1

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2 An act relating to health care facilities; amending s. 3 395.002, F.S.; revising a definition of the term 4 "urgent care" as it relates to the regulation of 5 hospitals and other licensed facilities; amending s. 6 395.107, F.S.; requiring that a urgent care center 7 publish a post a schedule of charges; providing 8 requirements for the schedule; amending s. 400.9935, 9 F.S.; adding additional responsibilities of medical 10 and clinic directors with respect to the posting of a 11 schedule of charges for services; amending s. 400.021, F.S.; revising definitions of the terms "geriatric 12 outpatient clinic" and "resident care plan" and 13 14 defining the term "therapeutic spa services"; amending 15 s. 400.1183, F.S.; revising requirements relating to 16 nursing home facility grievance reports; amending s. 400.141, F.S.; revising provisions relating to other 17 needed services provided by licensed nursing home 18 19 facilities, including respite care, adult day, and therapeutic spa services; revising provisions relating 20 21 to facilities eligible to share programming and staff; 22 deleting requirements for the submission of certain 23 reports to the Agency for Health Care Administration; amending s. 400.142, F.S.; deleting the agency's 24 25 authority to adopt rules relating to orders not to 26 resuscitate; amending s. 400.147, F.S.; revising 27 provisions relating to adverse incident reports; 28 deleting certain reporting requirements; creating s.

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56	the definition of "hospice"; amending s. 400.606,
55	Administration; amending s. 400.601, F.S.; revising
54	registration with the Agency for Health Care
53	Persons with Disabilities, are exempt from
52	disabilities, under contract with the Agency for
51	services only to persons with developmental
50	organizations that provide companion or homemaker
49	absence; amending s. 400.509, F.S.; providing that
48	administrator to serve during the administrator's
47	for each licensed entity, a qualified alternate
46	requiring an administrator to designate, in writing,
45	nurse registries under certain circumstances;
44	authorizing an administrator to manage up to five
43	made to s. 400.509, F.S., in references thereto;
42	registries, respectively, to incorporate the amendment
41	400.506(6)(a), F.S., relating to licensure of nurse
40	revising requirements for team members; reenacting s.
39	regard to training nursing home surveyor teams;
38	amending s. 400.275, F.S.; revising agency duties with
37	requirements for residents under 21 years of age;
36	rules relating to nursing home facility staffing
35	facility; 400.23, F.S.; specifying the content of
34	provide certain information to the nursing home
33	requiring a prospective respite care recipient to
32	receiving respite care in nursing home facilities;
31	respite care services; providing for rights of persons
30	home facility operated by a licensee that provides
29	400.172, F.S.; providing requirements for a nursing

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57 F.S.; revising the content requirements of the plan 58 accompanying an initial or change-of-ownership 59 application for licensure of a hospice; revising 60 requirements relating to certificates of need for certain hospice facilities; amending s. 400.915, F.S.; 61 62 correcting an obsolete cross-reference to 63 administrative rules; amending s. 400.931, F.S.; 64 requiring each applicant for initial licensure, change 65 of ownership, or license renewal to operate a licensed 66 home medical equipment provider at a location outside 67 the state to submit documentation of accreditation, or an application for accreditation, from an accrediting 68 69 organization that is recognized by the Agency for 70 Health Care Administration; requiring an applicant 71 that has applied for accreditation to provide proof of 72 accreditation within a specified time; deleting a 73 requirement that an applicant for a home medical 74 equipment provider license submit a surety bond to the 75 agency; amending s. 408.033, F.S.; providing that fees 76 assessed on selected health care facilities and 77 organizations may be collected prospectively at the 78 time of licensure renewal and prorated for the 79 licensing period; amending s. 408.034, F.S.; revising 80 agency authority relating to licensing of intermediate 81 care facilities for the developmentally disabled; 82 amending s. 408.036, F.S.; providing an exception from 83 certain requirement for exemption from certificate-of-84 need review for hospitals providing percutaneous

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85	coronary intervention for certain patients; amending
86	s. 408.0361, F.S.; revising the criteria for
87	qualifying for an exemption from certificate-of-need
88	review for hospitals providing cardiovascular
89	services; amending s. 408.10, F.S.; removing agency
90	authority to investigate certain consumer complaints;
91	repealing s. 408.802(11), F.S., removing applicability
92	of part II of ch. 408, F.S., relating to general
93	licensure requirements, to private review agents;
94	amending s. 408.804, F.S.; providing penalties for
95	altering, defacing, or falsifying a license
96	certificate issued by the agency or displaying such an
97	altered, defaced, or falsified certificate; amending
98	s. 408.806, F.S.; revising agency responsibilities for
99	notification of licensees of impending expiration of a
100	license; requiring payment of a late fee for a license
101	application to be considered complete under certain
102	circumstances; amending s. 408.8065, F.S.; revising
103	the requirements for becoming licensed as a home
104	health agency, home medical equipment provider, or
105	health care clinic; amending s. 408.810, F.S.;
106	requiring that the controlling interest of a health
107	care licensee notify the agency of certain court
108	proceedings; providing a penalty; amending s. 408.813,
109	F.S.; authorizing the agency to impose fines for
110	unclassified violations of part II of ch. 408, F.S.;
111	amending s. 429.195, F.S.; revising provisions
112	prohibiting certain rebates relating to assisted
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113 living facilities; amending s. 429.905, F.S.; defining 114 the term "day" for purposes of day care services 115 provided to adults who are not residents; amending s. 116 456.44, F.S.; revising the definition of the term 117 "addiction medicine specialist" to include board-118 certified psychiatrists; defining the term "board 119 eligible"; excluding a board-certified physiatrist as 120 an addiction medicine specialist; including the 121 American Board of Medical Specialties as a recognized 122 certification entity; revising the definition of the 123 term "chronic nonmalignant pain" to exclude reference to rheumatoid arthritis; exempting specified board-124 125 eligible health care providers from application of 126 certain provisions; adding the American Board of Pain 127 Medicine as a recognized board-certification entity 128 for purposes of exemption from application of certain 129 provisions; amending s. 458.3265, F.S.; defining the 130 term "board eligible"; revising the definition of the 131 term "chronic nonmalignant pain" to exclude reference to rheumatoid arthritis; permitting specified board-132 133 eligible physicians to own a pain-management clinic 134 without registering the clinic; permitting a 135 rheumatologist to own a pain-management clinic without 136 registering the clinic; including a physician 137 multispecialty practice to permitted ownership forms 138 of pain-management clinics; requiring at least one 139 specialist in multispecialty practice to be boardeligible; recognizing the American Board of Pain 140

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141	Medicine, the American Association of Physician
142	Specialists, and the American Osteopathic Association
143	as board-certification organizations for purposes of
144	determining a board-certified pain medicine specialist
145	as an owner of a pain-management clinic; amending s.
146	459.0137, F.S.; defining the term "board eligible";
147	revising the definition of the term "chronic
148	nonmalignant pain" to exclude reference to rheumatoid
149	arthritis; permitting a board-eligible rheumatologist
150	to own a pain-management clinic; including a physician
151	multispecialty practice to permitted ownership forms
152	of pain-management clinics; permitting specified
153	board-eligible physicians to own a pain-management
154	clinic without registering the clinic; permitting a
155	rheumatologist to own a pain-management clinic without
156	registering the clinic; adding multispecialty practice
157	to permitted ownership forms of pain-management
158	clinics; requiring at least one specialist in
159	multispecialty practice to be board eligible;
160	recognizing the American Board of Pain Medicine and
161	the American Association of Physician Specialists as
162	board-certification organizations for purposes of
163	determining a board-certified pain medicine specialist
164	as owner of a pain-management clinic; amending s.
165	483.23, F.S.; requiring the agency to refer criminal
166	acts regarding the operation of a clinical laboratory
167	to a local law enforcement agency; authorizing the
168	agency to issue and deliver notice to cease and desist
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169	and impose an administrative penalty for each act;
170	amending s. 483.245, F.S.; providing that a clinical
171	laboratory is prohibited from providing personnel to
172	perform functions or duties in a physician's office
173	unless the laboratory and the physician's office are
174	owned and operated by the same entity; prohibiting a
175	clinical laboratory from leasing space in a
176	physician's office; requiring the agency to
177	investigate complaints, impose fines, and deny an
178	application for a license or license renewal under
179	certain circumstances; amending s. 651.118, F.S.;
180	providing a funding limitation on sheltered nursing
181	home beds used to provide assisted living, rather than
182	extended congregate care services; authorizing certain
183	sharing of areas, services, and staff between such
184	sheltered beds and nursing home beds in those
185	facilities; amending s. 817.505, F.S.; conforming
186	provisions to changes made by the act; providing that
187	the licensure requirements of part X of ch. 400, F.S.,
188	do not apply to certain specified entities; providing
189	that the Agency for Health Care Administration may
190	deny or revoke the exemption from the licensure
191	requirements under certain circumstances; amending s.
192	409.912, F.S.; revising provisions requiring the
193	agency to post certain information relating to drugs
194	subject to prior authorization on its Internet
195	website; providing a definition of the term "step
196	edit"; amending s. 83.42, F.S., relating to exclusions
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197	from part II of ch. 83, F.S., the Florida Residential
198	Landlord and Tenant Act; clarifying that the
199	procedures in s. 400.0255, F.S., for transfers and
200	discharges are exclusive to residents of a nursing
201	home licensed under part II of ch. 400, F.S.; amending
202	s. 400.462, F.S.; revising the definition of
203	"remuneration" to exclude items having a value of \$15
204	or less; amending s. 408.037, F.S.; revising
205	requirements for the financial information to be
206	included in an application for a certificate of need;
207	amending s. 468.1695, F.S.; providing that a health
208	services administration or an equivalent major
209	satisfies the education requirements for nursing home
210	administrator applicants; providing an effective date.
211	
212	Be It Enacted by the Legislature of the State of Florida:
213	
214	Section 1. Subsection (30) of section 395.002, Florida
215	Statutes, is amended to read:
216	395.002 Definitions.—As used in this chapter:
217	(30) "Urgent care center" means a facility or clinic that
218	provides immediate but not emergent ambulatory medical care to
219	patients with or without an appointment . <u>The term includes an</u>
220	<u>offsite</u> It does not include the emergency department of a
221	hospital that is presented to the general public in any manner
222	as a department where immediate and not only emergent medical
223	care is provided. The term also includes:
224	(a) An offsite facility of a facility licensed under

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225	chapter 395, or a joint venture between a facility licensed
226	under chapter 395 and a provider licensed under chapter 458 or
227	chapter 459, that does not require a patient to make an
228	appointment and is presented to the general public in any manner
229	as a facility where immediate but not emergent medical care is
230	provided.
231	(b) A clinic organization that is licensed under part X of
232	chapter 400, maintains three or more locations using the same or
233	a similar name, does not require a patient to make an
234	appointment, and holds itself out to the general public in any
235	manner as a facility or clinic where immediate but not emergent
236	medical care is provided.
237	Section 2. Section 395.107, Florida Statutes, is amended
238	to read:
239	395.107 Urgent care centers; publishing and posting
240	schedule of charges; penalties
241	(1) An urgent care center must publish and post a schedule
242	of charges for the medical services offered to patients.
243	(2) The schedule of charges must describe the medical
244	services in language comprehensible to a layperson. The schedule
245	must include the prices charged to an uninsured person paying
246	for such services by cash, check, credit card, or debit card.
247	The schedule must be posted in a conspicuous place in the
248	reception area of the urgent care center and must include, but
249	is not limited to, the 50 services most frequently provided $rac{f by}$
250	the urgent care center. The schedule may group services by three
251	price levels, listing services in each price level. The posting
252	<u>may be a sign, which</u> must be at least 15 square feet in size <u>, or</u>
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253	may be through an electronic messaging board. If an urgent care
254	center is affiliated with a facility licensed under this
255	chapter, the schedule must include text that notifies the
256	insured patients whether the charges for medical services
257	received at the center will be the same as, or more than,
258	charges for medical services received at the affiliated
259	hospital. The text notifying the patient of the schedule of
260	charges shall be in a font size equal to or greater than the
261	font size used for prices and must be in a contrasting color.
262	The text that notifies the insured patients whether the charges
263	for medical services received at the center will be the same as,
264	or more than, charges for medical services received at the
265	affiliated hospital shall be included in all media and Internet
266	advertisements for the center and in language comprehensible to
267	a layperson.
268	(3) The posted text describing the medical services must
269	fill at least 12 square feet of the posting. A center may use an
270	electronic device or messaging board to post the schedule of
271	charges. Such a device must be at least 3 square feet and
272	patients must be able to access the schedule during all hours of
273	operation of the urgent care center.
274	(4) An urgent care center that is operated and used
275	exclusively for employees and the dependents of employees of the
276	business that owns or contracts for the urgent care center is
277	exempt from this section.
278	(5) The failure of an urgent care center to publish and
279	post a schedule of charges as required by this section shall
280	result in a fine of not more than \$1,000, per day, until the
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281 schedule is published and posted.

282 Section 3. Paragraph (i) of subsection (1) of section 283 400.9935, Florida Statutes, is amended to read:

284

400.9935 Clinic responsibilities.-

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

289 (i) Ensure that the clinic publishes a schedule of charges for the medical services offered to patients. The schedule must 290 291 include the prices charged to an uninsured person paying for 292 such services by cash, check, credit card, or debit card. The 293 schedule must be posted in a conspicuous place in the reception 294 area of the urgent care center and must include, but is not 295 limited to, the 50 services most frequently provided by the 296 clinic. The schedule may group services by three price levels, 297 listing services in each price level. The posting may be a sign 298 that must be at least 15 square feet in size or through an 299 electronic messaging board that is at least 3 square feet in size. The failure of a clinic to publish and post a schedule of 300 301 charges as required by this section shall result in a fine of 302 not more than \$1,000, per day, until the schedule is published 303 and posted.

304 Section 4. Subsections (8) and (16) of section 400.021, 305 Florida Statutes, are amended, and subsection (19) is added to 306 that section, to read:

307 400.021 Definitions.-When used in this part, unless the 308 context otherwise requires, the term:

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(8) "Geriatric outpatient clinic" means a site for
providing outpatient health care to persons 60 years of age or
older, which is staffed by a registered nurse, or a physician
assistant, or a licensed practical nurse under the direct
supervision of a registered nurse, advanced registered nurse
practitioner, physician assistant, or physician.

315 (16)"Resident care plan" means a written plan developed, 316 maintained, and reviewed not less than quarterly by a registered 317 nurse, with participation from other facility staff and the resident or his or her designee or legal representative, which 318 includes a comprehensive assessment of the needs of an 319 320 individual resident; the type and frequency of services required to provide the necessary care for the resident to attain or 321 322 maintain the highest practicable physical, mental, and 323 psychosocial well-being; a listing of services provided within 324 or outside the facility to meet those needs; and an explanation 325 of service goals. The resident care plan must be signed by the 326 director of nursing or another registered nurse employed by the 327 facility to whom institutional responsibilities have been 328 delegated and by the resident, the resident's designee, or the 329 resident's legal representative. The facility may not use an 330 agency or temporary registered nurse to satisfy the foregoing 331 requirement and must document the institutional responsibilities 332 that have been delegated to the registered nurse. (19) "Therapeutic spa services" means bathing, nail, and 333 hair care services and other similar services related to 334 335 personal hygiene.

336 Section 5. Subsection (2) of section 400.1183, Florida Page 12 of 69

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337	Statutes, is amended to read:
338	400.1183 Resident grievance procedures
339	(2) Each nursing home facility shall maintain records of
340	all grievances and <u>a</u> shall report, subject to agency inspection,
341	<u>of</u> to the agency at the time of relicensure the total number of
342	grievances handled during the prior licensure period, a
343	categorization of the cases underlying the grievances, and the
344	final disposition of the grievances.
345	Section 6. Paragraphs (p), (q), (s), (t), (u), (v), (w) of
346	subsection (1) of section 400.141, Florida Statutes, are
347	redesignated as paragraphs (o), (p), (q), (r), (s), (t), and
348	(u), respectively, and present paragraphs (f), (g), (j), (n),
349	(o), (p), (q), (r),and (s) of that subsection are amended, to
350	read:
351	400.141 Administration and management of nursing home
352	facilities
353	(1) Every licensed facility shall comply with all
354	applicable standards and rules of the agency and shall:
355	(f) Be allowed and encouraged by the agency to provide
356	other needed services under certain conditions. If the facility
357	has a standard licensure status, and has had no class I or class
358	II deficiencies during the past 2 years or has been awarded a
359	Gold Seal under the program established in s. 400.235, it may be
360	encouraged by the agency to provide services, including, but not
361	limited to, respite <u>, therapeutic spa,</u> and adult day services <u>to</u>
362	nonresidents, which enable individuals to move in and out of the
363	facility. A facility is not subject to any additional licensure
364	requirements for providing these services. Respite care may be
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365 offered to persons in need of short-term or temporary nursing 366 home services. Respite care must be provided in accordance with 367 this part and rules adopted by the agency. However, the agency 368 shall, by rule, adopt modified requirements for resident 369 assessment, resident care plans, resident contracts, physician 370 orders, and other provisions, as appropriate, for short-term or 371 temporary nursing home services. Providers of adult day services 372 must comply with the requirements of s. 429.905(2). The agency 373 shall allow for shared programming and staff in a facility which meets minimum standards and offers services pursuant to this 374 paragraph, but, if the facility is cited for deficiencies in 375 376 patient care, may require additional staff and programs appropriate to the needs of service recipients. A person who 377 378 receives respite care may not be counted as a resident of the 379 facility for purposes of the facility's licensed capacity unless 380 that person receives 24-hour respite care. A person receiving 381 either respite care for 24 hours or longer or adult day services 382 must be included when calculating minimum staffing for the 383 facility. Any costs and revenues generated by a nursing home 384 facility from nonresidential programs or services shall be 385 excluded from the calculations of Medicaid per diems for nursing 386 home institutional care reimbursement.

(g) If the facility has a standard license or is a Gold Seal facility, exceeds the minimum required hours of licensed nursing and certified nursing assistant direct care per resident per day, and is part of a continuing care facility licensed under chapter 651 or a retirement community that offers other services pursuant to part III of this chapter or part I or part

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393 III of chapter 429 on a single campus, be allowed to share 394 programming and staff. At the time of inspection and in the 395 semiannual report required pursuant to paragraph (o), a 396 continuing care facility or retirement community that uses this 397 option must demonstrate through staffing records that minimum 398 staffing requirements for the facility were met. Licensed nurses 399 and certified nursing assistants who work in the nursing home 400 facility may be used to provide services elsewhere on campus if 401 the facility exceeds the minimum number of direct care hours 402 required per resident per day and the total number of residents 403 receiving direct care services from a licensed nurse or a 404 certified nursing assistant does not cause the facility to 405 violate the staffing ratios required under s. 400.23(3)(a). 406 Compliance with the minimum staffing ratios must shall be based 407 on the total number of residents receiving direct care services, 408 regardless of where they reside on campus. If the facility 409 receives a conditional license, it may not share staff until the 410 conditional license status ends. This paragraph does not 411 restrict the agency's authority under federal or state law to 412 require additional staff if a facility is cited for deficiencies 413 in care which are caused by an insufficient number of certified 414 nursing assistants or licensed nurses. The agency may adopt 415 rules for the documentation necessary to determine compliance 416 with this provision.

(j) Keep full records of resident admissions and discharges; medical and general health status, including medical records, personal and social history, and identity and address of next of kin or other persons who may have responsibility for

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421	the affairs of the <u>resident</u> residents; and individual resident
422	care plans, including, but not limited to, prescribed services,
423	service frequency and duration, and service goals. The records
424	must shall be open to agency inspection by the agency. The
425	licensee shall maintain clinical records on each resident in
426	accordance with accepted professional standards and practices,
427	which must be complete, accurately documented, readily
428	accessible, and systematically organized.
429	(n) Submit to the agency the information specified in s.
430	400.071(1)(b) for a management company within 30 days after the
431	effective date of the management agreement.
432	(o)1. Submit semiannually to the agency, or more
433	frequently if requested by the agency, information regarding
434	facility staff-to-resident ratios, staff turnover, and staff
435	stability, including information regarding certified nursing
436	assistants, licensed nurses, the director of nursing, and the
437	facility administrator. For purposes of this reporting:
438	a. Staff-to-resident ratios must be reported in the
439	categories specified in s. 400.23(3)(a) and applicable rules.
440	The ratio must be reported as an average for the most recent
441	calendar quarter.
442	b. Staff turnover must be reported for the most recent 12-
443	month period ending on the last workday of the most recent
444	calendar quarter prior to the date the information is submitted.
445	The turnover rate must be computed quarterly, with the annual
446	rate being the cumulative sum of the quarterly rates. The
447	turnover rate is the total number of terminations or separations
448	experienced during the quarter, excluding any employee
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449 terminated during a probationary period of 3 months or less, 450 divided by the total number of staff employed at the end of the 451 period for which the rate is computed, and expressed as a 452 percentage. 453 c. The formula for determining staff stability is the

454 total number of employees that have been employed for more than 455 12 months, divided by the total number of employees employed at 456 the end of the most recent calendar quarter, and expressed as a 457 percentage.

458

(n) Comply with state minimum-staffing requirements:

459 1.d. A nursing facility that has failed to comply with 460 state minimum-staffing requirements for 2 consecutive days is prohibited from accepting new admissions until the facility has 461 462 achieved the minimum-staffing requirements for a period of 6 463 consecutive days. For the purposes of this subparagraph sub-464 subparagraph, any person who was a resident of the facility and 465 was absent from the facility for the purpose of receiving 466 medical care at a separate location or was on a leave of absence 467 is not considered a new admission. Failure by the facility to 468 impose such an admissions moratorium is subject to a \$1,000 fine 469 constitutes a class II deficiency.

470 <u>2.e.</u> A nursing facility that which does not have a 471 conditional license may be cited for failure to comply with the 472 standards in s. 400.23(3)(a)1.b. and c. only if it has failed to 473 meet those standards on 2 consecutive days or if it has failed 474 to meet at least 97 percent of those standards on any one day.

475 <u>3.f.</u> A facility <u>that</u> which has a conditional license must 476 be in compliance with the standards in s. 400.23(3)(a) at all

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477 times.

478 2. This paragraph does not limit the agency's ability to 479 impose a deficiency or take other actions if a facility does not 480 have enough staff to meet the residents' needs.

481 (o) (p) Notify a licensed physician when a resident 482 exhibits signs of dementia or cognitive impairment or has a 483 change of condition in order to rule out the presence of an 484 underlying physiological condition that may be contributing to 485 such dementia or impairment. The notification must occur within 30 days after the acknowledgment of such signs by facility 486 staff. If an underlying condition is determined to exist, the 487 488 facility shall arrange, with the appropriate health care 489 provider, arrange for the necessary care and services to treat 490 the condition.

491 (p) - (q) If the facility implements a dining and hospitality 492 attendant program, ensure that the program is developed and 493 implemented under the supervision of the facility director of 494 nursing. A licensed nurse, licensed speech or occupational 495 therapist, or a registered dietitian must conduct training of 496 dining and hospitality attendants. A person employed by a 497 facility as a dining and hospitality attendant must perform tasks under the direct supervision of a licensed nurse. 498

499 (r) Report to the agency any filing for bankruptcy 500 protection by the facility or its parent corporation, 501 divestiture or spin-off of its assets, or corporate 502 reorganization within 30 days after the completion of such 503 activity.

504

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(q) (s) Maintain general and professional liability

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505 insurance coverage that is in force at all times. In lieu of 506 <u>such general and professional liability insurance</u> coverage, a 507 state-designated teaching nursing home and its affiliated 508 assisted living facilities created under s. 430.80 may 509 demonstrate proof of financial responsibility as provided in s. 510 430.80(3)(g).

511 Section 7. Subsection (3) of section 400.142, Florida 512 Statutes, is amended to read:

513 400.142 Emergency medication kits; orders not to 514 resuscitate.-

(3) 515 Facility staff may withhold or withdraw 516 cardiopulmonary resuscitation if presented with an order not to 517 resuscitate executed pursuant to s. 401.45. The agency shall 518 adopt rules providing for the implementation of such orders. 519 Facility staff and facilities are shall not be subject to 520 criminal prosecution or civil liability, or nor be considered to 521 have engaged in negligent or unprofessional conduct, for 522 withholding or withdrawing cardiopulmonary resuscitation 523 pursuant to such an order and rules adopted by the agency. The 524 absence of an order not to resuscitate executed pursuant to s. 525 401.45 does not preclude a physician from withholding or 526 withdrawing cardiopulmonary resuscitation as otherwise permitted 527 by law.

528 Section 8. Subsections (9) through (15) of section 529 400.147, Florida Statutes, are renumbered as subsections (8) 530 through (13), respectively, and present subsections (7), (8), 531 and (10) of that section are amended to read: 532 400.147 Internal risk management and quality assurance

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533 program.-

534 (7)The nursing home facility shall initiate an 535 investigation and shall notify the agency within 1 business day 536 after the risk manager or his or her designee has received a 537 report pursuant to paragraph (1)(d). The facility must complete 538 the investigation and submit a report to the agency within 15 539 calendar days after the adverse incident occurred. The 540 notification must be made in writing and be provided 541 electronically, by facsimile device or overnight mail delivery. The agency shall develop a form for the report which 542 543 notification must include the name of the risk manager, information regarding the identity of the affected resident, the 544 545 type of adverse incident, the initiation of an investigation by 546 the facility, and whether the events causing or resulting in the 547 adverse incident represent a potential risk to any other 548 resident. The report notification is confidential as provided by 549 law and is not discoverable or admissible in any civil or 550 administrative action, except in disciplinary proceedings by the 551 agency or the appropriate regulatory board. The agency may 552 investigate, as it deems appropriate, any such incident and 553 prescribe measures that must or may be taken in response to the 554 incident. The agency shall review each report incident and 555 determine whether it potentially involved conduct by the health 556 care professional who is subject to disciplinary action, in 557 which case the provisions of s. 456.073 shall apply.

558 (8) (a) Each facility shall complete the investigation and 559 submit an adverse incident report to the agency for each adverse 560 incident within 15 calendar days after its occurrence. If, after Page 20 of 69

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561	a complete investigation, the risk manager determines that the
562	incident was not an adverse incident as defined in subsection
563	(5), the facility shall include this information in the report.
564	The agency shall develop a form for reporting this information.
565	(b) The information reported to the agency pursuant to
566	paragraph (a) which relates to persons licensed under chapter
567	458, chapter 459, chapter 461, or chapter 466 shall be reviewed
568	by the agency. The agency shall determine whether any of the
569	incidents potentially involved conduct by a health care
570	professional who is subject to disciplinary action, in which
571	case the provisions of s. 456.073 shall apply.
572	(c) The report submitted to the agency must also contain
573	the name of the risk manager of the facility.
574	(d) The adverse incident report is confidential as
575	provided by law and is not discoverable or admissible in any
576	civil or administrative action, except in disciplinary
577	proceedings by the agency or the appropriate regulatory board.
578	(10) By the 10th of each month, each facility subject to
579	this section shall report any notice received pursuant to s.
580	400.0233(2) and each initial complaint that was filed with the
581	clerk of the court and served on the facility during the
582	previous month by a resident or a resident's family member,
583	guardian, conservator, or personal legal representative. The
584	report must include the name of the resident, the resident's
585	date of birth and social security number, the Medicaid
586	identification number for Medicaid-eligible persons, the date or
587	dates of the incident leading to the claim or dates of
588	residency, if applicable, and the type of injury or violation of
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589	rights alleged to have occurred. Each facility shall also submit
590	a copy of the notices received pursuant to s. 400.0233(2) and
591	complaints filed with the clerk of the court. This report is
592	confidential as provided by law and is not discoverable or
593	admissible in any civil or administrative action, except in such
594	actions brought by the agency to enforce the provisions of this
595	part.
596	Section 9. Section 400.172, Florida Statutes, is created
597	to read:
598	400.172 Respite care provided in nursing home facilities
599	(1) For each person admitted for respite care as
600	authorized under s. 400.141(1)(f), a nursing home facility
601	operated by a licensee must:
602	(a) Have a written abbreviated plan of care that, at a
603	minimum, includes nutritional requirements, medication orders,
604	physician orders, nursing assessments, and dietary preferences.
605	The nursing or physician assessments may take the place of all
606	other assessments required for full-time residents.
607	(b) Have a contract that, at a minimum, specifies the
608	services to be provided to a resident receiving respite care,
609	including charges for services, activities, equipment, emergency
610	medical services, and the administration of medications. If
611	multiple admissions for a single person for respite care are
612	anticipated, the original contract is valid for 1 year after the
613	date the contract is executed.
614	(c) Ensure that each resident is released to his or her
615	caregiver or an individual designated in writing by the
616	caregiver.

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CODING: Words stricken are deletions; words <u>underlined</u> are additions.

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617	(2) A person admitted under the respite care program
618	shall:
619	(a) Be exempt from department rules relating to the
620	discharge planning process.
621	(b) Be covered by the residents' rights specified in s.
622	400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident
623	are not be considered trust funds subject to the requirements of
624	s. 400.022(1)(h) until the resident has been in the facility for
625	more than 14 consecutive days.
626	(c) Be allowed to use his or her personal medications
627	during the respite stay if permitted by facility policy. The
628	facility must obtain a physician's order for the medications.
629	The caregiver may provide information regarding the medications
630	as part of the nursing assessment and that information must
631	agree with the physician's order. Medications shall be released
632	with the resident upon discharge in accordance with current
633	physician's orders.
634	(d) Be entitled to reside in the facility for a total of
635	60 days within a contract year or for a total of 60 days within
636	a calendar year if the contract is for less than 12 months.
637	However, each single stay may not exceed 14 days. If a stay
638	exceeds 14 consecutive days, the facility must comply with all
639	assessment and care planning requirements applicable to nursing
640	home residents.
641	(e) Reside in a licensed nursing home bed.
642	(3) A prospective respite care resident must provide
643	medical information from a physician, physician assistant, or
644	nurse practitioner and any other information provided by the
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645	primary caregiver required by the facility before or when the
646	person is admitted to receive respite care. The medical
647	information must include a physician's order for respite care
648	and proof of a physical examination by a licensed physician,
649	physician assistant, or nurse practitioner. The physician's
650	order and physical examination may be used to provide
651	intermittent respite care for up to 12 months after the date the
652	order is written.
653	(4) The facility shall assume the duties of the primary
654	caregiver. To ensure continuity of care and services, the
655	resident may retain his or her personal physician and shall have
656	access to medically necessary services such as physical therapy,
657	occupational therapy, or speech therapy, as needed. The facility
658	shall arrange for transportation of the resident to these
659	services, if necessary.
660	Section 10. Subsection (5) of section 400.23, Florida
661	Statutes, is amended to read:
662	400.23 Rules; evaluation and deficiencies; licensure
663	status
664	(5) The agency, in collaboration with the Division of
665	Children's Medical Services of the Department of Health, must $_{m au}$
666	no later than December 31, 1993, adopt rules for:
667	(a) Minimum standards of care for persons under 21 years
668	of age who reside in nursing home facilities. The rules must
669	include a methodology for reviewing a nursing home facility
670	under ss. 408.031-408.045 which serves only persons under 21
671	years of age. A facility may be <u>exempted</u> exempt from these
672	standards for specific persons between 18 and 21 years of age,
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673	if the person's physician agrees that minimum standards of care
674	based on age are not necessary.
675	(b) Minimum staffing requirements for persons under 21
676	years of age who reside in nursing home facilities, which apply
677	in lieu of the requirements contained in subsection (3).
678	1. For persons under 21 years of age who require skilled
679	care:
680	a. A minimum combined average of 3.9 hours of direct care
681	per resident per day must be provided by licensed nurses,
682	respiratory therapists, respiratory care practitioners, and
683	certified nursing assistants.
684	b. A minimum licensed nursing staffing of 1.0 hour of
685	direct care per resident per day must be provided.
686	c. No more than 1.5 hours of certified nursing assistant
687	care per resident per day may be counted in determining the
688	minimum direct care hours required.
689	d. One registered nurse must be on duty on the site 24
690	hours per day on the unit where children reside.
691	2. For persons under 21 years of age who are medically
692	fragile:
693	a. A minimum combined average of 5.0 hours of direct care
694	per resident per day must be provided by licensed nurses,
695	respiratory therapists, respiratory care practitioners, and
696	certified nursing assistants.
697	b. A minimum licensed nursing staffing of 1.7 hours of
698	direct care per resident per day must be provided.
699	c. No more than 1.5 hours of certified nursing assistant
700	care per resident per day may be counted in determining the

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701	minimum direct care hours required.
702	d. One registered nurse must be on duty on the site 24
703	hours per day on the unit where children reside.
704	Section 11. Subsection (1) of section 400.275, Florida
705	Statutes, is amended to read:
706	400.275 Agency duties
707	(1) The agency shall ensure that each newly hired nursing
708	home surveyor, as a part of basic training, is assigned full-
709	time to a licensed nursing home for at least 2 days within a 7-
710	day period to observe facility operations outside of the survey
711	process before the surveyor begins survey responsibilities. Such
712	observations may not be the sole basis of a deficiency citation
713	against the facility. The agency may not assign an individual to
714	be a member of a survey team for purposes of a survey,
715	evaluation, or consultation visit at a nursing home facility in
716	which the surveyor was an employee within the preceding $2-5$
717	years.
718	Section 12. For the purpose of incorporating the amendment
719	made by this act to section 400.509, Florida Statutes, in a
720	reference thereto, paragraph (a) of subsection (6) of section
721	400.506, Florida Statutes, is reenacted, and subsection (18) is
722	added to that section, to read:
723	400.506 Licensure of nurse registries; requirements;
724	penalties
725	(6)(a) A nurse registry may refer for contract in private
726	residences registered nurses and licensed practical nurses
727	registered and licensed under part I of chapter 464, certified
728	nursing assistants certified under part II of chapter 464, home
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health aides who present documented proof of successful 729 730 completion of the training required by rule of the agency, and 731 companions or homemakers for the purposes of providing those services authorized under s. 400.509(1). A licensed nurse 732 733 registry shall ensure that each certified nursing assistant 734 referred for contract by the nurse registry and each home health 735 aide referred for contract by the nurse registry is adequately 736 trained to perform the tasks of a home health aide in the home 737 setting. Each person referred by a nurse registry must provide 738 current documentation that he or she is free from communicable 739 diseases.

740 (18) An administrator may manage only one nurse registry, 741 except that an administrator may manage up to five registries if 742 all five registries have identical controlling interests as 743 defined in s. 408.803 and are located within one agency 744 geographic service area or within an immediately contiguous 745 county. An administrator shall designate, in writing, for each 746 licensed entity, a qualified alternate administrator to serve 747 during the administrator's absence.

Section 13. Subsection (1) of section 400.509, FloridaStatutes, is amended to read:

400.509 Registration of particular service providers
exempt from licensure; certificate of registration; regulation
of registrants.-

(1) Any organization that provides companion services or homemaker services and does not provide a home health service to a person is exempt from licensure under this part. However, any organization that provides companion services or homemaker

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757	services must register with the agency. An organization under
758	contract with the Agency for Persons with Disabilities which
759	provides companion services only for persons with a
760	developmental disability, as defined in s. 393.063, is exempt
761	from registration.
762	Section 14. Subsection (3) of section 400.601, Florida
763	Statutes, is amended to read:
764	400.601 Definitions.—As used in this part, the term:
765	(3) "Hospice" means a centrally administered corporation
766	or a limited liability company that provides providing a
767	continuum of palliative and supportive care for the terminally
768	ill patient and his or her family.
769	Section 15. Paragraph (i) of subsection (1) and subsection
770	(4) of section 400.606, Florida Statutes, are amended to read:
771	400.606 License; application; renewal; conditional license
772	or permit; certificate of need
773	(1) In addition to the requirements of part II of chapter
774	408, the initial application and change of ownership application
775	must be accompanied by a plan for the delivery of home,
776	residential, and homelike inpatient hospice services to
777	terminally ill persons and their families. Such plan must
778	contain, but need not be limited to:
779	(i) The projected annual operating cost of the hospice.
780	
781	If the applicant is an existing licensed health care provider,
782	the application must be accompanied by a copy of the most recent
783	profit-loss statement and, if applicable, the most recent
784	licensure inspection report.
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785 A freestanding hospice facility that is primarily (4) 786 engaged in providing inpatient and related services and that is 787 not otherwise licensed as a health care facility shall be required to obtain a certificate of need. However, a 788 789 freestanding hospice facility that has with six or fewer beds is 790 shall not be required to comply with institutional standards 791 such as, but not limited to, standards requiring sprinkler 792 systems, emergency electrical systems, or special lavatory 793 devices. 794 Section 16. Section 400.915, Florida Statutes, is amended 795 to read: 796 400.915 Construction and renovation; requirements.-The 797 requirements for the construction or renovation of a PPEC center 798 shall comply with: 799 The provisions of chapter 553, which pertain to (1)800 building construction standards, including plumbing, electrical 801 code, glass, manufactured buildings, accessibility for the 802 physically disabled; The provisions of s. 633.022 and applicable rules 803 (2)804 pertaining to physical minimum standards for nonresidential 805 child care physical facilities in rule 10M-12.003, Florida 806 Administrative Code, Child Care Standards; and 807 The standards or rules adopted pursuant to this part (3) 808 and part II of chapter 408. 809 Section 17. Section 400.931, Florida Statutes, is amended to read: 810 811 400.931 Application for license; fee; provisional license; 812 temporary permit.-

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ENROLLED CS/CS/HB 787, Engrossed 1 2012 Legislature 813 In addition to the requirements of part II of chapter (1)814 408, the applicant must file with the application satisfactory 815 proof that the home medical equipment provider is in compliance 816 with this part and applicable rules, including: 817 A report, by category, of the equipment to be (a) provided, indicating those offered either directly by the 818 819 applicant or through contractual arrangements with existing 820 providers. Categories of equipment include: 821 Respiratory modalities. 1. 822 2. Ambulation aids. 823 Mobility aids. 3. 824 4. Sickroom setup. 825 5. Disposables. 826 (b) A report, by category, of the services to be provided, 827 indicating those offered either directly by the applicant or 828 through contractual arrangements with existing providers. Categories of services include: 829 830 1. Intake. 831 2. Equipment selection. 8.32 3. Delivery. 833 4. Setup and installation. 834 5. Patient training. 835 6. Ongoing service and maintenance. 836 7. Retrieval. 837 (c) A listing of those with whom the applicant contracts, both the providers the applicant uses to provide equipment or 838 services to its consumers and the providers for whom the 839 840 applicant provides services or equipment.

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841 An applicant for initial licensure, change of (2)842 ownership, or license renewal to operate a licensed home medical 843 equipment provider at a location outside the state must submit 844 documentation of accreditation or an application for 845 accreditation from an accrediting organization that is 846 recognized by the agency. An applicant that has applied for 847 accreditation must provide proof of accreditation that is not conditional or provisional within 120 days after the date the 848 agency receives the application for licensure or the application 849 850 shall be withdrawn from further consideration. Such 851 accreditation must be maintained by the home medical equipment 852 provider in order to maintain licensure. As an alternative to 853 submitting proof of financial ability to operate as required in 854 s. 408.810(8), the applicant may submit a \$50,000 surety bond to 855 the agency.

856 (3) As specified in part II of chapter 408, the home 857 medical equipment provider must also obtain and maintain 858 professional and commercial liability insurance. Proof of 859 liability insurance, as defined in s. 624.605, must be submitted 860 with the application. The agency shall set the required amounts 861 of liability insurance by rule, but the required amount must not 862 be less than \$250,000 per claim. In the case of contracted 863 services, it is required that the contractor have liability 864 insurance not less than \$250,000 per claim.

865 (4) When a change of the general manager of a home medical
866 equipment provider occurs, the licensee must notify the agency
867 of the change within 45 days.

868

(5) In accordance with s. 408.805, an applicant or a Page 31 of 69

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869 licensee shall pay a fee for each license application submitted 870 under this part, part II of chapter 408, and applicable rules. 871 The amount of the fee shall be established by rule and may not 872 exceed \$300 per biennium. The agency shall set the fees in an 873 amount that is sufficient to cover its costs in carrying out its 874 responsibilities under this part. However, state, county, or 875 municipal governments applying for licenses under this part are 876 exempt from the payment of license fees.

(6) An applicant for initial licensure, renewal, or change
of ownership shall also pay an inspection fee not to exceed
\$400, which shall be paid by all applicants except those not
subject to licensure inspection by the agency as described in s.
400.933.

882 Section 18. Paragraph (a) of subsection (2) of section883 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.-

885

884

(2) FUNDING.-

886 (a) The Legislature intends that the cost of local health 887 councils be borne by assessments on selected health care 888 facilities subject to facility licensure by the Agency for 889 Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing 890 891 centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for 892 exclusive use regulated under s. 483.035, home health agencies, 893 hospices, hospitals, intermediate care facilities for the 894 developmentally disabled, nursing homes, health care clinics, 895 896 and multiphasic testing centers and by assessments on

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897	organizations subject to certification by the agency pursuant to
898	chapter 641, part III, including health maintenance
899	organizations and prepaid health clinics. <u>Fees assessed may be</u>
900	collected prospectively at the time of licensure renewal and
901	prorated for the licensure period.
902	Section 19. Subsection (2) of section 408.034, Florida
903	Statutes, is amended to read:
904	408.034 Duties and responsibilities of agency; rules
905	(2) In the exercise of its authority to issue licenses to
906	health care facilities and health service providers, as provided
907	under chapters 393 and 395 and parts II <u>,</u> and IV <u>,</u> and VIII of
908	chapter 400, the agency may not issue a license to any health
909	care facility or health service provider that fails to receive a
910	certificate of need or an exemption for the licensed facility or
911	service.
912	Section 20. Paragraph (n) of subsection (3) of section
913	408.036, Florida Statutes, is amended to read:
914	408.036 Projects subject to review; exemptions
915	(3) EXEMPTIONSUpon request, the following projects are
916	subject to exemption from the provisions of subsection (1):
917	(n) For the provision of percutaneous coronary
918	intervention for patients presenting with emergency myocardial
919	infarctions in a hospital without an approved adult open-heart-
920	surgery program. In addition to any other documentation required
921	by the agency, a request for an exemption submitted under this
922	paragraph must comply with the following:
923	1. The applicant must certify that it will meet and

924 continuously maintain the requirements adopted by the agency for

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925 the provision of these services. These licensure requirements 926 shall be adopted by rule pursuant to ss. 120.536(1) and 120.54 927 and must be consistent with the guidelines published by the 928 American College of Cardiology and the American Heart 929 Association for the provision of percutaneous coronary 930 interventions in hospitals without adult open-heart services. At 931 a minimum, the rules <u>must</u> shall require the following:

a. Cardiologists must be experienced interventionalists
who have performed a minimum of 75 interventions within the
previous 12 months.

b. The hospital must provide a minimum of 36 emergency
interventions annually in order to continue to provide the
service.

c. The hospital must offer sufficient physician, nursing,
and laboratory staff to provide the services 24 hours a day, 7
days a week.

941 d. Nursing and technical staff must have demonstrated
942 experience in handling acutely ill patients requiring
943 intervention based on previous experience in dedicated
944 interventional laboratories or surgical centers.

945 e. Cardiac care nursing staff must be adept in hemodynamic 946 monitoring and Intra-aortic Balloon Pump (IABP) management.

947 f. Formalized written transfer agreements must be 948 developed with a hospital with an adult open-heart-surgery 949 program, and written transport protocols must be in place to 950 ensure safe and efficient transfer of a patient within 60 951 minutes. Transfer and transport agreements must be reviewed and 952 tested, with appropriate documentation maintained at least every

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953 3 months. However, a hospital located more than 100 road miles 954 from the closest Level II adult cardiovascular services program 955 does not need to meet the 60-minute transfer time protocol if 956 the hospital demonstrates that it has a formalized, written 957 transfer agreement with a hospital that has a Level II program. 958 The agreement must include written transport protocols that 959 ensure the safe and efficient transfer of a patient, taking into 960 consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of 961 962 ground and air ambulance service to transfer the patient.

963 g. Hospitals implementing the service must first undertake 964 a training program of 3 to 6 months' duration, which includes 965 establishing standards and testing logistics, creating quality 966 assessment and error management practices, and formalizing 967 patient-selection criteria.

968 2. The applicant must certify that it will use at all 969 times the patient-selection criteria for the performance of 970 primary angioplasty at hospitals without adult open-heart-971 surgery programs issued by the American College of Cardiology 972 and the American Heart Association. At a minimum, these criteria 973 would provide for the following:

a. Avoidance of interventions in hemodynamically stablepatients who have identified symptoms or medical histories.

b. Transfer of patients who have a history of coronarydisease and clinical presentation of hemodynamic instability.

3. The applicant must agree to submit a quarterly report
to the agency detailing patient characteristics, treatment, and
outcomes for all patients receiving emergency percutaneous

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981 coronary interventions pursuant to this paragraph. This report 982 must be submitted within 15 days after the close of each 983 calendar quarter.

984 4. The exemption provided by this paragraph does not apply 985 unless the agency determines that the hospital has taken all 986 necessary steps to be in compliance with all requirements of 987 this paragraph, including the training program required under 988 sub-subparagraph 1.g.

989 5. Failure of the hospital to continuously comply with the 990 requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. 991 and 3. will result in the immediate expiration of this 992 exemption.

993 6. Failure of the hospital to meet the volume requirements 994 of sub-subparagraphs 1.a. and b. within 18 months after the 995 program begins offering the service will result in the immediate 996 expiration of the exemption.

998 If the exemption for this service expires under subparagraph 5. 999 or subparagraph 6., the agency may not grant another exemption 1000 for this service to the same hospital for 2 years and then only 1001 upon a showing that the hospital will remain in compliance with 1002 the requirements of this paragraph through a demonstration of 1003 corrections to the deficiencies that caused expiration of the 1004 exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted pursuant to this 1005 1006 paragraph.

1007 Section 21. Paragraph (b) of subsection (3) of section 1008 408.0361, Florida Statutes, is amended to read:

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1009	408.0361 Cardiovascular services and burn unit licensure
1010	(3) In establishing rules for adult cardiovascular
1011	services, the agency shall include provisions that allow for:
1012	(b) For a hospital seeking a Level I program,
1013	demonstration that, for the most recent 12-month period as
1014	reported to the agency, it has provided a minimum of 300 adult
1015	inpatient and outpatient diagnostic cardiac catheterizations or,
1016	for the most recent 12-month period, has discharged or
1017	transferred at least 300 inpatients with the principal diagnosis
1018	of ischemic heart disease and that it has a formalized, written
1019	transfer agreement with a hospital that has a Level II program,
1020	including written transport protocols to ensure safe and
1021	efficient transfer of a patient within 60 minutes. However, a
1022	hospital located more than 100 road miles from the closest Level
1023	II adult cardiovascular services program does not need to meet
1024	the 60-minute transfer time protocol if the hospital
1025	demonstrates that it has a formalized, written transfer
1026	agreement with a hospital that has a Level II program. The
1027	agreement must include written transport protocols to ensure the
1028	safe and efficient transfer of a patient, taking into
1029	consideration the patient's clinical and physical
1030	characteristics, road and weather conditions, and viability of
1031	ground and air ambulance service to transfer the patient.
1032	Section 22. Section 408.10, Florida Statutes, is amended
1033	to read:
1034	408.10 Consumer complaints.—The agency shall÷
1035	(1) publish and make available to the public a toll-free
1036	telephone number for the purpose of handling consumer complaints
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1037	and shall serve as a liaison between consumer entities and other
1038	private entities and governmental entities for the disposition
1039	of problems identified by consumers of health care.
1040	(2) Be empowered to investigate consumer complaints
1041	relating to problems with health care facilities' billing
1042	practices and issue reports to be made public in any cases where
1043	the agency determines the health care facility has engaged in
1044	billing practices which are unreasonable and unfair to the
1045	consumer.
1046	Section 23. Subsection (11) of section 408.802, Florida
1047	Statutes, is repealed.
1048	Section 24. Subsection (3) is added to section 408.804,
1049	Florida Statutes, to read:
1050	408.804 License required; display
1051	(3) Any person who knowingly alters, defaces, or falsifies
1052	a license certificate issued by the agency, or causes or
1053	procures any person to commit such an offense, commits a
1054	misdemeanor of the second degree, punishable as provided in s.
1055	775.082 or s. 775.083. Any licensee or provider who displays an
1056	altered, defaced, or falsified license certificate is subject to
1057	the penalties set forth in s. 408.815 and an administrative fine
1058	of \$1,000 for each day of illegal display.
1059	Section 25. Paragraph (d) of subsection (2) of section
1060	408.806, Florida Statutes, is amended, and paragraph (e) is
1061	added to that subsection, to read:
1062	408.806 License application process
1063	(2)
1064	(d) The agency shall notify the licensee by mail or
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1065 electronically at least 90 days before the expiration of a 1066 license that a renewal license is necessary to continue 1067 operation. The licensee's failure to timely file submit a 1068 renewal application and license application fee with the agency 1069 shall result in a \$50 per day late fee charged to the licensee 1070 by the agency; however, the aggregate amount of the late fee may 1071 not exceed 50 percent of the licensure fee or \$500, whichever is less. The agency shall provide a courtesy notice to the licensee 1072 by United States mail, electronically, or by any other manner at 1073 1074 its address of record or mailing address, if provided, at least 1075 90 days before the expiration of a license. This courtesy notice 1076 must inform the licensee of the expiration of the license. If 1077 the agency does not provide the courtesy notice or the licensee 1078 does not receive the courtesy notice, the licensee continues to 1079 be legally obligated to timely file the renewal application and 1080 license application fee with the agency and is not excused from 1081 the payment of a late fee. If an application is received after 1082 the required filing date and exhibits a hand-canceled postmark 1083 obtained from a United States post office dated on or before the 1084 required filing date, no fine will be levied. 1085 The applicant must pay the late fee before a late (e) 1086 application is considered complete and failure to pay the late 1087 fee is considered an omission from the application for licensure 1088 pursuant to paragraph (3)(b). Section 26. Paragraph (b) of subsection (1) of section 1089 408.8065, Florida Statutes, is amended to read: 1090 1091 408.8065 Additional licensure requirements for home health 1092

agencies, home medical equipment providers, and health care

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1093 clinics.-

1103

(1) An applicant for initial licensure, or initial
licensure due to a change of ownership, as a home health agency,
home medical equipment provider, or health care clinic shall:

(b) Submit projected pro forma financial statements, including a balance sheet, income and expense statement, and a statement of cash flows for the first 2 years of operation which provide evidence that the applicant has sufficient assets, credit, and projected revenues to cover liabilities and expenses.

All documents required under this subsection must be prepared in accordance with generally accepted accounting principles and may be in a compilation form. The financial statements must be signed by a certified public accountant.

1108 Section 27. Subsection (9) of section 408.810, Florida
1109 Statutes, is amended to read:

1110 408.810 Minimum licensure requirements.—In addition to the 1111 licensure requirements specified in this part, authorizing 1112 statutes, and applicable rules, each applicant and licensee must 1113 comply with the requirements of this section in order to obtain 1114 and maintain a license.

(9) A controlling interest may not withhold from the agency any evidence of financial instability, including, but not limited to, checks returned due to insufficient funds, delinquent accounts, nonpayment of withholding taxes, unpaid utility expenses, nonpayment for essential services, or adverse court action concerning the financial viability of the provider

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1121	or any other provider licensed under this part that is under the
1122	control of the controlling interest. <u>A controlling interest</u>
1123	shall notify the agency within 10 days after a court action to
1124	initiate bankruptcy, foreclosure, or eviction proceedings
1125	concerning the provider in which the controlling interest is a
1126	petitioner or defendant. Any person who violates this subsection
1127	commits a misdemeanor of the second degree, punishable as
1128	provided in s. 775.082 or s. 775.083. Each day of continuing
1129	violation is a separate offense.
1130	Section 28. Subsection (3) is added to section 408.813,
1131	Florida Statutes, to read:
1132	408.813 Administrative fines; violations.—As a penalty for
1133	any violation of this part, authorizing statutes, or applicable
1134	rules, the agency may impose an administrative fine.
1135	(3) The agency may impose an administrative fine for a
1136	violation that is not designated as a class I, class II, class
1137	III, or class IV violation. Unless otherwise specified by law,
1138	the amount of the fine may not exceed \$500 for each violation.
1139	Unclassified violations include:
1140	(a) Violating any term or condition of a license.
1141	(b) Violating any provision of this part, authorizing
1142	statutes, or applicable rules.
1143	(c) Exceeding licensed capacity.
1144	(d) Providing services beyond the scope of the license.
1145	(e) Violating a moratorium imposed pursuant to s. 408.814.
1146	Section 29. Section 429.195, Florida Statutes, is amended
1147	to read:
1148	429.195 Rebates prohibited; penalties
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1149	(1) <u>An</u> It is unlawful for any assisted living facility
1150	licensed under this part <u>may not</u> to contract or promise to pay
1151	or receive any commission, bonus, kickback, or rebate or engage
1152	in any split-fee arrangement in any form whatsoever with any
1153	person, health care provider, or health care facility as
1154	provided under s. 817.505 physician, surgeon, organization,
1155	agency, or person, either directly or indirectly, for residents
1156	referred to an assisted living facility licensed under this
1157	part. A facility may employ or contract with persons to market
1158	the facility, provided the employee or contract provider clearly
1159	indicates that he or she represents the facility. A person or
1160	agency independent of the facility may provide placement or
1161	referral services for a fee to individuals seeking assistance in
1162	finding a suitable facility; however, any fee paid for placement
1163	or referral services must be paid by the individual looking for
1164	a facility, not by the facility.
1165	(2) This section does not apply to:
1166	(a) An individual employed by the assisted living
1167	facility, or with whom the facility contracts to provide
1168	marketing services for the facility, if the individual clearly
1169	indicates that he or she works with or for the facility.
1170	(b) Payments by an assisted living facility to a referral
1171	service that provides information, consultation, or referrals to
1172	consumers to assist them in finding appropriate care or housing
1173	options for seniors or disabled adults if the referred consumers
1174	are not Medicaid recipients.
1175	(c) A resident of an assisted living facility who refers a
1176	friend, family members, or other individuals with whom the
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1177 resident has a personal relationship to the assisted living 1178 facility, in which case the assisted living facility may provide 1179 a monetary reward to the resident for making such referral.

1180(3) (2)A violation of this section is shall be considered1181patient brokering and is punishable as provided in s. 817.505.

1182 Section 30. Subsection (2) of section 429.905, Florida
1183 Statutes, is amended to read:

1184 429.905 Exemptions; monitoring of adult day care center 1185 programs colocated with assisted living facilities or licensed 1186 nursing home facilities.-

1187 A licensed assisted living facility, a licensed (2) hospital, or a licensed nursing home facility may provide 1188 1189 services during the day which include, but are not limited to, 1190 social, health, therapeutic, recreational, nutritional, and 1191 respite services, to adults who are not residents. Such a 1192 facility need not be licensed as an adult day care center; 1193 however, the agency must monitor the facility during the regular 1194 inspection and at least biennially to ensure adequate space and 1195 sufficient staff. If an assisted living facility, a hospital, or 1196 a nursing home holds itself out to the public as an adult day 1197 care center, it must be licensed as such and meet all standards 1198 prescribed by statute and rule. For the purpose of this 1199 subsection, the term "day" means any portion of a 24-hour day. 1200 Section 31. Present paragraphs (a), (c), and (d) of

1201 subsection (1), paragraph (a) of subsection (2), and paragraph 1202 (e) of subsection (3) of section 456.44, Florida Statutes, are 1203 amended, and a new paragraph (d) is added to subsection (1) of 1204 that section, to read:

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1205	456.44 Controlled substance prescribing
1206	(1) DEFINITIONS
1207	(a) "Addiction medicine specialist" means a board-
1208	certified <u>psychiatrist</u> physiatrist with a subspecialty
1209	certification in addiction medicine or who is eligible for such
1210	subspecialty certification in addiction medicine, an addiction
1211	medicine physician certified or eligible for certification by
1212	the American Society of Addiction Medicine, or an osteopathic
1213	physician who holds a certificate of added qualification in
1214	Addiction Medicine through the American Osteopathic Association.
1215	(c) "Board-certified pain management physician" means a
1216	physician who possesses board certification in pain medicine by
1217	the American Board of Pain Medicine, board certification by the
1218	American Board of Interventional Pain Physicians, or board
1219	certification or subcertification in pain management or pain
1220	medicine by a specialty board recognized by the American
1221	Association of Physician Specialists or the American Board of
1222	Medical Specialties or an osteopathic physician who holds a
1223	certificate in Pain Management by the American Osteopathic
1224	Association.
1225	(d) "Board eligible" means successful completion of an
1226	anesthesia, physical medicine and rehabilitation, rheumatology,
1227	or neurology residency program approved by the Accreditation
1228	Council for Graduate Medical Education or the American
1229	Osteopathic Association for a period of 6 years from successful
1230	completion of such residency program.
1231	<u>(e)</u> (d) "Chronic nonmalignant pain" means pain unrelated to
1232	cancer or rheumatoid arthritis which persists beyond the usual
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1233 course of disease or the injury that is the cause of the pain or 1234 more than 90 days after surgery.

1235 (2) REGISTRATION.-Effective January 1, 2012, a physician
1236 licensed under chapter 458, chapter 459, chapter 461, or chapter
1237 466 who prescribes any controlled substance, <u>listed in Schedule</u>
1238 <u>II, Schedule III, or Schedule IV</u> as defined in s. 893.03, for
1239 the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance
prescribing practitioner on the physician's practitioner
profile.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

1247 The physician shall refer the patient as necessary for (e) 1248 additional evaluation and treatment in order to achieve 1249 treatment objectives. Special attention shall be given to those 1250 patients who are at risk for misusing their medications and 1251 those whose living arrangements pose a risk for medication 1252 misuse or diversion. The management of pain in patients with a 1253 history of substance abuse or with a comorbid psychiatric 1254 disorder requires extra care, monitoring, and documentation and 1255 requires consultation with or referral to an addiction medicine 1256 specialist or psychiatrist addictionologist or physiatrist.

1257

1258 This subsection does not apply to a <u>board-eligible or</u> board-1259 certified anesthesiologist, physiatrist, <u>rheumatologist</u>, or 1260 neurologist, or to a board-certified physician who has surgical

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1261	privileges at a hospital or ambulatory surgery center and
1262	primarily provides surgical services. This subsection does not
1263	apply to a <u>board-eligible or</u> board-certified medical specialist
1264	who has also completed a fellowship in pain medicine approved by
1265	the Accreditation Council for Graduate Medical Education or the
1266	American Osteopathic Association, or who is board eligible or
1267	board certified in pain medicine by the American Board of Pain
1268	Medicine or a board approved by the American Board of Medical
1269	Specialties or the American Osteopathic Association and performs
1270	interventional pain procedures of the type routinely billed
1271	using surgical codes. This subsection does not apply to a
1272	physician who prescribes medically necessary controlled
1273	substances for a patient during an inpatient stay in a hospital
1274	licensed under chapter 395.
1275	Section 32. Paragraph (a) of subsection (1) of section
1276	458.3265, Florida Statutes, is amended to read:
1277	458.3265 Pain-management clinics
1278	(1) REGISTRATION
1279	(a)1. As used in this section, the term:
1280	a. "Board eligible" means successful completion of an
1281	anesthesia, physical medicine and rehabilitation, rheumatology,
1282	or neurology residency program approved by the Accreditation
1283	Council for Graduate Medical Education or the American
1284	Osteopathic Association for a period of 6 years from successful
1285	completion of such residency program.
1286	b.a. "Chronic nonmalignant pain" means pain unrelated to
1287	cancer or rheumatoid arthritis which persists beyond the usual
1288	course of disease or the injury that is the cause of the pain or
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1289 more than 90 days after surgery.

1290 <u>c.b.</u> "Pain-management clinic" or "clinic" means any 1291 publicly or privately owned facility:

(I) That advertises in any medium for any type of painmanagement services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

1297 2. Each pain-management clinic must register with the 1298 department unless:

1299 a. That clinic is licensed as a facility pursuant to 1300 chapter 395;

b. The majority of the physicians who provide services inthe clinic primarily provide surgical services;

1303 c. The clinic is owned by a publicly held corporation 1304 whose shares are traded on a national exchange or on the over-1305 the-counter market and whose total assets at the end of the 1306 corporation's most recent fiscal quarter exceeded \$50 million;

d. The clinic is affiliated with an accredited medical
school at which training is provided for medical students,
residents, or fellows;

e. The clinic does not prescribe controlled substances forthe treatment of pain;

1312 f. The clinic is owned by a corporate entity exempt from 1313 federal taxation under 26 U.S.C. s. 501(c)(3);

1314 g. The clinic is wholly owned and operated by one or more 1315 <u>board-eligible or</u> board-certified anesthesiologists,

1316 physiatrists, rheumatologists, or neurologists; or

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1317	h. The clinic is wholly owned and operated by <u>a physician</u>
1318	multispecialty practice where one or more board-eligible or
1319	board-certified medical specialists who have also completed
1320	fellowships in pain medicine approved by the Accreditation
1321	Council for Graduate Medical Education, or who are also board-
1322	certified in pain medicine by the American Board of Pain
1323	Medicine or a board approved by the American Board of Medical
1324	Specialties, the American Association of Physician Specialists,
1325	or the American Osteopathic Association and perform
1326	interventional pain procedures of the type routinely billed
1327	using surgical codes.
1328	Section 33. Paragraph (a) of subsection (1) of section
1329	459.0137, Florida Statutes, is amended to read:
1330	459.0137 Pain-management clinics
1331	(1) REGISTRATION
1332	(a)1. As used in this section, the term:
1333	a. "Board eligible" means successful completion of an
1334	anesthesia, physical medicine and rehabilitation, rheumatology,
1335	or neurology residency program approved by the Accreditation
1336	Council for Graduate Medical Education or the American
1337	Osteopathic Association for a period of 6 years from successful
1338	completion of such residency program.
1339	<u>b.</u> a. "Chronic nonmalignant pain" means pain unrelated to
1340	cancer or rheumatoid arthritis which persists beyond the usual
1341	course of disease or the injury that is the cause of the pain or
1342	more than 90 days after surgery.
1343	<u>c.b. "Pain-management clinic" or "clinic" means any</u>
1344	publicly or privately owned facility:
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(I) That advertises in any medium for any type of pain-1346 management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

1350 2. Each pain-management clinic must register with the 1351 department unless:

1352 a. That clinic is licensed as a facility pursuant to1353 chapter 395;

b. The majority of the physicians who provide services inthe clinic primarily provide surgical services;

1356 c. The clinic is owned by a publicly held corporation 1357 whose shares are traded on a national exchange or on the over-1358 the-counter market and whose total assets at the end of the 1359 corporation's most recent fiscal quarter exceeded \$50 million;

d. The clinic is affiliated with an accredited medical
school at which training is provided for medical students,
residents, or fellows;

e. The clinic does not prescribe controlled substances forthe treatment of pain;

1365 f. The clinic is owned by a corporate entity exempt from 1366 federal taxation under 26 U.S.C. s. 501(c)(3);

1367g. The clinic is wholly owned and operated by one or more1368board-eligible or board-certified anesthesiologists,

1369 physiatrists, <u>rheumatologists</u>, or neurologists; or

h. The clinic is wholly owned and operated by <u>a physician</u>
 <u>multispecialty practice where</u> one or more <u>board-eligible or</u>
 board-certified medical specialists who have also completed

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1373	fellowships in pain medicine approved by the Accreditation
1374	Council for Graduate Medical Education or the American
1375	Osteopathic Association, or who are also board-certified in pain
1376	medicine by <u>the American Board of Pain Medicine or</u> a board
1377	approved by the American Board of Medical Specialties, the
1378	American Association of Physician Specialists, or the American
1379	Osteopathic Association and perform interventional pain
1380	procedures of the type routinely billed using surgical codes.
1381	Section 34. Paragraph (b) of subsection (1) of section
1382	483.23, Florida Statutes, is amended to read:
1383	483.23 Offenses; criminal penalties
1384	(1)
1385	(b) The performance of any act specified in paragraph (a)
1386	shall be referred by the agency to the local law enforcement
1387	agency and constitutes a misdemeanor of the second degree,
1388	punishable as provided in s. 775.082 or s. 775.083.
1389	Additionally, the agency may issue and deliver a notice to cease
1390	and desist from such act and may impose by citation an
1391	administrative penalty not to exceed \$5,000 per act. Each day
1392	that unlicensed activity continues after issuance of a notice to
1393	cease and desist constitutes a separate act.
1394	Section 35. Subsection (1) of section 483.245, Florida
1395	Statutes, is amended, and subsection (3) is added to that
1396	section, to read:
1397	483.245 Rebates prohibited; penalties
1398	(1) It is unlawful for any person to pay or receive any
1399	commission, bonus, kickback, or rebate or engage in any split-
1400	fee arrangement in any form whatsoever with any dialysis
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1401	facility, physician, surgeon, organization, agency, or person,
1402	either directly or indirectly, for patients referred to a
1403	clinical laboratory licensed under this part. <u>A clinical</u>
1404	laboratory is prohibited from, directly or indirectly, providing
1405	through employees, contractors, an independent staffing company,
1406	lease agreement, or otherwise, personnel to perform any
1407	functions or duties in a physician's office, or any part of a
1408	physician's office, for any purpose whatsoever, including for
1409	the collection or handling of specimens, unless the laboratory
1410	and the physician's office are wholly owned and operated by the
1411	same entity. A clinical laboratory is prohibited from leasing
1412	space within any part of a physician's office for any purpose,
1413	including for the purpose of establishing a collection station.
1414	(3) The agency shall promptly investigate all complaints
1415	of noncompliance with subsection (1). The agency shall impose a
1416	fine of \$5,000 for each separate violation of subsection (1). In
1417	addition, the agency shall deny an application for a license or
1418	license renewal if the applicant, or any other entity with one
1419	or more common controlling interests in the applicant,
1420	demonstrates a pattern of violating subsection (1). A pattern
1421	may be demonstrated by a showing of at least two such
1422	violations.
1423	Section 36. Subsection (8) of section 651.118, Florida
1424	Statutes, is amended to read:
1425	651.118 Agency for Health Care Administration;
1426	certificates of need; sheltered beds; community beds
1426 1427	certificates of need; sheltered beds; community beds (8) A provider may petition the Agency for Health Care
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1429 home beds to provide assisted living extended congregate care as 1430 defined in s. 429.02 if the beds are in a distinct area of the 1431 nursing home which can be adapted to meet the requirements for 1432 an assisted living facility as defined in s. 429.02 extended 1433 congregate care. The provider may subsequently use such beds as 1434 sheltered beds after notifying the agency of the intended 1435 change. Any sheltered beds used to provide assisted living 1436 extended congregate care pursuant to this subsection may not 1437 qualify for funding under the Medicaid waiver. Any sheltered 1438 beds used to provide assisted living extended congregate care 1439 pursuant to this subsection may share common areas, services, 1440 and staff with beds designated for nursing home care, provided that all of the beds are under common ownership. For the 1441 1442 purposes of this subsection, fire and life safety codes 1443 applicable to nursing home facilities shall apply. 1444 Section 37. Paragraph (j) is added to subsection (3) of section 817.505, Florida Statutes, to read: 1445 1446 817.505 Patient brokering prohibited; exceptions; 1447 penalties.-1448 This section shall not apply to: (3) 1449 Any activity permitted under s. 429.195(2). (j) 1450 Section 38. Paragraphs (m) and (n) are added to subsection 1451 (4) of section 400.9905, Florida Statutes, to read: 1452 400.9905 Definitions.-"Clinic" means an entity at which health care services 1453 (4) are provided to individuals and which tenders charges for 1454 reimbursement for such services, including a mobile clinic and a 1455 1456 portable equipment provider. For purposes of this part, the term Page 52 of 69

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1457	does not include and the licensure requirements of this part do
1458	not apply to:
1459	(m) Entities that are owned by a corporation that has \$250
1460	million or more in total annual sales of health care services
1461	provided by licensed health care practitioners where one or more
1462	of the owners is a health care practitioner who is licensed in
1463	this state and who is responsible for supervising the business
1464	activities of the entity and is legally responsible for the
1465	entity's compliance with state law for purposes of this part.
1466	(n) Entities that employ 50 or more licensed health care
1467	practitioners licensed under chapter 458 or chapter 459 where
1468	the billing for medical services is under a single tax
1469	identification number, the application for exemption under this
1470	subsection shall contain information that includes: the name,
1471	residence and business address and phone number of the entity
1472	that owns the practice; a complete list of the names and contact
1473	information of all the officers and directors of the
1474	corporation; the name, residence address, business address and
1475	medical license number of each licensed Florida health care
1476	practitioner employed by the entity; the corporate tax
1477	identification number of the entity seeking an exemption; a
1478	listing of health care services to be provided by the entity at
1479	the health care clinics owned or operated by the entity and a
1480	certified statement prepared by an independent certified public
1481	accountant which states that the entity and the health care
1482	clinics owned or operated by the entity have not received
1483	payment for health care services under personal injury
1484	protection insurance coverage for the preceding year. If the
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1485 <u>agency determines that an entity which is exempt under this</u> 1486 <u>subsection has received payments for medical services under</u> 1487 <u>personal injury protection insurance coverage the agency may</u> 1488 <u>deny or revoke the exemption from licensure under this</u> 1489 subsection.

1490 Section 39. Subsection (37) of section 409.912, Florida 1491 Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.-The 1492 1493 agency shall purchase goods and services for Medicaid recipients 1494 in the most cost-effective manner consistent with the delivery 1495 of quality medical care. To ensure that medical services are 1496 effectively utilized, the agency may, in any case, require a 1497 confirmation or second physician's opinion of the correct 1498 diagnosis for purposes of authorizing future services under the 1499 Medicaid program. This section does not restrict access to 1500 emergency services or poststabilization care services as defined 1501 in 42 C.F.R. part 438.114. Such confirmation or second opinion 1502 shall be rendered in a manner approved by the agency. The agency 1503 shall maximize the use of prepaid per capita and prepaid 1504 aggregate fixed-sum basis services when appropriate and other 1505 alternative service delivery and reimbursement methodologies, 1506 including competitive bidding pursuant to s. 287.057, designed 1507 to facilitate the cost-effective purchase of a case-managed 1508 continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute 1509 1510 inpatient, custodial, and other institutional care and the 1511 inappropriate or unnecessary use of high-cost services. The 1512 agency shall contract with a vendor to monitor and evaluate the

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1513 clinical practice patterns of providers in order to identify 1514 trends that are outside the normal practice patterns of a 1515 provider's professional peers or the national guidelines of a 1516 provider's professional association. The vendor must be able to 1517 provide information and counseling to a provider whose practice 1518 patterns are outside the norms, in consultation with the agency, 1519 to improve patient care and reduce inappropriate utilization. 1520 The agency may mandate prior authorization, drug therapy 1521 management, or disease management participation for certain 1522 populations of Medicaid beneficiaries, certain drug classes, or 1523 particular drugs to prevent fraud, abuse, overuse, and possible 1524 dangerous drug interactions. The Pharmaceutical and Therapeutics 1525 Committee shall make recommendations to the agency on drugs for 1526 which prior authorization is required. The agency shall inform 1527 the Pharmaceutical and Therapeutics Committee of its decisions 1528 regarding drugs subject to prior authorization. The agency is 1529 authorized to limit the entities it contracts with or enrolls as 1530 Medicaid providers by developing a provider network through 1531 provider credentialing. The agency may competitively bid single-1532 source-provider contracts if procurement of goods or services 1533 results in demonstrated cost savings to the state without 1534 limiting access to care. The agency may limit its network based 1535 on the assessment of beneficiary access to care, provider 1536 availability, provider quality standards, time and distance standards for access to care, the cultural competence of the 1537 1538 provider network, demographic characteristics of Medicaid 1539 beneficiaries, practice and provider-to-beneficiary standards, 1540 appointment wait times, beneficiary use of services, provider

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1541 turnover, provider profiling, provider licensure history, 1542 previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, 1543 1544 clinical and medical record audits, and other factors. Providers 1545 are not entitled to enrollment in the Medicaid provider network. 1546 The agency shall determine instances in which allowing Medicaid 1547 beneficiaries to purchase durable medical equipment and other 1548 goods is less expensive to the Medicaid program than long-term 1549 rental of the equipment or goods. The agency may establish rules 1550 to facilitate purchases in lieu of long-term rentals in order to 1551 protect against fraud and abuse in the Medicaid program as 1552 defined in s. 409.913. The agency may seek federal waivers 1553 necessary to administer these policies.

(37) (a) The agency shall implement a Medicaid prescribeddrug spending-control program that includes the following components:

1557 A Medicaid preferred drug list, which shall be a 1. 1558 listing of cost-effective therapeutic options recommended by the 1559 Medicaid Pharmacy and Therapeutics Committee established 1560 pursuant to s. 409.91195 and adopted by the agency for each 1561 therapeutic class on the preferred drug list. At the discretion 1562 of the committee, and when feasible, the preferred drug list 1563 should include at least two products in a therapeutic class. The 1564 agency may post the preferred drug list and updates to the list 1565 on an Internet website without following the rulemaking 1566 procedures of chapter 120. Antiretroviral agents are excluded 1567 from the preferred drug list. The agency shall also limit the 1568 amount of a prescribed drug dispensed to no more than a 34-day

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1569 supply unless the drug products' smallest marketed package is 1570 greater than a 34-day supply, or the drug is determined by the 1571 agency to be a maintenance drug in which case a 100-day maximum 1572 supply may be authorized. The agency may seek any federal 1573 waivers necessary to implement these cost-control programs and 1574 to continue participation in the federal Medicaid rebate 1575 program, or alternatively to negotiate state-only manufacturer 1576 rebates. The agency may adopt rules to administer this 1577 subparagraph. The agency shall continue to provide unlimited 1578 contraceptive drugs and items. The agency must establish 1579 procedures to ensure that:

a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed is provided in
an emergency or when the agency does not provide a response
within 24 hours as required by sub-subparagraph a.

1586 2. Reimbursement to pharmacies for Medicaid prescribed 1587 drugs shall be set at the lowest of: the average wholesale price 1588 (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) 1589 plus 1.5 percent, the federal upper limit (FUL), the state 1590 maximum allowable cost (SMAC), or the usual and customary (UAC) 1591 charge billed by the provider.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims

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1597 analyses, and case evaluations to determine the medical 1598 necessity and appropriateness of a patient's treatment plan and 1599 drug therapies. The agency may contract with a private 1600 organization to provide drug-program-management services. The 1601 Medicaid drug benefit management program shall include 1602 initiatives to manage drug therapies for HIV/AIDS patients, 1603 patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The 1604 1605 agency shall enroll any Medicaid recipient in the drug benefit 1606 management program if he or she meets the specifications of this 1607 provision and is not enrolled in a Medicaid health maintenance 1608 organization.

1609 The agency may limit the size of its pharmacy network 4. 1610 based on need, competitive bidding, price negotiations, 1611 credentialing, or similar criteria. The agency shall give 1612 special consideration to rural areas in determining the size and 1613 location of pharmacies included in the Medicaid pharmacy 1614 network. A pharmacy credentialing process may include criteria 1615 such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease 1616 1617 management services, and other characteristics. The agency may 1618 impose a moratorium on Medicaid pharmacy enrollment if it is 1619 determined that it has a sufficient number of Medicaidparticipating providers. The agency must allow dispensing 1620 1621 practitioners to participate as a part of the Medicaid pharmacy 1622 network regardless of the practitioner's proximity to any other 1623 entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing 1624

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1625 requirements applicable to his or her practice, as determined by 1626 the agency.

The agency shall develop and implement a program that 1627 5. 1628 requires Medicaid practitioners who prescribe drugs to use a 1629 counterfeit-proof prescription pad for Medicaid prescriptions. 1630 The agency shall require the use of standardized counterfeit-1631 proof prescription pads by Medicaid-participating prescribers or 1632 prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or 1633 statewide. 1634

1635 6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients 1636 1637 to provide rebates of at least 15.1 percent of the average 1638 manufacturer price for the manufacturer's generic products. 1639 These arrangements shall require that if a generic-drug 1640 manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a 1641 1642 supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level. 1643

1644 The agency may establish a preferred drug list as 7. 1645 described in this subsection, and, pursuant to the establishment 1646 of such preferred drug list, negotiate supplemental rebates from 1647 manufacturers that are in addition to those required by Title 1648 XIX of the Social Security Act and at no less than 14 percent of 1649 the average manufacturer price as defined in 42 U.S.C. s. 1936 1650 on the last day of a quarter unless the federal or supplemental 1651 rebate, or both, equals or exceeds 29 percent. There is no upper 1652 limit on the supplemental rebates the agency may negotiate. The

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1653 agency may determine that specific products, brand-name or 1654 generic, are competitive at lower rebate percentages. Agreement 1655 to pay the minimum supplemental rebate percentage guarantees a 1656 manufacturer that the Medicaid Pharmaceutical and Therapeutics 1657 Committee will consider a product for inclusion on the preferred 1658 drug list. However, a pharmaceutical manufacturer is not 1659 quaranteed placement on the preferred drug list by simply paying 1660 the minimum supplemental rebate. Agency decisions will be made 1661 on the clinical efficacy of a drug and recommendations of the 1662 Medicaid Pharmaceutical and Therapeutics Committee, as well as 1663 the price of competing products minus federal and state rebates. 1664 The agency may contract with an outside agency or contractor to 1665 conduct negotiations for supplemental rebates. For the purposes 1666 of this section, the term "supplemental rebates" means cash 1667 rebates. Value-added programs as a substitution for supplemental 1668 rebates are prohibited. The agency may seek any federal waivers to implement this initiative. 1669

1670 The agency shall expand home delivery of pharmacy 8. 1671 products. The agency may amend the state plan and issue a 1672 procurement, as necessary, in order to implement this program. 1673 The procurements must include agreements with a pharmacy or 1674 pharmacies located in the state to provide mail order delivery 1675 services at no cost to the recipients who elect to receive home 1676 delivery of pharmacy products. The procurement must focus on 1677 serving recipients with chronic diseases for which pharmacy 1678 expenditures represent a significant portion of Medicaid 1679 pharmacy expenditures or which impact a significant portion of 1680 the Medicaid population. The agency may seek and implement any

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1681 federal waivers necessary to implement this subparagraph.

1682 9. The agency shall limit to one dose per month any drug 1683 prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

1689 b. The agency, in conjunction with the Department of 1690 Children and Family Services, may implement the Medicaid 1691 behavioral drug management system that is designed to improve 1692 the quality of care and behavioral health prescribing practices 1693 based on best practice guidelines, improve patient adherence to 1694 medication plans, reduce clinical risk, and lower prescribed 1695 drug costs and the rate of inappropriate spending on Medicaid 1696 behavioral drugs. The program may include the following 1697 elements:

1698 Provide for the development and adoption of best (I) 1699 practice guidelines for behavioral health-related drugs such as 1700 antipsychotics, antidepressants, and medications for treating 1701 bipolar disorders and other behavioral conditions; translate 1702 them into practice; review behavioral health prescribers and 1703 compare their prescribing patterns to a number of indicators 1704 that are based on national standards; and determine deviations 1705 from best practice guidelines.

1706 (II) Implement processes for providing feedback to and 1707 educating prescribers using best practice educational materials 1708 and peer-to-peer consultation.

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1709 Assess Medicaid beneficiaries who are outliers in (III)1710 their use of behavioral health drugs with regard to the numbers 1711 and types of drugs taken, drug dosages, combination drug 1712 therapies, and other indicators of improper use of behavioral 1713 health drugs.

1714 Alert prescribers to patients who fail to refill (IV) 1715 prescriptions in a timely fashion, are prescribed multiple same-1716 class behavioral health drugs, and may have other potential 1717 medication problems.

Track spending trends for behavioral health drugs and 1718 (V)1719 deviation from best practice guidelines.

1720 Use educational and technological approaches to (VI) 1721 promote best practices, educate consumers, and train prescribers in the use of practice guidelines. 1722

1723

Disseminate electronic and published materials. (VII)

1724

(VIII) Hold statewide and regional conferences.

1725 Implement a disease management program with a model (IX) 1726 quality-based medication component for severely mentally ill 1727 individuals and emotionally disturbed children who are high users of care. 1728

1729 11. The agency shall implement a Medicaid prescription 1730 drug management system.

1731 The agency may contract with a vendor that has a. 1732 experience in operating prescription drug management systems in 1733 order to implement this system. Any management system that is 1734 implemented in accordance with this subparagraph must rely on 1735 cooperation between physicians and pharmacists to determine 1736 appropriate practice patterns and clinical guidelines to improve

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1737 the prescribing, dispensing, and use of drugs in the Medicaid 1738 program. The agency may seek federal waivers to implement this 1739 program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the adoption of best practice guidelines
for the prescribing and use of drugs in the Medicaid program,
including translating best practice guidelines into practice;
reviewing prescriber patterns and comparing them to indicators
that are based on national standards and practice patterns of
clinical peers in their community, statewide, and nationally;
and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

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1765 12. The agency may contract for drug rebate 1766 administration, including, but not limited to, calculating 1767 rebate amounts, invoicing manufacturers, negotiating disputes 1768 with manufacturers, and maintaining a database of rebate 1769 collections.

1770 13. The agency may specify the preferred daily dosing form 1771 or strength for the purpose of promoting best practices with 1772 regard to the prescribing of certain drugs as specified in the 1773 General Appropriations Act and ensuring cost-effective 1774 prescribing practices.

1775 14. The agency may require prior authorization for 1776 Medicaid-covered prescribed drugs. The agency may prior-1777 authorize the use of a product:

1778 1779

1782

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

1780 c. If the product has the potential for overuse, misuse,1781 or abuse.

1783 The agency may require the prescribing professional to provide 1784 information about the rationale and supporting medical evidence 1785 for the use of a drug. The agency shall may post prior 1786 authorization, step-edit criteria and protocol, and updates to 1787 the list of drugs that are subject to prior authorization on the 1788 agency's an Internet website within 21 days after the prior 1789 authorization and step-edit criteria and protocol and updates 1790 are approved by the agency. For purposes of this subparagraph, 1791 the term "step-edit" means an automatic electronic review of 1792 certain medications subject to prior authorization without

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1793 amending its rule or engaging in additional rulemaking.

1794 15. The agency, in conjunction with the Pharmaceutical and 1795 Therapeutics Committee, may require age-related prior 1796 authorizations for certain prescribed drugs. The agency may 1797 preauthorize the use of a drug for a recipient who may not meet 1798 the age requirement or may exceed the length of therapy for use 1799 of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may 1800 require the prescribing professional to provide information 1801 1802 about the rationale and supporting medical evidence for the use 1803 of a drug.

1804 The agency shall implement a step-therapy prior 16. 1805 authorization approval process for medications excluded from the 1806 preferred drug list. Medications listed on the preferred drug 1807 list must be used within the previous 12 months before the 1808 alternative medications that are not listed. The step-therapy 1809 prior authorization may require the prescriber to use the 1810 medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug 1811 Administration labeling. The trial period between the specified 1812 1813 steps may vary according to the medical indication. The step-1814 therapy approval process shall be developed in accordance with 1815 the committee as stated in s. 409.91195(7) and (8). A drug 1816 product may be approved without meeting the step-therapy prior 1817 authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation 1818 1819 that the product is medically necessary because:

1820

a.

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There is not a drug on the preferred drug list to treat

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1821 the disease or medical condition which is an acceptable clinical 1822 alternative;

1823 b. The alternatives have been ineffective in the treatment1824 of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of
the patient and the drug, the drug is likely to be ineffective,
or the number of doses have been ineffective.

1829 The agency shall work with the physician to determine the best 1830 alternative for the patient. The agency may adopt rules waiving 1831 the requirements for written clinical documentation for specific 1832 drugs in limited clinical situations.

1833 17. The agency shall implement a return and reuse program 1834 for drugs dispensed by pharmacies to institutional recipients, 1835 which includes payment of a \$5 restocking fee for the 1836 implementation and operation of the program. The return and 1837 reuse program shall be implemented electronically and in a 1838 manner that promotes efficiency. The program must permit a 1839 pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must 1840 1841 provide for the return to inventory of drugs that cannot be 1842 credited or returned in a cost-effective manner. The agency 1843 shall determine if the program has reduced the amount of 1844 Medicaid prescription drugs which are destroyed on an annual 1845 basis and if there are additional ways to ensure more 1846 prescription drugs are not destroyed which could safely be 1847 reused.

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(b) The agency shall implement this subsection to the **Page 66 of 69**

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1849 extent that funds are appropriated to administer the Medicaid 1850 prescribed-drug spending-control program. The agency may 1851 contract all or any part of this program to private 1852 organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.

Section 40. Subsection (1) of section 83.42, Florida 1859 Statutes, is amended to read:

1860 83.42 Exclusions from application of part.—This part does
1861 not apply to:

(1) Residency or detention in a facility, whether public
or private, when residence or detention is incidental to the
provision of medical, geriatric, educational, counseling,
religious, or similar services. For residents of a facility
<u>licensed under part II of chapter 400, the provisions of s.</u>
<u>400.0255 are the exclusive procedures for all transfers and</u>

1868 <u>discharges.</u>

1869 Section 41. Subsection (27) of section 400.462, Florida 1870 Statutes, is amended to read:

1871 400.462 Definitions.—As used in this part, the term: 1872 (27) "Remuneration" means any payment or other benefit 1873 made directly or indirectly, overtly or covertly, in cash or in 1874 kind. <u>However, if the term is used in any provision of law</u> 1875 <u>relating to health care providers, the term does not apply to an</u> 1876 item that has an individual value of up to \$15, including, but

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1877 <u>not limited to, a plaque, a certificate, a trophy, or a novelty</u> 1878 <u>item that is intended solely for presentation or is customarily</u> 1879 <u>given away solely for promotional, recognition, or advertising</u> 1880 purposes.

1881 Section 42. Paragraph (c) of subsection (1) of section 1882 408.037, Florida Statutes, is amended to read:

1883

408.037 Application content.-

1884 (1) Except as provided in subsection (2) for a general1885 hospital, an application for a certificate of need must contain:

(c) An audited financial statement of the applicant <u>or the</u>
<u>applicant's parent corporation if audited financial statements</u>
<u>of the applicant do not exist</u>. In an application submitted by an
existing health care facility, health maintenance organization,
or hospice, financial condition documentation must include, but
need not be limited to, a balance sheet and a profit-and-loss
statement of the 2 previous fiscal years' operation.

Section 43. Subsection (2) of section 468.1695, Florida
Statutes, is amended to read:

1895

468.1695 Licensure by examination.-

1896 (2) The department shall examine each applicant who the
1897 board certifies has completed the application form and remitted
1898 an examination fee set by the board not to exceed \$250 and who:

(a)1. Holds a baccalaureate degree from an accredited college or university and majored in health care administration, <u>health services administration, or an equivalent major</u>, or has credit for at least 60 semester hours in subjects, as prescribed by rule of the board, which prepare the applicant for total management of a nursing home; and

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1905 2. Has fulfilled the requirements of a college-affiliated 1906 or university-affiliated internship in nursing home 1907 administration or of a 1,000-hour nursing home administrator-in-1908 training program prescribed by the board; or

1909 (b)1. Holds a baccalaureate degree from an accredited 1910 college or university; and

1911 2.a. Has fulfilled the requirements of a 2,000-hour 1912 nursing home administrator-in-training program prescribed by the 1913 board; or

1914 b. Has 1 year of management experience allowing for the 1915 application of executive duties and skills, including the 1916 staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, 1917 1918 hospital, hospice, assisted living facility with a minimum of 60 licensed beds, or geriatric residential treatment program and, 1919 1920 if such experience is not in a skilled nursing facility, has 1921 fulfilled the requirements of a 1,000-hour nursing home 1922 administrator-in-training program prescribed by the board. 1923 Section 44. This act shall take effect July 1, 2012.

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