${\bf By}$ Senator Garcia

	40-01188-10 20102480
1	A bill to be entitled
2	An act relating to health care; amending s. 400.990,
3	F.S.; providing additional legislative findings;
4	amending s. 400.9905, F.S.; redefining the term
5	"clinic" for purposes of the Health Care Clinic Act to
6	include certain additional providers; defining the
7	term "specialty clinic"; including certain facilities
8	owned by publicly traded corporations excluded by the
9	definition of the term "clinic"; defining the terms
10	"infusion therapy" and "fraud"; amending s. 400.991,
11	F.S.; requiring specialty clinics to be subject to
12	licensure requirements; requiring additional persons
13	to be subject to background screening; revising
14	certain requirements for applying for licensure as a
15	health care clinic; creating additional requirements
16	for applying for licensure as a specialty clinic;
17	creating s. 400.9914, F.S.; providing additional
18	grounds under which the Agency for Health Care
19	Administration is required to deny or revoke a license
20	due to a finding of guilt for committing a felony;
21	providing grounds for the denial of specialty clinic
22	licensure; amending s. 400.9915, F.S.; providing
23	additional grounds for an emergency suspension of a
24	license; creating s. 400.9921, F.S.; providing
25	additional requirements for license renewal, and
26	transfer of ownership; amending s. 400.9925, F.S.;
27	authorizing the agency to adopt rules regarding
28	specialty clinics; amending s. 400.993, F.S.;
29	including specialty clinics within provisions

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30	regarding unlicensed clinics; amending s. 400.9935,
31	F.S.; including specialty clinics within provisions
32	regarding clinic responsibilities; revising the
33	responsibilities of the medical director and the
34	clinical director; requiring all persons providing
35	health care services to individuals in a specialty
36	clinic to comply with the licensure laws and rules
37	under which that person is licensed; providing for a
38	certificate of exemption from licensure as a clinic to
39	expire within a specified period; providing for
40	renewal of the certificate of exemption; providing the
41	application procedures for a certificate of exemption;
42	providing grounds for the denial, withdrawal, or
43	emergency suspension of a certificate of exemption by
44	the Agency for Health Care Administration; providing
45	that it is a third-degree felony for an applicant to
46	submit fraudulent or material and misleading
47	information to the agency; requiring specialty clinics
48	to display signs containing certain information
49	relating to insurance fraud; authorizing compliance
50	inspections by the Division of Insurance Fraud;
51	requiring clinics to allow inspection access;
52	requiring a specialty clinic to file an audited
53	report; providing requirements for the audited report;
54	requiring a specialty clinic to maintain compliance
55	with part X of ch. 400, F.S.; amending s. 400.995,
56	F.S.; authorizing the agency to impose administrative
57	penalties against a specialty clinic; authorizing the
58	agency to request a plan of corrective action from the

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59	clinic or specialty clinic; creating s. 400.996, F.S.;
60	creating a process whereby the agency receives,
61	documents, and processes complaints about specialty
62	clinics; requiring the agency to request that
63	complaints regarding billing fraud by a specialty
64	clinic be made by sworn affidavit; requiring the
65	agency to refer to the Office of Fiscal Integrity
66	within the Department of Financial Services any sworn
67	affidavit asserting billing fraud by a specialty
68	clinic; requiring the department to report findings
69	regarding billing fraud by a specialty clinic to the
70	agency; requiring the department to refer an
71	investigation to prosecutorial authorities and provide
72	investigative assistance under certain circumstances;
73	providing that it is a first-degree misdemeanor to
74	submit an affidavit asserting billing fraud by a
75	specialty clinic which is without any factual basis;
76	allowing the department to conduct unannounced
77	reviews, investigations, analyses, and audits to
78	investigate complaints of billing fraud by a specialty
79	clinic; authorizing the department to enter upon the
80	premises of a specialty clinic and immediately secure
81	copies of certain documents; requiring a specialty
82	clinic to allow full and immediate access to the
83	premises and records of the clinic to a department
84	officer or employee under s. 400.996, F.S.; providing
85	that failure to provide such access is a ground for
86	emergency suspension of the license of the specialty
87	clinic; permitting the agency to assess a fee against

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88	a specialty clinic equal to the cost of conducting a
89	review, investigation, analysis, or audit performed by
90	the agency or the department; providing that all
91	investigators designated by the Chief Financial
92	Officer to perform duties under part X of ch. 400,
93	F.S., and certified under s. 943.1395, F.S., are law
94	enforcement officers of the state; amending s.
95	408.802, F.S.; providing that specialty clinics are
96	subject to part X of ch. 400, F.S.; amending s.
97	408.820, F.S.; providing that specialty clinics are
98	exempt from s. 408.810(6), (7), and (10), F.S.;
99	amending s. 456.072, F.S.; providing that
100	intentionally placing false information in an
101	application for a certificate of exemption from clinic
102	licensure constitutes grounds for disciplinary action;
103	designating the Florida Center for Nursing as the
104	"Florida Barbara B. Lumpkin Center for Nursing";
105	directing the Department of Health to erect suitable
106	markers; authorizing additional positions and
107	providing an appropriation; providing an effective
108	date.
109	
110	Be It Enacted by the Legislature of the State of Florida:
111	
112	Section 1. Section 400.990, Florida Statutes, is amended to
113	read:
114	400.990 Short title; legislative findings
115	(1) This part, consisting of <u>ss. 400.990-400.996</u> ss.
116	400.990-400.995, may be cited as the "Health Care Clinic Act."

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117	(2) The Legislature finds that the regulation of health
118	care clinics must be strengthened to prevent significant cost
119	and harm to consumers. The purpose of this part is to provide
120	for the licensure, establishment, and enforcement of basic
121	standards for health care clinics and to provide administrative
122	oversight by the Agency for Health Care Administration.
123	(3) The Legislature further finds the additional regulation
124	of specialty health care clinics is necessary to prevent
125	significant fraudulent practices in the provision of infusion
126	therapy services in this state.
127	(4) The purpose of this part is to provide for the
128	licensure, establishment, and enforcement of basic standards for
129	health care clinics and to provide administrative oversight by
130	the Agency for Health Care Administration.
131	Section 2. Subsection (4) of section 400.9905, Florida
132	Statutes, is amended, and subsections (8), (9), and (10) are
133	added to that section, to read:
134	400.9905 Definitions
135	(4) "Clinic" means an entity at which health care services
136	are provided to individuals and which tenders charges for
137	reimbursement for such services, including a mobile clinic and a
138	portable equipment provider. For purposes of this part, the term
139	does not include and the licensure requirements of this part do
140	not apply to:
141	(a) Entities licensed or registered by the state under
142	chapter 395; or entities licensed or registered by the state and
143	providing only health care services within the scope of services
144	authorized under their respective licenses granted under ss.
145	383.30-383.335, chapter 390, chapter 394, chapter 397, this

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40-01188-10 20102480 146 chapter except part X, chapter 429, chapter 463, chapter 465, 147 chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 148 149 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 150 provides neonatal or pediatric hospital-based health care 151 152 services or other health care services by licensed practitioners 153 solely within a hospital licensed under chapter 395. 154 (b) Entities that own, directly or indirectly, entities 155 licensed or registered by the state pursuant to chapter 395; or 156 entities that own, directly or indirectly, entities licensed or 157 registered by the state and providing only health care services 158 within the scope of services authorized pursuant to their 159 respective licenses granted under ss. 383.30-383.335, chapter 160 390, chapter 394, chapter 397, this chapter except part X, 161 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 162 part I of chapter 483, chapter 484, chapter 651; end-stage renal 163 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 164 165 subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners 166 167 solely within a hospital licensed under chapter 395. (c) Entities that are owned, directly or indirectly, by an 168 entity licensed or registered by the state pursuant to chapter 169 170 395; or entities that are owned, directly or indirectly, by an

171 entity licensed or registered by the state and providing only 172 health care services within the scope of services authorized 173 pursuant to their respective licenses granted under ss. 383.30-174 383.335, chapter 390, chapter 394, chapter 397, this chapter

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40-01188-10 20102480 175 except part X, chapter 429, chapter 463, chapter 465, chapter 176 466, chapter 478, part I of chapter 483, chapter 484, or chapter 177 651; end-stage renal disease providers authorized under 42 178 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 179 180 provides neonatal or pediatric hospital-based health care 181 services by licensed practitioners solely within a hospital 182 under chapter 395. (d) Entities that are under common ownership, directly or 183 184 indirectly, with an entity licensed or registered by the state 185 pursuant to chapter 395; or entities that are under common 186 ownership, directly or indirectly, with an entity licensed or 187 registered by the state and providing only health care services 188 within the scope of services authorized pursuant to their 189 respective licenses granted under ss. 383.30-383.335, chapter 190 390, chapter 394, chapter 397, this chapter except part X, 191 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 192 part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, 193 194 subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or 195 pediatric hospital-based health care services by licensed 196 197 practitioners solely within a hospital licensed under chapter 198 395. 199 (e) An entity that is exempt from federal taxation under 26

(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

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40-01188-10 20102480 204 physician orders, any community college or university clinic, 205 and any entity owned or operated by the federal or state 206 government, including agencies, subdivisions, or municipalities thereof. 207 208 (f) A sole proprietorship, group practice, partnership, or corporation, or other legal entity that provides health care 209 210 services by physicians and physician assistants licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 211 466 covered by s. 627.419, that is directly supervised by one or 212 213 more of such physicians or physician assistants, and that is wholly owned by one or more of those physicians or physician 214 215 assistants or by a physician or physician assistant and the spouse, parent, child, or sibling of that physician or physician 216 217 assistant.

218 (g) A sole proprietorship, group practice, partnership, or 219 corporation, or other legal entity that provides health care 220 services by licensed health care practitioners under chapter 221 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 222 223 484, chapter 486, chapter 490, chapter 491, or part I, part III, 224 part X, part XIII, or part XIV of chapter 468, or s. 464.012, 225 which entities are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners 226 227 set forth in this paragraph and the spouse, parent, child, or 228 sibling of a licensed health care practitioner, so long as one 229 of the owners who is a licensed health care practitioner is 230 supervising the health care services business activities and is 231 legally responsible for the entity's compliance with all federal 232 and state laws. However, the a health care services provided may

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40-01188-10 20102480 233 not exceed the scope of the licensed owner's health care 234 practitioner may not supervise services beyond the scope of the 235 practitioner's license, except that, for the purposes of this 236 part, a clinic owned by a licensee in s. 456.053(3)(b) that 237 provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b). 238 239 (h) Clinical facilities affiliated with an accredited 240 medical school at which training is provided for medical students, residents, or fellows. 241 (i) Entities that provide only oncology or radiation 242 therapy services by physicians licensed under chapter 458 or 243 244 chapter 459 or entities that provide oncology or radiation 245 therapy services by physicians licensed under chapter 458 or 246 chapter 459 which are owned by a corporation whose shares are 247 publicly traded on a recognized stock exchange. 248 (j) Clinical facilities affiliated with a college of 249 chiropractic accredited by the Council on Chiropractic Education 250 at which training is provided for chiropractic students. 251 (k) Entities that provide licensed practitioners to staff 252 emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 253 254 90 percent of their gross annual revenues from the provision of 255 such services. Entities claiming an exemption from licensure 256 under this paragraph must provide documentation demonstrating 257 compliance. 258 (1) Orthotic or prosthetic Clinical facilities that are a 259 publicly traded corporation or that are wholly owned, directly 260 or indirectly, by a publicly traded corporation. As used in this

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paragraph, a publicly traded corporation is a corporation that

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262	issues securities traded on an exchange registered with the
263	United States Securities and Exchange Commission as a national
264	securities exchange.
265	(8) "Specialty clinic" means a clinic, as defined in
266	subsection (4) and including those entities exempt under that
267	subsection, which are not licensed as a home health agency that
268	provides infusion therapy services to treat conditions caused by
269	or related to HIV or AIDS to outpatients who remain less than 24
270	hours at the facility or to patients who receive such services
271	where they reside. The term does not include:
272	(a) Entities licensed under part II or part III;
273	(b) Entities licensed under part IV which provide infusion
274	therapy to patients only in the home or residence of the
275	patient; or
276	(c) Entities licensed under chapter 395.
277	(9) "Infusion therapy" includes, but is not limited to, the
278	therapeutic infusion of substances into, or injection of
279	substances through, the venous peripheral system and consists of
280	activities that include observing, initiating, monitoring,
281	discontinuing, maintaining, regulating, adjusting, documenting,
282	planning, intervening, and evaluating. This definition embraces
283	the administration of nutrition, antibiotic therapy, and fluid
284	and electrolyte repletion.
285	(10) "Fraud" means deception or misrepresentation made by a
286	person or business entity with the intent that the deception
287	will likely result in an unauthorized benefit to herself or
288	himself or to another person. The term includes any act that
289	constitutes fraud under applicable federal or state law.
290	Section 3. Section 400.991, Florida Statutes, is amended to

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read:

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292 400.991 License requirements; background screenings; 293 prohibitions.-

294 (1) (a) The requirements of part II of chapter 408 apply to 295 the provision of services that require licensure pursuant to 296 this part and part II of chapter 408 and to entities licensed by 297 or applying for such licensure from the agency pursuant to this 298 part. A license issued by the agency is required in order to 299 operate a clinic and a specialty clinic in this state. Each 300 clinic and specialty clinic location shall be licensed 301 separately regardless of whether the clinic or specialty clinic 302 is operated under the same business name or management as 303 another clinic or specialty clinic.

(b) Each mobile clinic and specialty clinic must obtain a 304 305 separate health care clinic license and must provide to the 306 agency, at least quarterly, its projected street location to 307 enable the agency to locate and inspect such clinic and 308 specialty clinic. A portable equipment provider must obtain a 309 health care clinic license for a single administrative office 310 and is not required to submit quarterly projected street 311 locations.

312 (c) A specialty clinic operating without a specialty clinic 313 license on or before January 1, 2011, shall be given until July 314 2, 2011, to obtain a specialty clinic license.

(2) The initial clinic license application <u>and specialty</u> <u>clinic license application</u> shall be filed with the agency by all clinics, as defined in s. 400.9905, on or before July 1, 2004. <u>A</u> <u>clinic license and specialty clinic license must be renewed</u> biennially.

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320	(3)(a) The application shall contain information that
321	includes, but need not be limited to, information pertaining to
322	the name, residence and business address, phone number, social
323	security number, and license number of the medical or clinic
324	director of the licensed medical providers employed or under
325	contract with the clinic.
326	(b) Any person or entity that has a pecuniary interest in a
327	clinic who may or may not own stock or an equivalent interest in
328	the clinic, but nonetheless has control over or the authority to
329	approve, directly or indirectly, clinic billing, policy,
330	business activities, or personnel decisions, including, but not
331	limited to, contracted or employed third-party billing persons
332	or entities, managers, and management companies, and persons and
333	entities, directly or indirectly, which lend, give, or gift
334	money of any denomination or anything of value exceeding an
335	aggregate of \$5,000, for clinic use, with or without an
336	expectation of a return of the money or thing of value, and
337	regardless of profit motive, are subject to background screening
338	requirements under this part.
339	(c) The agency may adopt rules to administer this
340	subsection.
341	(4) An application for a specialty clinic must contain, in
342	addition to the information required in subsection (3) and s.
343	408.806:
344	(a) The correct business name of each business entity and
345	full name of each individual holding any ownership interest of 5
346	percent or more, or any pecuniary interest of \$5,000 or more, in
347	any legal entity that owns or operates any specialty clinic
348	seeking licensure, whether such ownership or pecuniary interest

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349	arose out of a contract, loan, gift, investment, inheritance, or
350	any other source. Individual possession of an ownership or
351	pecuniary interest in any subject specialty clinic includes, but
352	is not limited to, a direct or indirect interest in:
353	1. The business operation, equipment, or legend
354	pharmaceuticals used in the clinic;
355	2. The premises in which the clinic provides its services;
356	or
357	3. Any legal entity that owns any such interest, directly
358	or indirectly, in the business operation of the clinic; the
359	equipment used in providing infusion therapy services at the
360	clinic; the legend pharmaceuticals used at the clinic; or the
361	premises in which the clinic provides its services.
362	(b) In the case of an incorporated business entity that
363	holds any ownership interest of 5 percent or more, or any
364	pecuniary interest of \$5,000 or more, in the specialty clinic,
365	copies of the articles of incorporation and bylaws, and the
366	names and addresses of all officers and directors of the
367	corporation.
368	(c) On a form furnished by the agency, a sworn, notarized
369	statement by each business entity and individual that holds any
370	ownership interest of 5 percent or more, or any pecuniary
371	interest of \$5,000 or more, in the subject specialty clinic
372	which discloses the nature and degree of each such ownership or
373	pecuniary interest and discloses the source of funds which gave
374	rise to each such ownership or pecuniary interest.
375	(d) On a form furnished by the agency, a sworn, notarized
376	statement by each individual and business entity that holds any
377	ownership interest of 5 percent or more, or any pecuniary

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378	interest of \$5,000 or more, in the subject specialty clinic
379	which discloses whether he or she has been an owner or part
380	owner, individually or through any business entity, of any
381	business entity whose health care license has been revoked or
382	suspended in any jurisdiction.
383	(e) On a form furnished by the agency, an estimate of the
384	costs for establishing the specialty clinic and the source of
385	funds for payment of those costs and for sustaining the
386	operation of the clinic until its operation produces a positive
387	cash flow.
388	
389	For purposes of this subsection, the terms "ownership or
390	pecuniary interest" does not include an individual whose
391	interest in a specialty clinic arises only out of his or her
392	interest in a lending company, insurance company, or banking
393	institution licensed by this state or any other state of the
394	United States; a company regularly trading on a national stock
395	exchange of the United States; or a governmental entity in the
396	United States.
397	(5)-(4) In addition to the requirements of part II of
398	chapter 408, the applicant must file with the application
399	satisfactory proof that the clinic <u>or specialty clinic</u> is in
400	compliance with this part and applicable rules, including:
401	(a) A listing of services to be provided either directly by
402	the applicant or through contractual arrangements with existing
403	providers;
404	(b) The number and discipline of each professional staff
405	member to be employed; and
406	(c) Proof of financial ability to operate as required under

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40-01188-10 20102480 407 s. 408.810(8). As an alternative to submitting proof of 408 financial ability to operate as required under s. 408.810(8), 409 the applicant may file a surety bond of at least \$500,000 which 410 guarantees that the clinic or specialty clinic will act in full 411 conformity with all legal requirements for operating a clinic, 412 payable to the agency. The agency may adopt rules to specify 413 related requirements for such surety bond. 414 (6) (5) Each applicant for licensure shall comply with the 415 following requirements: (a) As used in this subsection, the term "applicant" means 416 417 an individual individuals owning or controlling, directly or 418 indirectly, 5 percent or more of an interest in a clinic or an 419 individual owning or controlling, directly or indirectly, any 420 interest in a specialty clinic; the medical or clinic director, 421 or a similarly titled person who is responsible for the day-to-422 day operation of the licensed clinic; the financial officer or 423 similarly titled individual who is responsible for the financial 424 operation of the clinic; and licensed health care practitioners 425 at the clinic. 426 (b) Upon receipt of a completed, signed, and dated 427 application, the agency shall require background screening of 428 the applicant, in accordance with the level 2 standards for 429 screening set forth in paragraph (d) chapter 435. Proof of 430 compliance with the level 2 background screening requirements of 431 paragraph (d) chapter 435 which has been submitted within the 432 previous 5 years in compliance with the any other health care 433 clinic licensure requirements of this part state is acceptable 434 in fulfillment of this paragraph. Applicants who own less than 435 10 percent of a health care clinic are not required to submit

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437 (c) Each applicant must submit to the agency, with the 438 application, a description and explanation of any exclusions, 439 permanent suspensions, or terminations of an applicant from the Medicare or Medicaid programs. Proof of compliance with the 440 441 requirements for disclosure of ownership and control interest 442 under the Medicaid or Medicare programs may be accepted in lieu 443 of this submission. The description and explanation may indicate 444 whether such exclusions, suspensions, or terminations were 445 voluntary or not voluntary on the part of the applicant. The 446 agency may deny or revoke licensure based on information 447 received under this paragraph.

448 (d) A license may not be granted to a clinic if the 449 applicant, or a person or entity identified in paragraph (3)(b), 450 has been found guilty of, regardless of adjudication, or has 451 entered a plea of nolo contendere or guilty to, any offense 452 prohibited under the level 2 standards for screening set forth 453 in chapter 435; any felony under chapter 400, chapter 408, 454 chapter 409, chapter 440, chapter 624, chapter 626, chapter 627, 455 chapter 812, chapter 817, chapter 831, chapter 837, chapter 838, 456 chapter 895, or chapter 896; or any substantially comparable 457 offense or crime of another state or of the United States, if a 458 felony in that jurisdiction, within the past 10 years. Each 459 person required to provide background screening shall disclose 460 to the agency any arrest for any crime for which any court 461 disposition other than dismissal has been made within the past 462 10 years. Failure to provide such information is a material 463 omission in the application process., or a violation of insurance fraud under s. 817.234, within the past 5 years. If 464

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465	the applicant has been convicted of an offense prohibited under
466	the level 2 standards or insurance fraud in any jurisdiction,
467	the applicant must show that his or her civil rights have been
468	restored prior to submitting an application.
469	(e) Each applicant that performs the technical component of
470	magnetic resonance imaging, static radiographs, computed
471	tomography, or positron emission tomography, and also provides
472	the professional components of such services through an employee
473	or independent contractor, must provide to the agency on a form
474	provided by the agency, the name and address of the clinic, the
475	serial or operating number of each magnetic resonance imaging,
476	static radiograph, computed tomography, and positron emission
477	tomography machine, the name of the manufacturer of the machine,
478	and such other information as required by the agency to identify
479	the machine. The information must be provided to the agency upon
480	renewal of the clinic's licensure and within 30 days after a
481	clinic begins using a machine for which it has not provided the
482	information to the agency.
483	Section 4. Section 400.9914, Florida Statutes, is created
484	to read:
485	400.9914 Revocation or denial of a specialty clinic
486	licenseIn addition to s. 408.831, the agency:
487	(1) Shall deny or revoke a specialty clinic license if an
488	applicant has been found guilty of, regardless of adjudication,
489	or entered a plea of nolo contendere or guilty to, any felony
490	involving dishonesty or making a false statement in any
491	jurisdiction within the preceding 10 years.
492	(2) Shall deny a specialty clinic license application when
493	any business entity or individual possessing an ownership or

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494	pecuniary interest in the specialty clinic also possessed an
495	ownership or pecuniary interest, individually or through any
496	business entity, in any health care facility whose license was
497	revoked in any jurisdiction during the pendency of that
498	interest.
499	(3) May not issue a specialty clinic license to any
500	applicant to whom the agency has sent notice that there is a
501	pending question as to whether one or more of the individuals
502	having an ownership of 5 percent or more or a pecuniary interest
503	of \$5,000 or more in the clinic has a disqualifying criminal
504	record. The agency notice shall request the applicant to submit
505	any additional information necessary to resolve the pending
506	criminal background question within 21 days after receipt of the
507	notice. The agency shall deny a specialty clinic license
508	application if the applicant fails to resolve a criminal
509	background screening issue pertaining to an individual who is
510	required to meet criminal background screening requirements of
511	this part and the agency raised such background screening issue
512	by notice as set forth in this part.
513	Section 5. Section 400.9915, Florida Statutes, is amended
514	to read:
515	400.9915 Emergency suspension; costs
516	(1) Failure by a clinic <u>or specialty clinic licensed under</u>
517	this part to allow full and complete access to the premises and
518	to billing records or information to any representative of the
519	agency who makes a request to inspect the clinic or specialty
520	clinic to determine compliance with this part or failure by a
521	clinic or specialty clinic to employ a qualified medical
522	director or clinic director constitutes a ground for emergency

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523	suspension of the license by the agency pursuant to s. 408.814.
524	(2) In addition to any administrative fines imposed
525	pursuant to this part or part II of chapter 408, the agency may
526	assess a fee equal to the cost of conducting a complaint
527	investigation.
528	Section 6. Section 400.9921, Florida Statutes, is created
529	to read:
530	400.9921 License renewal; transfer of ownershipIn
531	addition to the requirements set forth in ss. 408.806 and
532	<u>408.807:</u>
533	(1) An application for license renewal must contain
534	information as required by the agency.
535	(2) The clinic or specialty clinic must file with the
536	renewal application satisfactory proof that it is in compliance
537	with this part and applicable rules. If there is evidence of
538	financial instability, the clinic or specialty clinic must
539	submit satisfactory proof of its financial ability to comply
540	with the requirements of this part.
541	(3) An application for change of ownership of a clinic or
542	specialty clinic is required only when 45 percent or more of the
543	ownership, voting shares, or controlling interest of a clinic or
544	specialty clinic is transferred or assigned, including the final
545	transfer or assignment of multiple transfers or assignments over
546	a 2-year period which cumulatively total 45 percent or greater.
547	(4) The license may not be sold, leased, assigned, or
548	otherwise transferred, voluntarily or involuntarily, and is
549	valid only for the clinic or specialty clinic owners and
550	location for which originally issued.
551	Section 7. Section 400.9925, Florida Statutes, is amended

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552 to read:

553

400.9925 Rulemaking authority; license fees.-

554 (1) The agency shall adopt rules necessary to administer 555 the clinic and specialty clinic administration, regulation, and licensure program, including rules pursuant to this part and 556 557 part II of chapter 408, establishing the specific licensure 558 requirements, procedures, forms, and fees. It shall adopt rules 559 establishing a procedure for the biennial renewal of licenses. 560 The agency may issue initial licenses for less than the full 2-561 year period by charging a prorated licensure fee and specifying 562 a different renewal date than would otherwise be required for 563 biennial licensure. The rules shall specify the expiration dates of licenses, the process of tracking compliance with financial 564 565 responsibility requirements, and any other conditions of renewal 566 required by law or rule.

567 (2) The agency shall adopt rules specifying limitations on the number of licensed clinics and specialty clinics and 568 569 licensees for which a medical director or a clinic director may 570 assume responsibility for purposes of this part. In determining 571 the quality of supervision a medical director or a clinic 572 director can provide, the agency shall consider the number of 573 clinic or specialty clinic employees, the clinic location or the 574 specialty clinic location, and the health care services provided 575 by the clinic or specialty 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.

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581	Section 8. Subsection (3) of section 400.993, Florida
582	Statutes, is amended to read:
583	400.993 Unlicensed clinics; reporting
584	(3) In addition to the requirements of part II of chapter
585	408, any health care provider who is aware of the operation of
586	an unlicensed clinic or specialty clinic shall report that
587	facility to the agency. Failure to report a clinic <u>or specialty</u>
588	<u>clinic</u> that the provider knows or has reasonable cause to
589	suspect is unlicensed shall be reported to the provider's
590	licensing board.
591	Section 9. Section 400.9935, Florida Statutes, is amended
592	to read:
593	400.9935 Clinic responsibilities
594	(1) Each clinic <u>and specialty clinic</u> shall appoint a
595	medical director or clinic director who shall agree in writing
596	to accept legal responsibility for the following activities on
597	behalf of the clinic <u>or specialty clinic</u> . The medical director
598	or the clinic director shall:
599	(a) Have signs identifying the medical director or clinic
600	director posted in a conspicuous location within the clinic
601	readily visible to all patients.
602	(b) Ensure that all practitioners providing health care
603	services or supplies to patients maintain a current active and
604	unencumbered Florida license.
605	(c) Review any patient referral contracts or agreements
606	executed by the clinic.
607	(d) Ensure that all health care practitioners at the clinic
608	have active appropriate certification or licensure for the level
609	of care being provided.

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610 (e) Serve as the clinic records owner as defined in s.611 456.057.

(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.

616 (g) Conduct systematic reviews of clinic billings to ensure 617 that the billings are not fraudulent or unlawful. Upon discovery of an unlawful charge, the medical director or clinic director 618 619 shall take immediate corrective action. If the clinic performs 620 only the technical component of magnetic resonance imaging, 621 static radiographs, computed tomography, or positron emission 622 tomography, and provides the professional interpretation of such 623 services, in a fixed facility that is accredited by the Joint 624 Commission on Accreditation of Healthcare Organizations or the 625 Accreditation Association for Ambulatory Health Care, and the 626 American College of Radiology; and if, in the preceding quarter, 627 the percentage of scans performed by that clinic which was billed to all personal injury protection insurance carriers was 628 629 less than 15 percent, the chief financial officer of the clinic 630 may, in a written acknowledgment provided to the agency, assume 631 the responsibility for the conduct of the systematic reviews of 632 clinic billings to ensure that the billings are not fraudulent or unlawful. 633

(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

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663

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639	clinical director's group practice to the clinic for magnetic
640	resonance imaging, static radiographs, computed tomography, or
641	positron emission tomography. A medical director who is found to
642	violate this paragraph commits a felony of the third degree,
643	punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
644	(i) Serve in that capacity for no more than a maximum of
645	five health care clinics that have a cumulative total of no more
646	than 200 employees and persons under contract with the health
647	care clinic at a given time. A medical or clinic director may
648	not supervise a health care clinic more than 200 miles away from
649	any other health care clinic supervised by the same medical or
650	clinic director. The agency may allow for waivers to the
651	limitations of this paragraph upon a showing of good cause and a
652	determination by the agency that the medical director will be
653	able to adequately perform the requirements of this subsection.
654	(2) Any contract to serve as a medical director or a clinic
655	director entered into or renewed by a physician or a licensed
656	health care practitioner in violation of this part is void as
657	contrary to public policy. This subsection shall apply to
658	contracts entered into or renewed on or after March 1, 2004.
659	(3) All charges or reimbursement claims made by or on
660	behalf of a clinic that is required to be licensed under this
661	part, but that is not so licensed, or that is otherwise
662	operating in violation of this part, are unlawful charges, and
660	

(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

therefore are noncompensable and unenforceable.

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668
     misleading license application or license renewal application,
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     or false or misleading information related to such application
670
     or department rule, commits a felony of the third degree,
671
     punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
672
           (5) Any licensed health care provider who violates this
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     part is subject to discipline in accordance with this chapter
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     and his or her respective practice act.
675
           (6) Any person or entity providing health care services
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     which is not a clinic or specialty clinic, as defined under s.
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     400.9905, may voluntarily apply for a certificate of exemption
678
     from licensure under its exempt status. Other than certificates
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     of exemptions granted pursuant to the exemption under s.
     400.9905(4)(f), certificates of exemption shall expire after 2
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681
     years and may be renewed. with the agency on a form that sets
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     forth its name or names and addresses, a statement of the
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     reasons why it cannot be defined as a clinic, and other
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     information deemed necessary by the agency. An exemption is not
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     transferable. The agency may charge an applicant for a
686
     certificate of exemption in an amount equal to $100 or the
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     actual cost of processing the certificate, whichever is less.
688
          (a) The agency shall provide a form that requires the name
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     or names and addresses, a statement of the reasons why the
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     applicant is exempt from licensure as a health care clinic or
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     specialty clinic, and other information deemed necessary by the
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     agency. The signature on an application for a certificate of
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     exemption must be notarized and signed by persons having
694
     knowledge of the truth of its contents. An exemption is not
695
     transferable and is valid only for the reasons, location,
696
     persons, and entity set forth on the application form. A person
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697	or entity that claims an exemption under this part or that holds
698	a current certificate of exemption must be exempt from the
699	licensing provisions of this part at all times, or such claim or
700	certificate is invalid from the date that such person or entity
701	is not exempt.
702	(b) The agency shall charge an applicant for a certificate
703	of exemption a fee of \$100 to cover the cost of processing the
704	certificate or the actual cost of processing the certificate,
705	whichever is less.
706	(c) An application for the renewal of a certificate of
707	exemption must be submitted to the agency before the expiration
708	of the certificate of exemption. The agency may investigate any
709	applicant, person, or entity claiming an exemption for purposes
710	of determining compliance when a certificate of exemption is
711	sought. Authorized personnel of the agency shall have access to
712	the premises of any certificateholder, applicant, or specialty
713	clinic, other than a person or entity who is exempt pursuant to
714	s. 400.9905(4)(f), for the sole purpose of determining
715	compliance with an exemption under this part. The agency shall
716	have access to all billings and records. The agency may deny or
717	withdraw a certificate of exemption when a person or entity does
718	not qualify under this part.
719	(d) A certificate of exemption is considered withdrawn when
720	the agency determines that an exempt status cannot be confirmed.
721	The provisions applicable to the unlicensed operation of a
722	health care clinic or specialty clinic apply to any health care
723	provider that self-determines or claims an exemption or that is
724	issued a certificate of exemption if, in fact, such clinic does
725	not meet the exemption claimed.

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726	(e) Any person or entity that submits an application for a
727	certificate of exemption which contains fraudulent or material
728	and misleading information commits a felony of the third degree,
729	punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
730	(f) A response to a request in writing for additional
731	information or clarification must be filed with the agency no
732	later than 21 days after receipt of the request or the
733	application shall be denied.
734	(g) The agency shall grant or deny an application for a
735	certificate of exemption in accordance with s. 120.60(1).
736	(h) A person or entity that qualifies as a health care
737	clinic or specialty clinic and has been denied a certificate of
738	exemption must file an initial application and pay the fee. A
739	certificate of exemption is valid only when issued and current.
740	(i) The agency shall issue an emergency order of suspension
741	of a certificate of exemption when the agency finds that the
742	applicant has provided false or misleading material information
743	or omitted any material fact from the application for a
744	certificate of exemption which is permitted or required by this
745	part, or has submitted false or misleading information to the
746	agency when self-determining an exempt status and materially
747	misleading the agency as to such status.
748	(7)(a) Each clinic engaged in magnetic resonance imaging
749	services must be accredited by the Joint Commission on
750	Accreditation of Healthcare Organizations, the American College
751	of Radiology, or the Accreditation Association for Ambulatory
752	Health Care, within 1 year after licensure. A clinic that is
753	accredited by the American College of Radiology or is within the

754 original 1-year period after licensure and replaces its core

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40-01188-10 20102480 755 magnetic resonance imaging equipment shall be given 1 year after 756 the date on which the equipment is replaced to attain 757 accreditation. However, a clinic may request a single, 6-month 758 extension if it provides evidence to the agency establishing 759 that, for good cause shown, such clinic cannot be accredited 760 within 1 year after licensure, and that such accreditation will 761 be completed within the 6-month extension. After obtaining 762 accreditation as required by this subsection, each such clinic must maintain accreditation as a condition of renewal of its 763 764 license. A clinic that files a change of ownership application 765 must comply with the original accreditation timeframe 766 requirements of the transferor. The agency shall deny a change 767 of ownership application if the clinic is not in compliance with 768 the accreditation requirements. When a clinic adds, replaces, or 769 modifies magnetic resonance imaging equipment and the 770 accreditation agency requires new accreditation, the clinic must 771 be accredited within 1 year after the date of the addition, 772 replacement, or modification but may request a single, 6-month 773 extension if the clinic provides evidence of good cause to the 774 agency. 775

(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 pertainingto any past variance and waiver granted to a magnetic resonance

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40-01188-10 20102480 784 imaging clinic from rule 64-2002, Florida Administrative Code, 785 by the Department of Health, until September 2004. After that 786 date, such clinic must request a variance and waiver from the 787 agency under s. 120.542. 788 (9) In addition to the requirements of part II of chapter 789 408, the clinic or specialty clinic shall display a sign in a 790 conspicuous location within the clinic or specialty clinic 791 readily visible to all patients indicating that, pursuant to s. 792 626.9892, the Department of Financial Services may pay rewards of up to \$25,000 to persons providing information leading to the 793 794 arrest and conviction of persons committing crimes investigated 795 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 796 authorized employee of the Division of Insurance Fraud may make 797 798 unannounced inspections of a clinic or specialty clinic licensed 799 under this part as necessary to determine whether the clinic or 800 specialty clinic is in compliance with this subsection. A 801 licensed clinic or specialty clinic shall allow full and complete access to the premises to such authorized employee of 802 803 the division who makes an inspection to determine compliance 804 with this subsection. 805 (10) In addition to the requirements set forth in s. 806 408.8065, every licensed specialty clinic shall annually file 807 with the agency, including concurrently with the filing of any change of ownership application, upon forms to be furnished by 808 809 the agency, an audited report showing the following information: 810 (a) A report of the number of patients served by the 811 specialty clinic during the previous 12-month period. The report 812 may exclude any partial month for the month when the report was

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813	prepared;
814	(b) Total specialty clinic operating expenses;
815	(c) Gross patient charges by payor category, including
816	Medicare, Medicaid, county indigent programs, any other
817	governmental programs, private insurance, self-paying patients,
818	nonpaying patients, and other payees;
819	(d) The cost of operation of the specialty clinic during
820	the previous 12-month period, excluding any partial month during
821	which time the report was prepared;
822	(e) Unless the specialty clinic can demonstrate that the
823	clinic already has furnished the required information regarding
824	a particular subject individual, the full name of any individual
825	who became an owner or became possessed of any pecuniary
826	interest in the subject clinic since the last report to the
827	agency, along with the disclosure of the information required by
828	s. 400.991 as to such individual; and
829	(f) A current statement of the source of funds for payment
830	of the costs of establishing the specialty clinic and for
831	sustaining the operation of the specialty clinic until its
832	operation produces a positive cash flow.
833	(11) Each licensee of a specialty clinic has a continuing
834	obligation to comply with this part and to report to the agency
835	any change of circumstance related to the clinic's continuing
836	compliance with this part. Such change of circumstance includes,
837	but is not limited to, any change in the ownership of the
838	specialty clinic, the addition of any individual or business
839	entity possessing a pecuniary interest in the specialty clinic,
840	the employment of any individual as a member of the specialty
841	clinic's staff who would be required to undergo a criminal

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842	
843	the time of the initial licensure, and any change in the medical
844	or clinic director. The specialty clinic shall furnish the
845	information about any change of circumstances which is required
846	under this part and s. 400.991 within 30 days after the
847	occurrence of such change of circumstance.
848	Section 10. Section 400.995, Florida Statutes, is amended
849	to read:
850	400.995 Agency administrative penalties
851	(1) In addition to the requirements of part II of chapter
852	408, the agency may deny the application for a license renewal,
853	revoke and suspend the license, and impose administrative fines
854	of up to \$5,000 per violation for violations of the requirements
855	$\overline{\operatorname{of}}$ this part or rules of the agency. In determining if a penalty
856	is to be imposed and in fixing the amount of the fine, the
857	agency shall consider the following factors:
858	(a) The gravity of the violation, including the probability
859	that death or serious physical or emotional harm to a patient
860	will result or has resulted, the severity of the action or
861	potential harm, and the extent to which the provisions of the
862	applicable laws or rules were violated.
863	(b) Actions taken by the owner, medical director, or clinic
864	director to correct violations.
865	(c) Any previous violations.
866	(d) The financial benefit to the clinic <u>or specialty clinic</u>
867	of committing or continuing the violation.
868	(2) Each day of continuing violation after the date fixed
869	for termination of the violation, as ordered by the agency,
870	constitutes an additional, separate, and distinct violation.
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871	(3) Any action taken to correct a violation shall be
872	documented in writing by the owner, medical director, or clinic
873	director of the clinic <u>or specialty clinic</u> and verified through
874	followup visits by agency personnel. The agency may impose a
875	fine and, in the case of an owner-operated clinic <u>or specialty</u>
876	<u>clinic</u> , revoke or deny a clinic's license when a clinic medical
877	director or clinic director knowingly misrepresents actions
878	taken to correct a violation.
879	(4) Any licensed clinic whose owner, medical director, or
880	clinic director concurrently operates an unlicensed clinic shall
881	be subject to an administrative fine of \$5,000 per day.
882	(5) Any clinic or specialty clinic whose owner fails to
883	apply for a change-of-ownership license and operates the clinic
884	or specialty clinic under the new ownership is subject to a fine
885	of \$5,000.
886	(6) As an alternative to or in conjunction with an
887	administrative action against a clinic or specialty clinic for
888	violations of this part and adopted rules During an inspection,
889	the agency shall make a reasonable attempt to discuss <u>during the</u>
890	inspection each violation with the owner, medical director, or
891	clinic director of the clinic or specialty clinic, prior to
892	written notification. The agency, instead of fixing a period
893	within which the clinic or specialty clinic shall enter into
894	compliance with standards, may request a plan of corrective
895	action from the clinic or specialty clinic which demonstrates a
896	good faith effort to remedy each violation by a specific date,
897	subject to the approval of the agency.
898	Section 11. Section 400.996, Florida Statutes, is created
899	to read:

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900	400.996 Specialty clinics; complaints; audits; referrals
901	(1) The agency shall receive, document, and process
902	complaints about specialty clinics. Upon receipt of any
903	complaint that asserts the existence of facts evidencing
904	possible billing fraud by a specialty clinic or by any employee
905	of a specialty clinic, the agency shall request the complainant
906	to make such assertions by sworn affidavit.
907	(2) Upon receipt of any sworn affidavit that asserts the
908	existence of facts evidencing possible billing fraud by a
909	specialty clinic or any of its employees, the agency shall refer
910	the complaint to the Office of Fiscal Integrity within the
911	Department of Financial Services.
912	(3) The Department of Financial Services shall report
913	findings to the agency for any appropriate licensure action.
914	Such report shall include a statement of facts as determined by
915	the Department of Financial Services to exist, specifically with
916	regard to the possible violations of licensure requirements. If,
917	during an investigation, the Department of Financial Services
918	has reason to believe that any criminal law of this state has or
919	may have been violated, the department shall refer such
920	investigation to appropriate prosecutorial agencies and shall
921	provide investigative assistance to those agencies as required.
922	(4) The investigating authority and the agency shall
923	cooperate with each other and prepare a record and share
924	information from which the agency may determine if any action
925	for sanctions under this part are warranted.
926	(5) A person commits a misdemeanor of the first degree,
927	punishable as provided in s. 775.082 or s. 775.083 if:
928	(a) He or she submits a sworn complaint that initiates a

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929	complaint investigation pursuant to this section; and
930	(b) The sworn complaint is determined to be totally without
931	any factual basis to support the assertions made in the
932	complaint that facts existed evidencing possible fraudulent
933	practices by a specialty clinic or any of its employees.
934	(6) The Office of Fiscal Integrity within the Department of
935	Financial Services shall conduct unannounced reviews,
936	investigations, analyses, and audits to investigate complaints
937	and, as necessary, to determine whether a specialty clinic's
938	billings are fraudulent or unlawful. The Department of Financial
939	Services may enter upon the premises of the clinic during
940	regular business hours and demand and immediately secure copies
941	of billing and other records of the clinic which will enable the
942	Department of Financial Services to investigate complaints or
943	determine whether a specialty clinic's billings are fraudulent
944	or unlawful.
945	(7) A licensed specialty clinic shall allow full, complete,
946	and immediate access to the premises and to billing records or
947	information to any such officer or employee who conducts a
948	review, investigation, analysis, or audit to determine
949	compliance with this part and with applicable rules. Failure to
950	allow full, complete, and immediate access to the premises and
951	to billing records or information to any representative of the
952	agency or Department of Financial Services who attempts to
953	conduct a review, investigation, analysis, or audit to determine
954	compliance with this part constitutes a ground for emergency
955	suspension of the license by the agency pursuant to s.
956	120.60(6).
957	(8) In addition to any administrative fines imposed, the

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958	agency may assess a fee equal to the cost of conducting any
959	review, investigation, analysis, or audit performed by the
960	agency or the Department of Financial Services.
961	(9) All investigators designated by the Chief Financial
962	Officer to perform duties under this part and who are certified
963	under s. 943.1395 are law enforcement officers of the state.
964	Such investigators may conduct criminal investigations, bear
965	arms, make arrests, and apply for, serve, and execute search
966	warrants, arrest warrants, capias, and other processes
967	throughout the state pertaining to fraud investigations under
968	this section.
969	Section 12. Subsection (27) of section 408.802, Florida
970	Statutes, is amended to read:
971	408.802 ApplicabilityThe provisions of this part apply to
972	the provision of services that require licensure as defined in
973	this part and to the following entities licensed, registered, or
974	certified by the agency, as described in chapters 112, 383, 390,
975	394, 395, 400, 429, 440, 483, and 765:
976	(27) Health care clinics and specialty clinics, as provided
977	under part X of chapter 400.
978	Section 13. Subsection (25) of section 408.820, Florida
979	Statutes, is amended to read:
980	408.820 ExemptionsExcept as prescribed in authorizing
981	statutes, the following exemptions shall apply to specified
982	requirements of this part:
983	(25) Health care clinics and specialty clinics, as provided
984	under part X of chapter 400, are exempt from s. 408.810(6), (7),
985	and (10).
986	Section 14. Paragraph (mm) is added to subsection (1) of

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987	section 456.072, Florida Statutes, to read:
988	456.072 Grounds for discipline; penalties; enforcement
989	(1) The following acts shall constitute grounds for which
990	the disciplinary actions specified in subsection (2) may be
991	taken:
992	(mm) Intentionally providing false information on an
993	application for a certificate of exemption from clinic licensure
994	under part XIII of chapter 400.
995	Section 15. Florida Barbara B. Lumpkin Center for Nursing
996	designated; Department of Health to erect suitable markers
997	(1) The Florida Center for Nursing, created by s. 464.0195,
998	Florida Statutes, and located in Orlando is designated as the
999	"Florida Barbara B. Lumpkin Center for Nursing."
1000	(2) The Department of Health is directed to erect suitable
1001	markers designating the Florida Barbara B. Lumpkin Center for
1002	Nursing as described in subsection (1).
1003	Section 16. The sums of \$212,528 in recurring funds from
1004	the Health Care Trust Fund, and \$25,347 in nonrecurring funds
1005	from the Health Care Trust Fund are appropriated to the Agency
1006	for Health Care Administration and four full-time equivalent
1007	positions and associated salary rate of 134,455 are authorized,
1008	for the 2010-2011 fiscal year for the purpose of administering
1009	the provisions of this act.
1010	Section 17. This act shall take effect July 1, 2010.

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