By the Committee on Health Regulation; and Senator Gardiner

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1 A bill to be entitled
2 An act relating to the reduction and simplification of
3 health care provider regulation; amending s. 112.0455,
4 F.S., relating to the Drug-Free Workplace Act;
5 deleting an obsolete provision; amending s. 318.21,
6 F.S.; revising distribution of funds from civil
7 penalties imposed for traffic infractions by county
8 courts; amending s. 381.00315, F.S.; directing the
9 Department of Health to accept funds from counties,
10 municipalities, and certain other entities for the
11 purchase of certain products made available under a
12 contract of the United States Department of Health and
13 Human Services for the manufacture and delivery of
14 such products in response to a public health
15 emergency; amending s. 381.0072, F.S.; limiting
16 Department of Health food service inspections in
17 nursing homes; requiring the department to coordinate
18 inspections with the Agency for Health Care
19 Administration; amending s. 381.06014, F.S.; defining
20 the term “volunteer donor”; requiring that certain
21 blood establishments disclose specified information on
22 the Internet; repealing s. 383.325, F.S., relating to
23 confidentiality of inspection reports of licensed
24 birth center facilities; amending s. 395.002, F.S.;
25 revising and deleting definitions applicable to
26 regulation of hospitals and other licensed facilities;
27 conforming a cross-reference; amending s. 395.003,
28 F.S.; deleting an obsolete provision; conforming a
29 cross-reference; amending s. 395.0193, F.S.; requiring

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30 a licensed facility to report certain peer review
31 information and final disciplinary actions to the
32 Division of Medical Quality Assurance of the
33 Department of Health rather than the Division of
34 Health Quality Assurance of the Agency for Health Care
35 Administration; amending s. 395.1023, F.S.; providing
36 for the Department of Children and Family Services
37 rather than the Department of Health to perform
38 certain functions with respect to child protection
39 cases; requiring certain hospitals to notify the
40 Department of Children and Family Services of
41 compliance; amending s. 395.1041, F.S., relating to
42 hospital emergency services and care; deleting
43 obsolete provisions; repealing s. 395.1046, F.S.,
44 relating to complaint investigation procedures;
45 amending s. 395.1055, F.S.; requiring licensed
46 facility beds to conform to standards specified by the
47 Agency for Health Care Administration, the Florida
48 Building Code, and the Florida Fire Prevention Code;
49 amending s. 395.10972, F.S.; revising a reference to
50 the Florida Society of Healthcare Risk Management to
51 conform to the current designation; amending s.
52 395.2050, F.S.; revising a reference to the federal
53 Health Care Financing Administration to conform to the
54 current designation; amending s. 395.3036, F.S.;
55 correcting a reference; repealing s. 395.3037, F.S.,
56 relating to redundant definitions; amending ss.
57 154.11, 394.741, 395.3038, 400.925, 400.9935, 408.05,
58 440.13, 627.645, 627.668, 627.669, 627.736, 641.495,

59 and 766.1015, F.S.; revising references to the Joint
60 Commission on Accreditation of Healthcare
61 Organizations, the Commission on Accreditation of
62 Rehabilitation Facilities, and the Council on
63 Accreditation to conform to their current
64 designations; amending s. 395.602, F.S.; revising the
65 definition of the term “rural hospital” to delete an
66 obsolete provision; amending s. 400.021, F.S.;
67 revising the definition of the term “geriatric
68 outpatient clinic”; amending s. 400.0255, F.S.;
69 correcting an obsolete cross-reference to
70 administrative rules; amending s. 400.063, F.S.;
71 deleting an obsolete provision; amending ss. 400.071
72 and 400.0712, F.S.; revising applicability of general
73 licensure requirements under part II of ch. 408, F.S.,
74 to applications for nursing home licensure; revising
75 provisions governing inactive licenses; amending s.
76 400.111, F.S.; providing for disclosure of controlling
77 interest of a nursing home facility upon request by
78 the Agency for Health Care Administration; amending s.
79 400.1183, F.S.; revising grievance record maintenance
80 and reporting requirements for nursing homes; amending
81 s. 400.141, F.S.; providing criteria for the provision
82 of respite services by nursing homes; requiring a
83 written plan of care; requiring a contract for
84 services; requiring resident release to caregivers to
85 be designated in writing; providing an exemption to
86 the application of discharge planning rules; providing
87 for residents’ rights; providing for use of personal

88 medications; providing terms of respite stay;
89 providing for communication of patient information;
90 requiring a physician order for care and proof of a
91 physical examination; providing for services for
92 respite patients and duties of facilities with respect
93 to such patients; conforming a cross-reference;
94 requiring facilities to maintain clinical records that
95 meet specified standards; providing a fine relating to
96 an admissions moratorium; deleting requirement for
97 facilities to submit certain information related to
98 management companies to the agency; deleting a
99 requirement for facilities to notify the agency of
100 certain bankruptcy filings to conform to changes made
101 by the act; amending s. 400.142, F.S.; deleting
102 language relating to agency adoption of rules;
103 amending 400.147, F.S.; revising reporting
104 requirements for licensed nursing home facilities
105 relating to adverse incidents; repealing s. 400.148,
106 F.S., relating to the Medicaid "Up-or-Out" Quality of
107 Care Contract Management Program; amending s. 400.162,
108 F.S., requiring nursing homes to provide a resident
109 property statement annually and upon request; amending
110 s. 400.179, F.S.; revising requirements for nursing
111 home lease bond alternative fees; deleting an obsolete
112 provision; amending s. 400.19, F.S.; revising
113 inspection requirements; repealing s. 400.195, F.S.,
114 relating to agency reporting requirements; amending s.
115 400.23, F.S.; deleting an obsolete provision;
116 correcting a reference; directing the agency to adopt

117 rules for minimum staffing standards in nursing homes
118 that serve persons under 21 years of age; providing
119 minimum staffing standards; amending s. 400.275, F.S.;
120 revising agency duties with regard to training nursing
121 home surveyor teams; revising requirements for team
122 members; amending s. 400.484, F.S.; revising the
123 schedule of home health agency inspection violations;
124 amending s. 400.606, F.S.; revising the content
125 requirements of the plan accompanying an initial or
126 change-of-ownership application for licensure of a
127 hospice; revising requirements relating to
128 certificates of need for certain hospice facilities;
129 amending s. 400.607, F.S.; revising grounds for agency
130 action against a hospice; amending s. 400.915, F.S.;
131 correcting an obsolete cross-reference to
132 administrative rules; amending s. 400.931, F.S.;
133 deleting a requirement that an applicant for a home
134 medical equipment provider license submit a surety
135 bond to the agency; amending s. 400.932, F.S.;
136 revising grounds for the imposition of administrative
137 penalties for certain violations by an employee of a
138 home medical equipment provider; amending s. 400.967,
139 F.S.; revising the schedule of inspection violations
140 for intermediate care facilities for the
141 developmentally disabled; providing a penalty for
142 certain violations; amending s. 400.9905, F.S.;
143 providing that part X of ch, 400, F.S., the Health
144 Care Clinic Act, does not apply to an entity owned by
145 a corporation with a specified amount of annual sales

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146 of health care services under certain circumstances or
147 to an entity owned or controlled by a publicly traded
148 entity with a specified amount of annual revenues;
149 amending s. 400.991, F.S.; conforming terminology;
150 revising application requirements relating to
151 documentation of financial ability to operate a mobile
152 clinic; amending s. 408.034, F.S.; revising agency
153 authority relating to licensing of intermediate care
154 facilities for the developmentally disabled; amending
155 s. 408.036, F.S.; deleting an exemption from certain
156 certificate-of-need review requirements for a hospice
157 or a hospice inpatient facility; amending s. 408.043,
158 F.S.; revising requirements for certain freestanding
159 inpatient hospice care facilities to obtain a
160 certificate of need; amending s. 408.061, F.S.;
161 revising health care facility data reporting
162 requirements; amending s. 408.10, F.S.; removing
163 agency authority to investigate certain consumer
164 complaints; amending s. 408.802, F.S.; removing
165 applicability of part II of ch. 408, F.S., relating to
166 general licensure requirements, to private review
167 agents; amending s. 408.804, F.S.; providing penalties
168 for altering, defacing, or falsifying a license
169 certificate issued by the agency or displaying such an
170 altered, defaced, or falsified certificate; amending
171 s. 408.806, F.S.; revising agency responsibilities for
172 notification of licensees of impending expiration of a
173 license; requiring payment of a late fee for a license
174 application to be considered complete under certain

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175 circumstances; amending s. 408.810, F.S.; revising
176 provisions relating to information required for
177 licensure; requiring proof of submission of notice to
178 a mortgagor or landlord regarding provision of
179 services requiring licensure; requiring disclosure of
180 information by a controlling interest of certain court
181 actions relating to financial instability within a
182 specified time period; amending s. 408.813, F.S.;
183 authorizing the agency to impose fines for
184 unclassified violations of part II of ch. 408, F.S.;
185 amending s. 408.815, F.S.; authorizing the agency to
186 extend a license expiration date under certain
187 circumstances; amending s. 409.221, F.S.; deleting a
188 reporting requirement relating to the consumer-
189 directed care program; amending s. 409.91196, F.S.;
190 conforming a cross-reference; amending s. 409.912,
191 F.S.; revising procedures for implementation of a
192 Medicaid prescribed-drug spending-control program;
193 amending s. 429.07, F.S.; deleting the requirement for
194 an assisted living facility to obtain an additional
195 license in order to provide limited nursing services;
196 deleting the requirement for the agency to conduct
197 quarterly monitoring visits of facilities that hold a
198 license to provide extended congregate care services;
199 deleting the requirement for the department to report
200 annually on the status of and recommendations related
201 to extended congregate care; deleting the requirement
202 for the agency to conduct monitoring visits at least
203 twice a year to facilities providing limited nursing

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204 services; increasing the licensure fees and the
205 maximum fee required for the standard license;
206 increasing the licensure fees for the extended
207 congregate care license; eliminating the license fee
208 for the limited nursing services license; transferring
209 from another provision of law the requirement that a
210 biennial survey of an assisted living facility include
211 specific actions to determine whether the facility is
212 adequately protecting residents' rights; providing
213 that an assisted living facility that has a class I or
214 class II violation is subject to monitoring visits;
215 requiring a registered nurse to participate in certain
216 monitoring visits; amending s. 429.11, F.S.; revising
217 licensure application requirements for assisted living
218 facilities to eliminate provisional licenses; amending
219 s. 429.12, F.S.; revising notification requirements
220 for the sale or transfer of ownership of an assisted
221 living facility; amending s. 429.14, F.S.; removing a
222 ground for the imposition of an administrative
223 penalty; clarifying provisions relating to a
224 facility's request for a hearing under certain
225 circumstances; authorizing the agency to provide
226 certain information relating to the licensure status
227 of assisted living facilities electronically or
228 through the agency's Internet website; amending s.
229 429.17, F.S.; deleting provisions relating to the
230 limited nursing services license; revising agency
231 responsibilities regarding the issuance of conditional
232 licenses; amending s. 429.19, F.S.; clarifying that a

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233 monitoring fee may be assessed in addition to an
234 administrative fine; amending s. 429.23, F.S.;
235 deleting reporting requirements for assisted living
236 facilities relating to liability claims; amending s.
237 429.255, F.S.; eliminating provisions authorizing the
238 use of volunteers to provide certain health-care-
239 related services in assisted living facilities;
240 authorizing assisted living facilities to provide
241 limited nursing services; requiring an assisted living
242 facility to be responsible for certain recordkeeping
243 and staff to be trained to monitor residents receiving
244 certain health-care-related services; amending s.
245 429.28, F.S.; deleting a requirement for a biennial
246 survey of an assisted living facility, to conform to
247 changes made by the act; amending s. 429.35, F.S.;
248 authorizing the agency to provide certain information
249 relating to the inspections of assisted living
250 facilities electronically or through the agency's
251 Internet website; amending s. 429.41, F.S., relating
252 to rulemaking; conforming provisions to changes made
253 by the act; amending s. 429.53, F.S.; revising
254 provisions relating to consultation by the agency;
255 revising a definition; amending s. 429.54, F.S.;
256 requiring licensed assisted living facilities to
257 electronically report certain data semiannually to the
258 agency in accordance with rules adopted by the
259 department; amending s. 429.71, F.S.; revising
260 schedule of inspection violations for adult family-
261 care homes; amending s. 429.911, F.S.; deleting a

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262 ground for agency action against an adult day care
263 center; amending s. 429.915, F.S.; revising agency
264 responsibilities regarding the issuance of conditional
265 licenses; amending s. 483.201, F.S.; providing for
266 disciplinary action against clinical laboratories
267 failing to disclose specified information on the
268 Internet; providing a maximum annual administrative
269 fine that may be imposed annually against certain
270 clinical laboratories for failure to comply with such
271 disclosure requirement; amending s. 483.294, F.S.;
272 revising frequency of agency inspections of
273 multiphasic health testing centers; amending s.
274 499.003, F.S.; revising the definition of the term
275 "health care entity" to clarify that a blood
276 establishment may be a health care entity and engage
277 in certain activities; removing a requirement that
278 certain prescription drug purchasers maintain a
279 separate inventory of certain prescription drugs;
280 amending s. 499.005, F.S.; clarifying provisions
281 prohibiting the unauthorized wholesale distribution of
282 a prescription drug that was purchased by a hospital
283 or other health care entity, to conform to changes
284 made by the act; amending s. 499.01, F.S.; exempting
285 certain blood establishments from the requirements to
286 be permitted as a prescription drug manufacturer and
287 register products; requiring that certain blood
288 establishments obtain a restricted prescription drug
289 distributor permit under specified conditions;
290 limiting the prescription drugs that a blood

291 establishment may distribute with the restricted
292 prescription drug distributor permit; authorizing the
293 Department of Health to adopt rules; amending s.
294 499.01212, F.S.; exempting prescription drugs
295 contained in sealed medical convenience kits from the
296 pedigree paper requirements under specified
297 circumstances; amending s. 633.081, F.S.; limiting
298 Fire Marshal inspections of nursing homes to once a
299 year; providing for additional inspections based on
300 complaints and violations identified in the course of
301 orientation or training activities; amending s.
302 766.202, F.S.; adding persons licensed under part XIV
303 of ch. 468, F.S., to the definition of "health care
304 provider"; amending ss. 394.4787, 400.0239, 408.07,
305 430.80, and 651.118, F.S.; conforming terminology and
306 cross-references; revising a reference; providing an
307 effective date.
308
309 Be It Enacted by the Legislature of the State of Florida:
310
311 Section 1. Present paragraph (e) of subsection (10) and
312 paragraph (e) of subsection (14) of section 112.0455, Florida
313 Statutes, are amended, and paragraphs (f) through (k) of
314 subsection (10) of that section are redesignated as paragraphs
315 (e) through (j), respectively, to read:
316 112.0455 Drug-Free Workplace Act.—
317 (10) EMPLOYER PROTECTION.—
318 ~~(e) Nothing in this section shall be construed to operate~~
319 ~~retroactively, and nothing in this section shall abrogate the~~

320 ~~right of an employer under state law to conduct drug tests prior~~
321 ~~to January 1, 1990. A drug test conducted by an employer prior~~
322 ~~to January 1, 1990, is not subject to this section.~~
323 (14) DISCIPLINE REMEDIES.—
324 (e) Upon resolving an appeal filed pursuant to paragraph
325 (c), and finding a violation of this section, the commission may
326 order the following relief:
327 1. Rescind the disciplinary action, expunge related records
328 from the personnel file of the employee or job applicant and
329 reinstate the employee.
330 2. Order compliance with paragraph (10)<u>(f)</u>~~(g)~~.
331 3. Award back pay and benefits.
332 4. Award the prevailing employee or job applicant the
333 necessary costs of the appeal, reasonable attorney's fees, and
334 expert witness fees.
335 Section 2. Paragraph (n) of subsection (1) of section
336 154.11, Florida Statutes, is amended to read:
337 154.11 Powers of board of trustees.—
338 (1) The board of trustees of each public health trust shall
339 be deemed to exercise a public and essential governmental
340 function of both the state and the county and in furtherance
341 thereof it shall, subject to limitation by the governing body of
342 the county in which such board is located, have all of the
343 powers necessary or convenient to carry out the operation and
344 governance of designated health care facilities, including, but
345 without limiting the generality of, the foregoing:
346 (n) To appoint originally the staff of physicians to
347 practice in any designated facility owned or operated by the
348 board and to approve the bylaws and rules to be adopted by the

349 medical staff of any designated facility owned and operated by
350 the board, such governing regulations to be in accordance with
351 the standards of The Joint Commission ~~on the Accreditation of~~
352 ~~Hospitals~~ which provide, among other things, for the method of
353 appointing additional staff members and for the removal of staff
354 members.
355 Section 3. Subsection (15) of section 318.21, Florida
356 Statutes, is amended to read:
357 318.21 Disposition of civil penalties by county courts.—All
358 civil penalties received by a county court pursuant to the
359 provisions of this chapter shall be distributed and paid monthly
360 as follows:
361 (15) Of the additional fine assessed under s. 318.18(3)(e)
362 for a violation of s. 316.1893, 50 percent of the moneys
363 received from the fines <u>shall be remitted to the Department of</u>
364 <u>Revenue and deposited into the Brain and Spinal Cord Injury</u>
365 <u>Trust Fund of Department of Health and</u> shall be appropriated to
366 the <u>Department of Health</u> ~~Agency for Health Care Administration~~
367 as general revenue to ~~provide an enhanced Medicaid payment to~~
368 ~~nursing homes that~~ serve Medicaid recipients <u>with spinal cord</u>
369 <u>injuries that are medically complex and who are technologically</u>
370 <u>and respiratory dependent</u> ~~with brain and spinal cord injuries~~.
371 The remaining 50 percent of the moneys received from the
372 enhanced fine imposed under s. 318.18(3)(e) shall be remitted to
373 the Department of Revenue and deposited into the Department of
374 Health Administrative Trust Fund to provide financial support to
375 certified trauma centers in the counties where enhanced penalty
376 zones are established to ensure the availability and
377 accessibility of trauma services. Funds deposited into the

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378 Administrative Trust Fund under this subsection shall be
379 allocated as follows:
380 (a) Fifty percent shall be allocated equally among all
381 Level I, Level II, and pediatric trauma centers in recognition
382 of readiness costs for maintaining trauma services.
383 (b) Fifty percent shall be allocated among Level I, Level
384 II, and pediatric trauma centers based on each center's relative
385 volume of trauma cases as reported in the Department of Health
386 Trauma Registry.
387 Section 4. Subsection (3) is added to section 381.00315,
388 Florida Statutes, to read:
389 381.00315 Public health advisories; public health
390 emergencies.—The State Health Officer is responsible for
391 declaring public health emergencies and issuing public health
392 advisories.
393 (3) To facilitate effective emergency management, when the
394 United States Department of Health and Human Services contracts
395 for the manufacture and delivery of licensable products in
396 response to a public health emergency and the terms of those
397 contracts are made available to the states, the department shall
398 accept funds provided by counties, municipalities, and other
399 entities designated in the state emergency management plan
400 required under s. 252.35(2)(a) for the purpose of participation
401 in such contracts. The department shall deposit the funds into
402 the Grants and Donations Trust Fund and expend the funds on
403 behalf of the donor county, municipality, or other entity for
404 the purchase the licensable products made available under the
405 contract.
406 Section 5. Paragraph (e) is added to subsection (2) of

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407 section 381.0072, Florida Statutes, to read:
408 381.0072 Food service protection.—It shall be the duty of
409 the Department of Health to adopt and enforce sanitation rules
410 consistent with law to ensure the protection of the public from
411 food-borne illness. These rules shall provide the standards and
412 requirements for the storage, preparation, serving, or display
413 of food in food service establishments as defined in this
414 section and which are not permitted or licensed under chapter
415 500 or chapter 509.
416 (2) DUTIES.—
417 (e) The department shall inspect food service
418 establishments in nursing homes licensed under part II of
419 chapter 400 twice each year. The department may make additional
420 inspections only in response to complaints. The department shall
421 coordinate inspections with the Agency for Health Care
422 Administration, such that the department's inspection is at
423 least 60 days after a recertification visit by the Agency for
424 Health Care Administration.
425 Section 6. Section 381.06014, Florida Statutes, is amended
426 to read:
427 381.06014 Blood establishments.—
428 (1) As used in this section, the term:
429 (a) "Blood establishment" means any person, entity, or
430 organization, operating within the state, which examines an
431 individual for the purpose of blood donation or which collects,
432 processes, stores, tests, or distributes blood or blood
433 components collected from the human body for the purpose of
434 transfusion, for any other medical purpose, or for the
435 production of any biological product.

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436 (b) “Volunteer donor” means a person who does not receive
437 remuneration, other than an incentive, for a blood donation
438 intended for transfusion, and the product container of the
439 donation from the person qualifies for labeling with the
440 statement “volunteer donor” under 21 C.F.R. 606.121.
441 (2) Any blood establishment operating in the state may not
442 conduct any activity defined in subsection (1) unless that blood
443 establishment is operated in a manner consistent with the
444 provisions of Title 21 parts 211 and 600-640, Code of Federal
445 Regulations.
446 (3) Any blood establishment determined to be operating in
447 the state in a manner not consistent with the provisions of
448 Title 21 parts 211 and 600-640, Code of Federal Regulations, and
449 in a manner that constitutes a danger to the health or well-
450 being of donors or recipients as evidenced by the federal Food
451 and Drug Administration’s inspection reports and the revocation
452 of the blood establishment’s license or registration shall be in
453 violation of this chapter and shall immediately cease all
454 operations in the state.
455 (4) The operation of a blood establishment in a manner not
456 consistent with the provisions of Title 21 parts 211 and 600-
457 640, Code of Federal Regulations, and in a manner that
458 constitutes a danger to the health or well-being of blood donors
459 or recipients as evidenced by the federal Food and Drug
460 Administration’s inspection process is declared a nuisance and
461 inimical to the public health, welfare, and safety. The Agency
462 for Health Care Administration or any state attorney may bring
463 an action for an injunction to restrain such operations or
464 enjoin the future operation of the blood establishment.

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465 (5) A blood establishment that collects blood or blood
466 components from volunteer donors must disclose on the Internet
467 information to educate and inform donors and the public about
468 the blood establishment's activities. A hospital that collects
469 blood or blood components from volunteer donors for its own use
470 or for health care providers that are part of its business
471 entity is exempt from the disclosure requirements in this
472 subsection. The information required to be disclosed under this
473 subsection may be cumulative for all blood establishments within
474 a business entity. Disciplinary action against the blood
475 establishment's clinical laboratory license may be taken as
476 provided in s. 483.201 for a blood establishment that is
477 required to disclose but fails to disclose on its website all of
478 the following information:
479 (a) A description of the steps involved in collecting,
480 processing, and distributing volunteer donations, presented in a
481 manner appropriate for the donating public.
482 (b) By March 1 of each year, the number of units of blood
483 components, identified by component, that were:
484 1. Produced by the blood establishment during the preceding
485 calendar year;
486 2. Obtained from other sources during the preceding
487 calendar year;
488 3. Distributed during the preceding year to health care
489 providers located outside this state. However, if the blood
490 establishment collects donations in a county outside this state,
491 distributions to health care providers in that county shall be
492 excluded. Such information shall be aggregated by health care
493 providers located within the United States and its territories

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494 or outside the United States and its territories; and
495 4. Distributed to entities that are not health care
496 providers during the preceding year. Such information shall be
497 aggregated by purchasers located within the United States and
498 its territories or outside the United States and its
499 territories.
500
501 For purposes of this paragraph, the components that must be
502 reported include whole blood, red blood cells, leukoreduced red
503 blood cells, fresh frozen plasma or the equivalent, recovered
504 plasma, platelets, and cryoprecipitated antihemophilic factor.
505 (c) The blood establishment's conflict-of-interest policy,
506 policy concerning related-party transactions, whistleblower
507 policy, and policy for determining executive compensation. If a
508 change to any of these documents occurs, the revised document
509 must be available on the blood establishment's website by the
510 following March 1.
511 (d)1. The most recent 3 years of the Return of Organization
512 Exempt from Income Tax, Internal Revenue Service Form 990, if
513 the business entity for the blood establishment is eligible to
514 file such return. The Form 990 must be available on the blood
515 establishment's website within 30 calendar days after filing it
516 with the Internal Revenue Service; or
517 2. If the business entity for the blood establishment is
518 not eligible to file the Form 990 return, a balance sheet,
519 income statement, statement of changes in cash flow, and the
520 expression of an opinion thereon by an independent certified
521 public accountant who audited or reviewed such financial
522 statements. Such documents must be available on the blood

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523 establishment’s website within 120 days after the end of the
524 blood establishment’s fiscal year and must remain on the blood
525 establishment’s website for at least 36 months.
526 Section 7. Section 383.325, Florida Statutes, is repealed.
527 Section 8. Subsection (7) of section 394.4787, Florida
528 Statutes, is amended to read:
529 394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and
530 394.4789.—As used in this section and ss. 394.4786, 394.4788,
531 and 394.4789:
532 (7) “Specialty psychiatric hospital” means a hospital
533 licensed by the agency pursuant to s. 395.002(26) ~~(28)~~ and part
534 II of chapter 408 as a specialty psychiatric hospital.
535 Section 9. Subsection (2) of section 394.741, Florida
536 Statutes, is amended to read:
537 394.741 Accreditation requirements for providers of
538 behavioral health care services.—
539 (2) Notwithstanding any provision of law to the contrary,
540 accreditation shall be accepted by the agency and department in
541 lieu of the agency’s and department’s facility licensure onsite
542 review requirements and shall be accepted as a substitute for
543 the department’s administrative and program monitoring
544 requirements, except as required by subsections (3) and (4),
545 for:
546 (a) Any organization from which the department purchases
547 behavioral health care services that is accredited by The Joint
548 Commission ~~on Accreditation of Healthcare Organizations~~ or the
549 Council on Accreditation ~~for Children and Family Services~~, or
550 has those services that are being purchased by the department
551 accredited by the Commission on Accreditation of Rehabilitation

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552 <u>Facilities</u> ~~CARF—the Rehabilitation Accreditation Commission~~.
553 (b) Any mental health facility licensed by the agency or
554 any substance abuse component licensed by the department that is
555 accredited by The Joint Commission ~~on Accreditation of~~
556 ~~Healthcare Organizations~~, <u>the Commission on Accreditation of</u>
557 <u>Rehabilitation Facilities</u> ~~CARF—the Rehabilitation Accreditation~~
558 ~~Commission~~, or the Council on Accreditation ~~of Children and~~
559 ~~Family Services~~.
560 (c) Any network of providers from which the department or
561 the agency purchases behavioral health care services accredited
562 by The Joint Commission ~~on Accreditation of Healthcare~~
563 ~~Organizations~~, <u>the Commission on Accreditation of Rehabilitation</u>
564 <u>Facilities</u> ~~CARF—the Rehabilitation Accreditation Commission~~, the
565 Council on Accreditation ~~of Children and Family Services~~, or the
566 National Committee for Quality Assurance. A provider
567 organization, which is part of an accredited network, is
568 afforded the same rights under this part.
569 Section 10. Present subsections (15) through (32) of
570 section 395.002, Florida Statutes, are renumbered as subsections
571 (14) through (28), respectively, and present subsections (1),
572 (14), (24), (30), and (31), and paragraph (c) of present
573 subsection (28) of that section are amended to read:
574 395.002 Definitions.—As used in this chapter:
575 (1) "Accrediting organizations" means <u>nationally recognized</u>
576 <u>or approved accrediting organizations whose standards</u>
577 <u>incorporate comparable licensure requirements as determined by</u>
578 <u>the agency</u> ~~the Joint Commission on Accreditation of Healthcare~~
579 ~~Organizations, the American Osteopathic Association, the~~
580 ~~Commission on Accreditation of Rehabilitation Facilities, and~~

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581 ~~the Accreditation Association for Ambulatory Health Care, Inc~~.
582 ~~(14) "Initial denial determination" means a determination~~
583 ~~by a private review agent that the health care services~~
584 ~~furnished or proposed to be furnished to a patient are~~
585 ~~inappropriate, not medically necessary, or not reasonable.~~
586 ~~(24) "Private review agent" means any person or entity~~
587 ~~which performs utilization review services for third-party~~
588 ~~payors on a contractual basis for outpatient or inpatient~~
589 ~~services. However, the term shall not include full-time~~
590 ~~employees, personnel, or staff of health insurers, health~~
591 ~~maintenance organizations, or hospitals, or wholly owned~~
592 ~~subsidiaries thereof or affiliates under common ownership, when~~
593 ~~performing utilization review for their respective hospitals,~~
594 ~~health maintenance organizations, or insureds of the same~~
595 ~~insurance group. For this purpose, health insurers, health~~
596 ~~maintenance organizations, and hospitals, or wholly owned~~
597 ~~subsidiaries thereof or affiliates under common ownership,~~
598 ~~include such entities engaged as administrators of self-~~
599 ~~insurance as defined in s. 624.031.~~
600 (26)~~(28)~~ "Specialty hospital" means any facility which
601 meets the provisions of subsection (12), and which regularly
602 makes available either:
603 (c) Intensive residential treatment programs for children
604 and adolescents as defined in subsection (14) ~~(15)~~.
605 ~~(30) "Utilization review" means a system for reviewing the~~
606 ~~medical necessity or appropriateness in the allocation of health~~
607 ~~care resources of hospital services given or proposed to be~~
608 ~~given to a patient or group of patients.~~
609 ~~(31) "Utilization review plan" means a description of the~~

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610 ~~policies and procedures governing utilization review activities~~
611 ~~performed by a private review agent.~~
612 Section 11. Paragraph (c) of subsection (1) and paragraph
613 (b) of subsection (2) of section 395.003, Florida Statutes, are
614 amended to read:
615 395.003 Licensure; denial, suspension, and revocation.—
616 (1)
617 ~~(c) Until July 1, 2006, additional emergency departments~~
618 ~~located off the premises of licensed hospitals may not be~~
619 ~~authorized by the agency.~~
620 (2)
621 (b) The agency shall, at the request of a licensee that is
622 a teaching hospital as defined in s. 408.07(45), issue a single
623 license to a licensee for facilities that have been previously
624 licensed as separate premises, provided such separately licensed
625 facilities, taken together, constitute the same premises as
626 defined in s. 395.002<u>(22)</u>~~(23)~~. Such license for the single
627 premises shall include all of the beds, services, and programs
628 that were previously included on the licenses for the separate
629 premises. The granting of a single license under this paragraph
630 shall not in any manner reduce the number of beds, services, or
631 programs operated by the licensee.
632 Section 12. Paragraph (e) of subsection (2) and subsection
633 (4) of section 395.0193, Florida Statutes, are amended to read:
634 395.0193 Licensed facilities; peer review; disciplinary
635 powers; agency or partnership with physicians.—
636 (2) Each licensed facility, as a condition of licensure,
637 shall provide for peer review of physicians who deliver health
638 care services at the facility. Each licensed facility shall

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639 develop written, binding procedures by which such peer review
640 shall be conducted. Such procedures shall include:
641 (e) Recording of agendas and minutes which do not contain
642 confidential material, for review by the Division of Medical
643 Quality Assurance of the department ~~Health Quality Assurance of~~
644 ~~the agency~~.
645 (4) Pursuant to ss. 458.337 and 459.016, any disciplinary
646 actions taken under subsection (3) shall be reported in writing
647 to the Division of Medical Quality Assurance of the department
648 ~~Health Quality Assurance of the agency~~ within 30 working days
649 after its initial occurrence, regardless of the pendency of
650 appeals to the governing board of the hospital. The notification
651 shall identify the disciplined practitioner, the action taken,
652 and the reason for such action. All final disciplinary actions
653 taken under subsection (3), if different from those which were
654 reported to the department ~~agency~~ within 30 days after the
655 initial occurrence, shall be reported within 10 working days to
656 the Division of Medical Quality Assurance of the department
657 ~~Health Quality Assurance of the agency~~ in writing and shall
658 specify the disciplinary action taken and the specific grounds
659 therefor. The division shall review each report and determine
660 whether it potentially involved conduct by the licensee that is
661 subject to disciplinary action, in which case s. 456.073 shall
662 apply. The reports are not subject to inspection under s.
663 119.07(1) even if the division’s investigation results in a
664 finding of probable cause.
665 Section 13. Section 395.1023, Florida Statutes, is amended
666 to read:
667 395.1023 Child abuse and neglect cases; duties.—Each

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668 licensed facility shall adopt a protocol that, at a minimum,
669 requires the facility to:
670 (1) Incorporate a facility policy that every staff member
671 has an affirmative duty to report, pursuant to chapter 39, any
672 actual or suspected case of child abuse, abandonment, or
673 neglect; and
674 (2) In any case involving suspected child abuse,
675 abandonment, or neglect, designate, at the request of the
676 Department of Children and Family Services, a staff physician to
677 act as a liaison between the hospital and the Department of
678 Children and Family Services office which is investigating the
679 suspected abuse, abandonment, or neglect, and the child
680 protection team, as defined in s. 39.01, when the case is
681 referred to such a team.
682
683 Each general hospital and appropriate specialty hospital shall
684 comply with the provisions of this section and shall notify the
685 agency and the Department of Children and Family Services of its
686 compliance by sending a copy of its policy to the agency and the
687 Department of Children and Family Services as required by rule.
688 The failure by a general hospital or appropriate specialty
689 hospital to comply shall be punished by a fine not exceeding
690 $1,000, to be fixed, imposed, and collected by the agency. Each
691 day in violation is considered a separate offense.
692 Section 14. Subsection (2) and paragraph (d) of subsection
693 (3) of section 395.1041, Florida Statutes, are amended to read:
694 395.1041 Access to emergency services and care.—
695 (2) INVENTORY OF HOSPITAL EMERGENCY SERVICES.—The agency
696 shall establish and maintain an inventory of hospitals with

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697 emergency services. The inventory shall list all services within
698 the service capability of the hospital, and such services shall
699 appear on the face of the hospital license. Each hospital having
700 emergency services shall notify the agency of its service
701 capability in the manner and form prescribed by the agency. The
702 agency shall use the inventory to assist emergency medical
703 services providers and others in locating appropriate emergency
704 medical care. The inventory shall also be made available to the
705 general public. ~~On or before August 1, 1992, the agency shall~~
706 ~~request that each hospital identify the services which are~~
707 ~~within its service capability. On or before November 1, 1992,~~
708 ~~the agency shall notify each hospital of the service capability~~
709 ~~to be included in the inventory. The hospital has 15 days from~~
710 ~~the date of receipt to respond to the notice. By December 1,~~
711 ~~1992, the agency shall publish a final inventory.~~ Each hospital
712 shall reaffirm its service capability when its license is
713 renewed and shall notify the agency of the addition of a new
714 service or the termination of a service prior to a change in its
715 service capability.
716 (3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF
717 FACILITY OR HEALTH CARE PERSONNEL.—
718 (d)1. Every hospital shall ensure the provision of services
719 within the service capability of the hospital, at all times,
720 either directly or indirectly through an arrangement with
721 another hospital, through an arrangement with one or more
722 physicians, or as otherwise made through prior arrangements. A
723 hospital may enter into an agreement with another hospital for
724 purposes of meeting its service capability requirement, and
725 appropriate compensation or other reasonable conditions may be

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726 negotiated for these backup services.
727 2. If any arrangement requires the provision of emergency
728 medical transportation, such arrangement must be made in
729 consultation with the applicable provider and may not require
730 the emergency medical service provider to provide transportation
731 that is outside the routine service area of that provider or in
732 a manner that impairs the ability of the emergency medical
733 service provider to timely respond to prehospital emergency
734 calls.
735 3. A hospital shall not be required to ensure service
736 capability at all times as required in subparagraph 1. if, prior
737 to the receiving of any patient needing such service capability,
738 such hospital has demonstrated to the agency that it lacks the
739 ability to ensure such capability and it has exhausted all
740 reasonable efforts to ensure such capability through backup
741 arrangements. In reviewing a hospital’s demonstration of lack of
742 ability to ensure service capability, the agency shall consider
743 factors relevant to the particular case, including the
744 following:
745 a. Number and proximity of hospitals with the same service
746 capability.
747 b. Number, type, credentials, and privileges of
748 specialists.
749 c. Frequency of procedures.
750 d. Size of hospital.
751 4. The agency shall publish ~~proposed~~ rules implementing a
752 reasonable exemption procedure ~~by November 1, 1992~~. ~~Subparagraph~~
753 ~~1. shall become effective upon the effective date of said rules~~
754 ~~or January 31, 1993, whichever is earlier. For a period not to~~

755 ~~exceed 1 year from the effective date of subparagraph 1., a~~
756 ~~hospital requesting an exemption shall be deemed to be exempt~~
757 ~~from offering the service until the agency initially acts to~~
758 ~~deny or grant the original request.~~ The agency has 45 days from
759 the date of receipt of the request to approve or deny the
760 request. ~~After the first year from the effective date of~~
761 ~~subparagraph 1.,~~ If the agency fails to initially act within the
762 time period, the hospital is deemed to be exempt from offering
763 the service until the agency initially acts to deny the request.
764 Section 15. <u>Section 395.1046, Florida Statutes, is</u>
765 <u>repealed.</u>
766 Section 16. Paragraph (e) of subsection (1) of section
767 395.1055, Florida Statutes, is amended to read:
768 395.1055 Rules and enforcement.—
769 (1) The agency shall adopt rules pursuant to ss. 120.536(1)
770 and 120.54 to implement the provisions of this part, which shall
771 include reasonable and fair minimum standards for ensuring that:
772 (e) Licensed facility beds conform to minimum space,
773 equipment, and furnishings standards as specified by the <u>agency,</u>
774 <u>the Florida Building Code, and the Florida Fire Prevention Code</u>
775 ~~department~~.
776 Section 17. Subsection (1) of section 395.10972, Florida
777 Statutes, is amended to read:
778 395.10972 Health Care Risk Manager Advisory Council.—The
779 Secretary of Health Care Administration may appoint a seven-
780 member advisory council to advise the agency on matters
781 pertaining to health care risk managers. The members of the
782 council shall serve at the pleasure of the secretary. The
783 council shall designate a chair. The council shall meet at the

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784 call of the secretary or at those times as may be required by
785 rule of the agency. The members of the advisory council shall
786 receive no compensation for their services, but shall be
787 reimbursed for travel expenses as provided in s. 112.061. The
788 council shall consist of individuals representing the following
789 areas:
790 (1) Two shall be active health care risk managers,
791 including one risk manager who is recommended by and a member of
792 the Florida Society for ~~of~~ Healthcare Risk Management and
793 Patient Safety.
794 Section 18. Subsection (3) of section 395.2050, Florida
795 Statutes, is amended to read:
796 395.2050 Routine inquiry for organ and tissue donation;
797 certification for procurement activities; death records review.—
798 (3) Each organ procurement organization designated by the
799 federal Centers for Medicare and Medicaid Services ~~Health Care~~
800 ~~Financing Administration~~ and licensed by the state shall conduct
801 an annual death records review in the organ procurement
802 organization's affiliated donor hospitals. The organ procurement
803 organization shall enlist the services of every Florida licensed
804 tissue bank and eye bank affiliated with or providing service to
805 the donor hospital and operating in the same service area to
806 participate in the death records review.
807 Section 19. Subsection (2) of section 395.3036, Florida
808 Statutes, is amended to read:
809 395.3036 Confidentiality of records and meetings of
810 corporations that lease public hospitals or other public health
811 care facilities.—The records of a private corporation that
812 leases a public hospital or other public health care facility

813 are confidential and exempt from the provisions of s. 119.07(1)
814 and s. 24(a), Art. I of the State Constitution, and the meetings
815 of the governing board of a private corporation are exempt from
816 s. 286.011 and s. 24(b), Art. I of the State Constitution when
817 the public lessor complies with the public finance
818 accountability provisions of s. 155.40(5) with respect to the
819 transfer of any public funds to the private lessee and when the
820 private lessee meets at least three of the five following
821 criteria:
822 (2) The public lessor and the private lessee do not
823 commingle any of their funds in any account maintained by either
824 of them, other than the payment of the rent and administrative
825 fees or the transfer of funds pursuant to s. 155.40(2)
826 ~~subsection (2)~~.
827 Section 20. Section 395.3037, Florida Statutes, is
828 repealed.
829 Section 21. Subsections (1), (4), and (5) of section
830 395.3038, Florida Statutes, are amended to read:
831 395.3038 State-listed primary stroke centers and
832 comprehensive stroke centers; notification of hospitals.—
833 (1) The agency shall make available on its website and to
834 the department a list of the name and address of each hospital
835 that meets the criteria for a primary stroke center and the name
836 and address of each hospital that meets the criteria for a
837 comprehensive stroke center. The list of primary and
838 comprehensive stroke centers shall include only those hospitals
839 that attest in an affidavit submitted to the agency that the
840 hospital meets the named criteria, or those hospitals that
841 attest in an affidavit submitted to the agency that the hospital

842 is certified as a primary or a comprehensive stroke center by
843 The Joint Commission ~~on Accreditation of Healthcare~~
844 ~~Organizations~~.
845 (4) The agency shall adopt by rule criteria for a primary
846 stroke center which are substantially similar to the
847 certification standards for primary stroke centers of The Joint
848 Commission ~~on Accreditation of Healthcare Organizations~~.
849 (5) The agency shall adopt by rule criteria for a
850 comprehensive stroke center. However, if The Joint Commission ~~on~~
851 ~~Accreditation of Healthcare Organizations~~ establishes criteria
852 for a comprehensive stroke center, the agency shall establish
853 criteria for a comprehensive stroke center which are
854 substantially similar to those criteria established by The Joint
855 Commission ~~on Accreditation of Healthcare Organizations~~.
856 Section 22. Paragraph (e) of subsection (2) of section
857 395.602, Florida Statutes, is amended to read:
858 395.602 Rural hospitals.—
859 (2) DEFINITIONS.—As used in this part:
860 (e) “Rural hospital” means an acute care hospital licensed
861 under this chapter, having 100 or fewer licensed beds and an
862 emergency room, which is:
863 1. The sole provider within a county with a population
864 density of no greater than 100 persons per square mile;
865 2. An acute care hospital, in a county with a population
866 density of no greater than 100 persons per square mile, which is
867 at least 30 minutes of travel time, on normally traveled roads
868 under normal traffic conditions, from any other acute care
869 hospital within the same county;
870 3. A hospital supported by a tax district or subdistrict

871 whose boundaries encompass a population of 100 persons or fewer
872 per square mile;
873 ~~4. A hospital in a constitutional charter county with a~~
874 ~~population of over 1 million persons that has imposed a local~~
875 ~~option health service tax pursuant to law and in an area that~~
876 ~~was directly impacted by a catastrophic event on August 24,~~
877 ~~1992, for which the Governor of Florida declared a state of~~
878 ~~emergency pursuant to chapter 125, and has 120 beds or less that~~
879 ~~serves an agricultural community with an emergency room~~
880 ~~utilization of no less than 20,000 visits and a Medicaid~~
881 ~~inpatient utilization rate greater than 15 percent;~~
882 4.~~5.~~ A hospital with a service area that has a population
883 of 100 persons or fewer per square mile. As used in this
884 subparagraph, the term “service area” means the fewest number of
885 zip codes that account for 75 percent of the hospital’s
886 discharges for the most recent 5-year period, based on
887 information available from the hospital inpatient discharge
888 database in the Florida Center for Health Information and Policy
889 Analysis at the Agency for Health Care Administration; or
890 5.~~6.~~ A hospital designated as a critical access hospital,
891 as defined in s. 408.07(15).
892
893 Population densities used in this paragraph must be based upon
894 the most recently completed United States census. A hospital
895 that received funds under s. 409.9116 for a quarter beginning no
896 later than July 1, 2002, is deemed to have been and shall
897 continue to be a rural hospital from that date through June 30,
898 2015, if the hospital continues to have 100 or fewer licensed
899 beds and an emergency room~~, or meets the criteria of~~

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900 ~~subparagraph 4~~. An acute care hospital that has not previously
901 been designated as a rural hospital and that meets the criteria
902 of this paragraph shall be granted such designation upon
903 application, including supporting documentation to the Agency
904 for Health Care Administration.
905 Section 23. Subsection (8) of section 400.021, Florida
906 Statutes, is amended to read:
907 400.021 Definitions.—When used in this part, unless the
908 context otherwise requires, the term:
909 (8) "Geriatric outpatient clinic" means a site for
910 providing outpatient health care to persons 60 years of age or
911 older, which is staffed by a registered nurse or a physician
912 assistant, or a licensed practical nurse under the direct
913 supervision of a registered nurse, advanced registered nurse
914 practitioner, or physician.
915 Section 24. Paragraph (g) of subsection (2) of section
916 400.0239, Florida Statutes, is amended to read:
917 400.0239 Quality of Long-Term Care Facility Improvement
918 Trust Fund.—
919 (2) Expenditures from the trust fund shall be allowable for
920 direct support of the following:
921 (g) Other initiatives authorized by the Centers for
922 Medicare and Medicaid Services for the use of federal civil
923 monetary penalties~~, including projects recommended through the~~
924 ~~Medicaid "Up-or-Out" Quality of Care Contract Management Program~~
925 ~~pursuant to s. 400.148~~.
926 Section 25. Subsection (15) of section 400.0255, Florida
927 Statutes, is amended to read
928 400.0255 Resident transfer or discharge; requirements and

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929 procedures; hearings.—
930 (15)(a) The department's Office of Appeals Hearings shall
931 conduct hearings under this section. The office shall notify the
932 facility of a resident's request for a hearing.
933 (b) The department shall, by rule, establish procedures to
934 be used for fair hearings requested by residents. These
935 procedures shall be equivalent to the procedures used for fair
936 hearings for other Medicaid cases appearing in s. 409.285 and
937 applicable rules, chapter 10-2, part VI, Florida Administrative
938 Code. The burden of proof must be clear and convincing evidence.
939 A hearing decision must be rendered within 90 days after receipt
940 of the request for hearing.
941 (c) If the hearing decision is favorable to the resident
942 who has been transferred or discharged, the resident must be
943 readmitted to the facility's first available bed.
944 (d) The decision of the hearing officer shall be final. Any
945 aggrieved party may appeal the decision to the district court of
946 appeal in the appellate district where the facility is located.
947 Review procedures shall be conducted in accordance with the
948 Florida Rules of Appellate Procedure.
949 Section 26. Subsection (2) of section 400.063, Florida
950 Statutes, is amended to read:
951 400.063 Resident protection.—
952 (2) The agency is authorized to establish for each
953 facility, subject to intervention by the agency, a separate bank
954 account for the deposit to the credit of the agency of any
955 moneys received from the Health Care Trust Fund or any other
956 moneys received for the maintenance and care of residents in the
957 facility, and the agency is authorized to disburse moneys from

958 such account to pay obligations incurred for the purposes of
959 this section. The agency is authorized to requisition moneys
960 from the Health Care Trust Fund in advance of an actual need for
961 cash on the basis of an estimate by the agency of moneys to be
962 spent under the authority of this section. Any bank account
963 established under this section need not be approved in advance
964 of its creation as required by s. 17.58, but shall be secured by
965 depository insurance equal to or greater than the balance of
966 such account or by the pledge of collateral security ~~in~~
967 ~~conformance with criteria established in s. 18.11~~. The agency
968 shall notify the Chief Financial Officer of any such account so
969 established and shall make a quarterly accounting to the Chief
970 Financial Officer for all moneys deposited in such account.
971 Section 27. Subsections (1) and (5) of section 400.071,
972 Florida Statutes, are amended to read:
973 400.071 Application for license.—
974 (1) In addition to the requirements of part II of chapter
975 408, the application for a license shall be under oath and must
976 contain the following:
977 (a) The location of the facility for which a license is
978 sought and an indication, as in the original application, that
979 such location conforms to the local zoning ordinances.
980 ~~(b) A signed affidavit disclosing any financial or~~
981 ~~ownership interest that a controlling interest as defined in~~
982 ~~part II of chapter 408 has held in the last 5 years in any~~
983 ~~entity licensed by this state or any other state to provide~~
984 ~~health or residential care which has closed voluntarily or~~
985 ~~involuntarily; has filed for bankruptcy; has had a receiver~~
986 ~~appointed; has had a license denied, suspended, or revoked; or~~

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987 ~~has had an injunction issued against it which was initiated by a~~
988 ~~regulatory agency. The affidavit must disclose the reason any~~
989 ~~such entity was closed, whether voluntarily or involuntarily.~~
990 ~~(c) The total number of beds and the total number of~~
991 ~~Medicare and Medicaid certified beds.~~
992 (b) ~~(d)~~ Information relating to the applicant and employees
993 which the agency requires by rule. The applicant must
994 demonstrate that sufficient numbers of qualified staff, by
995 training or experience, will be employed to properly care for
996 the type and number of residents who will reside in the
997 facility.
998 (c) ~~(e)~~ Copies of any civil verdict or judgment involving
999 the applicant rendered within the 10 years preceding the
1000 application, relating to medical negligence, violation of
1001 residents' rights, or wrongful death. As a condition of
1002 licensure, the licensee agrees to provide to the agency copies
1003 of any new verdict or judgment involving the applicant, relating
1004 to such matters, within 30 days after filing with the clerk of
1005 the court. The information required in this paragraph shall be
1006 maintained in the facility's licensure file and in an agency
1007 database which is available as a public record.
1008 (5) As a condition of licensure, each facility must
1009 establish ~~and submit with its application~~ a plan for quality
1010 assurance and for conducting risk management.
1011 Section 28. Section 400.0712, Florida Statutes, is amended
1012 to read:
1013 400.0712 Application for inactive license.—
1014 ~~(1) As specified in this section, the agency may issue an~~
1015 ~~inactive license to a nursing home facility for all or a portion~~

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1016 ~~of its beds. Any request by a licensee that a nursing home or~~
1017 ~~portion of a nursing home become inactive must be submitted to~~
1018 ~~the agency in the approved format. The facility may not initiate~~
1019 ~~any suspension of services, notify residents, or initiate~~
1020 ~~inactivity before receiving approval from the agency; and a~~
1021 ~~licensee that violates this provision may not be issued an~~
1022 ~~inactive license.~~
1023 (1)~~(2)~~ In addition to the powers granted under part II of
1024 chapter 408, the agency may issue an inactive license to a
1025 nursing home that chooses to use an unoccupied contiguous
1026 portion of the facility for an alternative use to meet the needs
1027 of elderly persons through the use of less restrictive, less
1028 institutional services.
1029 (a) An inactive license issued under this subsection may be
1030 granted for a period not to exceed the current licensure
1031 expiration date but may be renewed by the agency at the time of
1032 licensure renewal.
1033 (b) A request to extend the inactive license must be
1034 submitted to the agency in the approved format and approved by
1035 the agency in writing.
1036 (c) Nursing homes that receive an inactive license to
1037 provide alternative services shall not receive preference for
1038 participation in the Assisted Living for the Elderly Medicaid
1039 waiver.
1040 (2)~~(3)~~ The agency shall adopt rules pursuant to ss.
1041 120.536(1) and 120.54 necessary to implement this section.
1042 Section 29. Section 400.111, Florida Statutes, is amended
1043 to read:
1044 400.111 Disclosure of controlling interest.—In addition to

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1045 the requirements of part II of chapter 408, when requested by
1046 the agency, the licensee shall submit a signed affidavit
1047 disclosing any financial or ownership interest that a
1048 controlling interest has held within the last 5 years in any
1049 entity licensed by the state or any other state to provide
1050 health or residential care which entity has closed voluntarily
1051 or involuntarily; has filed for bankruptcy; has had a receiver
1052 appointed; has had a license denied, suspended, or revoked; or
1053 has had an injunction issued against it which was initiated by a
1054 regulatory agency. The affidavit must disclose the reason such
1055 entity was closed, whether voluntarily or involuntarily.
1056 Section 30. Subsection (2) of section 400.1183, Florida
1057 Statutes, is amended to read:
1058 400.1183 Resident grievance procedures.—
1059 (2) Each facility shall maintain records of all grievances
1060 for agency inspection and shall report to the agency at the time
1061 of relicensure the total number of grievances handled during the
1062 prior licensure period, a categorization of the cases underlying
1063 the grievances, and the final disposition of the grievances.
1064 Section 31. Paragraphs (o) through (w) of subsection (1) of
1065 section 400.141, Florida Statutes, are redesignated as
1066 paragraphs (n) through (u), respectively, and present paragraphs
1067 (f), (g), (j), (n), (o), and (r) of that subsection are amended,
1068 to read:
1069 400.141 Administration and management of nursing home
1070 facilities.—
1071 (1) Every licensed facility shall comply with all
1072 applicable standards and rules of the agency and shall:
1073 (f) Be allowed and encouraged by the agency to provide

1074 other needed services under certain conditions. If the facility
1075 has a standard licensure status~~, and has had no class I or class~~
1076 ~~II deficiencies during the past 2 years~~ or has been awarded a
1077 Gold Seal under the program established in s. 400.235, it may ~~be~~
1078 ~~encouraged by the agency to~~ provide services, including, but not
1079 limited to, respite and adult day services, which enable
1080 individuals to move in and out of the facility. A facility is
1081 not subject to any additional licensure requirements for
1082 providing these services.
1083 1. Respite care may be offered to persons in need of short-
1084 term or temporary nursing home services. For each person
1085 admitted under the respite care program, the facility licensee
1086 must:
1087 a. Have a written abbreviated plan of care that, at a
1088 minimum, includes nutritional requirements, medication orders,
1089 physician orders, nursing assessments, and dietary preferences.
1090 The nursing or physician assessments may take the place of all
1091 other assessments required for full-time residents.
1092 b. Have a contract that, at a minimum, specifies the
1093 services to be provided to the respite resident, including
1094 charges for services, activities, equipment, emergency medical
1095 services, and the administration of medications. If multiple
1096 respite admissions for a single person are anticipated, the
1097 original contract is valid for 1 year after the date of
1098 execution.
1099 c. Ensure that each resident is released to his or her
1100 caregiver or an individual designated in writing by the
1101 caregiver.
1102 2. A person admitted under the respite care program is:

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1103 a. Exempt from requirements in rule related to discharge
1104 planning.
1105 b. Covered by the resident's rights set forth in s.
1106 400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident
1107 shall not be considered trust funds subject to the requirements
1108 of s. 400.022(1)(h) until the resident has been in the facility
1109 for more than 14 consecutive days.
1110 c. Allowed to use his or her personal medications for the
1111 respite stay if permitted by facility policy. The facility must
1112 obtain a physician's orders for the medications. The caregiver
1113 may provide information regarding the medications as part of the
1114 nursing assessment, which must agree with the physician's
1115 orders. Medications shall be released with the resident upon
1116 discharge in accordance with current orders.
1117 3. A person receiving respite care is entitled to a total
1118 of 60 days in the facility within a contract year or a calendar
1119 year if the contract is for less than 12 months. However, each
1120 single stay may not exceed 14 days. If a stay exceeds 14
1121 consecutive days, the facility must comply with all assessment
1122 and care planning requirements applicable to nursing home
1123 residents.
1124 4. A person receiving respite care must reside in a
1125 licensed nursing home bed.
1126 5. A prospective respite resident must provide medical
1127 information from a physician, a physician assistant, or a nurse
1128 practitioner and other information from the primary caregiver as
1129 may be required by the facility prior to or at the time of
1130 admission to receive respite care. The medical information must
1131 include a physician's order for respite care and proof of a

1132 physical examination by a licensed physician, physician
1133 assistant, or nurse practitioner. The physician’s order and
1134 physical examination may be used to provide intermittent respite
1135 care for up to 12 months after the date the order is written.
1136 6. The facility must assume the duties of the primary
1137 caregiver. To ensure continuity of care and services, the
1138 resident is entitled to retain his or her personal physician and
1139 must have access to medically necessary services such as
1140 physical therapy, occupational therapy, or speech therapy, as
1141 needed. The facility must arrange for transportation to these
1142 services if necessary. ~~Respite care must be provided in~~
1143 ~~accordance with this part and rules adopted by the agency.~~
1144 ~~However, the agency shall, by rule, adopt modified requirements~~
1145 ~~for resident assessment, resident care plans, resident~~
1146 ~~contracts, physician orders, and other provisions, as~~
1147 ~~appropriate, for short-term or temporary nursing home services.~~
1148 7. The agency shall allow for shared programming and staff
1149 in a facility which meets minimum standards and offers services
1150 pursuant to this paragraph, but, if the facility is cited for
1151 deficiencies in patient care, may require additional staff and
1152 programs appropriate to the needs of service recipients. A
1153 person who receives respite care may not be counted as a
1154 resident of the facility for purposes of the facility’s licensed
1155 capacity unless that person receives 24-hour respite care. A
1156 person receiving either respite care for 24 hours or longer or
1157 adult day services must be included when calculating minimum
1158 staffing for the facility. Any costs and revenues generated by a
1159 nursing home facility from nonresidential programs or services
1160 shall be excluded from the calculations of Medicaid per diems

1161 for nursing home institutional care reimbursement.
1162 (g) If the facility has a standard license or is a Gold
1163 Seal facility, exceeds the minimum required hours of licensed
1164 nursing and certified nursing assistant direct care per resident
1165 per day, and is part of a continuing care facility licensed
1166 under chapter 651 or a retirement community that offers other
1167 services pursuant to part III of this chapter or part I or part
1168 III of chapter 429 on a single campus, be allowed to share
1169 programming and staff. At the time of inspection and in the
1170 semiannual report required pursuant to paragraph (n) ~~(o)~~, a
1171 continuing care facility or retirement community that uses this
1172 option must demonstrate through staffing records that minimum
1173 staffing requirements for the facility were met. Licensed nurses
1174 and certified nursing assistants who work in the nursing home
1175 facility may be used to provide services elsewhere on campus if
1176 the facility exceeds the minimum number of direct care hours
1177 required per resident per day and the total number of residents
1178 receiving direct care services from a licensed nurse or a
1179 certified nursing assistant does not cause the facility to
1180 violate the staffing ratios required under s. 400.23(3)(a).
1181 Compliance with the minimum staffing ratios shall be based on
1182 total number of residents receiving direct care services,
1183 regardless of where they reside on campus. If the facility
1184 receives a conditional license, it may not share staff until the
1185 conditional license status ends. This paragraph does not
1186 restrict the agency's authority under federal or state law to
1187 require additional staff if a facility is cited for deficiencies
1188 in care which are caused by an insufficient number of certified
1189 nursing assistants or licensed nurses. The agency may adopt

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1190 rules for the documentation necessary to determine compliance
1191 with this provision.
1192 (j) Keep full records of resident admissions and
1193 discharges; medical and general health status, including medical
1194 records, personal and social history, and identity and address
1195 of next of kin or other persons who may have responsibility for
1196 the affairs of the residents; and individual resident care plans
1197 including, but not limited to, prescribed services, service
1198 frequency and duration, and service goals. The records shall be
1199 open to inspection by the agency. The facility must maintain
1200 clinical records on each resident in accordance with accepted
1201 professional standards and practices that are complete,
1202 accurately documented, readily accessible, and systematically
1203 organized.
1204 ~~(n) Submit to the agency the information specified in s.~~
1205 ~~400.071(1)(b) for a management company within 30 days after the~~
1206 ~~effective date of the management agreement.~~
1207 (n)~~(o)~~1. Submit semiannually to the agency, or more
1208 frequently if requested by the agency, information regarding
1209 facility staff-to-resident ratios, staff turnover, and staff
1210 stability, including information regarding certified nursing
1211 assistants, licensed nurses, the director of nursing, and the
1212 facility administrator. For purposes of this reporting:
1213 a. Staff-to-resident ratios must be reported in the
1214 categories specified in s. 400.23(3)(a) and applicable rules.
1215 The ratio must be reported as an average for the most recent
1216 calendar quarter.
1217 b. Staff turnover must be reported for the most recent 12-
1218 month period ending on the last workday of the most recent

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1219 calendar quarter prior to the date the information is submitted.
1220 The turnover rate must be computed quarterly, with the annual
1221 rate being the cumulative sum of the quarterly rates. The
1222 turnover rate is the total number of terminations or separations
1223 experienced during the quarter, excluding any employee
1224 terminated during a probationary period of 3 months or less,
1225 divided by the total number of staff employed at the end of the
1226 period for which the rate is computed, and expressed as a
1227 percentage.
1228 c. The formula for determining staff stability is the total
1229 number of employees that have been employed for more than 12
1230 months, divided by the total number of employees employed at the
1231 end of the most recent calendar quarter, and expressed as a
1232 percentage.
1233 d. A nursing facility that has failed to comply with state
1234 minimum-staffing requirements for 2 consecutive days is
1235 prohibited from accepting new admissions until the facility has
1236 achieved the minimum-staffing requirements for a period of 6
1237 consecutive days. For the purposes of this sub-subparagraph, any
1238 person who was a resident of the facility and was absent from
1239 the facility for the purpose of receiving medical care at a
1240 separate location or was on a leave of absence is not considered
1241 a new admission. Failure to impose such an admissions moratorium
1242 is subject to a $1,000 fine ~~constitutes a class II deficiency~~.
1243 e. A nursing facility which does not have a conditional
1244 license may be cited for failure to comply with the standards in
1245 s. 400.23(3)(a)1.a. only if it has failed to meet those
1246 standards on 2 consecutive days or if it has failed to meet at
1247 least 97 percent of those standards on any one day.

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1248 f. A facility which has a conditional license must be in
1249 compliance with the standards in s. 400.23(3)(a) at all times.
1250 2. This paragraph does not limit the agency's ability to
1251 impose a deficiency or take other actions if a facility does not
1252 have enough staff to meet the residents' needs.
1253 ~~(r) Report to the agency any filing for bankruptcy~~
1254 ~~protection by the facility or its parent corporation,~~
1255 ~~divestiture or spin-off of its assets, or corporate~~
1256 ~~reorganization within 30 days after the completion of such~~
1257 ~~activity.~~
1258 Section 32. Subsection (3) of section 400.142, Florida
1259 Statutes, is amended to read:
1260 400.142 Emergency medication kits; orders not to
1261 resuscitate.—
1262 (3) Facility staff may withhold or withdraw cardiopulmonary
1263 resuscitation if presented with an order not to resuscitate
1264 executed pursuant to s. 401.45. ~~The agency shall adopt rules~~
1265 ~~providing for the implementation of such orders.~~ Facility staff
1266 and facilities shall not be subject to criminal prosecution or
1267 civil liability, nor be considered to have engaged in negligent
1268 or unprofessional conduct, for withholding or withdrawing
1269 cardiopulmonary resuscitation pursuant to such an order and
1270 rules adopted by the agency. The absence of an order not to
1271 resuscitate executed pursuant to s. 401.45 does not preclude a
1272 physician from withholding or withdrawing cardiopulmonary
1273 resuscitation as otherwise permitted by law.
1274 Section 33. Subsections (11) through (15) of section
1275 400.147, Florida Statutes, are renumbered as subsections (10)
1276 through (14), respectively, and present subsection (10) is

1277 amended to read:
1278 400.147 Internal risk management and quality assurance
1279 program.—
1280 ~~(10) By the 10th of each month, each facility subject to~~
1281 ~~this section shall report any notice received pursuant to s.~~
1282 ~~400.0233(2) and each initial complaint that was filed with the~~
1283 ~~clerk of the court and served on the facility during the~~
1284 ~~previous month by a resident or a resident’s family member,~~
1285 ~~guardian, conservator, or personal legal representative. The~~
1286 ~~report must include the name of the resident, the resident’s~~
1287 ~~date of birth and social security number, the Medicaid~~
1288 ~~identification number for Medicaid-eligible persons, the date or~~
1289 ~~dates of the incident leading to the claim or dates of~~
1290 ~~residency, if applicable, and the type of injury or violation of~~
1291 ~~rights alleged to have occurred. Each facility shall also submit~~
1292 ~~a copy of the notices received pursuant to s. 400.0233(2) and~~
1293 ~~complaints filed with the clerk of the court. This report is~~
1294 ~~confidential as provided by law and is not discoverable or~~
1295 ~~admissible in any civil or administrative action, except in such~~
1296 ~~actions brought by the agency to enforce the provisions of this~~
1297 ~~part.~~
1298 Section 34. Section 400.148, Florida Statutes, is repealed.
1299 Section 35. Paragraph (f) of subsection (5) of section
1300 400.162, Florida Statutes, is amended to read:
1301 400.162 Property and personal affairs of residents.—
1302 (5)
1303 (f) At least every 3 months, the licensee shall furnish the
1304 resident and the guardian, trustee, or conservator, if any, for
1305 the resident a complete and verified statement of all funds ~~and~~

1306 ~~other property~~ to which this subsection applies, detailing the
1307 amounts ~~and items~~ received, together with their sources and
1308 disposition. For resident property, the licensee shall furnish
1309 such a statement annually and within 7 calendar days after a
1310 request for a statement. In any event, the licensee shall
1311 furnish such statements ~~a statement~~ annually and upon the
1312 discharge or transfer of a resident. Any governmental agency or
1313 private charitable agency contributing funds or other property
1314 on account of a resident also shall be entitled to receive such
1315 statements ~~statement~~ annually and upon discharge or transfer and
1316 such other report as it may require pursuant to law.
1317 Section 36. Paragraphs (d) and (e) of subsection (2) of
1318 section 400.179, Florida Statutes, are amended to read:
1319 400.179 Liability for Medicaid underpayments and
1320 overpayments.—
1321 (2) Because any transfer of a nursing facility may expose
1322 the fact that Medicaid may have underpaid or overpaid the
1323 transferor, and because in most instances, any such underpayment
1324 or overpayment can only be determined following a formal field
1325 audit, the liabilities for any such underpayments or
1326 overpayments shall be as follows:
1327 (d) Where the transfer involves a facility that has been
1328 leased by the transferor:
1329 1. The transferee shall, as a condition to being issued a
1330 license by the agency, acquire, maintain, and provide proof to
1331 the agency of a bond with a term of 30 months, renewable
1332 annually, in an amount not less than the total of 3 months'
1333 Medicaid payments to the facility computed on the basis of the
1334 preceding 12-month average Medicaid payments to the facility.

1335 2. A leasehold licensee may meet the requirements of
1336 subparagraph 1. by payment of a nonrefundable fee, paid at
1337 initial licensure, paid at the time of any subsequent change of
1338 ownership, and paid annually thereafter, in the amount of 1
1339 percent of the total of 3 months' Medicaid payments to the
1340 facility computed on the basis of the preceding 12-month average
1341 Medicaid payments to the facility. If a preceding 12-month
1342 average is not available, projected Medicaid payments may be
1343 used. The fee shall be deposited into the Grants and Donations
1344 Trust Fund and shall be accounted for separately as a Medicaid
1345 nursing home overpayment account. These fees shall be used at
1346 the sole discretion of the agency to repay nursing home Medicaid
1347 overpayments. Payment of this fee shall not release the licensee
1348 from any liability for any Medicaid overpayments, nor shall
1349 payment bar the agency from seeking to recoup overpayments from
1350 the licensee and any other liable party. As a condition of
1351 exercising this lease bond alternative, licensees paying this
1352 fee must maintain an existing lease bond through the end of the
1353 30-month term period of that bond. The agency is herein granted
1354 specific authority to promulgate all rules pertaining to the
1355 administration and management of this account, including
1356 withdrawals from the account, subject to federal review and
1357 approval. This provision shall take effect upon becoming law and
1358 shall apply to any leasehold license application. The financial
1359 viability of the Medicaid nursing home overpayment account shall
1360 be determined by the agency through annual review of the account
1361 balance and the amount of total outstanding, unpaid Medicaid
1362 overpayments owing from leasehold licensees to the agency as
1363 determined by final agency audits. By March 31 of each year, the

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1364 agency shall assess the cumulative fees collected under this
1365 subparagraph, minus any amounts used to repay nursing home
1366 Medicaid overpayments and amounts transferred to contribute to
1367 the General Revenue Fund pursuant to s. 215.20. If the net
1368 cumulative collections, minus amounts utilized to repay nursing
1369 home Medicaid overpayments, exceed $25 million, the provisions
1370 of this paragraph shall not apply for the subsequent fiscal
1371 year.
1372 3. The leasehold licensee may meet the bond requirement
1373 through other arrangements acceptable to the agency. The agency
1374 is herein granted specific authority to promulgate rules
1375 pertaining to lease bond arrangements.
1376 4. All existing nursing facility licensees, operating the
1377 facility as a leasehold, shall acquire, maintain, and provide
1378 proof to the agency of the 30-month bond required in
1379 subparagraph 1., above, on and after July 1, 1993, for each
1380 license renewal.
1381 5. It shall be the responsibility of all nursing facility
1382 operators, operating the facility as a leasehold, to renew the
1383 30-month bond and to provide proof of such renewal to the agency
1384 annually.
1385 6. Any failure of the nursing facility operator to acquire,
1386 maintain, renew annually, or provide proof to the agency shall
1387 be grounds for the agency to deny, revoke, and suspend the
1388 facility license to operate such facility and to take any
1389 further action, including, but not limited to, enjoining the
1390 facility, asserting a moratorium pursuant to part II of chapter
1391 408, or applying for a receiver, deemed necessary to ensure
1392 compliance with this section and to safeguard and protect the

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1393 health, safety, and welfare of the facility's residents. A lease
1394 agreement required as a condition of bond financing or
1395 refinancing under s. 154.213 by a health facilities authority or
1396 required under s. 159.30 by a county or municipality is not a
1397 leasehold for purposes of this paragraph and is not subject to
1398 the bond requirement of this paragraph.
1399 ~~(e) For the 2009-2010 fiscal year only, the provisions of~~
1400 ~~paragraph (d) shall not apply. This paragraph expires July 1,~~
1401 ~~2010.~~
1402 Section 37. Subsection (3) of section 400.19, Florida
1403 Statutes, is amended to read:
1404 400.19 Right of entry and inspection.—
1405 (3) The agency shall every 15 months conduct at least one
1406 unannounced inspection to determine compliance by the licensee
1407 with statutes, and with rules promulgated under the provisions
1408 of those statutes, governing minimum standards of construction,
1409 quality and adequacy of care, and rights of residents. The
1410 survey shall be conducted every 6 months for the next 2-year
1411 period if the facility has been cited for a class I deficiency,
1412 has been cited for two or more class II deficiencies arising
1413 from separate surveys or investigations within a 60-day period,
1414 or has had three or more substantiated complaints within a 6-
1415 month period, each resulting in at least one class I or class II
1416 deficiency. In addition to any other fees or fines in this part,
1417 the agency shall assess a fine for each facility that is subject
1418 to the 6-month survey cycle. The fine for the 2-year period
1419 shall be $6,000, one-half to be paid at the completion of each
1420 survey. The agency may adjust this fine by the change in the
1421 Consumer Price Index, based on the 12 months immediately

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1422 preceding the increase, to cover the cost of the additional
1423 surveys. The agency shall verify through subsequent inspection
1424 that any deficiency identified during inspection is corrected.
1425 However, the agency may verify the correction of a class III or
1426 class IV deficiency ~~unrelated to resident rights or resident~~
1427 ~~care~~ without reinspecting the facility if adequate written
1428 documentation has been received from the facility, which
1429 provides assurance that the deficiency has been corrected. The
1430 giving or causing to be given of advance notice of such
1431 unannounced inspections by an employee of the agency to any
1432 unauthorized person shall constitute cause for suspension of not
1433 fewer than 5 working days according to the provisions of chapter
1434 110.
1435 Section 38. Section 400.195, Florida Statutes, is repealed.
1436 Section 39. Subsection (5) of section 400.23, Florida
1437 Statutes, is amended to read:
1438 400.23 Rules; evaluation and deficiencies; licensure
1439 status.—
1440 (5)(a) The agency, in collaboration with the Division of
1441 Children's Medical Services Network of the Department of Health,
1442 must~~, no later than December 31, 1993,~~ adopt rules for minimum
1443 standards of care for persons under 21 years of age who reside
1444 in nursing home facilities. The rules must include a methodology
1445 for reviewing a nursing home facility under ss. 408.031-408.045
1446 which serves only persons under 21 years of age. A facility may
1447 be exempt from these standards for specific persons between 18
1448 and 21 years of age, if the person's physician agrees that
1449 minimum standards of care based on age are not necessary.
1450 (b) The agency, in collaboration with the Division of

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1451 Children’s Medical Services Network, shall adopt rules for
1452 minimum staffing requirements for nursing home facilities that
1453 serve persons under 21 years of age, which shall apply in lieu
1454 of the standards contained in subsection (3).
1455 1. For persons under 21 years of age who require skilled
1456 care, the requirements shall include a minimum combined average
1457 of licensed nurses, respiratory therapists, and certified
1458 nursing assistants of 3.9 hours of direct care per resident per
1459 day for each nursing home facility.
1460 2. For persons under 21 years of age who are fragile, the
1461 requirements shall include a minimum combined average of
1462 licensed nurses, respiratory therapists, respiratory care
1463 practitioners, and certified nursing assistants of 5 hours of
1464 direct care per resident per day for each nursing home facility.
1465 Section 40. Subsection (1) of section 400.275, Florida
1466 Statutes, is amended to read:
1467 400.275 Agency duties.—
1468 (1) ~~The agency shall ensure that each newly hired nursing~~
1469 ~~home surveyor, as a part of basic training, is assigned full-~~
1470 ~~time to a licensed nursing home for at least 2 days within a 7-~~
1471 ~~day period to observe facility operations outside of the survey~~
1472 ~~process before the surveyor begins survey responsibilities. Such~~
1473 ~~observations may not be the sole basis of a deficiency citation~~
1474 ~~against the facility.~~ The agency may not assign an individual to
1475 be a member of a survey team for purposes of a survey,
1476 evaluation, or consultation visit at a nursing home facility in
1477 which the surveyor was an employee within the preceding 2 ~~5~~
1478 years.
1479 Section 41. Subsection (2) of section 400.484, Florida

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1480 Statutes, is amended to read:

1481 400.484 Right of inspection; <u>violations</u> ~~deficiencies~~;

1482 fines.—

1483 (2) The agency shall impose fines for various classes of

1484 <u>violations</u> ~~deficiencies~~ in accordance with the following

1485 schedule:

1486 (a) <u>Class I violations are defined in s. 408.813.</u> ~~A class I~~

1487 ~~deficiency is any act, omission, or practice that results in a~~

1488 ~~patient's death, disablement, or permanent injury, or places a~~

1489 ~~patient at imminent risk of death, disablement, or permanent~~

1490 ~~injury.~~ Upon finding a class I <u>violation</u> ~~deficiency~~, the agency

1491 shall impose an administrative fine in the amount of $15,000 for

1492 each occurrence and each day that the <u>violation</u> ~~deficiency~~

1493 exists.

1494 (b) <u>Class II violations are defined in s. 408.813.</u> ~~A class~~

1495 ~~II deficiency is any act, omission, or practice that has a~~

1496 ~~direct adverse effect on the health, safety, or security of a~~

1497 ~~patient.~~ Upon finding a class II <u>violation</u> ~~deficiency~~, the

1498 agency shall impose an administrative fine in the amount of

1499 $5,000 for each occurrence and each day that the <u>violation</u>

1500 ~~deficiency~~ exists.

1501 (c) <u>Class III violations are defined in s. 408.813.</u> ~~A class~~

1502 ~~III deficiency is any act, omission, or practice that has an~~

1503 ~~indirect, adverse effect on the health, safety, or security of a~~

1504 ~~patient.~~ Upon finding an uncorrected or repeated class III

1505 <u>violation</u> ~~deficiency~~, the agency shall impose an administrative

1506 fine not to exceed $1,000 for each occurrence and each day that

1507 the uncorrected or repeated <u>violation</u> ~~deficiency~~ exists.

1508 (d) <u>Class IV violations are defined in s. 408.813.</u> ~~A class~~

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1509 ~~IV deficiency is any act, omission, or practice related to~~
1510 ~~required reports, forms, or documents which does not have the~~
1511 ~~potential of negatively affecting patients. These violations are~~
1512 ~~of a type that the agency determines do not threaten the health,~~
1513 ~~safety, or security of patients.~~ Upon finding an uncorrected or
1514 repeated class IV violation ~~deficiency~~, the agency shall impose
1515 an administrative fine not to exceed $500 for each occurrence
1516 and each day that the uncorrected or repeated violation
1517 ~~deficiency~~ exists.
1518 Section 42. Paragraph (i) of subsection (1) and subsection
1519 (4) of section 400.606, Florida Statutes, are amended to read:
1520 400.606 License; application; renewal; conditional license
1521 or permit; certificate of need.—
1522 (1) In addition to the requirements of part II of chapter
1523 408, the initial application and change of ownership application
1524 must be accompanied by a plan for the delivery of home,
1525 residential, and homelike inpatient hospice services to
1526 terminally ill persons and their families. Such plan must
1527 contain, but need not be limited to:
1528 ~~(i) The projected annual operating cost of the hospice.~~
1529
1530 If the applicant is an existing licensed health care provider,
1531 the application must be accompanied by a copy of the most recent
1532 profit-loss statement and, if applicable, the most recent
1533 licensure inspection report.
1534 (4) A freestanding hospice facility that is ~~primarily~~
1535 engaged in providing inpatient and related services and that is
1536 not otherwise licensed as a health care facility shall be
1537 required to obtain a certificate of need. However, a

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1538 freestanding hospice facility with six or fewer beds shall not
1539 be required to comply with institutional standards such as, but
1540 not limited to, standards requiring sprinkler systems, emergency
1541 electrical systems, or special lavatory devices.
1542 Section 43. Subsection (2) of section 400.607, Florida
1543 Statutes, is amended to read:
1544 400.607 Denial, suspension, revocation of license;
1545 emergency actions; imposition of administrative fine; grounds.—
1546 (2) A violation of this part, part II of chapter 408, or
1547 applicable rules ~~Any of the following actions~~ by a licensed
1548 hospice or any of its employees shall be grounds for
1549 administrative action by the agency against a hospice.~~:~~
1550 ~~(a) A violation of the provisions of this part, part II of~~
1551 ~~chapter 408, or applicable rules.~~
1552 ~~(b) An intentional or negligent act materially affecting~~
1553 ~~the health or safety of a patient.~~
1554 Section 44. Section 400.915, Florida Statutes, is amended
1555 to read:
1556 400.915 Construction and renovation; requirements.—The
1557 requirements for the construction or renovation of a PPEC center
1558 shall comply with:
1559 (1) The provisions of chapter 553, which pertain to
1560 building construction standards, including plumbing, electrical
1561 code, glass, manufactured buildings, accessibility for the
1562 physically disabled;
1563 (2) The provisions of s. 633.022 and applicable rules
1564 pertaining to physical ~~minimum~~ standards for nonresidential
1565 child care ~~physical~~ facilities ~~in rule 10M-12.003, Florida~~
1566 ~~Administrative Code, Child Care Standards~~; and

1567 (3) The standards or rules adopted pursuant to this part
1568 and part II of chapter 408.
1569 Section 45. Subsection (1) of section 400.925, Florida
1570 Statutes, is amended to read:
1571 400.925 Definitions.—As used in this part, the term:
1572 (1) “Accrediting organizations” means The Joint Commission
1573 ~~on Accreditation of Healthcare Organizations~~ or other national
1574 accreditation agencies whose standards for accreditation are
1575 comparable to those required by this part for licensure.
1576 Section 46. Subsections (3) through (6) of section 400.931,
1577 Florida Statutes, are renumbered as subsections (2) through (5),
1578 respectively, and present subsection (2) of that section is
1579 amended to read:
1580 400.931 Application for license; fee~~; provisional license;~~
1581 ~~temporary permit~~.—
1582 ~~(2) As an alternative to submitting proof of financial~~
1583 ~~ability to operate as required in s. 408.810(8), the applicant~~
1584 ~~may submit a $50,000 surety bond to the agency.~~
1585 Section 47. Subsection (2) of section 400.932, Florida
1586 Statutes, is amended to read:
1587 400.932 Administrative penalties.—
1588 (2) A violation of this part, part II of chapter 408, or
1589 applicable rules ~~Any of the following actions~~ by an employee of
1590 a home medical equipment provider shall be ~~are~~ grounds for
1591 administrative action or penalties by the agency.~~:~~
1592 ~~(a) Violation of this part, part II of chapter 408, or~~
1593 ~~applicable rules.~~
1594 ~~(b) An intentional, reckless, or negligent act that~~
1595 ~~materially affects the health or safety of a patient.~~

1596 Section 48. Subsection (3) of section 400.967, Florida
1597 Statutes, is amended to read:
1598 400.967 Rules and classification of violations
1599 ~~deficiencies~~.—
1600 (3) The agency shall adopt rules to provide that, when the
1601 criteria established under this part and part II of chapter 408
1602 are not met, such violations ~~deficiencies~~ shall be classified
1603 according to the nature of the violation ~~deficiency~~. The agency
1604 shall indicate the classification on the face of the notice of
1605 deficiencies as follows:
1606 (a) Class I violations ~~deficiencies~~ are defined in s.
1607 408.813 ~~those which the agency determines present an imminent~~
1608 ~~danger to the residents or guests of the facility or a~~
1609 ~~substantial probability that death or serious physical harm~~
1610 ~~would result therefrom~~. ~~The condition or practice constituting a~~
1611 ~~class I violation must be abated or eliminated immediately,~~
1612 ~~unless a fixed period of time, as determined by the agency, is~~
1613 ~~required for correction.~~ A class I violation ~~deficiency~~ is
1614 subject to a civil penalty in an amount not less than $5,000 and
1615 not exceeding $10,000 for each violation ~~deficiency~~. A fine may
1616 be levied notwithstanding the correction of the violation
1617 ~~deficiency~~.
1618 (b) Class II violations ~~deficiencies~~ are defined in s.
1619 408.813 ~~those which the agency determines have a direct or~~
1620 ~~immediate relationship to the health, safety, or security of the~~
1621 ~~facility residents, other than class I deficiencies~~. A class II
1622 violation ~~deficiency~~ is subject to a civil penalty in an amount
1623 not less than $1,000 and not exceeding $5,000 for each violation
1624 ~~deficiency~~. A citation for a class II violation ~~deficiency~~ shall

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1625 specify the time within which the violation ~~deficiency~~ must be
1626 corrected. If a class II violation ~~deficiency~~ is corrected
1627 within the time specified, no civil penalty shall be imposed,
1628 unless it is a repeated offense.
1629 (c) Class III violations ~~deficiencies~~ are defined in s.
1630 408.813 ~~those which the agency determines to have an indirect or~~
1631 ~~potential relationship to the health, safety, or security of the~~
1632 ~~facility residents, other than class I or class II deficiencies~~.
1633 A class III violation ~~deficiency~~ is subject to a civil penalty
1634 of not less than $500 and not exceeding $1,000 for each
1635 deficiency. A citation for a class III violation ~~deficiency~~
1636 shall specify the time within which the violation ~~deficiency~~
1637 must be corrected. If a class III violation ~~deficiency~~ is
1638 corrected within the time specified, no civil penalty shall be
1639 imposed, unless it is a repeated offense.
1640 (d) Class IV violations are defined in s. 408.813. Upon
1641 finding an uncorrected or repeated class IV violation, the
1642 agency shall impose an administrative fine not to exceed $500
1643 for each occurrence and each day that the uncorrected or
1644 repeated violation exists.
1645 Section 49. Subsections (4) and (7) of section 400.9905,
1646 Florida Statutes, are amended to read:
1647 400.9905 Definitions.—
1648 (4) “Clinic” means an entity at which health care services
1649 are provided to individuals and which tenders charges for
1650 reimbursement for such services, including a mobile clinic and a
1651 portable health service or equipment provider. For purposes of
1652 this part, the term does not include and the licensure
1653 requirements of this part do not apply to:

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1654 (a) Entities licensed or registered by the state under
1655 chapter 395; or entities licensed or registered by the state and
1656 providing only health care services within the scope of services
1657 authorized under their respective licenses granted under ss.
1658 383.30-383.335, chapter 390, chapter 394, chapter 397, this
1659 chapter except part X, chapter 429, chapter 463, chapter 465,
1660 chapter 466, chapter 478, part I of chapter 483, chapter 484, or
1661 chapter 651; end-stage renal disease providers authorized under
1662 42 C.F.R. part 405, subpart U; or providers certified under 42
1663 C.F.R. part 485, subpart B or subpart H; or any entity that
1664 provides neonatal or pediatric hospital-based health care
1665 services or other health care services by licensed practitioners
1666 solely within a hospital licensed under chapter 395.
1667 (b) Entities that own, directly or indirectly, entities
1668 licensed or registered by the state pursuant to chapter 395; or
1669 entities that own, directly or indirectly, entities licensed or
1670 registered by the state and providing only health care services
1671 within the scope of services authorized pursuant to their
1672 respective licenses granted under ss. 383.30-383.335, chapter
1673 390, chapter 394, chapter 397, this chapter except part X,
1674 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
1675 part I of chapter 483, chapter 484, chapter 651; end-stage renal
1676 disease providers authorized under 42 C.F.R. part 405, subpart
1677 U; or providers certified under 42 C.F.R. part 485, subpart B or
1678 subpart H; or any entity that provides neonatal or pediatric
1679 hospital-based health care services by licensed practitioners
1680 solely within a hospital licensed under chapter 395.
1681 (c) Entities that are owned, directly or indirectly, by an
1682 entity licensed or registered by the state pursuant to chapter

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1683 395; or entities that are owned, directly or indirectly, by an
1684 entity licensed or registered by the state and providing only
1685 health care services within the scope of services authorized
1686 pursuant to their respective licenses granted under ss. 383.30-
1687 383.335, chapter 390, chapter 394, chapter 397, this chapter
1688 except part X, chapter 429, chapter 463, chapter 465, chapter
1689 466, chapter 478, part I of chapter 483, chapter 484, or chapter
1690 651; end-stage renal disease providers authorized under 42
1691 C.F.R. part 405, subpart U; or providers certified under 42
1692 C.F.R. part 485, subpart B or subpart H; or any entity that
1693 provides neonatal or pediatric hospital-based health care
1694 services by licensed practitioners solely within a hospital
1695 under chapter 395.
1696 (d) Entities that are under common ownership, directly or
1697 indirectly, with an entity licensed or registered by the state
1698 pursuant to chapter 395; or entities that are under common
1699 ownership, directly or indirectly, with an entity licensed or
1700 registered by the state and providing only health care services
1701 within the scope of services authorized pursuant to their
1702 respective licenses granted under ss. 383.30-383.335, chapter
1703 390, chapter 394, chapter 397, this chapter except part X,
1704 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
1705 part I of chapter 483, chapter 484, or chapter 651; end-stage
1706 renal disease providers authorized under 42 C.F.R. part 405,
1707 subpart U; or providers certified under 42 C.F.R. part 485,
1708 subpart B or subpart H; or any entity that provides neonatal or
1709 pediatric hospital-based health care services by licensed
1710 practitioners solely within a hospital licensed under chapter
1711 395.

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1712 (e) An entity that is exempt from federal taxation under 26
1713 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan
1714 under 26 U.S.C. s. 409 that has a board of trustees not less
1715 than two-thirds of which are Florida-licensed health care
1716 practitioners and provides only physical therapy services under
1717 physician orders, any community college or university clinic,
1718 and any entity owned or operated by the federal or state
1719 government, including agencies, subdivisions, or municipalities
1720 thereof.
1721 (f) A sole proprietorship, group practice, partnership, or
1722 corporation that provides health care services by physicians
1723 covered by s. 627.419, that is directly supervised by one or
1724 more of such physicians, and that is wholly owned by one or more
1725 of those physicians or by a physician and the spouse, parent,
1726 child, or sibling of that physician.
1727 (g) A sole proprietorship, group practice, partnership, or
1728 corporation that provides health care services by licensed
1729 health care practitioners under chapter 457, chapter 458,
1730 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
1731 chapter 466, chapter 467, chapter 480, chapter 484, chapter 486,
1732 chapter 490, chapter 491, or part I, part III, part X, part
1733 XIII, or part XIV of chapter 468, or s. 464.012, which are
1734 wholly owned by one or more licensed health care practitioners,
1735 or the licensed health care practitioners set forth in this
1736 paragraph and the spouse, parent, child, or sibling of a
1737 licensed health care practitioner, so long as one of the owners
1738 who is a licensed health care practitioner is supervising the
1739 business activities and is legally responsible for the entity’s
1740 compliance with all federal and state laws. However, a health

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1741 care practitioner may not supervise services beyond the scope of
1742 the practitioner's license, except that, for the purposes of
1743 this part, a clinic owned by a licensee in s. 456.053(3)(b) that
1744 provides only services authorized pursuant to s. 456.053(3)(b)
1745 may be supervised by a licensee specified in s. 456.053(3)(b).
1746 (h) Clinical facilities affiliated with an accredited
1747 medical school at which training is provided for medical
1748 students, residents, or fellows.
1749 (i) Entities that provide only oncology or radiation
1750 therapy services by physicians licensed under chapter 458 or
1751 chapter 459 or entities that provide oncology or radiation
1752 therapy services by physicians licensed under chapter 458 or
1753 chapter 459 which are owned by a corporation whose shares are
1754 publicly traded on a recognized stock exchange.
1755 (j) Clinical facilities affiliated with a college of
1756 chiropractic accredited by the Council on Chiropractic Education
1757 at which training is provided for chiropractic students.
1758 (k) Entities that provide licensed practitioners to staff
1759 emergency departments or to deliver anesthesia services in
1760 facilities licensed under chapter 395 and that derive at least
1761 90 percent of their gross annual revenues from the provision of
1762 such services. Entities claiming an exemption from licensure
1763 under this paragraph must provide documentation demonstrating
1764 compliance.
1765 (l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or
1766 perinatology clinical facilities that are a publicly traded
1767 corporation or that are wholly owned, directly or indirectly, by
1768 a publicly traded corporation. As used in this paragraph, a
1769 publicly traded corporation is a corporation that issues

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1770 securities traded on an exchange registered with the United
1771 States Securities and Exchange Commission as a national
1772 securities exchange.
1773 (m) Entities that are owned by a corporation that has $250
1774 million or more in total annual sales of health care services
1775 provided by licensed health care practitioners if one or more of
1776 the owners of the entity is a health care practitioner who is
1777 licensed in this state, is responsible for supervising the
1778 business activities of the entity, and is legally responsible
1779 for the entity's compliance with state law for purposes of this
1780 section.
1781 (n) Entities that are owned or controlled, directly or
1782 indirectly, by a publicly traded entity with $100 million or
1783 more, in the aggregate, in total annual revenues derived from
1784 providing health care services by licensed health care
1785 practitioners that are employed or contracted by an entity
1786 described in this paragraph.
1787 (7) "Portable health service or equipment provider" means
1788 an entity that contracts with or employs persons to provide
1789 portable health care services or equipment to multiple locations
1790 ~~performing treatment or diagnostic testing of individuals~~, that
1791 bills third-party payors for those services, and that otherwise
1792 meets the definition of a clinic in subsection (4).
1793 Section 50. Paragraph (b) of subsection (1) and paragraph
1794 (c) of subsection (4) of section 400.991, Florida Statutes, are
1795 amended to read:
1796 400.991 License requirements; background screenings;
1797 prohibitions.—
1798 (1)

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1799 (b) Each mobile clinic must obtain a separate health care
1800 clinic license and must provide to the agency, at least
1801 quarterly, its projected street location to enable the agency to
1802 locate and inspect such clinic. A portable health service or
1803 equipment provider must obtain a health care clinic license for
1804 a single administrative office and is not required to submit
1805 quarterly projected street locations.
1806 (4) In addition to the requirements of part II of chapter
1807 408, the applicant must file with the application satisfactory
1808 proof that the clinic is in compliance with this part and
1809 applicable rules, including:
1810 (c) Proof of financial ability to operate as required under
1811 ss. ~~s.~~ 408.810(8) and 408.8065. ~~As an alternative to submitting~~
1812 ~~proof of financial ability to operate as required under s.~~
1813 ~~408.810(8), the applicant may file a surety bond of at least~~
1814 ~~$500,000 which guarantees that the clinic will act in full~~
1815 ~~conformity with all legal requirements for operating a clinic,~~
1816 ~~payable to the agency. The agency may adopt rules to specify~~
1817 ~~related requirements for such surety bond.~~
1818 Section 51. Paragraph (g) of subsection (1) and paragraph
1819 (a) of subsection (7) of section 400.9935, Florida Statutes, are
1820 amended to read:
1821 400.9935 Clinic responsibilities.—
1822 (1) Each clinic shall appoint a medical director or clinic
1823 director who shall agree in writing to accept legal
1824 responsibility for the following activities on behalf of the
1825 clinic. The medical director or the clinic director shall:
1826 (g) Conduct systematic reviews of clinic billings to ensure
1827 that the billings are not fraudulent or unlawful. Upon discovery

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1828 of an unlawful charge, the medical director or clinic director
1829 shall take immediate corrective action. If the clinic performs
1830 only the technical component of magnetic resonance imaging,
1831 static radiographs, computed tomography, or positron emission
1832 tomography, and provides the professional interpretation of such
1833 services, in a fixed facility that is accredited by The Joint
1834 Commission ~~on Accreditation of Healthcare Organizations~~ or the
1835 Accreditation Association for Ambulatory Health Care, and the
1836 American College of Radiology; and if, in the preceding quarter,
1837 the percentage of scans performed by that clinic which was
1838 billed to all personal injury protection insurance carriers was
1839 less than 15 percent, the chief financial officer of the clinic
1840 may, in a written acknowledgment provided to the agency, assume
1841 the responsibility for the conduct of the systematic reviews of
1842 clinic billings to ensure that the billings are not fraudulent
1843 or unlawful.
1844 (7)(a) Each clinic engaged in magnetic resonance imaging
1845 services must be accredited by The Joint Commission ~~on~~
1846 ~~Accreditation of Healthcare Organizations~~, the American College
1847 of Radiology, or the Accreditation Association for Ambulatory
1848 Health Care, within 1 year after licensure. A clinic that is
1849 accredited by the American College of Radiology or is within the
1850 original 1-year period after licensure and replaces its core
1851 magnetic resonance imaging equipment shall be given 1 year after
1852 the date on which the equipment is replaced to attain
1853 accreditation. However, a clinic may request a single, 6-month
1854 extension if it provides evidence to the agency establishing
1855 that, for good cause shown, such clinic cannot be accredited
1856 within 1 year after licensure, and that such accreditation will

1857 be completed within the 6-month extension. After obtaining
1858 accreditation as required by this subsection, each such clinic
1859 must maintain accreditation as a condition of renewal of its
1860 license. A clinic that files a change of ownership application
1861 must comply with the original accreditation timeframe
1862 requirements of the transferor. The agency shall deny a change
1863 of ownership application if the clinic is not in compliance with
1864 the accreditation requirements. When a clinic adds, replaces, or
1865 modifies magnetic resonance imaging equipment and the
1866 accreditation agency requires new accreditation, the clinic must
1867 be accredited within 1 year after the date of the addition,
1868 replacement, or modification but may request a single, 6-month
1869 extension if the clinic provides evidence of good cause to the
1870 agency.
1871 Section 52. Subsection (2) of section 408.034, Florida
1872 Statutes, is amended to read:
1873 408.034 Duties and responsibilities of agency; rules.—
1874 (2) In the exercise of its authority to issue licenses to
1875 health care facilities and health service providers, as provided
1876 under chapters 393 and 395 and parts II, ~~and~~ IV, and VIII of
1877 chapter 400, the agency may not issue a license to any health
1878 care facility or health service provider that fails to receive a
1879 certificate of need or an exemption for the licensed facility or
1880 service.
1881 Section 53. Paragraph (d) of subsection (1) of section
1882 408.036, Florida Statutes, is amended to read:
1883 408.036 Projects subject to review; exemptions.—
1884 (1) APPLICABILITY.—Unless exempt under subsection (3), all
1885 health-care-related projects, as described in paragraphs (a)-

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1886 (g), are subject to review and must file an application for a
1887 certificate of need with the agency. The agency is exclusively
1888 responsible for determining whether a health-care-related
1889 project is subject to review under ss. 408.031-408.045.
1890 (d) The establishment of a hospice or hospice inpatient
1891 facility~~, except as provided in s. 408.043~~.
1892 Section 54. Subsection (2) of section 408.043, Florida
1893 Statutes, is amended to read:
1894 408.043 Special provisions.—
1895 (2) HOSPICES.—When an application is made for a certificate
1896 of need to establish or to expand a hospice, the need for such
1897 hospice shall be determined on the basis of the need for and
1898 availability of hospice services in the community. The formula
1899 on which the certificate of need is based shall discourage
1900 regional monopolies and promote competition. The inpatient
1901 hospice care component of a hospice which is a freestanding
1902 facility, or a part of a facility, ~~which is primarily engaged in~~
1903 ~~providing inpatient care and related services~~ and is not
1904 licensed as a health care facility shall also be required to
1905 obtain a certificate of need. Provision of hospice care by any
1906 current provider of health care is a significant change in
1907 service and therefore requires a certificate of need for such
1908 services.
1909 Section 55. Paragraph (k) of subsection (3) of section
1910 408.05, Florida Statutes, is amended to read:
1911 408.05 Florida Center for Health Information and Policy
1912 Analysis.—
1913 (3) COMPREHENSIVE HEALTH INFORMATION SYSTEM.—In order to
1914 produce comparable and uniform health information and statistics

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1915 for the development of policy recommendations, the agency shall
1916 perform the following functions:
1917 (k) Develop, in conjunction with the State Consumer Health
1918 Information and Policy Advisory Council, and implement a long-
1919 range plan for making available health care quality measures and
1920 financial data that will allow consumers to compare health care
1921 services. The health care quality measures and financial data
1922 the agency must make available shall include, but is not limited
1923 to, pharmaceuticals, physicians, health care facilities, and
1924 health plans and managed care entities. The agency shall submit
1925 the initial plan to the Governor, the President of the Senate,
1926 and the Speaker of the House of Representatives by January 1,
1927 2006, and shall update the plan and report on the status of its
1928 implementation annually thereafter. The agency shall also make
1929 the plan and status report available to the public on its
1930 Internet website. As part of the plan, the agency shall identify
1931 the process and timeframes for implementation, any barriers to
1932 implementation, and recommendations of changes in the law that
1933 may be enacted by the Legislature to eliminate the barriers. As
1934 preliminary elements of the plan, the agency shall:
1935 1. Make available patient-safety indicators, inpatient
1936 quality indicators, and performance outcome and patient charge
1937 data collected from health care facilities pursuant to s.
1938 408.061(1)(a) and (2). The terms “patient-safety indicators” and
1939 “inpatient quality indicators” shall be as defined by the
1940 Centers for Medicare and Medicaid Services, the National Quality
1941 Forum, The Joint Commission ~~on Accreditation of Healthcare~~
1942 ~~Organizations~~, the Agency for Healthcare Research and Quality,
1943 the Centers for Disease Control and Prevention, or a similar

1944 national entity that establishes standards to measure the
1945 performance of health care providers, or by other states. The
1946 agency shall determine which conditions, procedures, health care
1947 quality measures, and patient charge data to disclose based upon
1948 input from the council. When determining which conditions and
1949 procedures are to be disclosed, the council and the agency shall
1950 consider variation in costs, variation in outcomes, and
1951 magnitude of variations and other relevant information. When
1952 determining which health care quality measures to disclose, the
1953 agency:
1954 a. Shall consider such factors as volume of cases; average
1955 patient charges; average length of stay; complication rates;
1956 mortality rates; and infection rates, among others, which shall
1957 be adjusted for case mix and severity, if applicable.
1958 b. May consider such additional measures that are adopted
1959 by the Centers for Medicare and Medicaid Studies, National
1960 Quality Forum, The Joint Commission ~~on Accreditation of~~
1961 ~~Healthcare Organizations~~, the Agency for Healthcare Research and
1962 Quality, Centers for Disease Control and Prevention, or a
1963 similar national entity that establishes standards to measure
1964 the performance of health care providers, or by other states.
1965
1966 When determining which patient charge data to disclose, the
1967 agency shall include such measures as the average of
1968 undiscounted charges on frequently performed procedures and
1969 preventive diagnostic procedures, the range of procedure charges
1970 from highest to lowest, average net revenue per adjusted patient
1971 day, average cost per adjusted patient day, and average cost per
1972 admission, among others.

1973 2. Make available performance measures, benefit design, and
1974 premium cost data from health plans licensed pursuant to chapter
1975 627 or chapter 641. The agency shall determine which health care
1976 quality measures and member and subscriber cost data to
1977 disclose, based upon input from the council. When determining
1978 which data to disclose, the agency shall consider information
1979 that may be required by either individual or group purchasers to
1980 assess the value of the product, which may include membership
1981 satisfaction, quality of care, current enrollment or membership,
1982 coverage areas, accreditation status, premium costs, plan costs,
1983 premium increases, range of benefits, copayments and
1984 deductibles, accuracy and speed of claims payment, credentials
1985 of physicians, number of providers, names of network providers,
1986 and hospitals in the network. Health plans shall make available
1987 to the agency any such data or information that is not currently
1988 reported to the agency or the office.

1989 3. Determine the method and format for public disclosure of
1990 data reported pursuant to this paragraph. The agency shall make
1991 its determination based upon input from the State Consumer
1992 Health Information and Policy Advisory Council. At a minimum,
1993 the data shall be made available on the agency's Internet
1994 website in a manner that allows consumers to conduct an
1995 interactive search that allows them to view and compare the
1996 information for specific providers. The website must include
1997 such additional information as is determined necessary to ensure
1998 that the website enhances informed decisionmaking among
1999 consumers and health care purchasers, which shall include, at a
2000 minimum, appropriate guidance on how to use the data and an
2001 explanation of why the data may vary from provider to provider.

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2002 The data specified in subparagraph 1. shall be released no later
2003 than January 1, 2006, for the reporting of infection rates, and
2004 no later than October 1, 2005, for mortality rates and
2005 complication rates. The data specified in subparagraph 2. shall
2006 be released no later than October 1, 2006.
2007 4. Publish on its website undiscounted charges for no fewer
2008 than 150 of the most commonly performed adult and pediatric
2009 procedures, including outpatient, inpatient, diagnostic, and
2010 preventative procedures.
2011 Section 56. Paragraph (a) of subsection (1) of section
2012 408.061, Florida Statutes, is amended to read:
2013 408.061 Data collection; uniform systems of financial
2014 reporting; information relating to physician charges;
2015 confidential information; immunity.—
2016 (1) The agency shall require the submission by health care
2017 facilities, health care providers, and health insurers of data
2018 necessary to carry out the agency’s duties. Specifications for
2019 data to be collected under this section shall be developed by
2020 the agency with the assistance of technical advisory panels
2021 including representatives of affected entities, consumers,
2022 purchasers, and such other interested parties as may be
2023 determined by the agency.
2024 (a) Data submitted by health care facilities, including the
2025 facilities as defined in chapter 395, shall include, but are not
2026 limited to: case-mix data, patient admission and discharge data,
2027 hospital emergency department data which shall include the
2028 number of patients treated in the emergency department of a
2029 licensed hospital reported by patient acuity level, data on
2030 hospital-acquired infections as specified by rule, data on

2031 complications as specified by rule, data on readmissions as
2032 specified by rule, with patient and provider-specific
2033 identifiers included, actual charge data by diagnostic groups,
2034 financial data, accounting data, operating expenses, expenses
2035 incurred for rendering services to patients who cannot or do not
2036 pay, interest charges, depreciation expenses based on the
2037 expected useful life of the property and equipment involved, and
2038 demographic data. The agency shall adopt nationally recognized
2039 risk adjustment methodologies or software consistent with the
2040 standards of the Agency for Healthcare Research and Quality and
2041 as selected by the agency for all data submitted as required by
2042 this section. Data may be obtained from documents such as, but
2043 not limited to: leases, contracts, debt instruments, itemized
2044 patient bills, medical record abstracts, and related diagnostic
2045 information. Reported data elements shall be reported
2046 electronically and ~~in accordance with rule 59E-7.012, Florida~~
2047 ~~Administrative Code. Data submitted shall be~~ certified by the
2048 chief executive officer or an appropriate and duly authorized
2049 representative or employee of the licensed facility that the
2050 information submitted is true and accurate.
2051 Section 57. Subsection (43) of section 408.07, Florida
2052 Statutes, is amended to read:
2053 408.07 Definitions.—As used in this chapter, with the
2054 exception of ss. 408.031-408.045, the term:
2055 (43) “Rural hospital” means an acute care hospital licensed
2056 under chapter 395, having 100 or fewer licensed beds and an
2057 emergency room, and which is:
2058 (a) The sole provider within a county with a population
2059 density of no greater than 100 persons per square mile;

2060 (b) An acute care hospital, in a county with a population
2061 density of no greater than 100 persons per square mile, which is
2062 at least 30 minutes of travel time, on normally traveled roads
2063 under normal traffic conditions, from another acute care
2064 hospital within the same county;
2065 (c) A hospital supported by a tax district or subdistrict
2066 whose boundaries encompass a population of 100 persons or fewer
2067 per square mile;
2068 (d) A hospital with a service area that has a population of
2069 100 persons or fewer per square mile. As used in this paragraph,
2070 the term “service area” means the fewest number of zip codes
2071 that account for 75 percent of the hospital’s discharges for the
2072 most recent 5-year period, based on information available from
2073 the hospital inpatient discharge database in the Florida Center
2074 for Health Information and Policy Analysis at the Agency for
2075 Health Care Administration; or
2076 (e) A critical access hospital.
2077
2078 Population densities used in this subsection must be based upon
2079 the most recently completed United States census. A hospital
2080 that received funds under s. 409.9116 for a quarter beginning no
2081 later than July 1, 2002, is deemed to have been and shall
2082 continue to be a rural hospital from that date through June 30,
2083 2015, if the hospital continues to have 100 or fewer licensed
2084 beds and an emergency room~~, or meets the criteria of s.~~
2085 ~~395.602(2)(e)4~~. An acute care hospital that has not previously
2086 been designated as a rural hospital and that meets the criteria
2087 of this subsection shall be granted such designation upon
2088 application, including supporting documentation, to the Agency

2089 for Health Care Administration.
2090 Section 58. Section 408.10, Florida Statutes, is amended to
2091 read:
2092 408.10 Consumer complaints.—The agency shall~~:~~
2093 ~~(1)~~ publish and make available to the public a toll-free
2094 telephone number for the purpose of handling consumer complaints
2095 and shall serve as a liaison between consumer entities and other
2096 private entities and governmental entities for the disposition
2097 of problems identified by consumers of health care.
2098 ~~(2) Be empowered to investigate consumer complaints~~
2099 ~~relating to problems with health care facilities' billing~~
2100 ~~practices and issue reports to be made public in any cases where~~
2101 ~~the agency determines the health care facility has engaged in~~
2102 ~~billing practices which are unreasonable and unfair to the~~
2103 ~~consumer.~~
2104 Section 59. Subsections (12) through (30) of section
2105 408.802, Florida Statutes, are renumbered as subsections (11)
2106 through (29), respectively, and present subsection (11) of that
2107 section is amended to read:
2108 408.802 Applicability.—The provisions of this part apply to
2109 the provision of services that require licensure as defined in
2110 this part and to the following entities licensed, registered, or
2111 certified by the agency, as described in chapters 112, 383, 390,
2112 394, 395, 400, 429, 440, 483, and 765:
2113 ~~(11) Private review agents, as provided under part I of~~
2114 ~~chapter 395.~~
2115 Section 60. Subsection (3) is added to section 408.804,
2116 Florida Statutes, to read:
2117 408.804 License required; display.—

2118 (3) Any person who knowingly alters, defaces, or falsifies
2119 a license certificate issued by the agency, or causes or
2120 procures any person to commit such an offense, commits a
2121 misdemeanor of the second degree, punishable as provided in s.
2122 775.082 or s 775.083. Any licensee or provider who displays an
2123 altered, defaced, or falsified license certificate is subject to
2124 the penalties set forth in s. 408.815 and an administrative fine
2125 of $1,000 for each day of illegal display.
2126 Section 61. Paragraph (d) of subsection (2) of section
2127 408.806, Florida Statutes, is amended, present subsections (3)
2128 through (8) are renumbered as subsections (4) through (9),
2129 respectively, and a new subsection (3) is added to that section,
2130 to read:
2131 408.806 License application process.—
2132 (2)
2133 (d) ~~The agency shall notify the licensee by mail or~~
2134 ~~electronically at least 90 days before the expiration of a~~
2135 ~~license that a renewal license is necessary to continue~~
2136 ~~operation.~~ The licensee's failure to timely file ~~submit~~ a
2137 renewal application and license application fee with the agency
2138 shall result in a $50 per day late fee charged to the licensee
2139 by the agency; however, the aggregate amount of the late fee may
2140 not exceed 50 percent of the licensure fee or $500, whichever is
2141 less. The agency shall provide a courtesy notice to the licensee
2142 by United States mail, electronically, or by any other manner at
2143 its address of record or mailing address, if provided, at least
2144 90 days prior to the expiration of a license informing the
2145 licensee of the expiration of the license. If the agency does
2146 not provide the courtesy notice or the licensee does not receive

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2147 the courtesy notice, the licensee continues to be legally
2148 obligated to timely file the renewal application and license
2149 application fee with the agency and is not excused from the
2150 payment of a late fee. If an application is received after the
2151 required filing date and exhibits a hand-canceled postmark
2152 obtained from a United States post office dated on or before the
2153 required filing date, no fine will be levied.
2154 (3) Payment of the late fee is required to consider any
2155 late application complete, and failure to pay the late fee is
2156 considered an omission from the application.
2157 Section 62. Subsections (6) and (9) of section 408.810,
2158 Florida Statutes, are amended to read:
2159 408.810 Minimum licensure requirements.—In addition to the
2160 licensure requirements specified in this part, authorizing
2161 statutes, and applicable rules, each applicant and licensee must
2162 comply with the requirements of this section in order to obtain
2163 and maintain a license.
2164 (6)(a) An applicant must provide the agency with proof of
2165 the applicant's legal right to occupy the property before a
2166 license may be issued. Proof may include, but need not be
2167 limited to, copies of warranty deeds, lease or rental
2168 agreements, contracts for deeds, quitclaim deeds, or other such
2169 documentation.
2170 (b) In the event the property is encumbered by a mortgage
2171 or is leased, an applicant must provide the agency with proof
2172 that the mortgagor or landlord has been provided written notice
2173 of the applicant's intent as mortgagee or tenant to provide
2174 services that require licensure and instruct the mortgagor or
2175 landlord to serve the agency by certified mail with copies of

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2176 any foreclosure or eviction actions initiated by the mortgagor
2177 or landlord against the applicant.
2178 (9) A controlling interest may not withhold from the agency
2179 any evidence of financial instability, including, but not
2180 limited to, checks returned due to insufficient funds,
2181 delinquent accounts, nonpayment of withholding taxes, unpaid
2182 utility expenses, nonpayment for essential services, or adverse
2183 court action concerning the financial viability of the provider
2184 or any other provider licensed under this part that is under the
2185 control of the controlling interest. A controlling interest
2186 shall notify the agency within 10 days after a court action to
2187 initiate bankruptcy, foreclosure, or eviction proceedings
2188 concerning the provider, in which the controlling interest is a
2189 petitioner or defendant. Any person who violates this subsection
2190 commits a misdemeanor of the second degree, punishable as
2191 provided in s. 775.082 or s. 775.083. Each day of continuing
2192 violation is a separate offense.
2193 Section 63. Subsection (3) is added to section 408.813,
2194 Florida Statutes, to read:
2195 408.813 Administrative fines; violations.—As a penalty for
2196 any violation of this part, authorizing statutes, or applicable
2197 rules, the agency may impose an administrative fine.
2198 (3) The agency may impose an administrative fine for a
2199 violation that does not qualify as a class I, class II, class
2200 III, or class IV violation. Unless otherwise specified by law,
2201 the amount of the fine shall not exceed $500 for each violation.
2202 Unclassified violations may include:
2203 (a) Violating any term or condition of a license.
2204 (b) Violating any provision of this part, authorizing

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2205 statutes, or applicable rules.

2206 (c) Exceeding licensed capacity.

2207 (d) Providing services beyond the scope of the license.

2208 (e) Violating a moratorium imposed pursuant to s. 408.814.

2209 Section 64. Subsection (5) is added to section 408.815,
2210 Florida Statutes, to read:

2211 408.815 License or application denial; revocation.—

2212 (5) In order to ensure the health, safety, and welfare of
2213 clients when a license has been denied, revoked, or is set to
2214 terminate, the agency may extend the license expiration date for
2215 a period of up to 30 days for the sole purpose of allowing the
2216 safe and orderly discharge of clients. The agency may impose
2217 conditions on the extension, including, but not limited to,
2218 prohibiting or limiting admissions, expedited discharge
2219 planning, required status reports, and mandatory monitoring by
2220 the agency or third parties. In imposing these conditions, the
2221 agency shall take into consideration the nature and number of
2222 clients, the availability and location of acceptable alternative
2223 placements, and the ability of the licensee to continue
2224 providing care to the clients. The agency may terminate the
2225 extension or modify the conditions at any time. This authority
2226 is in addition to any other authority granted to the agency
2227 under chapter 120, this part, and authorizing statutes but
2228 creates no right or entitlement to an extension of a license
2229 expiration date.

2230 Section 65. Paragraph (k) of subsection (4) of section
2231 409.221, Florida Statutes, is amended to read:

2232 409.221 Consumer-directed care program.—

2233 (4) CONSUMER-DIRECTED CARE.—

2234 ~~(k) *Reviews and reports.*—The agency and the Departments of~~
2235 ~~Elderly Affairs, Health, and Children and Family Services and~~
2236 ~~the Agency for Persons with Disabilities shall each, on an~~
2237 ~~ongoing basis, review and assess the implementation of the~~
2238 ~~consumer-directed care program. By January 15 of each year, the~~
2239 ~~agency shall submit a written report to the Legislature that~~
2240 ~~includes each department's review of the program and contains~~
2241 ~~recommendations for improvements to the program.~~
2242 Section 66. Subsection (1) of section 409.91196, Florida
2243 Statutes, is amended to read:
2244 409.91196 Supplemental rebate agreements; public records
2245 and public meetings exemption.—
2246 (1) The rebate amount, percent of rebate, manufacturer's
2247 pricing, and supplemental rebate, and other trade secrets as
2248 defined in s. 688.002 that the agency has identified for use in
2249 negotiations, held by the Agency for Health Care Administration
2250 under s. 409.912(39)(a)8.~~7.~~ are confidential and exempt from s.
2251 119.07(1) and s. 24(a), Art. I of the State Constitution.
2252 Section 67. Paragraph (a) of subsection (39) of section
2253 409.912, Florida Statutes, is amended to read:
2254 409.912 Cost-effective purchasing of health care.—The
2255 agency shall purchase goods and services for Medicaid recipients
2256 in the most cost-effective manner consistent with the delivery
2257 of quality medical care. To ensure that medical services are
2258 effectively utilized, the agency may, in any case, require a
2259 confirmation or second physician's opinion of the correct
2260 diagnosis for purposes of authorizing future services under the
2261 Medicaid program. This section does not restrict access to
2262 emergency services or poststabilization care services as defined

2263 in 42 C.F.R. part 438.114. Such confirmation or second opinion
2264 shall be rendered in a manner approved by the agency. The agency
2265 shall maximize the use of prepaid per capita and prepaid
2266 aggregate fixed-sum basis services when appropriate and other
2267 alternative service delivery and reimbursement methodologies,
2268 including competitive bidding pursuant to s. 287.057, designed
2269 to facilitate the cost-effective purchase of a case-managed
2270 continuum of care. The agency shall also require providers to
2271 minimize the exposure of recipients to the need for acute
2272 inpatient, custodial, and other institutional care and the
2273 inappropriate or unnecessary use of high-cost services. The
2274 agency shall contract with a vendor to monitor and evaluate the
2275 clinical practice patterns of providers in order to identify
2276 trends that are outside the normal practice patterns of a
2277 provider’s professional peers or the national guidelines of a
2278 provider’s professional association. The vendor must be able to
2279 provide information and counseling to a provider whose practice
2280 patterns are outside the norms, in consultation with the agency,
2281 to improve patient care and reduce inappropriate utilization.
2282 The agency may mandate prior authorization, drug therapy
2283 management, or disease management participation for certain
2284 populations of Medicaid beneficiaries, certain drug classes, or
2285 particular drugs to prevent fraud, abuse, overuse, and possible
2286 dangerous drug interactions. The Pharmaceutical and Therapeutics
2287 Committee shall make recommendations to the agency on drugs for
2288 which prior authorization is required. The agency shall inform
2289 the Pharmaceutical and Therapeutics Committee of its decisions
2290 regarding drugs subject to prior authorization. The agency is
2291 authorized to limit the entities it contracts with or enrolls as

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2292 Medicaid providers by developing a provider network through
2293 provider credentialing. The agency may competitively bid single-
2294 source-provider contracts if procurement of goods or services
2295 results in demonstrated cost savings to the state without
2296 limiting access to care. The agency may limit its network based
2297 on the assessment of beneficiary access to care, provider
2298 availability, provider quality standards, time and distance
2299 standards for access to care, the cultural competence of the
2300 provider network, demographic characteristics of Medicaid
2301 beneficiaries, practice and provider-to-beneficiary standards,
2302 appointment wait times, beneficiary use of services, provider
2303 turnover, provider profiling, provider licensure history,
2304 previous program integrity investigations and findings, peer
2305 review, provider Medicaid policy and billing compliance records,
2306 clinical and medical record audits, and other factors. Providers
2307 shall not be entitled to enrollment in the Medicaid provider
2308 network. The agency shall determine instances in which allowing
2309 Medicaid beneficiaries to purchase durable medical equipment and
2310 other goods is less expensive to the Medicaid program than long-
2311 term rental of the equipment or goods. The agency may establish
2312 rules to facilitate purchases in lieu of long-term rentals in
2313 order to protect against fraud and abuse in the Medicaid program
2314 as defined in s. 409.913. The agency may seek federal waivers
2315 necessary to administer these policies.
2316 (39)(a) The agency shall implement a Medicaid prescribed-
2317 drug spending-control program that includes the following
2318 components:
2319 1. A Medicaid preferred drug list, which shall be a listing
2320 of cost-effective therapeutic options recommended by the

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2321 Medicaid Pharmacy and Therapeutics Committee established
2322 pursuant to s. 409.91195 and adopted by the agency for each
2323 therapeutic class on the preferred drug list. At the discretion
2324 of the committee, and when feasible, the preferred drug list
2325 should include at least two products in a therapeutic class. The
2326 agency may post the preferred drug list and updates to the
2327 preferred drug list on an Internet website without following the
2328 rulemaking procedures of chapter 120. Antiretroviral agents are
2329 excluded from the preferred drug list. The agency shall also
2330 limit the amount of a prescribed drug dispensed to no more than
2331 a 34-day supply unless the drug products' smallest marketed
2332 package is greater than a 34-day supply, or the drug is
2333 determined by the agency to be a maintenance drug in which case
2334 a 100-day maximum supply may be authorized. The agency is
2335 authorized to seek any federal waivers necessary to implement
2336 these cost-control programs and to continue participation in the
2337 federal Medicaid rebate program, or alternatively to negotiate
2338 state-only manufacturer rebates. The agency may adopt rules to
2339 implement this subparagraph. The agency shall continue to
2340 provide unlimited contraceptive drugs and items. The agency must
2341 establish procedures to ensure that:
2342 a. There is a response to a request for prior consultation
2343 by telephone or other telecommunication device within 24 hours
2344 after receipt of a request for prior consultation; and
2345 b. A 72-hour supply of the drug prescribed is provided in
2346 an emergency or when the agency does not provide a response
2347 within 24 hours as required by sub-subparagraph a.
2348 2. Reimbursement to pharmacies for Medicaid prescribed
2349 drugs shall be set at the lesser of: the average wholesale price

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2350 (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC)
2351 plus 4.75 percent, the federal upper limit (FUL), the state
2352 maximum allowable cost (SMAC), or the usual and customary (UAC)
2353 charge billed by the provider.
2354 3. For a prescribed drug billed as a 340B prescribed
2355 medication, the claim must meet the requirements of the Deficit
2356 Reduction Act of 2005 and the federal 340B program, contain a
2357 national drug code, and be billed at the actual acquisition cost
2358 or payment shall be denied.
2359 4.~~3.~~ The agency shall develop and implement a process for
2360 managing the drug therapies of Medicaid recipients who are using
2361 significant numbers of prescribed drugs each month. The
2362 management process may include, but is not limited to,
2363 comprehensive, physician-directed medical-record reviews, claims
2364 analyses, and case evaluations to determine the medical
2365 necessity and appropriateness of a patient's treatment plan and
2366 drug therapies. The agency may contract with a private
2367 organization to provide drug-program-management services. The
2368 Medicaid drug benefit management program shall include
2369 initiatives to manage drug therapies for HIV/AIDS patients,
2370 patients using 20 or more unique prescriptions in a 180-day
2371 period, and the top 1,000 patients in annual spending. The
2372 agency shall enroll any Medicaid recipient in the drug benefit
2373 management program if he or she meets the specifications of this
2374 provision and is not enrolled in a Medicaid health maintenance
2375 organization.
2376 5.~~4.~~ The agency may limit the size of its pharmacy network
2377 based on need, competitive bidding, price negotiations,
2378 credentialing, or similar criteria. The agency shall give

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2379 special consideration to rural areas in determining the size and
2380 location of pharmacies included in the Medicaid pharmacy
2381 network. A pharmacy credentialing process may include criteria
2382 such as a pharmacy's full-service status, location, size,
2383 patient educational programs, patient consultation, disease
2384 management services, and other characteristics. The agency may
2385 impose a moratorium on Medicaid pharmacy enrollment when it is
2386 determined that it has a sufficient number of Medicaid-
2387 participating providers. The agency must allow dispensing
2388 practitioners to participate as a part of the Medicaid pharmacy
2389 network regardless of the practitioner's proximity to any other
2390 entity that is dispensing prescription drugs under the Medicaid
2391 program. A dispensing practitioner must meet all credentialing
2392 requirements applicable to his or her practice, as determined by
2393 the agency.
2394 <u>6.</u>~~5.~~ The agency shall develop and implement a program that
2395 requires Medicaid practitioners who prescribe drugs to use a
2396 counterfeit-proof prescription pad for Medicaid prescriptions.
2397 The agency shall require the use of standardized counterfeit-
2398 proof prescription pads by Medicaid-participating prescribers or
2399 prescribers who write prescriptions for Medicaid recipients. The
2400 agency may implement the program in targeted geographic areas or
2401 statewide.
2402 <u>7.</u>~~6.~~ The agency may enter into arrangements that require
2403 manufacturers of generic drugs prescribed to Medicaid recipients
2404 to provide rebates of at least 15.1 percent of the average
2405 manufacturer price for the manufacturer's generic products.
2406 These arrangements shall require that if a generic-drug
2407 manufacturer pays federal rebates for Medicaid-reimbursed drugs

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2408 at a level below 15.1 percent, the manufacturer must provide a
2409 supplemental rebate to the state in an amount necessary to
2410 achieve a 15.1-percent rebate level.
2411 8.~~7.~~ The agency may establish a preferred drug list as
2412 described in this subsection, and, pursuant to the establishment
2413 of such preferred drug list, it is authorized to negotiate
2414 supplemental rebates from manufacturers that are in addition to
2415 those required by Title XIX of the Social Security Act and at no
2416 less than 14 percent of the average manufacturer price as
2417 defined in 42 U.S.C. s. 1936 on the last day of a quarter unless
2418 the federal or supplemental rebate, or both, equals or exceeds
2419 29 percent. There is no upper limit on the supplemental rebates
2420 the agency may negotiate. The agency may determine that specific
2421 products, brand-name or generic, are competitive at lower rebate
2422 percentages. Agreement to pay the minimum supplemental rebate
2423 percentage will guarantee a manufacturer that the Medicaid
2424 Pharmaceutical and Therapeutics Committee will consider a
2425 product for inclusion on the preferred drug list. However, a
2426 pharmaceutical manufacturer is not guaranteed placement on the
2427 preferred drug list by simply paying the minimum supplemental
2428 rebate. Agency decisions will be made on the clinical efficacy
2429 of a drug and recommendations of the Medicaid Pharmaceutical and
2430 Therapeutics Committee, as well as the price of competing
2431 products minus federal and state rebates. The agency is
2432 authorized to contract with an outside agency or contractor to
2433 conduct negotiations for supplemental rebates. For the purposes
2434 of this section, the term “supplemental rebates” means cash
2435 rebates. Effective July 1, 2004, value-added programs as a
2436 substitution for supplemental rebates are prohibited. The agency

2437 is authorized to seek any federal waivers to implement this
2438 initiative.
2439 9.~~8.~~ The Agency for Health Care Administration shall expand
2440 home delivery of pharmacy products. To assist Medicaid patients
2441 in securing their prescriptions and reduce program costs, the
2442 agency shall expand its current mail-order-pharmacy diabetes-
2443 supply program to include all generic and brand-name drugs used
2444 by Medicaid patients with diabetes. Medicaid recipients in the
2445 current program may obtain nondiabetes drugs on a voluntary
2446 basis. This initiative is limited to the geographic area covered
2447 by the current contract. The agency may seek and implement any
2448 federal waivers necessary to implement this subparagraph.
2449 10.~~9.~~ The agency shall limit to one dose per month any drug
2450 prescribed to treat erectile dysfunction.
2451 11.~~10.~~a. The agency may implement a Medicaid behavioral
2452 drug management system. The agency may contract with a vendor
2453 that has experience in operating behavioral drug management
2454 systems to implement this program. The agency is authorized to
2455 seek federal waivers to implement this program.
2456 b. The agency, in conjunction with the Department of
2457 Children and Family Services, may implement the Medicaid
2458 behavioral drug management system that is designed to improve
2459 the quality of care and behavioral health prescribing practices
2460 based on best practice guidelines, improve patient adherence to
2461 medication plans, reduce clinical risk, and lower prescribed
2462 drug costs and the rate of inappropriate spending on Medicaid
2463 behavioral drugs. The program may include the following
2464 elements:
2465 (I) Provide for the development and adoption of best

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2466 practice guidelines for behavioral health-related drugs such as
2467 antipsychotics, antidepressants, and medications for treating
2468 bipolar disorders and other behavioral conditions; translate
2469 them into practice; review behavioral health prescribers and
2470 compare their prescribing patterns to a number of indicators
2471 that are based on national standards; and determine deviations
2472 from best practice guidelines.
2473 (II) Implement processes for providing feedback to and
2474 educating prescribers using best practice educational materials
2475 and peer-to-peer consultation.
2476 (III) Assess Medicaid beneficiaries who are outliers in
2477 their use of behavioral health drugs with regard to the numbers
2478 and types of drugs taken, drug dosages, combination drug
2479 therapies, and other indicators of improper use of behavioral
2480 health drugs.
2481 (IV) Alert prescribers to patients who fail to refill
2482 prescriptions in a timely fashion, are prescribed multiple same-
2483 class behavioral health drugs, and may have other potential
2484 medication problems.
2485 (V) Track spending trends for behavioral health drugs and
2486 deviation from best practice guidelines.
2487 (VI) Use educational and technological approaches to
2488 promote best practices, educate consumers, and train prescribers
2489 in the use of practice guidelines.
2490 (VII) Disseminate electronic and published materials.
2491 (VIII) Hold statewide and regional conferences.
2492 (IX) Implement a disease management program with a model
2493 quality-based medication component for severely mentally ill
2494 individuals and emotionally disturbed children who are high

2495 users of care.
2496 12.~~11.~~a. The agency shall implement a Medicaid prescription
2497 drug management system. The agency may contract with a vendor
2498 that has experience in operating prescription drug management
2499 systems in order to implement this system. Any management system
2500 that is implemented in accordance with this subparagraph must
2501 rely on cooperation between physicians and pharmacists to
2502 determine appropriate practice patterns and clinical guidelines
2503 to improve the prescribing, dispensing, and use of drugs in the
2504 Medicaid program. The agency may seek federal waivers to
2505 implement this program.
2506 b. The drug management system must be designed to improve
2507 the quality of care and prescribing practices based on best
2508 practice guidelines, improve patient adherence to medication
2509 plans, reduce clinical risk, and lower prescribed drug costs and
2510 the rate of inappropriate spending on Medicaid prescription
2511 drugs. The program must:
2512 (I) Provide for the development and adoption of best
2513 practice guidelines for the prescribing and use of drugs in the
2514 Medicaid program, including translating best practice guidelines
2515 into practice; reviewing prescriber patterns and comparing them
2516 to indicators that are based on national standards and practice
2517 patterns of clinical peers in their community, statewide, and
2518 nationally; and determine deviations from best practice
2519 guidelines.
2520 (II) Implement processes for providing feedback to and
2521 educating prescribers using best practice educational materials
2522 and peer-to-peer consultation.
2523 (III) Assess Medicaid recipients who are outliers in their

2524 use of a single or multiple prescription drugs with regard to
2525 the numbers and types of drugs taken, drug dosages, combination
2526 drug therapies, and other indicators of improper use of
2527 prescription drugs.
2528 (IV) Alert prescribers to patients who fail to refill
2529 prescriptions in a timely fashion, are prescribed multiple drugs
2530 that may be redundant or contraindicated, or may have other
2531 potential medication problems.
2532 (V) Track spending trends for prescription drugs and
2533 deviation from best practice guidelines.
2534 (VI) Use educational and technological approaches to
2535 promote best practices, educate consumers, and train prescribers
2536 in the use of practice guidelines.
2537 (VII) Disseminate electronic and published materials.
2538 (VIII) Hold statewide and regional conferences.
2539 (IX) Implement disease management programs in cooperation
2540 with physicians and pharmacists, along with a model quality-
2541 based medication component for individuals having chronic
2542 medical conditions.
2543 13.~~12.~~ The agency is authorized to contract for drug rebate
2544 administration, including, but not limited to, calculating
2545 rebate amounts, invoicing manufacturers, negotiating disputes
2546 with manufacturers, and maintaining a database of rebate
2547 collections.
2548 14.~~13.~~ The agency may specify the preferred daily dosing
2549 form or strength for the purpose of promoting best practices
2550 with regard to the prescribing of certain drugs as specified in
2551 the General Appropriations Act and ensuring cost-effective
2552 prescribing practices.

2553 15.~~14.~~ The agency may require prior authorization for
2554 Medicaid-covered prescribed drugs. The agency may, but is not
2555 required to, prior-authorize the use of a product:
2556 a. For an indication not approved in labeling;
2557 b. To comply with certain clinical guidelines; or
2558 c. If the product has the potential for overuse, misuse, or
2559 abuse.
2560
2561 The agency may require the prescribing professional to provide
2562 information about the rationale and supporting medical evidence
2563 for the use of a drug. The agency may post prior authorization
2564 criteria and protocol and updates to the list of drugs that are
2565 subject to prior authorization on an Internet website without
2566 amending its rule or engaging in additional rulemaking.
2567 16.~~15.~~ The agency, in conjunction with the Pharmaceutical
2568 and Therapeutics Committee, may require age-related prior
2569 authorizations for certain prescribed drugs. The agency may
2570 preauthorize the use of a drug for a recipient who may not meet
2571 the age requirement or may exceed the length of therapy for use
2572 of this product as recommended by the manufacturer and approved
2573 by the Food and Drug Administration. Prior authorization may
2574 require the prescribing professional to provide information
2575 about the rationale and supporting medical evidence for the use
2576 of a drug.
2577 17.~~16.~~ The agency shall implement a step-therapy prior
2578 authorization approval process for medications excluded from the
2579 preferred drug list. Medications listed on the preferred drug
2580 list must be used within the previous 12 months prior to the
2581 alternative medications that are not listed. The step-therapy

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2582 prior authorization may require the prescriber to use the
2583 medications of a similar drug class or for a similar medical
2584 indication unless contraindicated in the Food and Drug
2585 Administration labeling. The trial period between the specified
2586 steps may vary according to the medical indication. The step-
2587 therapy approval process shall be developed in accordance with
2588 the committee as stated in s. 409.91195(7) and (8). A drug
2589 product may be approved without meeting the step-therapy prior
2590 authorization criteria if the prescribing physician provides the
2591 agency with additional written medical or clinical documentation
2592 that the product is medically necessary because:
2593 a. There is not a drug on the preferred drug list to treat
2594 the disease or medical condition which is an acceptable clinical
2595 alternative;
2596 b. The alternatives have been ineffective in the treatment
2597 of the beneficiary’s disease; or
2598 c. Based on historic evidence and known characteristics of
2599 the patient and the drug, the drug is likely to be ineffective,
2600 or the number of doses have been ineffective.
2601
2602 The agency shall work with the physician to determine the best
2603 alternative for the patient. The agency may adopt rules waiving
2604 the requirements for written clinical documentation for specific
2605 drugs in limited clinical situations.
2606 18.~~17.~~ The agency shall implement a return and reuse
2607 program for drugs dispensed by pharmacies to institutional
2608 recipients, which includes payment of a $5 restocking fee for
2609 the implementation and operation of the program. The return and
2610 reuse program shall be implemented electronically and in a

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2611 manner that promotes efficiency. The program must permit a
2612 pharmacy to exclude drugs from the program if it is not
2613 practical or cost-effective for the drug to be included and must
2614 provide for the return to inventory of drugs that cannot be
2615 credited or returned in a cost-effective manner. The agency
2616 shall determine if the program has reduced the amount of
2617 Medicaid prescription drugs which are destroyed on an annual
2618 basis and if there are additional ways to ensure more
2619 prescription drugs are not destroyed which could safely be
2620 reused. The agency's conclusion and recommendations shall be
2621 reported to the Legislature by December 1, 2005.
2622 Section 68. Subsections (3) and (4) of section 429.07,
2623 Florida Statutes, are amended, and subsections (6) and (7) are
2624 added to that section, to read:
2625 429.07 License required; fee; inspections.—
2626 (3) In addition to the requirements of s. 408.806, each
2627 license granted by the agency must state the type of care for
2628 which the license is granted. Licenses shall be issued for one
2629 or more of the following categories of care: standard, extended
2630 congregate care, ~~limited nursing services,~~ or limited mental
2631 health.
2632 (a) A standard license shall be issued to a facility
2633 ~~facilities~~ providing one or more of the personal services
2634 identified in s. 429.02. Such licensee ~~facilities~~ may also
2635 employ or contract with a person ~~licensed under part I of~~
2636 ~~chapter 464~~ to ~~administer medications and~~ perform other tasks as
2637 specified in s. 429.255.
2638 (b) An extended congregate care license shall be issued to
2639 a licensee ~~facilities~~ providing, directly or through contract,

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2640 services beyond those authorized in paragraph (a), including
2641 acts performed pursuant to part I of chapter 464 by persons
2642 licensed thereunder, and supportive services defined by rule to
2643 persons who otherwise would be disqualified from continued
2644 residence in a facility licensed under this part.
2645 1. In order for extended congregate care services to be
2646 provided in a facility licensed under this part, the agency must
2647 first determine that all requirements established in law and
2648 rule are met and must specifically designate, on the ~~facility's~~
2649 license, that such services may be provided and whether the
2650 designation applies to all or part of a facility. Such
2651 designation may be made at the time of initial licensure or
2652 relicensure, or upon request in writing by a licensee under this
2653 part and part II of chapter 408. Notification of approval or
2654 denial of such request shall be made in accordance with part II
2655 of chapter 408. An existing licensee ~~facilities~~ qualifying to
2656 provide extended congregate care services must have maintained a
2657 standard license and ~~may~~ not ~~have~~ been subject to administrative
2658 sanctions during the previous 2 years, or since initial
2659 licensure if ~~the facility has been~~ licensed for less than 2
2660 years, for any of the following reasons:
2661 a. A class I or class II violation;
2662 b. Three or more repeat or recurring class III violations
2663 of identical or similar resident care standards as specified in
2664 rule from which a pattern of noncompliance is found by the
2665 agency;
2666 c. Three or more class III violations that were not
2667 corrected in accordance with the corrective action plan approved
2668 by the agency;

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2669 d. Violation of resident care standards resulting in a
2670 requirement to employ the services of a consultant pharmacist or
2671 consultant dietitian;
2672 e. Denial, suspension, or revocation of a license for
2673 another facility under this part in which the applicant for an
2674 extended congregate care license has at least 25 percent
2675 ownership interest; or
2676 f. Imposition of a moratorium pursuant to this part or part
2677 II of chapter 408 or initiation of injunctive proceedings.
2678 2. A licensee ~~Facilities~~ that is ~~are~~ licensed to provide
2679 extended congregate care services shall maintain a written
2680 progress report for ~~on~~ each person who receives such services,
2681 and the ~~which~~ report must describe ~~describes~~ the type, amount,
2682 duration, scope, and outcome of services that are rendered and
2683 the general status of the resident’s health. ~~A registered nurse,~~
2684 ~~or appropriate designee, representing the agency shall visit~~
2685 ~~such facilities at least quarterly to monitor residents who are~~
2686 ~~receiving extended congregate care services and to determine if~~
2687 ~~the facility is in compliance with this part, part II of chapter~~
2688 ~~408, and rules that relate to extended congregate care. One of~~
2689 ~~these visits may be in conjunction with the regular survey. The~~
2690 ~~monitoring visits may be provided through contractual~~
2691 ~~arrangements with appropriate community agencies. A registered~~
2692 ~~nurse shall serve as part of the team that inspects such~~
2693 ~~facility. The agency may waive one of the required yearly~~
2694 ~~monitoring visits for a facility that has been licensed for at~~
2695 ~~least 24 months to provide extended congregate care services,~~
2696 ~~if, during the inspection, the registered nurse determines that~~
2697 ~~extended congregate care services are being provided~~

2698 ~~appropriately, and if the facility has no class I or class II~~
2699 ~~violations and no uncorrected class III violations. Before such~~
2700 ~~decision is made, the agency shall consult with the long-term~~
2701 ~~care ombudsman council for the area in which the facility is~~
2702 ~~located to determine if any complaints have been made and~~
2703 ~~substantiated about the quality of services or care. The agency~~
2704 ~~may not waive one of the required yearly monitoring visits if~~
2705 ~~complaints have been made and substantiated.~~
2706 3. <u>Licensees</u> ~~Facilities~~ that are licensed to provide
2707 extended congregate care services shall:
2708 a. Demonstrate the capability to meet unanticipated
2709 resident service needs.
2710 b. Offer a physical environment that promotes a homelike
2711 setting, provides for resident privacy, promotes resident
2712 independence, and allows sufficient congregate space as defined
2713 by rule.
2714 c. Have sufficient staff available, taking into account the
2715 physical plant and firesafety features of the building, to
2716 assist with the evacuation of residents in an emergency, as
2717 necessary.
2718 d. Adopt and follow policies and procedures that maximize
2719 resident independence, dignity, choice, and decisionmaking to
2720 permit residents to age in place to the extent possible, so that
2721 moves due to changes in functional status are minimized or
2722 avoided.
2723 e. Allow residents or, if applicable, a resident's
2724 representative, designee, surrogate, guardian, or attorney in
2725 fact to make a variety of personal choices, participate in
2726 developing service plans, and share responsibility in

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2727 decisionmaking.

2728 f. Implement the concept of managed risk.

2729 g. Provide, either directly or through contract, the
2730 services of a person licensed pursuant to part I of chapter 464.

2731 h. In addition to the training mandated in s. 429.52,
2732 provide specialized training as defined by rule for facility
2733 staff.

2734 4. Licensees ~~Facilities~~ licensed to provide extended
2735 congregate care services are exempt from the criteria for
2736 continued residency as set forth in rules adopted under s.
2737 429.41. Licensees ~~Facilities so licensed~~ shall adopt their own
2738 requirements within guidelines for continued residency set forth
2739 by rule. However, such licensees ~~facilities~~ may not serve
2740 residents who require 24-hour nursing supervision. Licensees
2741 ~~Facilities~~ licensed to provide extended congregate care services
2742 shall provide each resident with a written copy of facility
2743 policies governing admission and retention.

2744 5. The primary purpose of extended congregate care services
2745 is to allow residents, as they become more impaired, the option
2746 of remaining in a familiar setting from which they would
2747 otherwise be disqualified for continued residency. A facility
2748 licensed to provide extended congregate care services may also
2749 admit an individual who exceeds the admission criteria for a
2750 facility with a standard license, if the individual is
2751 determined appropriate for admission to the extended congregate
2752 care facility.

2753 6. Before admission of an individual to a facility licensed
2754 to provide extended congregate care services, the individual
2755 must undergo a medical examination as provided in s. 429.26(4)

2756 and the facility must develop a preliminary service plan for the
2757 individual.
2758 7. When a licensee ~~facility~~ can no longer provide or
2759 arrange for services in accordance with the resident's service
2760 plan and needs and the licensee's ~~facility's~~ policy, the
2761 licensee ~~facility~~ shall make arrangements for relocating the
2762 person in accordance with s. 429.28(1)(k).
2763 8. Failure to provide extended congregate care services may
2764 result in denial of extended congregate care license renewal.
2765 ~~9. No later than January 1 of each year, the department, in~~
2766 ~~consultation with the agency, shall prepare and submit to the~~
2767 ~~Governor, the President of the Senate, the Speaker of the House~~
2768 ~~of Representatives, and the chairs of appropriate legislative~~
2769 ~~committees, a report on the status of, and recommendations~~
2770 ~~related to, extended congregate care services. The status report~~
2771 ~~must include, but need not be limited to, the following~~
2772 ~~information:~~
2773 ~~a. A description of the facilities licensed to provide such~~
2774 ~~services, including total number of beds licensed under this~~
2775 ~~part.~~
2776 ~~b. The number and characteristics of residents receiving~~
2777 ~~such services.~~
2778 ~~c. The types of services rendered that could not be~~
2779 ~~provided through a standard license.~~
2780 ~~d. An analysis of deficiencies cited during licensure~~
2781 ~~inspections.~~
2782 ~~e. The number of residents who required extended congregate~~
2783 ~~care services at admission and the source of admission.~~
2784 ~~f. Recommendations for statutory or regulatory changes.~~

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2785 ~~g. The availability of extended congregate care to state~~
2786 ~~clients residing in facilities licensed under this part and in~~
2787 ~~need of additional services, and recommendations for~~
2788 ~~appropriations to subsidize extended congregate care services~~
2789 ~~for such persons.~~
2790 ~~h. Such other information as the department considers~~
2791 ~~appropriate.~~
2792 ~~(c) A limited nursing services license shall be issued to a~~
2793 ~~facility that provides services beyond those authorized in~~
2794 ~~paragraph (a) and as specified in this paragraph.~~
2795 ~~1. In order for limited nursing services to be provided in~~
2796 ~~a facility licensed under this part, the agency must first~~
2797 ~~determine that all requirements established in law and rule are~~
2798 ~~met and must specifically designate, on the facility's license,~~
2799 ~~that such services may be provided. Such designation may be made~~
2800 ~~at the time of initial licensure or relicensure, or upon request~~
2801 ~~in writing by a licensee under this part and part II of chapter~~
2802 ~~408. Notification of approval or denial of such request shall be~~
2803 ~~made in accordance with part II of chapter 408. Existing~~
2804 ~~facilities qualifying to provide limited nursing services shall~~
2805 ~~have maintained a standard license and may not have been subject~~
2806 ~~to administrative sanctions that affect the health, safety, and~~
2807 ~~welfare of residents for the previous 2 years or since initial~~
2808 ~~licensure if the facility has been licensed for less than 2~~
2809 ~~years.~~
2810 ~~2. Facilities that are licensed to provide limited nursing~~
2811 ~~services shall maintain a written progress report on each person~~
2812 ~~who receives such nursing services, which report describes the~~
2813 ~~type, amount, duration, scope, and outcome of services that are~~

2814 ~~rendered and the general status of the resident's health. A~~
2815 ~~registered nurse representing the agency shall visit such~~
2816 ~~facilities at least twice a year to monitor residents who are~~
2817 ~~receiving limited nursing services and to determine if the~~
2818 ~~facility is in compliance with applicable provisions of this~~
2819 ~~part, part II of chapter 408, and related rules. The monitoring~~
2820 ~~visits may be provided through contractual arrangements with~~
2821 ~~appropriate community agencies. A registered nurse shall also~~
2822 ~~serve as part of the team that inspects such facility.~~
2823 ~~3. A person who receives limited nursing services under~~
2824 ~~this part must meet the admission criteria established by the~~
2825 ~~agency for assisted living facilities. When a resident no longer~~
2826 ~~meets the admission criteria for a facility licensed under this~~
2827 ~~part, arrangements for relocating the person shall be made in~~
2828 ~~accordance with s. 429.28(1)(k), unless the facility is licensed~~
2829 ~~to provide extended congregate care services.~~
2830 (4) In accordance with s. 408.805, an applicant or licensee
2831 shall pay a fee for each license application submitted under
2832 this part, part II of chapter 408, and applicable rules. The
2833 amount of the fee shall be established by rule.
2834 (a) The biennial license fee required of a facility is <u>$356</u>
2835 ~~$300~~ per license, with an additional fee of <u>$67.50</u> ~~$50~~ per
2836 resident based on the total licensed resident capacity of the
2837 facility, except that no additional fee will be assessed for
2838 beds designated for recipients of optional state supplementation
2839 payments provided for in s. 409.212. The total fee may not
2840 exceed <u>$18,000</u> ~~$10,000~~.
2841 (b) In addition to the total fee assessed under paragraph
2842 (a), the agency shall require facilities that are licensed to

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2843 provide extended congregate care services under this part to pay
2844 an additional fee per licensed facility. The amount of the
2845 biennial fee shall be $501 ~~$400~~ per license, with an additional
2846 fee of $10 per resident based on the total licensed resident
2847 capacity of the facility.
2848 ~~(c) In addition to the total fee assessed under paragraph~~
2849 ~~(a), the agency shall require facilities that are licensed to~~
2850 ~~provide limited nursing services under this part to pay an~~
2851 ~~additional fee per licensed facility. The amount of the biennial~~
2852 ~~fee shall be $250 per license, with an additional fee of $10 per~~
2853 ~~resident based on the total licensed resident capacity of the~~
2854 ~~facility.~~
2855 (6) In order to determine whether the facility is
2856 adequately protecting residents' rights as provided in s.
2857 429.28, the biennial survey shall include private informal
2858 conversations with a sample of residents and consultation with
2859 the ombudsman council in the planning and service area in which
2860 the facility is located to discuss residents' experiences within
2861 the facility.
2862 (7) An assisted living facility that has been cited within
2863 the previous 24-month period for a class I or class II
2864 violation, regardless of the status of any enforcement or
2865 disciplinary action, is subject to periodic unannounced
2866 monitoring to determine if the facility is in compliance with
2867 this part, part II of chapter 408, and applicable rules.
2868 Monitoring may occur through a desk review or an onsite
2869 assessment. If the class I or class II violation relates to
2870 providing or failing to provide nursing care, a registered nurse
2871 must participate in at least two onsite monitoring visits within

2872 a 12-month period.
2873 Section 69. Subsection (7) of section 429.11, Florida
2874 Statutes, is renumbered as subsection (6), and present
2875 subsection (6) of that section is amended to read:
2876 429.11 Initial application for license~~; provisional~~
2877 ~~license~~.—
2878 ~~(6) In addition to the license categories available in s.~~
2879 ~~408.808, a provisional license may be issued to an applicant~~
2880 ~~making initial application for licensure or making application~~
2881 ~~for a change of ownership. A provisional license shall be~~
2882 ~~limited in duration to a specific period of time not to exceed 6~~
2883 ~~months, as determined by the agency.~~
2884 Section 70. Section 429.12, Florida Statutes, is amended to
2885 read:
2886 429.12 Sale or transfer of ownership of a facility.—It is
2887 the intent of the Legislature to protect the rights of the
2888 residents of an assisted living facility when the facility is
2889 sold or the ownership thereof is transferred. Therefore, in
2890 addition to the requirements of part II of chapter 408, whenever
2891 a facility is sold or the ownership thereof is transferred,
2892 including leasing~~:~~.
2893 ~~(1)~~ The transferee shall notify the residents, in writing,
2894 of the change of ownership within 7 days after receipt of the
2895 new license.
2896 ~~(2) The transferor of a facility the license of which is~~
2897 ~~denied pending an administrative hearing shall, as a part of the~~
2898 ~~written change-of-ownership contract, advise the transferee that~~
2899 ~~a plan of correction must be submitted by the transferee and~~
2900 ~~approved by the agency at least 7 days before the change of~~

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2901 ~~ownership and that failure to correct the condition which~~
2902 ~~resulted in the moratorium pursuant to part II of chapter 408 or~~
2903 ~~denial of licensure is grounds for denial of the transferee's~~
2904 ~~license.~~
2905 Section 71. Paragraphs (b) through (l) of subsection (1) of
2906 section 429.14, Florida Statutes, are redesignated as paragraphs
2907 (a) through (k), respectively, and present paragraph (a) of
2908 subsection (1) and subsections (5) and (6) of that section are
2909 amended to read:
2910 429.14 Administrative penalties.—
2911 (1) In addition to the requirements of part II of chapter
2912 408, the agency may deny, revoke, and suspend any license issued
2913 under this part and impose an administrative fine in the manner
2914 provided in chapter 120 against a licensee of an assisted living
2915 facility for a violation of any provision of this part, part II
2916 of chapter 408, or applicable rules, or for any of the following
2917 actions by a licensee of an assisted living facility, for the
2918 actions of any person subject to level 2 background screening
2919 under s. 408.809, or for the actions of any facility employee:
2920 ~~(a) An intentional or negligent act seriously affecting the~~
2921 ~~health, safety, or welfare of a resident of the facility.~~
2922 (5) An action taken by the agency to suspend, deny, or
2923 revoke a facility's license under this part or part II of
2924 chapter 408, in which the agency claims that the facility owner
2925 or an employee of the facility has threatened the health,
2926 safety, or welfare of a resident of the facility <u>shall</u> be heard
2927 by the Division of Administrative Hearings of the Department of
2928 Management Services within 120 days after receipt of the
2929 facility's request for a hearing, unless that time limitation is

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2930 waived by both parties. The administrative law judge must render
2931 a decision within 30 days after receipt of a proposed
2932 recommended order.
2933 (6) The agency shall provide to the Division of Hotels and
2934 Restaurants of the Department of Business and Professional
2935 Regulation, on a monthly basis, a list of those assisted living
2936 facilities that have had their licenses denied, suspended, or
2937 revoked or that are involved in an appellate proceeding pursuant
2938 to s. 120.60 related to the denial, suspension, or revocation of
2939 a license. This information may be provided electronically or
2940 through the agency’s Internet website.
2941 Section 72. Subsections (1), (4), and (5) of section
2942 429.17, Florida Statutes, are amended to read:
2943 429.17 Expiration of license; renewal; conditional
2944 license.—
2945 (1) ~~Limited nursing,~~ Extended congregate care~~,~~ and limited
2946 mental health licenses shall expire at the same time as the
2947 facility’s standard license, regardless of when issued.
2948 (4) In addition to the license categories available in s.
2949 408.808, a conditional license may be issued to an applicant for
2950 license renewal if the applicant fails to meet all standards and
2951 requirements for licensure. A conditional license issued under
2952 this subsection shall be limited in duration to a specific
2953 period of time not to exceed 6 months, as determined by the
2954 agency~~, and shall be accompanied by an agency-approved plan of~~
2955 ~~correction~~.
2956 (5) When an extended congregate care ~~or limited nursing~~
2957 ~~license~~ is requested during a facility’s biennial license
2958 period, the fee shall be prorated in order to permit the

2959 additional license to expire at the end of the biennial license
2960 period. The fee shall be calculated as of the date the
2961 additional license application is received by the agency.
2962 Section 73. Subsection (7) of section 429.19, Florida
2963 Statutes, is amended to read:
2964 429.19 Violations; imposition of administrative fines;
2965 grounds.—
2966 (7) In addition to any administrative fines imposed, the
2967 agency may assess a survey or monitoring fee, equal to the
2968 lesser of one half of the facility’s biennial license and bed
2969 fee or $500, to cover the cost of conducting initial complaint
2970 investigations that result in the finding of a violation that
2971 was the subject of the complaint or to monitor the health,
2972 safety, or security of residents under s. 429.07(7) ~~monitoring~~
2973 ~~visits conducted under s. 429.28(3)(c) to verify the correction~~
2974 ~~of the violations~~.
2975 Section 74. Subsections (6) through (10) of section 429.23,
2976 Florida Statutes, are renumbered as subsections (5) through (9),
2977 respectively, and present subsection (5) of that section is
2978 amended to read:
2979 429.23 Internal risk management and quality assurance
2980 program; adverse incidents and reporting requirements.—
2981 ~~(5) Each facility shall report monthly to the agency any~~
2982 ~~liability claim filed against it. The report must include the~~
2983 ~~name of the resident, the dates of the incident leading to the~~
2984 ~~claim, if applicable, and the type of injury or violation of~~
2985 ~~rights alleged to have occurred. This report is not discoverable~~
2986 ~~in any civil or administrative action, except in such actions~~
2987 ~~brought by the agency to enforce the provisions of this part.~~

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2988 Section 75. Paragraph (a) of subsection (1) and subsection
2989 (2) of section 429.255, Florida Statutes, are amended to read:
2990 429.255 Use of personnel; emergency care.—
2991 (1)(a) Persons under contract to the facility or~~,~~ facility
2992 staff~~, or volunteers,~~ who are licensed according to part I of
2993 chapter 464, or those persons exempt under s. 464.022(1), and
2994 others as defined by rule, may administer medications to
2995 residents, take residents' vital signs, manage individual weekly
2996 pill organizers for residents who self-administer medication,
2997 give prepackaged enemas ordered by a physician, observe
2998 residents, document observations on the appropriate resident's
2999 record, report observations to the resident's physician, and
3000 contract or allow residents or a resident's representative,
3001 designee, surrogate, guardian, or attorney in fact to contract
3002 with a third party, provided residents meet the criteria for
3003 appropriate placement as defined in s. 429.26. Persons under
3004 contract to the facility or facility staff who are licensed
3005 according to part I of chapter 464 may provide limited nursing
3006 services. Nursing assistants certified pursuant to part II of
3007 chapter 464 may take residents' vital signs as directed by a
3008 licensed nurse or physician. The facility is responsible for
3009 maintaining documentation of services provided under this
3010 paragraph as required by rule and ensuring that staff are
3011 adequately trained to monitor residents receiving these
3012 services.
3013 (2) In facilities licensed to provide extended congregate
3014 care, persons under contract to the facility or~~,~~ facility staff~~,~~
3015 ~~or volunteers,~~ who are licensed according to part I of chapter
3016 464, or those persons exempt under s. 464.022(1), or those

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3017 persons certified as nursing assistants pursuant to part II of
3018 chapter 464, may also perform all duties within the scope of
3019 their license or certification, as approved by the facility
3020 administrator and pursuant to this part.
3021 Section 76. Subsection (3) of section 429.28, Florida
3022 Statutes, is amended to read:
3023 429.28 Resident bill of rights.—
3024 ~~(3)(a) The agency shall conduct a survey to determine~~
3025 ~~general compliance with facility standards and compliance with~~
3026 ~~residents' rights as a prerequisite to initial licensure or~~
3027 ~~licensure renewal.~~
3028 ~~(b) In order to determine whether the facility is~~
3029 ~~adequately protecting residents' rights, the biennial survey~~
3030 ~~shall include private informal conversations with a sample of~~
3031 ~~residents and consultation with the ombudsman council in the~~
3032 ~~planning and service area in which the facility is located to~~
3033 ~~discuss residents' experiences within the facility.~~
3034 ~~(c) During any calendar year in which no survey is~~
3035 ~~conducted, the agency shall conduct at least one monitoring~~
3036 ~~visit of each facility cited in the previous year for a class I~~
3037 ~~or class II violation, or more than three uncorrected class III~~
3038 ~~violations.~~
3039 ~~(d) The agency may conduct periodic followup inspections as~~
3040 ~~necessary to monitor the compliance of facilities with a history~~
3041 ~~of any class I, class II, or class III violations that threaten~~
3042 ~~the health, safety, or security of residents.~~
3043 ~~(e) The agency may conduct complaint investigations as~~
3044 ~~warranted to investigate any allegations of noncompliance with~~
3045 ~~requirements required under this part or rules adopted under~~

3046 ~~this part.~~

3047 Section 77. Subsection (2) of section 429.35, Florida
3048 Statutes, is amended to read:
3049 429.35 Maintenance of records; reports.—
3050 (2) Within 60 days after the date of the biennial
3051 inspection visit required under s. 408.811 or within 30 days
3052 after the date of any interim visit, the agency shall forward
3053 the results of the inspection to the local ombudsman council in
3054 whose planning and service area, as defined in part II of
3055 chapter 400, the facility is located; to at least one public
3056 library or, in the absence of a public library, the county seat
3057 in the county in which the inspected assisted living facility is
3058 located; and, when appropriate, to the district Adult Services
3059 and Mental Health Program Offices. This information may be
3060 provided electronically or through the agency's Internet
3061 website.

3062 Section 78. Paragraphs (i) and (j) of subsection (1) of
3063 section 429.41, Florida Statutes, are amended to read:
3064 429.41 Rules establishing standards.—
3065 (1) It is the intent of the Legislature that rules
3066 published and enforced pursuant to this section shall include
3067 criteria by which a reasonable and consistent quality of
3068 resident care and quality of life may be ensured and the results
3069 of such resident care may be demonstrated. Such rules shall also
3070 ensure a safe and sanitary environment that is residential and
3071 noninstitutional in design or nature. It is further intended
3072 that reasonable efforts be made to accommodate the needs and
3073 preferences of residents to enhance the quality of life in a
3074 facility. The agency, in consultation with the department, may

3075 adopt rules to administer the requirements of part II of chapter
3076 408. In order to provide safe and sanitary facilities and the
3077 highest quality of resident care accommodating the needs and
3078 preferences of residents, the department, in consultation with
3079 the agency, the Department of Children and Family Services, and
3080 the Department of Health, shall adopt rules, policies, and
3081 procedures to administer this part, which must include
3082 reasonable and fair minimum standards in relation to:
3083 (i) Facilities holding an ~~a limited nursing,~~ extended
3084 congregate care~~,~~ or limited mental health license.
3085 (j) The establishment of specific criteria to define
3086 appropriateness of resident admission and continued residency in
3087 a facility holding a standard, ~~limited nursing,~~ extended
3088 congregate care, and limited mental health license.
3089 Section 79. Subsections (1) and (2) of section 429.53,
3090 Florida Statutes, are amended to read:
3091 429.53 Consultation by the agency.—
3092 (1) The ~~area offices of licensure and certification of the~~
3093 agency shall provide consultation to the following upon request:
3094 (a) A licensee of a facility.
3095 (b) A person interested in obtaining a license to operate a
3096 facility under this part.
3097 (2) As used in this section, "consultation" includes:
3098 (a) An explanation of the requirements of this part and
3099 rules adopted pursuant thereto;
3100 (b) An explanation of the license application and renewal
3101 procedures;
3102 ~~(c) The provision of a checklist of general local and state~~
3103 ~~approvals required prior to constructing or developing a~~

~~facility and a listing of the types of agencies responsible for such approvals;~~

~~(d) An explanation of benefits and financial assistance available to a recipient of supplemental security income residing in a facility;~~

(c)~~(e)~~ Any other information which the agency deems necessary to promote compliance with the requirements of this part; and

~~(f) A preconstruction review of a facility to ensure compliance with agency rules and this part.~~

Section 80. Subsections (1) and (2) of section 429.54, Florida Statutes, are renumbered as subsections (2) and (3), respectively, and a new subsection (1) is added to that section to read:

429.54 Collection of information; local subsidy.—

(1) A facility that is licensed under this part must report electronically to the agency semiannually data related to the facility, including, but not limited to, the total number of residents, the number of residents who are receiving limited mental health services, the number of residents who are receiving extended congregate care services, the number of residents who are receiving limited nursing services, and professional staffing employed by or under contract with the licensee to provide resident services. The department, in consultation with the agency, shall adopt rules to administer this subsection.

Section 81. Subsections (1) and (5) of section 429.71, Florida Statutes, are amended to read:

429.71 Classification of violations ~~deficiencies~~;

3133 administrative fines.—

3134 (1) In addition to the requirements of part II of chapter
3135 408 and in addition to any other liability or penalty provided
3136 by law, the agency may impose an administrative fine on a
3137 provider according to the following classification:

3138 (a) Class I violations are <u>defined in s. 408.813</u> ~~those~~
3139 ~~conditions or practices related to the operation and maintenance~~
3140 ~~of an adult family-care home or to the care of residents which~~
3141 ~~the agency determines present an imminent danger to the~~
3142 ~~residents or guests of the facility or a substantial probability~~
3143 ~~that death or serious physical or emotional harm would result~~
3144 ~~therefrom. The condition or practice that constitutes a class I~~
3145 ~~violation must be abated or eliminated within 24 hours, unless a~~
3146 ~~fixed period, as determined by the agency, is required for~~
3147 ~~correction~~. A class I <u>violation</u> ~~deficiency~~ is subject to an
3148 administrative fine in an amount not less than $500 and not
3149 exceeding $1,000 for each violation. ~~A fine may be levied~~
3150 ~~notwithstanding the correction of the deficiency.~~

3151 (b) Class II violations are <u>defined in s. 408.813</u> ~~those~~
3152 ~~conditions or practices related to the operation and maintenance~~
3153 ~~of an adult family-care home or to the care of residents which~~
3154 ~~the agency determines directly threaten the physical or~~
3155 ~~emotional health, safety, or security of the residents, other~~
3156 ~~than class I violations~~. A class II violation is subject to an
3157 administrative fine in an amount not less than $250 and not
3158 exceeding $500 for each violation. ~~A citation for a class II~~
3159 ~~violation must specify the time within which the violation is~~
3160 ~~required to be corrected. If a class II violation is corrected~~
3161 ~~within the time specified, no civil penalty shall be imposed,~~

3162 ~~unless it is a repeated offense.~~
3163 (c) Class III violations are defined in s. 408.813 ~~those~~
3164 ~~conditions or practices related to the operation and maintenance~~
3165 ~~of an adult family-care home or to the care of residents which~~
3166 ~~the agency determines indirectly or potentially threaten the~~
3167 ~~physical or emotional health, safety, or security of residents,~~
3168 ~~other than class I or class II violations~~. A class III violation
3169 is subject to an administrative fine in an amount not less than
3170 $100 and not exceeding $250 for each violation. ~~A citation for a~~
3171 ~~class III violation shall specify the time within which the~~
3172 ~~violation is required to be corrected.~~ If a class III violation
3173 is corrected within the time specified, no civil penalty shall
3174 be imposed, unless it is a repeated violation ~~offense~~.
3175 (d) Class IV violations are defined in s. 408.813 ~~those~~
3176 ~~conditions or occurrences related to the operation and~~
3177 ~~maintenance of an adult family-care home, or related to the~~
3178 ~~required reports, forms, or documents, which do not have the~~
3179 ~~potential of negatively affecting the residents~~. ~~A provider that~~
3180 ~~does not correct~~ A class IV violation ~~within the time limit~~
3181 ~~specified by the agency~~ is subject to an administrative fine in
3182 an amount not less than $50 and not exceeding $100 for each
3183 violation. Any class IV violation that is corrected during the
3184 time the agency survey is conducted will be identified as an
3185 agency finding and not as a violation, unless it is a repeat
3186 violation.
3187 ~~(5) As an alternative to or in conjunction with an~~
3188 ~~administrative action against a provider, the agency may request~~
3189 ~~a plan of corrective action that demonstrates a good faith~~
3190 ~~effort to remedy each violation by a specific date, subject to~~

3191 ~~the approval of the agency.~~
3192 Section 82. Paragraphs (b) through (e) of subsection (2) of
3193 section 429.911, Florida Statutes, are redesignated as
3194 paragraphs (a) through (d), respectively, and present paragraph
3195 (a) of that subsection is amended to read:
3196 429.911 Denial, suspension, revocation of license;
3197 emergency action; administrative fines; investigations and
3198 inspections.—
3199 (2) Each of the following actions by the owner of an adult
3200 day care center or by its operator or employee is a ground for
3201 action by the agency against the owner of the center or its
3202 operator or employee:
3203 ~~(a) An intentional or negligent act materially affecting~~
3204 ~~the health or safety of center participants.~~
3205 Section 83. Section 429.915, Florida Statutes, is amended
3206 to read:
3207 429.915 Conditional license.—In addition to the license
3208 categories available in part II of chapter 408, the agency may
3209 issue a conditional license to an applicant for license renewal
3210 or change of ownership if the applicant fails to meet all
3211 standards and requirements for licensure. A conditional license
3212 issued under this subsection must be limited to a specific
3213 period not exceeding 6 months, as determined by the agency~~, and~~
3214 ~~must be accompanied by an approved plan of correction~~.
3215 Section 84. Paragraphs (b) and (h) of subsection (3) of
3216 section 430.80, Florida Statutes, are amended to read:
3217 430.80 Implementation of a teaching nursing home pilot
3218 project.—
3219 (3) To be designated as a teaching nursing home, a nursing

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3220 home licensee must, at a minimum:
3221 (b) Participate in a nationally recognized accreditation
3222 program and hold a valid accreditation, such as the
3223 accreditation awarded by The Joint Commission ~~on Accreditation~~
3224 ~~of Healthcare Organizations~~;
3225 (h) Maintain insurance coverage pursuant to s.
3226 400.141(1)(q) ~~(s)~~ or proof of financial responsibility in a
3227 minimum amount of $750,000. Such proof of financial
3228 responsibility may include:
3229 1. Maintaining an escrow account consisting of cash or
3230 assets eligible for deposit in accordance with s. 625.52; or
3231 2. Obtaining and maintaining pursuant to chapter 675 an
3232 unexpired, irrevocable, nontransferable and nonassignable letter
3233 of credit issued by any bank or savings association organized
3234 and existing under the laws of this state or any bank or savings
3235 association organized under the laws of the United States that
3236 has its principal place of business in this state or has a
3237 branch office which is authorized to receive deposits in this
3238 state. The letter of credit shall be used to satisfy the
3239 obligation of the facility to the claimant upon presentment of a
3240 final judgment indicating liability and awarding damages to be
3241 paid by the facility or upon presentment of a settlement
3242 agreement signed by all parties to the agreement when such final
3243 judgment or settlement is a result of a liability claim against
3244 the facility.
3245 Section 85. Paragraph (a) of subsection (2) of section
3246 440.13, Florida Statutes, is amended to read:
3247 440.13 Medical services and supplies; penalty for
3248 violations; limitations.—

3249 (2) MEDICAL TREATMENT; DUTY OF EMPLOYER TO FURNISH.—
3250 (a) Subject to the limitations specified elsewhere in this
3251 chapter, the employer shall furnish to the employee such
3252 medically necessary remedial treatment, care, and attendance for
3253 such period as the nature of the injury or the process of
3254 recovery may require, which is in accordance with established
3255 practice parameters and protocols of treatment as provided for
3256 in this chapter, including medicines, medical supplies, durable
3257 medical equipment, orthoses, prostheses, and other medically
3258 necessary apparatus. Remedial treatment, care, and attendance,
3259 including work-hardening programs or pain-management programs
3260 accredited by the Commission on Accreditation of Rehabilitation
3261 Facilities or The Joint Commission ~~on the Accreditation of~~
3262 ~~Health Organizations~~ or pain-management programs affiliated with
3263 medical schools, shall be considered as covered treatment only
3264 when such care is given based on a referral by a physician as
3265 defined in this chapter. Medically necessary treatment, care,
3266 and attendance does not include chiropractic services in excess
3267 of 24 treatments or rendered 12 weeks beyond the date of the
3268 initial chiropractic treatment, whichever comes first, unless
3269 the carrier authorizes additional treatment or the employee is
3270 catastrophically injured.
3271
3272 Failure of the carrier to timely comply with this subsection
3273 shall be a violation of this chapter and the carrier shall be
3274 subject to penalties as provided for in s. 440.525.
3275 Section 86. Subsection (11) is added to section 483.201,
3276 Florida Statutes, to read:
3277 483.201 Grounds for disciplinary action against clinical

3278 laboratories.—In addition to the requirements of part II of
3279 chapter 408, the following acts constitute grounds for which a
3280 disciplinary action specified in s. 483.221 may be taken against
3281 a clinical laboratory:
3282 (11) A blood establishment that collects blood or blood
3283 components from volunteer donors failing to disclose information
3284 concerning its activities as required by s. 381.06014. Each day
3285 of violation constitutes a separate violation and each separate
3286 violation is subject to a separate fine. If multiple licensed
3287 establishments operated by a single business entity fail to meet
3288 such disclosure requirements, the agency may assess fines
3289 against only one of the business entity's clinical laboratory
3290 licenses. The total administrative fine may not exceed $10,000
3291 for each annual reporting period.
3292 Section 87. Section 483.294, Florida Statutes, is amended
3293 to read:
3294 483.294 Inspection of centers.—In accordance with s.
3295 408.811, the agency shall biennially, at least once annually,
3296 inspect the premises and operations of all centers subject to
3297 licensure under this part.
3298 Section 88. Subsection (23) and paragraph (a) of subsection
3299 (53) of section 499.003, Florida Statutes, are amended to read:
3300 499.003 Definitions of terms used in this part.—As used in
3301 this part, the term:
3302 (23) "Health care entity" means a closed pharmacy or any
3303 person, organization, or business entity that provides
3304 diagnostic, medical, surgical, or dental treatment or care, or
3305 chronic or rehabilitative care, but does not include any
3306 wholesale distributor or retail pharmacy licensed under state

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3307 law to deal in prescription drugs. However, a blood
3308 establishment may be a health care entity and engage in the
3309 wholesale distribution of prescription drugs under s.
3310 499.01(2)(g)1.c.
3311 (53) "Wholesale distribution" means distribution of
3312 prescription drugs to persons other than a consumer or patient,
3313 but does not include:
3314 (a) Any of the following activities, which is not a
3315 violation of s. 499.005(21) if such activity is conducted in
3316 accordance with s. 499.01(2)(g):
3317 1. The purchase or other acquisition by a hospital or other
3318 health care entity that is a member of a group purchasing
3319 organization of a prescription drug for its own use from the
3320 group purchasing organization or from other hospitals or health
3321 care entities that are members of that organization.
3322 2. The sale, purchase, or trade of a prescription drug or
3323 an offer to sell, purchase, or trade a prescription drug by a
3324 charitable organization described in s. 501(c)(3) of the
3325 Internal Revenue Code of 1986, as amended and revised, to a
3326 nonprofit affiliate of the organization to the extent otherwise
3327 permitted by law.
3328 3. The sale, purchase, or trade of a prescription drug or
3329 an offer to sell, purchase, or trade a prescription drug among
3330 hospitals or other health care entities that are under common
3331 control. For purposes of this subparagraph, "common control"
3332 means the power to direct or cause the direction of the
3333 management and policies of a person or an organization, whether
3334 by ownership of stock, by voting rights, by contract, or
3335 otherwise.

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3336 4. The sale, purchase, trade, or other transfer of a
3337 prescription drug from or for any federal, state, or local
3338 government agency or any entity eligible to purchase
3339 prescription drugs at public health services prices pursuant to
3340 Pub. L. No. 102-585, s. 602 to a contract provider or its
3341 subcontractor for eligible patients of the agency or entity
3342 under the following conditions:
3343 a. The agency or entity must obtain written authorization
3344 for the sale, purchase, trade, or other transfer of a
3345 prescription drug under this subparagraph from the State Surgeon
3346 General or his or her designee.
3347 b. The contract provider or subcontractor must be
3348 authorized by law to administer or dispense prescription drugs.
3349 c. In the case of a subcontractor, the agency or entity
3350 must be a party to and execute the subcontract.
3351 ~~d. A contract provider or subcontractor must maintain~~
3352 ~~separate and apart from other prescription drug inventory any~~
3353 ~~prescription drugs of the agency or entity in its possession.~~
3354 d.~~e.~~ The contract provider and subcontractor must maintain
3355 and produce immediately for inspection all records of movement
3356 or transfer of all the prescription drugs belonging to the
3357 agency or entity, including, but not limited to, the records of
3358 receipt and disposition of prescription drugs. Each contractor
3359 and subcontractor dispensing or administering these drugs must
3360 maintain and produce records documenting the dispensing or
3361 administration. Records that are required to be maintained
3362 include, but are not limited to, a perpetual inventory itemizing
3363 drugs received and drugs dispensed by prescription number or
3364 administered by patient identifier, which must be submitted to

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3365 the agency or entity quarterly.
3366 e.~~f.~~ The contract provider or subcontractor may administer
3367 or dispense the prescription drugs only to the eligible patients
3368 of the agency or entity or must return the prescription drugs
3369 for or to the agency or entity. The contract provider or
3370 subcontractor must require proof from each person seeking to
3371 fill a prescription or obtain treatment that the person is an
3372 eligible patient of the agency or entity and must, at a minimum,
3373 maintain a copy of this proof as part of the records of the
3374 contractor or subcontractor required under sub-subparagraph d.
3375 ~~e.~~
3376 f.~~g.~~ In addition to the departmental inspection authority
3377 set forth in s. 499.051, the establishment of the contract
3378 provider and subcontractor and all records pertaining to
3379 prescription drugs subject to this subparagraph shall be subject
3380 to inspection by the agency or entity. All records relating to
3381 prescription drugs of a manufacturer under this subparagraph
3382 shall be subject to audit by the manufacturer of those drugs,
3383 without identifying individual patient information.
3384 Section 89. Subsection (21) of section 499.005, Florida
3385 Statutes, is amended to read:
3386 499.005 Prohibited acts.—It is unlawful for a person to
3387 perform or cause the performance of any of the following acts in
3388 this state:
3389 (21) The wholesale distribution of any prescription drug
3390 that was:
3391 (a) Purchased by a public or private hospital or other
3392 health care entity, except as authorized in s. 499.01(2)(g)1.c.;
3393 or

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3394 (b) Donated or supplied at a reduced price to a charitable
3395 organization.
3396 Section 90. Paragraphs (a) and (g) of subsection (2) of
3397 section 499.01, Florida Statutes, are amended to read:
3398 499.01 Permits.—
3399 (2) The following permits are established:
3400 (a) *Prescription drug manufacturer permit.*—A prescription
3401 drug manufacturer permit is required for any person that is a
3402 manufacturer of a prescription drug and that manufactures or
3403 distributes such prescription drugs in this state.
3404 1. A person that operates an establishment permitted as a
3405 prescription drug manufacturer may engage in wholesale
3406 distribution of prescription drugs manufactured at that
3407 establishment and must comply with all of the provisions of this
3408 part, except s. 499.01212, and the rules adopted under this
3409 part, except s. 499.01212, that apply to a wholesale
3410 distributor.
3411 2. A prescription drug manufacturer must comply with all
3412 appropriate state and federal good manufacturing practices.
3413 3. A blood establishment as defined in s. 381.06014,
3414 operating in a manner consistent with the provisions of Title 21
3415 C.F.R. Parts 211 and 600-640, and manufacturing only the
3416 prescription drugs described in s. 499.003(53)(d) is not
3417 required to be permitted as a prescription drug manufacturer
3418 under this paragraph or register products under s. 499.015.
3419 (g) *Restricted prescription drug distributor permit.*—
3420 1. A restricted prescription drug distributor permit is
3421 required for:
3422 a. Any person that engages in the distribution of a

3423 prescription drug, which distribution is not considered
3424 "wholesale distribution" under s. 499.003(53)(a).
3425 b.~~1.~~ Any ~~A~~ person who engages in the receipt or
3426 distribution of a prescription drug in this state for the
3427 purpose of processing its return or its destruction ~~must obtain~~
3428 ~~a permit as a restricted prescription drug distributor~~ if such
3429 person is not the person initiating the return, the prescription
3430 drug wholesale supplier of the person initiating the return, or
3431 the manufacturer of the drug.
3432 c. A blood establishment located in this state that
3433 collects blood and blood components only from volunteer donors
3434 as defined in s. 381.06014 or pursuant to an authorized
3435 practitioner's order for medical treatment or therapy and
3436 engages in the wholesale distribution of a prescription drug not
3437 described in s. 499.003(53)(d) to a health care entity. The
3438 health care entity receiving a prescription drug distributed
3439 under this sub-subparagraph must be licensed as a closed
3440 pharmacy or provide health care services at that establishment.
3441 The blood establishment must operate in accordance with s.
3442 381.06014 and may distribute only:
3443 (I) Prescription drugs indicated for a bleeding or clotting
3444 disorder or anemia;
3445 (II) Blood-collection containers approved under s. 505 of
3446 the federal act;
3447 (III) Drugs that are blood derivatives, or a recombinant or
3448 synthetic form of a blood derivative; or
3449 (IV) Prescription drugs identified in rules adopted by the
3450 department which are essential to services performed or provided
3451 by blood establishments and authorized for distribution by blood

3452 establishments under federal law,

3453

3454 as long as all of the health care services provided by the blood
3455 establishment are related to its activities as a registered
3456 blood establishment or the health care services consist of
3457 collecting, processing, storing, or administering human
3458 hematopoietic stem cells or progenitor cells or performing
3459 diagnostic testing of specimens if such specimens are tested
3460 together with specimens undergoing routine donor testing.

3461 2. Storage, handling, and recordkeeping of these
3462 distributions by a person permitted as a restricted prescription
3463 drug distributor must comply with the requirements for wholesale
3464 distributors under s. 499.0121, but not those set forth in s.
3465 499.01212 if the distribution occurs pursuant to sub-
3466 subparagraph 1.a. or sub-subparagraph 1.b.

3467 3. A person who applies for a permit as a restricted
3468 prescription drug distributor, or for the renewal of such a
3469 permit, must provide to the department the information required
3470 under s. 499.012.

3471 4. The department may adopt rules regarding the
3472 distribution of prescription drugs by hospitals, health care
3473 entities, charitable organizations, or other persons not
3474 involved in wholesale distribution, and blood establishments;
3475 which rules are necessary for the protection of the public
3476 health, safety, and welfare. The department may adopt rules
3477 related to the transportation, storage, and recordkeeping of
3478 prescription drugs which are essential to services performed or
3479 provided by a blood establishment, including requirements for
3480 the use of prescription drugs in mobile blood-collection

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3481 vehicles.

3482 Section 91. Paragraph (i) is added to subsection (3) of
3483 section 499.01212, Florida Statutes, to read:

3484 499.01212 Pedigree paper.—

3485 (3) EXCEPTIONS.—A pedigree paper is not required for:

3486 (i) The wholesale distribution of prescription drugs
3487 contained within a sealed medical convenience kit if the kit:

3488 1. Is assembled in an establishment that is registered as a
3489 medical device manufacturer with the Food and Drug
3490 Administration; and

3491 2. Does not contain any controlled substance that appears
3492 in any schedule contained in or subject to chapter 893 or the
3493 federal Comprehensive Drug Abuse Prevention and Control Act of
3494 1970.

3495 Section 92. Subsection (1) of section 627.645, Florida
3496 Statutes, is amended to read:

3497 627.645 Denial of health insurance claims restricted.—

3498 (1) No claim for payment under a health insurance policy or
3499 self-insured program of health benefits for treatment, care, or
3500 services in a licensed hospital which is accredited by The Joint
3501 Commission ~~on the Accreditation of Hospitals~~, the American
3502 Osteopathic Association, or the Commission on the Accreditation
3503 of Rehabilitative Facilities shall be denied because such
3504 hospital lacks major surgical facilities and is primarily of a
3505 rehabilitative nature, if such rehabilitation is specifically
3506 for treatment of physical disability.

3507 Section 93. Paragraph (c) of subsection (2) of section
3508 627.668, Florida Statutes, is amended to read:

3509 627.668 Optional coverage for mental and nervous disorders

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3510 required; exception.—
3511 (2) Under group policies or contracts, inpatient hospital
3512 benefits, partial hospitalization benefits, and outpatient
3513 benefits consisting of durational limits, dollar amounts,
3514 deductibles, and coinsurance factors shall not be less favorable
3515 than for physical illness generally, except that:
3516 (c) Partial hospitalization benefits shall be provided
3517 under the direction of a licensed physician. For purposes of
3518 this part, the term “partial hospitalization services” is
3519 defined as those services offered by a program accredited by The
3520 Joint Commission ~~on Accreditation of Hospitals (JCAH)~~ or in
3521 compliance with equivalent standards. Alcohol rehabilitation
3522 programs accredited by The Joint Commission ~~on Accreditation of~~
3523 ~~Hospitals~~ or approved by the state and licensed drug abuse
3524 rehabilitation programs shall also be qualified providers under
3525 this section. In any benefit year, if partial hospitalization
3526 services or a combination of inpatient and partial
3527 hospitalization are utilized, the total benefits paid for all
3528 such services shall not exceed the cost of 30 days of inpatient
3529 hospitalization for psychiatric services, including physician
3530 fees, which prevail in the community in which the partial
3531 hospitalization services are rendered. If partial
3532 hospitalization services benefits are provided beyond the limits
3533 set forth in this paragraph, the durational limits, dollar
3534 amounts, and coinsurance factors thereof need not be the same as
3535 those applicable to physical illness generally.
3536 Section 94. Subsection (3) of section 627.669, Florida
3537 Statutes, is amended to read:
3538 627.669 Optional coverage required for substance abuse

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3539 impaired persons; exception.—
3540 (3) The benefits provided under this section shall be
3541 applicable only if treatment is provided by, or under the
3542 supervision of, or is prescribed by, a licensed physician or
3543 licensed psychologist and if services are provided in a program
3544 accredited by The Joint Commission ~~on Accreditation of Hospitals~~
3545 or approved by the state.
3546 Section 95. Paragraph (a) of subsection (1) of section
3547 627.736, Florida Statutes, is amended to read:
3548 627.736 Required personal injury protection benefits;
3549 exclusions; priority; claims.—
3550 (1) REQUIRED BENEFITS.—Every insurance policy complying
3551 with the security requirements of s. 627.733 shall provide
3552 personal injury protection to the named insured, relatives
3553 residing in the same household, persons operating the insured
3554 motor vehicle, passengers in such motor vehicle, and other
3555 persons struck by such motor vehicle and suffering bodily injury
3556 while not an occupant of a self-propelled vehicle, subject to
3557 the provisions of subsection (2) and paragraph (4)(e), to a
3558 limit of $10,000 for loss sustained by any such person as a
3559 result of bodily injury, sickness, disease, or death arising out
3560 of the ownership, maintenance, or use of a motor vehicle as
3561 follows:
3562 (a) *Medical benefits.*—Eighty percent of all reasonable
3563 expenses for medically necessary medical, surgical, X-ray,
3564 dental, and rehabilitative services, including prosthetic
3565 devices, and medically necessary ambulance, hospital, and
3566 nursing services. However, the medical benefits shall provide
3567 reimbursement only for such services and care that are lawfully

3568 provided, supervised, ordered, or prescribed by a physician
3569 licensed under chapter 458 or chapter 459, a dentist licensed
3570 under chapter 466, or a chiropractic physician licensed under
3571 chapter 460 or that are provided by any of the following persons
3572 or entities:
3573 1. A hospital or ambulatory surgical center licensed under
3574 chapter 395.
3575 2. A person or entity licensed under ss. 401.2101-401.45
3576 that provides emergency transportation and treatment.
3577 3. An entity wholly owned by one or more physicians
3578 licensed under chapter 458 or chapter 459, chiropractic
3579 physicians licensed under chapter 460, or dentists licensed
3580 under chapter 466 or by such practitioner or practitioners and
3581 the spouse, parent, child, or sibling of that practitioner or
3582 those practitioners.
3583 4. An entity wholly owned, directly or indirectly, by a
3584 hospital or hospitals.
3585 5. A health care clinic licensed under ss. 400.990-400.995
3586 that is:
3587 a. Accredited by The Joint Commission ~~on Accreditation of~~
3588 ~~Healthcare Organizations~~, the American Osteopathic Association,
3589 the Commission on Accreditation of Rehabilitation Facilities, or
3590 the Accreditation Association for Ambulatory Health Care, Inc.;
3591 or
3592 b. A health care clinic that:
3593 (I) Has a medical director licensed under chapter 458,
3594 chapter 459, or chapter 460;
3595 (II) Has been continuously licensed for more than 3 years
3596 or is a publicly traded corporation that issues securities

3597 traded on an exchange registered with the United States
3598 Securities and Exchange Commission as a national securities
3599 exchange; and
3600 (III) Provides at least four of the following medical
3601 specialties:
3602 (A) General medicine.
3603 (B) Radiography.
3604 (C) Orthopedic medicine.
3605 (D) Physical medicine.
3606 (E) Physical therapy.
3607 (F) Physical rehabilitation.
3608 (G) Prescribing or dispensing outpatient prescription
3609 medication.
3610 (H) Laboratory services.
3611
3612 The Financial Services Commission shall adopt by rule the form
3613 that must be used by an insurer and a health care provider
3614 specified in subparagraph 3., subparagraph 4., or subparagraph
3615 5. to document that the health care provider meets the criteria
3616 of this paragraph, which rule must include a requirement for a
3617 sworn statement or affidavit.
3618
3619 Only insurers writing motor vehicle liability insurance in this
3620 state may provide the required benefits of this section, and no
3621 such insurer shall require the purchase of any other motor
3622 vehicle coverage other than the purchase of property damage
3623 liability coverage as required by s. 627.7275 as a condition for
3624 providing such required benefits. Insurers may not require that
3625 property damage liability insurance in an amount greater than

3626 $10,000 be purchased in conjunction with personal injury
3627 protection. Such insurers shall make benefits and required
3628 property damage liability insurance coverage available through
3629 normal marketing channels. Any insurer writing motor vehicle
3630 liability insurance in this state who fails to comply with such
3631 availability requirement as a general business practice shall be
3632 deemed to have violated part IX of chapter 626, and such
3633 violation shall constitute an unfair method of competition or an
3634 unfair or deceptive act or practice involving the business of
3635 insurance; and any such insurer committing such violation shall
3636 be subject to the penalties afforded in such part, as well as
3637 those which may be afforded elsewhere in the insurance code.
3638 Section 96. Section 633.081, Florida Statutes, is amended
3639 to read:
3640 633.081 Inspection of buildings and equipment; orders;
3641 firesafety inspection training requirements; certification;
3642 disciplinary action.—The State Fire Marshal and her or his
3643 agents shall, at any reasonable hour, when the department has
3644 reasonable cause to believe that a violation of this chapter or
3645 s. 509.215, or a rule promulgated thereunder, or a minimum
3646 firesafety code adopted by a local authority, may exist, inspect
3647 any and all buildings and structures which are subject to the
3648 requirements of this chapter or s. 509.215 and rules promulgated
3649 thereunder. The authority to inspect shall extend to all
3650 equipment, vehicles, and chemicals which are located within the
3651 premises of any such building or structure. <u>The State Fire</u>
3652 <u>Marshal and her or his agents shall inspect nursing homes</u>
3653 <u>licensed under part II of chapter 400 only once every calendar</u>
3654 <u>year and upon receiving a complaint forming the basis of a</u>

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3655 reasonable cause to believe that a violation of this chapter or
3656 s. 509.215, or a rule promulgated thereunder, or a minimum
3657 firesafety code adopted by a local authority may exist and upon
3658 identifying such a violation in the course of conducting
3659 orientation or training activities within a nursing home.
3660 (1) Each county, municipality, and special district that
3661 has firesafety enforcement responsibilities shall employ or
3662 contract with a firesafety inspector. The firesafety inspector
3663 must conduct all firesafety inspections that are required by
3664 law. The governing body of a county, municipality, or special
3665 district that has firesafety enforcement responsibilities may
3666 provide a schedule of fees to pay only the costs of inspections
3667 conducted pursuant to this subsection and related administrative
3668 expenses. Two or more counties, municipalities, or special
3669 districts that have firesafety enforcement responsibilities may
3670 jointly employ or contract with a firesafety inspector.
3671 (2) Every firesafety inspection conducted pursuant to state
3672 or local firesafety requirements shall be by a person certified
3673 as having met the inspection training requirements set by the
3674 State Fire Marshal. Such person shall:
3675 (a) Be a high school graduate or the equivalent as
3676 determined by the department;
3677 (b) Not have been found guilty of, or having pleaded guilty
3678 or nolo contendere to, a felony or a crime punishable by
3679 imprisonment of 1 year or more under the law of the United
3680 States, or of any state thereof, which involves moral turpitude,
3681 without regard to whether a judgment of conviction has been
3682 entered by the court having jurisdiction of such cases;
3683 (c) Have her or his fingerprints on file with the

3684 department or with an agency designated by the department;
3685 (d) Have good moral character as determined by the
3686 department;
3687 (e) Be at least 18 years of age;
3688 (f) Have satisfactorily completed the firesafety inspector
3689 certification examination as prescribed by the department; and
3690 (g)1. Have satisfactorily completed, as determined by the
3691 department, a firesafety inspector training program of not less
3692 than 200 hours established by the department and administered by
3693 agencies and institutions approved by the department for the
3694 purpose of providing basic certification training for firesafety
3695 inspectors; or
3696 2. Have received in another state training which is
3697 determined by the department to be at least equivalent to that
3698 required by the department for approved firesafety inspector
3699 education and training programs in this state.
3700 (3) Each special state firesafety inspection which is
3701 required by law and is conducted by or on behalf of an agency of
3702 the state must be performed by an individual who has met the
3703 provision of subsection (2), except that the duration of the
3704 training program shall not exceed 120 hours of specific training
3705 for the type of property that such special state firesafety
3706 inspectors are assigned to inspect.
3707 (4) A firefighter certified pursuant to s. 633.35 may
3708 conduct firesafety inspections, under the supervision of a
3709 certified firesafety inspector, while on duty as a member of a
3710 fire department company conducting inservice firesafety
3711 inspections without being certified as a firesafety inspector,
3712 if such firefighter has satisfactorily completed an inservice

3713 fire department company inspector training program of at least
3714 24 hours' duration as provided by rule of the department.
3715 (5) Every firesafety inspector or special state firesafety
3716 inspector certificate is valid for a period of 3 years from the
3717 date of issuance. Renewal of certification shall be subject to
3718 the affected person's completing proper application for renewal
3719 and meeting all of the requirements for renewal as established
3720 under this chapter or by rule promulgated thereunder, which
3721 shall include completion of at least 40 hours during the
3722 preceding 3-year period of continuing education as required by
3723 the rule of the department or, in lieu thereof, successful
3724 passage of an examination as established by the department.
3725 (6) The State Fire Marshal may deny, refuse to renew,
3726 suspend, or revoke the certificate of a firesafety inspector or
3727 special state firesafety inspector if it finds that any of the
3728 following grounds exist:
3729 (a) Any cause for which issuance of a certificate could
3730 have been refused had it then existed and been known to the
3731 State Fire Marshal.
3732 (b) Violation of this chapter or any rule or order of the
3733 State Fire Marshal.
3734 (c) Falsification of records relating to the certificate.
3735 (d) Having been found guilty of or having pleaded guilty or
3736 nolo contendere to a felony, whether or not a judgment of
3737 conviction has been entered.
3738 (e) Failure to meet any of the renewal requirements.
3739 (f) Having been convicted of a crime in any jurisdiction
3740 which directly relates to the practice of fire code inspection,
3741 plan review, or administration.

3742 (g) Making or filing a report or record that the
3743 certificateholder knows to be false, or knowingly inducing
3744 another to file a false report or record, or knowingly failing
3745 to file a report or record required by state or local law, or
3746 knowingly impeding or obstructing such filing, or knowingly
3747 inducing another person to impede or obstruct such filing.
3748 (h) Failing to properly enforce applicable fire codes or
3749 permit requirements within this state which the
3750 certificateholder knows are applicable by committing willful
3751 misconduct, gross negligence, gross misconduct, repeated
3752 negligence, or negligence resulting in a significant danger to
3753 life or property.
3754 (i) Accepting labor, services, or materials at no charge or
3755 at a noncompetitive rate from any person who performs work that
3756 is under the enforcement authority of the certificateholder and
3757 who is not an immediate family member of the certificateholder.
3758 For the purpose of this paragraph, the term "immediate family
3759 member" means a spouse, child, parent, sibling, grandparent,
3760 aunt, uncle, or first cousin of the person or the person's
3761 spouse or any person who resides in the primary residence of the
3762 certificateholder.
3763 (7) The department shall provide by rule for the
3764 certification of firesafety inspectors.
3765 Section 97. Subsection (12) of section 641.495, Florida
3766 Statutes, is amended to read:
3767 641.495 Requirements for issuance and maintenance of
3768 certificate.—
3769 (12) The provisions of part I of chapter 395 do not apply
3770 to a health maintenance organization that, on or before January

3771 1, 1991, provides not more than 10 outpatient holding beds for
3772 short-term and hospice-type patients in an ambulatory care
3773 facility for its members, provided that such health maintenance
3774 organization maintains current accreditation by The Joint
3775 Commission ~~on Accreditation of Health Care Organizations~~, the
3776 Accreditation Association for Ambulatory Health Care, or the
3777 National Committee for Quality Assurance.
3778 Section 98. Subsection (13) of section 651.118, Florida
3779 Statutes, is amended to read:
3780 651.118 Agency for Health Care Administration; certificates
3781 of need; sheltered beds; community beds.—
3782 (13) Residents, as defined in this chapter, are not
3783 considered new admissions for the purpose of s.
3784 400.141(1)(n)~~(o)~~1.d.
3785 Section 99. Subsection (2) of section 766.1015, Florida
3786 Statutes, is amended to read:
3787 766.1015 Civil immunity for members of or consultants to
3788 certain boards, committees, or other entities.—
3789 (2) Such committee, board, group, commission, or other
3790 entity must be established in accordance with state law or in
3791 accordance with requirements of The Joint Commission ~~on~~
3792 ~~Accreditation of Healthcare Organizations~~, established and duly
3793 constituted by one or more public or licensed private hospitals
3794 or behavioral health agencies, or established by a governmental
3795 agency. To be protected by this section, the act, decision,
3796 omission, or utterance may not be made or done in bad faith or
3797 with malicious intent.
3798 Section 100. Subsection (4) of section 766.202, Florida
3799 Statutes, is amended to read:

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3800 766.202 Definitions; ss. 766.201-766.212.—As used in ss.
3801 766.201-766.212, the term:
3802 (4) "Health care provider" means any hospital, ambulatory
3803 surgical center, or mobile surgical facility as defined and
3804 licensed under chapter 395; a birth center licensed under
3805 chapter 383; any person licensed under chapter 458, chapter 459,
3806 chapter 460, chapter 461, chapter 462, chapter 463, part I of
3807 chapter 464, chapter 466, chapter 467, part XIV of chapter 468,
3808 or chapter 486; a clinical lab licensed under chapter 483; a
3809 health maintenance organization certificated under part I of
3810 chapter 641; a blood bank; a plasma center; an industrial
3811 clinic; a renal dialysis facility; or a professional association
3812 partnership, corporation, joint venture, or other association
3813 for professional activity by health care providers.
3814 Section 101. This act shall take effect July 1, 2010.