on an unlicensed specialty clinic that continues to
30		operate after AHCA notification and on any specialty
31		clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership.

1	-	Provides that the AHCA, as an alternative to or in
2		conjunction with an administrative action against a specialty clinic for violations, must make a reasonable
3		attempt to discuss each violation and recommended corrective action with the owner, medical director, or
4		clinic director of the specialty clinic, prior to written notification, and that the AHCA may request a plan of corrective action as specified.
5	_	Provides that certain administrative fines imposed on a
6		specialty clinic be deposited into the Health Care Trust Fund.
7	_	Requires the AHCA to receive, document, and process
8		complaints about specialty clinics and complaints to the Office of Fiscal Integrity (OIF) of the Division of
9		Insurance Fraud (DIF) upon receipt of any sworn affidavit that asserts the existence of facts evidencing possible
10 11		billing fraud, and requires the DIF to report findings to the AHCA for any appropriate licensure action and refer possible criminal law violations to appropriate
12		prosecutorial agencies and provide investigative assistance to those agencies as required.
13	_	Provides that any person submitting a sworn complaint
14		that is determined to be totally without factual basis commits a first degree misdemeanor.
15	-	Requires the OIF to conduct unannounced reviews,
16		investigations, analyses, and audits to investigate complaints and to determine whether specialty clinic billings are fraudulent or unlawful, and authorizes the
17		DIF to enter upon the premises of the clinic during
18		regular business hours and demand and immediately secure copies of billing and other records of the clinic that will enable it to investigate complaints or determine
19		fraud or unlawful actions.
20	-	Provides that a licensed specialty clinic must allow access to the premises and to billing records or other
21		information to determine compliance with laws, and provides sanctions for failure to allow such access.
22	_	Provides that all investigators who are designated by the
23		Chief Financial Officer to perform duties under the Health Care Clinic Act and who are certified law
24		enforcement officers are law enforcement officers of the state authorized to conduct criminal investigations, bear
25		arms, make arrests, and apply for, serve, and execute search warrants, arrest warrants, capias, and other
26		process throughout the state pertaining to fraud investigations as provided.
27		invebergations as provided.
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