By the Committee on Health Regulation; and Senator Latvala

588-02834A-11 20111736c1

1 A bill to be entitled
2 An act relating to health care; amending s. 83.42,
3 F.S., relating to exclusions from part II of ch. 83,
4 F.S., the Florida Residential Landlord and Tenant Act;
5 clarifying that the procedures in s. 400.0255, F.S.,
6 for transfers and discharges are exclusive to
7 residents of a nursing home licensed under part II of
8 ch. 400, F.S.; amending s. 112.0455, F.S., relating to
9 the Drug-Free Workplace Act; deleting an obsolete
10 provision; deleting a provision that requires a
11 laboratory to submit to the Agency for Health Care
12 Administration a monthly report containing statistical
13 information regarding the testing of employees and job
14 applicants; repealing s. 383.325, F.S., relating to
15 confidentiality of inspection reports of licensed
16 birth center facilities; amending s. 395.002, F.S.;
17 revising and deleting definitions applicable to
18 regulation of hospitals and other licensed facilities;
19 conforming a cross-reference; amending s. 395.003,
20 F.S.; deleting an obsolete provision; conforming a
21 cross-reference; amending s. 395.0161, F.S.; deleting
22 a requirement that facilities licensed under part I of
23 ch. 395, F.S., pay licensing fees at the time of
24 inspection; amending s. 395.0193, F.S.; requiring a
25 licensed facility to report certain peer review
26 information and final disciplinary actions to the
27 Division of Medical Quality Assurance of the
28 Department of Health rather than the Division of
29 Health Quality Assurance of the Agency for Health Care

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30 Administration; amending s. 395.1023, F.S.; providing
31 for the Department of Children and Family Services
32 rather than the Department of Health to perform
33 certain functions with respect to child protection
34 cases; requiring certain hospitals to notify the
35 Department of Children and Family Services of
36 compliance; amending s. 395.1041, F.S., relating to
37 hospital emergency services and care; deleting
38 obsolete provisions; repealing s. 395.1046, F.S.,
39 relating to complaint investigation procedures;
40 amending s. 395.1055, F.S.; requiring licensed
41 facility beds to conform to standards specified by the
42 Agency for Health Care Administration, the Florida
43 Building Code, and the Florida Fire Prevention Code;
44 amending s. 395.10972, F.S.; revising a reference to
45 the Florida Society of Healthcare Risk Management to
46 conform to the current designation; amending s.
47 395.2050, F.S.; revising a reference to the federal
48 Health Care Financing Administration to conform to the
49 current designation; amending s. 395.3036, F.S.;
50 correcting a reference; repealing s. 395.3037, F.S.,
51 relating to redundant definitions; amending ss.
52 154.11, 394.741, 395.3038, 400.925, 400.9935, 408.05,
53 440.13, 627.645, 627.668, 627.669, 627.736, 641.495,
54 and 766.1015, F.S.; revising references to the Joint
55 Commission on Accreditation of Healthcare
56 Organizations, the Commission on Accreditation of
57 Rehabilitation Facilities, and the Council on
58 Accreditation to conform to their current

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59 designations; amending s. 395.602, F.S.; revising the
60 definition of the term "rural hospital" to delete an
61 obsolete provision; amending s. 400.021, F.S.;
62 revising the definition of the terms "geriatric
63 outpatient clinic" and "resident care plan"; amending
64 s. 400.0234, F.S.; conforming provisions to changes
65 made by the act; amending s. 400.0255, F.S.;
66 correcting an obsolete cross-reference to
67 administrative rules; amending s. 400.063, F.S.;
68 deleting an obsolete provision; amending ss. 400.071
69 and 400.0712, F.S.; revising applicability of general
70 licensure requirements under part II of ch. 408, F.S.,
71 to applications for nursing home licensure; revising
72 provisions governing inactive licenses; amending s.
73 400.111, F.S.; providing for disclosure of controlling
74 interest of a nursing home facility upon request by
75 the Agency for Health Care Administration; amending s.
76 400.1183, F.S.; revising grievance record maintenance
77 and reporting requirements for nursing homes; amending
78 s. 400.141, F.S.; providing criteria for the provision
79 of respite services by nursing homes; requiring a
80 written plan of care; requiring a contract for
81 services; requiring resident release to caregivers to
82 be designated in writing; providing an exemption to
83 the application of discharge planning rules; providing
84 for residents' rights; providing for use of personal
85 medications; providing terms of respite stay;
86 providing for communication of patient information;
87 requiring a physician's order for care and proof of a

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88 physical examination; providing for services for
89 respite patients and duties of facilities with respect
90 to such patients; conforming a cross-reference;
91 requiring facilities to maintain clinical records that
92 meet specified standards; providing a fine relating to
93 an admissions moratorium; deleting requirement for
94 facilities to submit certain information related to
95 management companies to the agency; deleting a
96 requirement for facilities to notify the agency of
97 certain bankruptcy filings to conform to changes made
98 by the act; authorizing a facility to charge a fee to
99 copy a resident's records; amending s. 400.142, F.S.;
100 deleting language relating to agency adoption of
101 rules; repealing s. 400.145, F.S., relating
102 requirements for furnishing the records of residents
103 in a licensed nursing home to certain specified
104 parties; amending 400.147, F.S.; revising reporting
105 requirements for licensed nursing home facilities
106 relating to adverse incidents; repealing s. 400.148,
107 F.S., relating to the Medicaid "Up-or-Out" Quality of
108 Care Contract Management Program; amending s. 400.179,
109 F.S.; deleting an obsolete provision; amending s.
110 400.19, F.S.; revising inspection requirements;
111 amending s. 400.23, F.S.; deleting an obsolete
112 provision; correcting a reference; deleting a
113 requirement that the rules for minimum standards of
114 care for persons under 21 years of age include a
115 certain methodology; directing the agency to adopt
116 rules for minimum staffing standards in nursing homes

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117 that serve persons under 21 years of age; providing
118 minimum staffing standards; amending s. 400.275, F.S.;
119 revising agency duties with regard to training nursing
120 home surveyor teams; revising requirements for team
121 members; amending s. 400.462, F.S.; redefining the
122 term "remuneration" for purposes of the Home Health
123 Services Act; amending s. 400.484, F.S.; revising the
124 schedule of home health agency inspection violations;
125 amending s. 400.506, F.S.; providing that a nurse
126 registry is exempt from certain license penalties and
127 fines otherwise imposed by the Agency for Health Care
128 Administration on a nurse registry under certain
129 circumstances; authorizing an administrator to manage
130 up to five nurse registries under certain
131 circumstances; requiring an administrator to
132 designate, in writing, for each licensed entity, a
133 qualified alternate administrator to serve during the
134 administrator's absence; amending s. 400.509, F.S.;
135 providing that organizations that provide companion
136 services only to persons with developmental
137 disabilities, under contract with the Agency for
138 Persons with Disabilities, are exempt from
139 registration with the Agency for Health Care
140 Administration; reenacting ss. 400.464(5)(b) and
141 400.506(6)(a), F.S., relating to home health agencies
142 and licensure of nurse registries, respectively, to
143 incorporate the amendment made to s. 400.509, F.S., in
144 references thereto; amending s. 400.606, F.S.;
145 revising the content requirements of the plan

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146 accompanying an initial or change-of-ownership
147 application for licensure of a hospice; revising
148 requirements relating to certificates of need for
149 certain hospice facilities; amending s. 400.607, F.S.;
150 revising grounds for agency action against a hospice;
151 amending s. 400.915, F.S.; correcting an obsolete
152 cross-reference to administrative rules; amending s.
153 400.931, F.S.; requiring each applicant for initial
154 licensure, change of ownership, or renewal to operate
155 a licensed home medical equipment provider at a
156 location outside the state to submit documentation of
157 accreditation, or an application for accreditation,
158 from an accrediting organization that is recognized by
159 the Agency for Health Care Administration; requiring
160 an applicant that has applied for accreditation to
161 provide proof of accreditation within a specified
162 time; deleting a requirement that an applicant for a
163 home medical equipment provider license submit a
164 surety bond to the agency; amending s. 400.932, F.S.;
165 revising grounds for the imposition of administrative
166 penalties for certain violations by an employee of a
167 home medical equipment provider; amending s. 400.967,
168 F.S.; revising the schedule of inspection violations
169 for intermediate care facilities for the
170 developmentally disabled; providing a penalty for
171 certain violations; amending s. 400.9905, F.S.;
172 revising the definitions of the terms "clinic" and
173 "portable equipment provider"; providing that part X
174 of ch. 400, F.S., the Health Care Clinic Act, does not

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175 apply to certain clinical facilities, an entity owned
176 by a corporation with a specified amount of annual
177 sales of health care services under certain
178 circumstances, an entity owned or controlled by a
179 publicly traded entity with a specified amount of
180 annual revenues, or an entity that employs at least a
181 certain number of health care practitioners and bills
182 for medical services under a single corporate tax
183 identification number; amending s. 400.991, F.S.;
184 conforming terminology; revising application
185 requirements relating to documentation of financial
186 ability to operate a mobile clinic; amending s.
187 408.033, F.S.; providing that fees assessed on
188 selected health care facilities and organizations may
189 be collected prospectively at the time of licensure
190 renewal and prorated for the licensing period;
191 amending s. 408.034, F.S.; revising agency authority
192 relating to licensing of intermediate care facilities
193 for the developmentally disabled; amending s. 408.036,
194 F.S.; deleting an exemption from certain certificate-
195 of-need review requirements for a hospice or a hospice
196 inpatient facility; deleting a requirement that the
197 agency submit a report to the Legislature providing
198 information concerning the number of requests it
199 receives for an exemption from certificate-of-need
200 review; amending s. 408.037, F.S.; revising
201 requirements for the financial information to be
202 included in an application for a certificate of need;
203 amending s. 408.043, F.S.; revising requirements for

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204 certain freestanding inpatient hospice care facilities
205 to obtain a certificate of need; amending s. 408.061,
206 F.S.; revising health care facility data reporting
207 requirements; amending s. 408.10, F.S.; removing
208 agency authority to investigate certain consumer
209 complaints; amending s. 408.802, F.S.; removing
210 applicability of part II of ch. 408, F.S., relating to
211 general licensure requirements, to private review
212 agents; amending s. 408.804, F.S.; providing penalties
213 for altering, defacing, or falsifying a license
214 certificate issued by the agency or displaying such an
215 altered, defaced, or falsified certificate; amending
216 s. 408.806, F.S.; revising agency responsibilities for
217 notification of licensees of impending expiration of a
218 license; requiring payment of a late fee for a license
219 application to be considered complete under certain
220 circumstances; amending s. 408.8065, F.S.; revising
221 the requirements for becoming licensed as a home
222 health agency, home medical equipment provider, or
223 health care clinic; amending s. 408.809, F.S.;
224 revising provisions to include a schedule for
225 background rescreenings of certain employees; amending
226 s. 408.813, F.S.; authorizing the agency to impose
227 fines for unclassified violations of part II of ch.
228 408, F.S.; amending s. 408.815, F.S.; authorizing the
229 agency to extend a license expiration date under
230 certain circumstances; amending s. 409.91196, F.S.;
231 conforming a cross-reference; amending s. 409.912,
232 F.S.; revising procedures for implementation of a

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233 Medicaid prescribed-drug spending-control program;
234 amending s. 429.07, F.S.; deleting the requirement for
235 an assisted living facility to obtain an additional
236 license in order to provide limited nursing services;
237 deleting the requirement for the agency to conduct
238 quarterly monitoring visits of facilities that hold a
239 license to provide extended congregate care services;
240 deleting the requirement for the department to report
241 annually on the status of and recommendations related
242 to extended congregate care; deleting the requirement
243 for the agency to conduct monitoring visits at least
244 twice a year to facilities providing limited nursing
245 services; increasing the additional licensing fee per
246 resident based on the total licensed resident capacity
247 of the facility; eliminating the license fee for the
248 limited nursing services license; transferring from
249 another provision of law the requirement that a
250 biennial survey of an assisted living facility include
251 specific actions to determine whether the facility is
252 adequately protecting residents' rights; providing
253 that under specified conditions an assisted living
254 facility that has a class I or class II violation is
255 subject to periodic unannounced monitoring; requiring
256 a registered nurse to participate in certain
257 monitoring visits; amending s. 429.11, F.S.; revising
258 licensure application requirements for assisted living
259 facilities to eliminate provisional licenses; amending
260 s. 429.12, F.S.; deleting a requirement that a
261 transferor of an assisted living facility advise the

262 transferee to submit a plan for correction of certain
263 deficiencies to the Agency for Health Care
264 Administration before ownership of the facility is
265 transferred; amending s. 429.17, F.S.; deleting
266 provisions relating to the limited nursing services
267 license; revising agency responsibilities regarding
268 the issuance of conditional licenses; amending s.
269 429.195, F.S.; prohibiting an assisted living facility
270 from contracting or promising to pay or receive any
271 commission, bonus, kickback, or rebate or engage in
272 any split-fee arrangement with any health care
273 provider or health care facility; providing
274 exceptions; amending s. 429.23, F.S.; deleting
275 reporting requirements for assisted living facilities
276 relating to liability claims; amending s. 429.255,
277 F.S.; eliminating provisions authorizing the use of
278 volunteers to provide certain health-care-related
279 services in assisted living facilities; authorizing
280 assisted living facilities to provide limited nursing
281 services; requiring an assisted living facility to be
282 responsible for certain recordkeeping and staff to be
283 trained to monitor residents receiving certain health-
284 care-related services; amending s. 429.28, F.S.;
285 deleting a requirement for a biennial survey of an
286 assisted living facility, to conform to changes made
287 by the act; conforming a cross-reference; amending s.
288 429.294, F.S.; conforming provisions to changes made
289 by the act; amending s. 429.41, F.S., relating to
290 rulemaking; conforming provisions to changes made by

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291 the act; deleting the requirement for the Department
292 of Elderly Affairs to submit to the Legislature a copy
293 of proposed rules regarding the quality of resident
294 care in an assisted living facility; amending s.
295 429.53, F.S.; revising provisions relating to
296 consultation by the agency; revising a definition;
297 amending s. 429.54, F.S.; requiring licensed assisted
298 living facilities to electronically report certain
299 data semiannually to the agency in accordance with
300 rules adopted by the department; amending s. 429.71,
301 F.S.; revising schedule of inspection violations for
302 adult family-care homes; amending s. 429.915, F.S.;
303 revising agency responsibilities regarding the
304 issuance of conditional licenses; repealing s.
305 440.102(9)(d), F.S., relating to a laboratory’s
306 requirement to submit to the Agency for Health Care
307 Administration a monthly report containing statistical
308 information regarding the testing of employees and job
309 applicants; amending s. 483.035, F.S.; providing for a
310 clinical laboratory to be operated by certain nurses;
311 amending s. 483.051, F.S.; requiring the Agency for
312 Health Care Administration to provide for biennial
313 licensure of all nonwaived laboratories that meet
314 certain requirements; requiring the agency to
315 prescribe qualifications for such licensure; defining
316 nonwaived laboratories as laboratories that do not
317 have a certificate of waiver from the Centers for
318 Medicare and Medicaid Services; deleting requirements
319 for the registration of an alternate site testing

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320 location when the clinical laboratory applies to renew
321 its license; amending s. 483.294, F.S.; revising
322 frequency of agency inspections of multiphasic health
323 testing centers; amending s. 626.9541, F.S.;
324 authorizing an insurer offering a group or individual
325 health benefit plan to offer a wellness program;
326 authorizing rewards or incentives; providing for
327 verification of a member's inability to participate
328 for medical reasons; providing that such rewards or
329 incentives are not insurance benefits; amending s.
330 766.202, F.S.; adding persons licensed under part XIV
331 of ch. 468, F.S., to the definition of "health care
332 provider"; amending ss. 394.4787, 400.0239, 408.07,
333 430.80, and 651.118, F.S.; conforming terminology and
334 references to changes made by the act; revising a
335 reference; amending s. 817.505, F.S.; providing that
336 it is not patient brokering for an assisted living
337 facility to offer payment under certain circumstances;
338 amending s. 381.06014, F.S.; redefining the term
339 "blood establishment" and defining the term "volunteer
340 donor"; prohibiting local governments from restricting
341 access to public facilities or infrastructure for
342 certain activities based on whether a blood
343 establishment is operating as a for-profit
344 organization or not-for-profit organization;
345 prohibiting a blood establishment from considering
346 whether certain customers are operating as for-profit
347 organizations or not-for-profit organizations when
348 determining service fees for selling blood or blood

349 components; requiring that certain blood
350 establishments disclose specified information on the
351 Internet; authorizing the Department of Legal Affairs
352 to assess a civil penalty against a blood
353 establishment that fails to disclose specified
354 information on the Internet; providing that the civil
355 penalty accrues to the state and requiring that it be
356 deposited as received into the General Revenue Fund;
357 amending s. 499.003, F.S.; redefining the term "health
358 care entity" to clarify that a blood establishment is
359 a health care entity that may engage in certain
360 activities; amending s. 499.005, F.S.; clarifying
361 provisions that prohibit the unauthorized wholesale
362 distribution of a prescription drug that was purchased
363 by a hospital or other health care entity or donated
364 or supplied at a reduced price to a charitable
365 organization, to conform to changes made by the act;
366 amending s. 499.01, F.S.; exempting certain blood
367 establishments from the requirements to be permitted
368 as a prescription drug manufacturer and register
369 products; requiring that certain blood establishments
370 obtain a restricted prescription drug distributor
371 permit under specified conditions; limiting the
372 prescription drugs that a blood establishment may
373 distribute under a restricted prescription drug
374 distributor permit; authorizing the Department of
375 Health to adopt rules regarding the distribution of
376 prescription drugs by blood establishments; providing
377 an effective date.

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379 Be It Enacted by the Legislature of the State of Florida:

380

381 Section 1. Subsection (1) of section 83.42, Florida
382 Statutes, is amended to read:
383 83.42 Exclusions from application of part.—This part does
384 not apply to:
385 (1) Residency or detention in a facility, whether public or
386 private, when residence or detention is incidental to the
387 provision of medical, geriatric, educational, counseling,
388 religious, or similar services. The procedures for all transfers
389 and discharges as provided in s. 400.0255 apply only to
390 residents of a facility licensed under part II of chapter 400.
391 Section 2. Present paragraphs (f) through (k) of subsection
392 (10) of section 112.0455, Florida Statutes, are redesignated as
393 paragraphs (e) through (j), respectively, and present paragraph
394 (e) of subsection (10), subsection (12), and paragraph (e) of
395 subsection (14) of that section are amended to read:
396 112.0455 Drug-Free Workplace Act.—
397 (10) EMPLOYER PROTECTION.—
398 ~~(e) Nothing in this section shall be construed to operate~~
399 ~~retroactively, and nothing in this section shall abrogate the~~
400 ~~right of an employer under state law to conduct drug tests prior~~
401 ~~to January 1, 1990. A drug test conducted by an employer prior~~
402 ~~to January 1, 1990, is not subject to this section.~~
403 (12) DRUG-TESTING STANDARDS; LABORATORIES.—
404 (a) The requirements of part II of chapter 408 apply to the
405 provision of services that require licensure pursuant to this
406 section and part II of chapter 408 and to entities licensed by

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407 or applying for such licensure from the Agency for Health Care
408 Administration pursuant to this section. A license issued by the
409 agency is required in order to operate a laboratory.
410 (b) A laboratory may analyze initial or confirmation drug
411 specimens only if:
412 1. The laboratory is licensed and approved by the Agency
413 for Health Care Administration using criteria established by the
414 United States Department of Health and Human Services as general
415 guidelines for modeling the state drug testing program and in
416 accordance with part II of chapter 408. Each applicant for
417 licensure and licensee must comply with all requirements of part
418 II of chapter 408.
419 2. The laboratory has written procedures to ensure chain of
420 custody.
421 3. The laboratory follows proper quality control
422 procedures, including, but not limited to:
423 a. The use of internal quality controls including the use
424 of samples of known concentrations which are used to check the
425 performance and calibration of testing equipment, and periodic
426 use of blind samples for overall accuracy.
427 b. An internal review and certification process for drug
428 test results, conducted by a person qualified to perform that
429 function in the testing laboratory.
430 c. Security measures implemented by the testing laboratory
431 to preclude adulteration of specimens and drug test results.
432 d. Other necessary and proper actions taken to ensure
433 reliable and accurate drug test results.
434 (c) A laboratory shall disclose to the employer a written
435 test result report within 7 working days after receipt of the

436 sample. All laboratory reports of a drug test result shall, at a
437 minimum, state:
438 1. The name and address of the laboratory which performed
439 the test and the positive identification of the person tested.
440 2. Positive results on confirmation tests only, or negative
441 results, as applicable.
442 3. A list of the drugs for which the drug analyses were
443 conducted.
444 4. The type of tests conducted for both initial and
445 confirmation tests and the minimum cutoff levels of the tests.
446 5. Any correlation between medication reported by the
447 employee or job applicant pursuant to subparagraph (8)(b)2. and
448 a positive confirmed drug test result.
449
450 No report shall disclose the presence or absence of any drug
451 other than a specific drug and its metabolites listed pursuant
452 to this section.
453 ~~(d) The laboratory shall submit to the Agency for Health~~
454 ~~Care Administration a monthly report with statistical~~
455 ~~information regarding the testing of employees and job~~
456 ~~applicants. The reports shall include information on the methods~~
457 ~~of analyses conducted, the drugs tested for, the number of~~
458 ~~positive and negative results for both initial and confirmation~~
459 ~~tests, and any other information deemed appropriate by the~~
460 ~~Agency for Health Care Administration. No monthly report shall~~
461 ~~identify specific employees or job applicants.~~
462 (d)~~(e)~~ Laboratories shall provide technical assistance to
463 the employer, employee, or job applicant for the purpose of
464 interpreting any positive confirmed test results which could

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465 have been caused by prescription or nonprescription medication
466 taken by the employee or job applicant.
467 (14) DISCIPLINE REMEDIES.—
468 (e) Upon resolving an appeal filed pursuant to paragraph
469 (c), and finding a violation of this section, the commission may
470 order the following relief:
471 1. Rescind the disciplinary action, expunge related records
472 from the personnel file of the employee or job applicant and
473 reinstate the employee.
474 2. Order compliance with paragraph (10)(f)~~(g)~~.
475 3. Award back pay and benefits.
476 4. Award the prevailing employee or job applicant the
477 necessary costs of the appeal, reasonable attorney's fees, and
478 expert witness fees.
479 Section 3. Paragraph (n) of subsection (1) of section
480 154.11, Florida Statutes, is amended to read:
481 154.11 Powers of board of trustees.—
482 (1) The board of trustees of each public health trust shall
483 be deemed to exercise a public and essential governmental
484 function of both the state and the county and in furtherance
485 thereof it shall, subject to limitation by the governing body of
486 the county in which such board is located, have all of the
487 powers necessary or convenient to carry out the operation and
488 governance of designated health care facilities, including, but
489 without limiting the generality of, the foregoing:
490 (n) To appoint originally the staff of physicians to
491 practice in any designated facility owned or operated by the
492 board and to approve the bylaws and rules to be adopted by the
493 medical staff of any designated facility owned and operated by

494 the board, such governing regulations to be in accordance with
495 the standards of the Joint Commission ~~on the Accreditation of~~
496 ~~Hospitals~~ which provide, among other things, for the method of
497 appointing additional staff members and for the removal of staff
498 members.
499 Section 4. Section 383.325, Florida Statutes, is repealed.
500 Section 5. Subsection (7) of section 394.4787, Florida
501 Statutes, is amended to read:
502 394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and
503 394.4789.—As used in this section and ss. 394.4786, 394.4788,
504 and 394.4789:
505 (7) "Specialty psychiatric hospital" means a hospital
506 licensed by the agency pursuant to s. 395.002(26) ~~(28)~~ and part
507 II of chapter 408 as a specialty psychiatric hospital.
508 Section 6. Subsection (2) of section 394.741, Florida
509 Statutes, is amended to read:
510 394.741 Accreditation requirements for providers of
511 behavioral health care services.—
512 (2) Notwithstanding any provision of law to the contrary,
513 accreditation shall be accepted by the agency and department in
514 lieu of the agency's and department's facility licensure onsite
515 review requirements and shall be accepted as a substitute for
516 the department's administrative and program monitoring
517 requirements, except as required by subsections (3) and (4),
518 for:
519 (a) Any organization from which the department purchases
520 behavioral health care services that is accredited by the Joint
521 Commission ~~on Accreditation of Healthcare Organizations~~ or the
522 Council on Accreditation ~~for Children and Family Services~~, or

523 has those services that are being purchased by the department
524 accredited by the Commission on Accreditation of Rehabilitation
525 Facilities ~~CARF—the Rehabilitation Accreditation Commission~~.
526 (b) Any mental health facility licensed by the agency or
527 any substance abuse component licensed by the department that is
528 accredited by the Joint Commission ~~on Accreditation of~~
529 ~~Healthcare Organizations~~, the Commission on Accreditation of
530 Rehabilitation Facilities ~~CARF—the Rehabilitation Accreditation~~
531 ~~Commission~~, or the Council on Accreditation ~~of Children and~~
532 ~~Family Services~~.
533 (c) Any network of providers from which the department or
534 the agency purchases behavioral health care services accredited
535 by the Joint Commission ~~on Accreditation of Healthcare~~
536 ~~Organizations~~, the Commission on Accreditation of Rehabilitation
537 Facilities ~~CARF—the Rehabilitation Accreditation Commission~~, the
538 Council on Accreditation ~~of Children and Family Services~~, or the
539 National Committee for Quality Assurance. A provider
540 organization, which is part of an accredited network, is
541 afforded the same rights under this part.
542 Section 7. Present subsections (15) through (32) of section
543 395.002, Florida Statutes, are renumbered as subsections (14)
544 through (28), respectively, and present subsections (1), (14),
545 (24), (30), and (31) and paragraph (c) of present subsection
546 (28) of that section are amended to read:
547 395.002 Definitions.—As used in this chapter:
548 (1) "Accrediting organizations" means nationally recognized
549 or approved accrediting organizations whose standards
550 incorporate comparable licensure requirements as determined by
551 the agency ~~the Joint Commission on Accreditation of Healthcare~~

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552 ~~Organizations, the American Osteopathic Association, the~~
553 ~~Commission on Accreditation of Rehabilitation Facilities, and~~
554 ~~the Accreditation Association for Ambulatory Health Care, Inc~~.
555 ~~(14) “Initial denial determination” means a determination~~
556 ~~by a private review agent that the health care services~~
557 ~~furnished or proposed to be furnished to a patient are~~
558 ~~inappropriate, not medically necessary, or not reasonable.~~
559 ~~(24) “Private review agent” means any person or entity~~
560 ~~which performs utilization review services for third-party~~
561 ~~payors on a contractual basis for outpatient or inpatient~~
562 ~~services. However, the term shall not include full-time~~
563 ~~employees, personnel, or staff of health insurers, health~~
564 ~~maintenance organizations, or hospitals, or wholly owned~~
565 ~~subsidiaries thereof or affiliates under common ownership, when~~
566 ~~performing utilization review for their respective hospitals,~~
567 ~~health maintenance organizations, or insureds of the same~~
568 ~~insurance group. For this purpose, health insurers, health~~
569 ~~maintenance organizations, and hospitals, or wholly owned~~
570 ~~subsidiaries thereof or affiliates under common ownership,~~
571 ~~include such entities engaged as administrators of self-~~
572 ~~insurance as defined in s. 624.031.~~
573 (26) ~~(28)~~ “Specialty hospital” means any facility which
574 meets the provisions of subsection (12), and which regularly
575 makes available either:
576 (c) Intensive residential treatment programs for children
577 and adolescents as defined in subsection (14) ~~(15)~~.
578 ~~(30) “Utilization review” means a system for reviewing the~~
579 ~~medical necessity or appropriateness in the allocation of health~~
580 ~~care resources of hospital services given or proposed to be~~

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581 ~~given to a patient or group of patients.~~
582 ~~(31) “Utilization review plan” means a description of the~~
583 ~~policies and procedures governing utilization review activities~~
584 ~~performed by a private review agent.~~
585 Section 8. Paragraph (c) of subsection (1) and paragraph
586 (b) of subsection (2) of section 395.003, Florida Statutes, are
587 amended to read:
588 395.003 Licensure; denial, suspension, and revocation.—
589 (1)
590 ~~(c) Until July 1, 2006, additional emergency departments~~
591 ~~located off the premises of licensed hospitals may not be~~
592 ~~authorized by the agency.~~
593 (2)
594 (b) The agency shall, at the request of a licensee that is
595 a teaching hospital as defined in s. 408.07(45), issue a single
596 license to a licensee for facilities that have been previously
597 licensed as separate premises, provided such separately licensed
598 facilities, taken together, constitute the same premises as
599 defined in s. 395.002(22) ~~(23)~~. Such license for the single
600 premises shall include all of the beds, services, and programs
601 that were previously included on the licenses for the separate
602 premises. The granting of a single license under this paragraph
603 shall not in any manner reduce the number of beds, services, or
604 programs operated by the licensee.
605 Section 9. Subsection (3) of section 395.0161, Florida
606 Statutes, is amended to read:
607 395.0161 Licensure inspection.—
608 (3) In accordance with s. 408.805, an applicant or licensee
609 shall pay a fee for each license application submitted under

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610 this part, part II of chapter 408, and applicable rules. With
611 the exception of state-operated licensed facilities, each
612 facility licensed under this part shall pay to the agency~~, at~~
613 ~~the time of inspection,~~ the following fees:
614 (a) *Inspection for licensure.*—A fee shall be paid which is
615 not less than $8 per hospital bed, nor more than $12 per
616 hospital bed, except that the minimum fee shall be $400 per
617 facility.
618 (b) *Inspection for lifesafety only.*—A fee shall be paid
619 which is not less than 75 cents per hospital bed, nor more than
620 $1.50 per hospital bed, except that the minimum fee shall be $40
621 per facility.
622 Section 10. Paragraph (e) of subsection (2) and subsection
623 (4) of section 395.0193, Florida Statutes, are amended to read:
624 395.0193 Licensed facilities; peer review; disciplinary
625 powers; agency or partnership with physicians.—
626 (2) Each licensed facility, as a condition of licensure,
627 shall provide for peer review of physicians who deliver health
628 care services at the facility. Each licensed facility shall
629 develop written, binding procedures by which such peer review
630 shall be conducted. Such procedures shall include:
631 (e) Recording of agendas and minutes which do not contain
632 confidential material, for review by the Division of Medical
633 Quality Assurance of the department ~~Health Quality Assurance of~~
634 ~~the agency~~.
635 (4) Pursuant to ss. 458.337 and 459.016, any disciplinary
636 actions taken under subsection (3) shall be reported in writing
637 to the Division of Medical Quality Assurance of the department
638 ~~Health Quality Assurance of the agency~~ within 30 working days

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639 after its initial occurrence, regardless of the pendency of
640 appeals to the governing board of the hospital. The notification
641 shall identify the disciplined practitioner, the action taken,
642 and the reason for such action. All final disciplinary actions
643 taken under subsection (3), if different from those which were
644 reported to the department ~~agency~~ within 30 days after the
645 initial occurrence, shall be reported within 10 working days to
646 the Division of Medical Quality Assurance of the department
647 ~~Health Quality Assurance of the agency~~ in writing and shall
648 specify the disciplinary action taken and the specific grounds
649 therefor. The division shall review each report and determine
650 whether it potentially involved conduct by the licensee that is
651 subject to disciplinary action, in which case s. 456.073 shall
652 apply. The reports are not subject to inspection under s.
653 119.07(1) even if the division's investigation results in a
654 finding of probable cause.
655 Section 11. Section 395.1023, Florida Statutes, is amended
656 to read:
657 395.1023 Child abuse and neglect cases; duties.—Each
658 licensed facility shall adopt a protocol that, at a minimum,
659 requires the facility to:
660 (1) Incorporate a facility policy that every staff member
661 has an affirmative duty to report, pursuant to chapter 39, any
662 actual or suspected case of child abuse, abandonment, or
663 neglect; and
664 (2) In any case involving suspected child abuse,
665 abandonment, or neglect, designate, at the request of the
666 Department of Children and Family Services, a staff physician to
667 act as a liaison between the hospital and the Department of

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668 Children and Family Services office which is investigating the
669 suspected abuse, abandonment, or neglect, and the child
670 protection team, as defined in s. 39.01, when the case is
671 referred to such a team.
672
673 Each general hospital and appropriate specialty hospital shall
674 comply with the provisions of this section and shall notify the
675 agency and the Department of Children and Family Services of its
676 compliance by sending a copy of its policy to the agency and the
677 Department of Children and Family Services as required by rule.
678 The failure by a general hospital or appropriate specialty
679 hospital to comply shall be punished by a fine not exceeding
680 $1,000, to be fixed, imposed, and collected by the agency. Each
681 day in violation is considered a separate offense.
682 Section 12. Subsection (2) and paragraph (d) of subsection
683 (3) of section 395.1041, Florida Statutes, are amended to read:
684 395.1041 Access to emergency services and care.—
685 (2) INVENTORY OF HOSPITAL EMERGENCY SERVICES.—The agency
686 shall establish and maintain an inventory of hospitals with
687 emergency services. The inventory shall list all services within
688 the service capability of the hospital, and such services shall
689 appear on the face of the hospital license. Each hospital having
690 emergency services shall notify the agency of its service
691 capability in the manner and form prescribed by the agency. The
692 agency shall use the inventory to assist emergency medical
693 services providers and others in locating appropriate emergency
694 medical care. The inventory shall also be made available to the
695 general public. ~~On or before August 1, 1992, the agency shall~~
696 ~~request that each hospital identify the services which are~~

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697 ~~within its service capability. On or before November 1, 1992,~~
698 ~~the agency shall notify each hospital of the service capability~~
699 ~~to be included in the inventory. The hospital has 15 days from~~
700 ~~the date of receipt to respond to the notice. By December 1,~~
701 ~~1992, the agency shall publish a final inventory.~~ Each hospital
702 shall reaffirm its service capability when its license is
703 renewed and shall notify the agency of the addition of a new
704 service or the termination of a service prior to a change in its
705 service capability.
706 (3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF
707 FACILITY OR HEALTH CARE PERSONNEL.—
708 (d)1. Every hospital shall ensure the provision of services
709 within the service capability of the hospital, at all times,
710 either directly or indirectly through an arrangement with
711 another hospital, through an arrangement with one or more
712 physicians, or as otherwise made through prior arrangements. A
713 hospital may enter into an agreement with another hospital for
714 purposes of meeting its service capability requirement, and
715 appropriate compensation or other reasonable conditions may be
716 negotiated for these backup services.
717 2. If any arrangement requires the provision of emergency
718 medical transportation, such arrangement must be made in
719 consultation with the applicable provider and may not require
720 the emergency medical service provider to provide transportation
721 that is outside the routine service area of that provider or in
722 a manner that impairs the ability of the emergency medical
723 service provider to timely respond to prehospital emergency
724 calls.
725 3. A hospital shall not be required to ensure service

726 capability at all times as required in subparagraph 1. if, prior
727 to the receiving of any patient needing such service capability,
728 such hospital has demonstrated to the agency that it lacks the
729 ability to ensure such capability and it has exhausted all
730 reasonable efforts to ensure such capability through backup
731 arrangements. In reviewing a hospital’s demonstration of lack of
732 ability to ensure service capability, the agency shall consider
733 factors relevant to the particular case, including the
734 following:
735 a. Number and proximity of hospitals with the same service
736 capability.
737 b. Number, type, credentials, and privileges of
738 specialists.
739 c. Frequency of procedures.
740 d. Size of hospital.
741 4. The agency shall publish ~~proposed~~ rules implementing a
742 reasonable exemption procedure ~~by November 1, 1992~~. ~~Subparagraph~~
743 ~~1. shall become effective upon the effective date of said rules~~
744 ~~or January 31, 1993, whichever is earlier. For a period not to~~
745 ~~exceed 1 year from the effective date of subparagraph 1., a~~
746 ~~hospital requesting an exemption shall be deemed to be exempt~~
747 ~~from offering the service until the agency initially acts to~~
748 ~~deny or grant the original request.~~ The agency has 45 days after
749 ~~from~~ the date of receipt of the request to approve or deny the
750 request. ~~After the first year from the effective date of~~
751 ~~subparagraph 1.,~~ If the agency fails to initially act within
752 that ~~the~~ time period, the hospital is deemed to be exempt from
753 offering the service until the agency initially acts to deny the
754 request.

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755 Section 13. Section 395.1046, Florida Statutes, is
756 repealed.
757 Section 14. Paragraph (e) of subsection (1) of section
758 395.1055, Florida Statutes, is amended to read:
759 395.1055 Rules and enforcement.—
760 (1) The agency shall adopt rules pursuant to ss. 120.536(1)
761 and 120.54 to implement the provisions of this part, which shall
762 include reasonable and fair minimum standards for ensuring that:
763 (e) Licensed facility beds conform to minimum space,
764 equipment, and furnishings standards as specified by the agency,
765 the Florida Building Code, and the Florida Fire Prevention Code
766 ~~department~~.
767 Section 15. Subsection (1) of section 395.10972, Florida
768 Statutes, is amended to read:
769 395.10972 Health Care Risk Manager Advisory Council.—The
770 Secretary of Health Care Administration may appoint a seven-
771 member advisory council to advise the agency on matters
772 pertaining to health care risk managers. The members of the
773 council shall serve at the pleasure of the secretary. The
774 council shall designate a chair. The council shall meet at the
775 call of the secretary or at those times as may be required by
776 rule of the agency. The members of the advisory council shall
777 receive no compensation for their services, but shall be
778 reimbursed for travel expenses as provided in s. 112.061. The
779 council shall consist of individuals representing the following
780 areas:
781 (1) Two shall be active health care risk managers,
782 including one risk manager who is recommended by and a member of
783 the Florida Society for ~~of~~ Healthcare Risk Management and

784 Patient Safety.
785 Section 16. Subsection (3) of section 395.2050, Florida
786 Statutes, is amended to read:
787 395.2050 Routine inquiry for organ and tissue donation;
788 certification for procurement activities; death records review.—
789 (3) Each organ procurement organization designated by the
790 federal Centers for Medicare and Medicaid Services ~~Health Care~~
791 ~~Financing Administration~~ and licensed by the state shall conduct
792 an annual death records review in the organ procurement
793 organization's affiliated donor hospitals. The organ procurement
794 organization shall enlist the services of every Florida licensed
795 tissue bank and eye bank affiliated with or providing service to
796 the donor hospital and operating in the same service area to
797 participate in the death records review.
798 Section 17. Subsection (2) of section 395.3036, Florida
799 Statutes, is amended to read:
800 395.3036 Confidentiality of records and meetings of
801 corporations that lease public hospitals or other public health
802 care facilities.—The records of a private corporation that
803 leases a public hospital or other public health care facility
804 are confidential and exempt from the provisions of s. 119.07(1)
805 and s. 24(a), Art. I of the State Constitution, and the meetings
806 of the governing board of a private corporation are exempt from
807 s. 286.011 and s. 24(b), Art. I of the State Constitution when
808 the public lessor complies with the public finance
809 accountability provisions of s. 155.40(5) with respect to the
810 transfer of any public funds to the private lessee and when the
811 private lessee meets at least three of the five following
812 criteria:

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813 (2) The public lessor and the private lessee do not
814 commingle any of their funds in any account maintained by either
815 of them, other than the payment of the rent and administrative
816 fees or the transfer of funds pursuant to s. 155.40 ~~subsection~~
817 ~~(2)~~.
818 Section 18. Section 395.3037, Florida Statutes, is
819 repealed.
820 Section 19. Subsections (1), (4), and (5) of section
821 395.3038, Florida Statutes, are amended to read:
822 395.3038 State-listed primary stroke centers and
823 comprehensive stroke centers; notification of hospitals.—
824 (1) The agency shall make available on its website and to
825 the department a list of the name and address of each hospital
826 that meets the criteria for a primary stroke center and the name
827 and address of each hospital that meets the criteria for a
828 comprehensive stroke center. The list of primary and
829 comprehensive stroke centers shall include only those hospitals
830 that attest in an affidavit submitted to the agency that the
831 hospital meets the named criteria, or those hospitals that
832 attest in an affidavit submitted to the agency that the hospital
833 is certified as a primary or a comprehensive stroke center by
834 the Joint Commission ~~on Accreditation of Healthcare~~
835 ~~Organizations~~.
836 (4) The agency shall adopt by rule criteria for a primary
837 stroke center which are substantially similar to the
838 certification standards for primary stroke centers of the Joint
839 Commission ~~on Accreditation of Healthcare Organizations~~.
840 (5) The agency shall adopt by rule criteria for a
841 comprehensive stroke center. However, if the Joint Commission ~~on~~

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842 ~~Accreditation of Healthcare Organizations~~ establishes criteria
843 for a comprehensive stroke center, the agency shall establish
844 criteria for a comprehensive stroke center which are
845 substantially similar to those criteria established by the Joint
846 Commission ~~on Accreditation of Healthcare Organizations~~.
847 Section 20. Paragraph (e) of subsection (2) of section
848 395.602, Florida Statutes, is amended to read:
849 395.602 Rural hospitals.—
850 (2) DEFINITIONS.—As used in this part:
851 (e) “Rural hospital” means an acute care hospital licensed
852 under this chapter, having 100 or fewer licensed beds and an
853 emergency room, which is:
854 1. The sole provider within a county with a population
855 density of no greater than 100 persons per square mile;
856 2. An acute care hospital, in a county with a population
857 density of no greater than 100 persons per square mile, which is
858 at least 30 minutes of travel time, on normally traveled roads
859 under normal traffic conditions, from any other acute care
860 hospital within the same county;
861 3. A hospital supported by a tax district or subdistrict
862 whose boundaries encompass a population of 100 persons or fewer
863 per square mile;
864 ~~4. A hospital in a constitutional charter county with a~~
865 ~~population of over 1 million persons that has imposed a local~~
866 ~~option health service tax pursuant to law and in an area that~~
867 ~~was directly impacted by a catastrophic event on August 24,~~
868 ~~1992, for which the Governor of Florida declared a state of~~
869 ~~emergency pursuant to chapter 125, and has 120 beds or less that~~
870 ~~serves an agricultural community with an emergency room~~

871 ~~utilization of no less than 20,000 visits and a Medicaid~~
872 ~~inpatient utilization rate greater than 15 percent;~~
873 4.~~5.~~ A hospital with a service area that has a population
874 of 100 persons or fewer per square mile. As used in this
875 subparagraph, the term “service area” means the fewest number of
876 zip codes that account for 75 percent of the hospital’s
877 discharges for the most recent 5-year period, based on
878 information available from the hospital inpatient discharge
879 database in the Florida Center for Health Information and Policy
880 Analysis at the Agency for Health Care Administration; or
881 5.~~6.~~ A hospital designated as a critical access hospital,
882 as defined in s. 408.07(15).
883
884 Population densities used in this paragraph must be based upon
885 the most recently completed United States census. A hospital
886 that received funds under s. 409.9116 for a quarter beginning no
887 later than July 1, 2002, is deemed to have been and shall
888 continue to be a rural hospital from that date through June 30,
889 2015, if the hospital continues to have 100 or fewer licensed
890 beds and an emergency room~~, or meets the criteria of~~
891 ~~subparagraph 4~~. An acute care hospital that has not previously
892 been designated as a rural hospital and that meets the criteria
893 of this paragraph shall be granted such designation upon
894 application, including supporting documentation to the Agency
895 for Health Care Administration.
896 Section 21. Subsections (8) and (16) of section 400.021,
897 Florida Statutes, are amended to read:
898 400.021 Definitions.—When used in this part, unless the
899 context otherwise requires, the term:

900 (8) "Geriatric outpatient clinic" means a site for
901 providing outpatient health care to persons 60 years of age or
902 older, which is staffed by a registered nurse or a physician
903 assistant, or a licensed practical nurse under the direct
904 supervision of a registered nurse, advanced registered nurse
905 practitioner, or physician.
906 (16) "Resident care plan" means a written plan developed,
907 maintained, and reviewed not less than quarterly by a registered
908 nurse, with participation from other facility staff and the
909 resident or his or her designee or legal representative, which
910 includes a comprehensive assessment of the needs of an
911 individual resident; the type and frequency of services required
912 to provide the necessary care for the resident to attain or
913 maintain the highest practicable physical, mental, and
914 psychosocial well-being; a listing of services provided within
915 or outside the facility to meet those needs; and an explanation
916 of service goals. The resident care plan must be signed by the
917 director of nursing or another registered nurse employed by the
918 facility to whom institutional responsibilities have been
919 delegated and by the resident, the resident's designee, or the
920 resident's legal representative. The facility may not use an
921 agency or temporary registered nurse to satisfy the foregoing
922 requirement and must document the institutional responsibilities
923 that have been delegated to the registered nurse.
924 Section 22. Subsection (1) of section 400.0234, Florida
925 Statutes, is amended to read:
926 400.0234 Availability of facility records for investigation
927 of resident's rights violations and defenses; penalty.—
928 (1) Failure to provide complete copies of a resident's

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929 records, including, but not limited to, all medical records and
930 the resident's chart, within the control or possession of the
931 facility <u>constitutes</u> ~~in accordance with s. 400.145 shall~~
932 ~~constitute~~ evidence of failure of that party to comply with good
933 faith discovery requirements and <u>waives</u> ~~shall waive~~ the good
934 faith certificate and presuit notice requirements under this
935 part by the requesting party.
936 Section 23. Paragraph (g) of subsection (2) of section
937 400.0239, Florida Statutes, is amended to read:
938 400.0239 Quality of Long-Term Care Facility Improvement
939 Trust Fund.—
940 (2) Expenditures from the trust fund shall be allowable for
941 direct support of the following:
942 (g) Other initiatives authorized by the Centers for
943 Medicare and Medicaid Services for the use of federal civil
944 monetary penalties~~, including projects recommended through the~~
945 ~~Medicaid "Up-or-Out" Quality of Care Contract Management Program~~
946 ~~pursuant to s. 400.148~~.
947 Section 24. Subsection (15) of section 400.0255, Florida
948 Statutes, is amended to read
949 400.0255 Resident transfer or discharge; requirements and
950 procedures; hearings.—
951 (15)(a) The department's Office of Appeals Hearings shall
952 conduct hearings under this section. The office shall notify the
953 facility of a resident's request for a hearing.
954 (b) The department shall, by rule, establish procedures to
955 be used for fair hearings requested by residents. These
956 procedures shall be equivalent to the procedures used for fair
957 hearings for other Medicaid cases <u>appearing in s. 409.285 and</u>

958 applicable rules~~, chapter 10-2, part VI, Florida Administrative~~
959 ~~Code~~. The burden of proof must be clear and convincing evidence.
960 A hearing decision must be rendered within 90 days after receipt
961 of the request for hearing.
962 (c) If the hearing decision is favorable to the resident
963 who has been transferred or discharged, the resident must be
964 readmitted to the facility's first available bed.
965 (d) The decision of the hearing officer shall be final. Any
966 aggrieved party may appeal the decision to the district court of
967 appeal in the appellate district where the facility is located.
968 Review procedures shall be conducted in accordance with the
969 Florida Rules of Appellate Procedure.
970 Section 25. Subsection (2) of section 400.063, Florida
971 Statutes, is amended to read:
972 400.063 Resident protection.—
973 (2) The agency is authorized to establish for each
974 facility, subject to intervention by the agency, a separate bank
975 account for the deposit to the credit of the agency of any
976 moneys received from the Health Care Trust Fund or any other
977 moneys received for the maintenance and care of residents in the
978 facility, and the agency is authorized to disburse moneys from
979 such account to pay obligations incurred for the purposes of
980 this section. The agency is authorized to requisition moneys
981 from the Health Care Trust Fund in advance of an actual need for
982 cash on the basis of an estimate by the agency of moneys to be
983 spent under the authority of this section. Any bank account
984 established under this section need not be approved in advance
985 of its creation as required by s. 17.58, but shall be secured by
986 depository insurance equal to or greater than the balance of

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987 such account or by the pledge of collateral security ~~in~~
988 ~~conformance with criteria established in s. 18.11~~. The agency
989 shall notify the Chief Financial Officer of any such account so
990 established and shall make a quarterly accounting to the Chief
991 Financial Officer for all moneys deposited in such account.
992 Section 26. Subsections (1) and (5) of section 400.071,
993 Florida Statutes, are amended to read:
994 400.071 Application for license.—
995 (1) In addition to the requirements of part II of chapter
996 408, the application for a license shall be under oath and must
997 contain the following:
998 (a) The location of the facility for which a license is
999 sought and an indication, as in the original application, that
1000 such location conforms to the local zoning ordinances.
1001 ~~(b) A signed affidavit disclosing any financial or~~
1002 ~~ownership interest that a controlling interest as defined in~~
1003 ~~part II of chapter 408 has held in the last 5 years in any~~
1004 ~~entity licensed by this state or any other state to provide~~
1005 ~~health or residential care which has closed voluntarily or~~
1006 ~~involuntarily; has filed for bankruptcy; has had a receiver~~
1007 ~~appointed; has had a license denied, suspended, or revoked; or~~
1008 ~~has had an injunction issued against it which was initiated by a~~
1009 ~~regulatory agency. The affidavit must disclose the reason any~~
1010 ~~such entity was closed, whether voluntarily or involuntarily.~~
1011 ~~(c) The total number of beds and the total number of~~
1012 ~~Medicare and Medicaid certified beds.~~
1013 (b) ~~(d)~~ Information relating to the applicant and employees
1014 which the agency requires by rule. The applicant must
1015 demonstrate that sufficient numbers of qualified staff, by

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1016 training or experience, will be employed to properly care for
1017 the type and number of residents who will reside in the
1018 facility.
1019 ~~(c) Copies of any civil verdict or judgment involving the~~
1020 ~~applicant rendered within the 10 years preceding the~~
1021 ~~application, relating to medical negligence, violation of~~
1022 ~~residents' rights, or wrongful death. As a condition of~~
1023 ~~licensure, the licensee agrees to provide to the agency copies~~
1024 ~~of any new verdict or judgment involving the applicant, relating~~
1025 ~~to such matters, within 30 days after filing with the clerk of~~
1026 ~~the court. The information required in this paragraph shall be~~
1027 ~~maintained in the facility's licensure file and in an agency~~
1028 ~~database which is available as a public record.~~
1029 (5) As a condition of licensure, each facility must
1030 establish ~~and submit with its application~~ a plan for quality
1031 assurance and for conducting risk management.
1032 Section 27. Section 400.0712, Florida Statutes, is amended
1033 to read:
1034 400.0712 Application for inactive license.—
1035 ~~(1) As specified in this section, the agency may issue an~~
1036 ~~inactive license to a nursing home facility for all or a portion~~
1037 ~~of its beds. Any request by a licensee that a nursing home or~~
1038 ~~portion of a nursing home become inactive must be submitted to~~
1039 ~~the agency in the approved format. The facility may not initiate~~
1040 ~~any suspension of services, notify residents, or initiate~~
1041 ~~inactivity before receiving approval from the agency; and a~~
1042 ~~licensee that violates this provision may not be issued an~~
1043 ~~inactive license.~~
1044 <u>(1)</u>~~(2)~~ <u>In addition to the powers granted under part II of</u>

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1045 chapter 408, the agency may issue an inactive license for a
1046 portion of the total beds to a nursing home that chooses to use
1047 an unoccupied contiguous portion of the facility for an
1048 alternative use to meet the needs of elderly persons through the
1049 use of less restrictive, less institutional services.
1050 (a) An inactive license issued under this subsection may be
1051 granted for a period not to exceed the current licensure
1052 expiration date but may be renewed by the agency at the time of
1053 licensure renewal.
1054 (b) A request to extend the inactive license must be
1055 submitted to the agency in the approved format and approved by
1056 the agency in writing.
1057 (c) Nursing homes that receive an inactive license to
1058 provide alternative services shall not receive preference for
1059 participation in the Assisted Living for the Elderly Medicaid
1060 waiver.
1061 (2) ~~(3)~~ The agency shall adopt rules pursuant to ss.
1062 120.536(1) and 120.54 necessary to implement this section.
1063 Section 28. Section 400.111, Florida Statutes, is amended
1064 to read:
1065 400.111 Disclosure of controlling interest.—In addition to
1066 the requirements of part II of chapter 408, when requested by
1067 the agency, the licensee shall submit a signed affidavit
1068 disclosing any financial or ownership interest that a
1069 controlling interest has held within the last 5 years in any
1070 entity licensed by the state or any other state to provide
1071 health or residential care which entity has closed voluntarily
1072 or involuntarily; has filed for bankruptcy; has had a receiver
1073 appointed; has had a license denied, suspended, or revoked; or

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1074 has had an injunction issued against it which was initiated by a
1075 regulatory agency. The affidavit must disclose the reason such
1076 entity was closed, whether voluntarily or involuntarily.
1077 Section 29. Subsection (2) of section 400.1183, Florida
1078 Statutes, is amended to read:
1079 400.1183 Resident grievance procedures.—
1080 (2) Each facility shall maintain records of all grievances
1081 and shall retain a log for agency inspection of ~~report to the~~
1082 ~~agency at the time of relicensure~~ the total number of grievances
1083 handled ~~during the prior licensure period~~, a categorization of
1084 the cases underlying the grievances, and the final disposition
1085 of the grievances.
1086 Section 30. Paragraphs (o) through (w) of subsection (1) of
1087 section 400.141, Florida Statutes, are redesignated as
1088 paragraphs (n) through (u), respectively, present paragraphs
1089 (f), (g), (j), (n), (o), and (r) of that subsection are amended,
1090 and subsection (3) is added to that section, to read:
1091 400.141 Administration and management of nursing home
1092 facilities.—
1093 (1) Every licensed facility shall comply with all
1094 applicable standards and rules of the agency and shall:
1095 (f) Be allowed and encouraged by the agency to provide
1096 other needed services under certain conditions. If the facility
1097 has a standard licensure status~~, and has had no class I or class~~
1098 ~~II deficiencies during the past 2 years or has been awarded a~~
1099 ~~Gold Seal under the program established in s. 400.235~~, it may ~~be~~
1100 ~~encouraged by the agency to~~ provide services, including, but not
1101 limited to, respite and adult day services, which enable
1102 individuals to move in and out of the facility. A facility is

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1103 not subject to any additional licensure requirements for
1104 providing these services, under the following conditions:.
1105 1. Respite care may be offered to persons in need of short-
1106 term or temporary nursing home services. For each person
1107 admitted under the respite care program, the facility licensee
1108 must:
1109 a. Have a written abbreviated plan of care that, at a
1110 minimum, includes nutritional requirements, medication orders,
1111 physician orders, nursing assessments, and dietary preferences.
1112 The nursing or physician assessments may take the place of all
1113 other assessments required for full-time residents.
1114 b. Have a contract that, at a minimum, specifies the
1115 services to be provided to the respite resident, including
1116 charges for services, activities, equipment, emergency medical
1117 services, and the administration of medications. If multiple
1118 respite admissions for a single person are anticipated, the
1119 original contract is valid for 1 year after the date of
1120 execution.
1121 c. Ensure that each resident is released to his or her
1122 caregiver or an individual designated in writing by the
1123 caregiver.
1124 2. A person admitted under the respite care program is:
1125 a. Exempt from requirements in rule related to discharge
1126 planning.
1127 b. Covered by the residents' rights set forth in s.
1128 400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident
1129 shall not be considered trust funds subject to the requirements
1130 of s. 400.022(1)(h) until the resident has been in the facility
1131 for more than 14 consecutive days.

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1132 c. Allowed to use his or her personal medications for the
1133 respite stay if permitted by facility policy. The facility must
1134 obtain a physician’s order for the medications. The caregiver
1135 may provide information regarding the medications as part of the
1136 nursing assessment and that information must agree with the
1137 physician’s order. Medications shall be released with the
1138 resident upon discharge in accordance with current physician’s
1139 orders.
1140 3. A person receiving respite care is entitled to reside in
1141 the facility for a total of 60 days within a contract year or
1142 within a calendar year if the contract is for less than 12
1143 months. However, each single stay may not exceed 14 days. If a
1144 stay exceeds 14 consecutive days, the facility must comply with
1145 all assessment and care planning requirements applicable to
1146 nursing home residents.
1147 4. A person receiving respite care must reside in a
1148 licensed nursing home bed.
1149 5. A prospective respite resident must provide medical
1150 information from a physician, a physician assistant, or a nurse
1151 practitioner and other information from the primary caregiver as
1152 may be required by the facility prior to or at the time of
1153 admission to receive respite care. The medical information must
1154 include a physician’s order for respite care and proof of a
1155 physical examination by a licensed physician, physician
1156 assistant, or nurse practitioner. The physician’s order and
1157 physical examination may be used to provide intermittent respite
1158 care for up to 12 months after the date the order is written.
1159 6. The facility must assume the duties of the primary
1160 caregiver. To ensure continuity of care and services, the

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1161 resident is entitled to retain his or her personal physician and
1162 must have access to medically necessary services such as
1163 physical therapy, occupational therapy, or speech therapy, as
1164 needed. The facility must arrange for transportation to these
1165 services if necessary. ~~Respite care must be provided in~~
1166 ~~accordance with this part and rules adopted by the agency.~~
1167 ~~However, the agency shall, by rule, adopt modified requirements~~
1168 ~~for resident assessment, resident care plans, resident~~
1169 ~~contracts, physician orders, and other provisions, as~~
1170 ~~appropriate, for short-term or temporary nursing home services.~~
1171 7. The agency shall allow for shared programming and staff
1172 in a facility which meets minimum standards and offers services
1173 pursuant to this paragraph, but, if the facility is cited for
1174 deficiencies in patient care, may require additional staff and
1175 programs appropriate to the needs of service recipients. A
1176 person who receives respite care may not be counted as a
1177 resident of the facility for purposes of the facility's licensed
1178 capacity unless that person receives 24-hour respite care. A
1179 person receiving either respite care for 24 hours or longer or
1180 adult day services must be included when calculating minimum
1181 staffing for the facility. Any costs and revenues generated by a
1182 nursing home facility from nonresidential programs or services
1183 shall be excluded from the calculations of Medicaid per diems
1184 for nursing home institutional care reimbursement.
1185 (g) If the facility has a standard license ~~or is a Gold~~
1186 ~~Seal facility~~, exceeds the minimum required hours of licensed
1187 nursing and certified nursing assistant direct care per resident
1188 per day, and is part of a continuing care facility licensed
1189 under chapter 651 or a retirement community that offers other

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1190 services pursuant to part III of this chapter or part I or part
1191 III of chapter 429 on a single campus, be allowed to share
1192 programming and staff. At the time of inspection ~~and in the~~
1193 ~~semiannual report required pursuant to paragraph (o)~~, a
1194 continuing care facility or retirement community that uses this
1195 option must demonstrate through staffing records that minimum
1196 staffing requirements for the facility were met. Licensed nurses
1197 and certified nursing assistants who work in the nursing home
1198 facility may be used to provide services elsewhere on campus if
1199 the facility exceeds the minimum number of direct care hours
1200 required per resident per day and the total number of residents
1201 receiving direct care services from a licensed nurse or a
1202 certified nursing assistant does not cause the facility to
1203 violate the staffing ratios required under s. 400.23(3)(a).
1204 Compliance with the minimum staffing ratios shall be based on
1205 total number of residents receiving direct care services,
1206 regardless of where they reside on campus. If the facility
1207 receives a conditional license, it may not share staff until the
1208 conditional license status ends. This paragraph does not
1209 restrict the agency's authority under federal or state law to
1210 require additional staff if a facility is cited for deficiencies
1211 in care which are caused by an insufficient number of certified
1212 nursing assistants or licensed nurses. The agency may adopt
1213 rules for the documentation necessary to determine compliance
1214 with this provision.
1215 (j) Keep full records of resident admissions and
1216 discharges; medical and general health status, including medical
1217 records, personal and social history, and identity and address
1218 of next of kin or other persons who may have responsibility for

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1219 the affairs of the residents; and individual resident care plans
1220 including, but not limited to, prescribed services, service
1221 frequency and duration, and service goals. The records shall be
1222 open to inspection by the agency. The facility must maintain
1223 clinical records on each resident in accordance with accepted
1224 professional standards and practices that are complete,
1225 accurately documented, readily accessible, and systematically
1226 organized.
1227 ~~(n) Submit to the agency the information specified in s.~~
1228 ~~400.071(1)(b) for a management company within 30 days after the~~
1229 ~~effective date of the management agreement.~~
1230 (n)~~(o)~~1. ~~Submit semiannually to the agency, or more~~
1231 ~~frequently if requested by the agency, information regarding~~
1232 ~~facility staff-to-resident ratios, staff turnover, and staff~~
1233 ~~stability, including information regarding certified nursing~~
1234 ~~assistants, licensed nurses, the director of nursing, and the~~
1235 ~~facility administrator. For purposes of this reporting:~~
1236 ~~a. Staff-to-resident ratios must be reported in the~~
1237 ~~categories specified in s. 400.23(3)(a) and applicable rules.~~
1238 ~~The ratio must be reported as an average for the most recent~~
1239 ~~calendar quarter.~~
1240 ~~b. Staff turnover must be reported for the most recent 12-~~
1241 ~~month period ending on the last workday of the most recent~~
1242 ~~calendar quarter prior to the date the information is submitted.~~
1243 ~~The turnover rate must be computed quarterly, with the annual~~
1244 ~~rate being the cumulative sum of the quarterly rates. The~~
1245 ~~turnover rate is the total number of terminations or separations~~
1246 ~~experienced during the quarter, excluding any employee~~
1247 ~~terminated during a probationary period of 3 months or less,~~

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1248 ~~divided by the total number of staff employed at the end of the~~
1249 ~~period for which the rate is computed, and expressed as a~~
1250 ~~percentage.~~
1251 ~~c. The formula for determining staff stability is the total~~
1252 ~~number of employees that have been employed for more than 12~~
1253 ~~months, divided by the total number of employees employed at the~~
1254 ~~end of the most recent calendar quarter, and expressed as a~~
1255 ~~percentage.~~
1256 ~~d.~~ A nursing facility that has failed to comply with state
1257 minimum-staffing requirements for 2 consecutive days is
1258 prohibited from accepting new admissions until the facility has
1259 achieved the minimum-staffing requirements for a period of 6
1260 consecutive days. For the purposes of this sub-subparagraph, any
1261 person who was a resident of the facility and was absent from
1262 the facility for the purpose of receiving medical care at a
1263 separate location or was on a leave of absence is not considered
1264 a new admission. Failure to impose such an admissions moratorium
1265 is subject to a $1,000 fine ~~constitutes a class II deficiency~~.
1266 2.~~e.~~ A nursing facility which does not have a conditional
1267 license may be cited for failure to comply with the standards in
1268 s. 400.23(3)(a)1.b. and c. only if it has failed to meet those
1269 standards on 2 consecutive days or if it has failed to meet at
1270 least 97 percent of those standards on any one day.
1271 3.~~f.~~ A facility which has a conditional license must be in
1272 compliance with the standards in s. 400.23(3)(a) at all times.
1273 (r)~~2.~~ This subsection ~~paragraph~~ does not limit the agency's
1274 ability to impose a deficiency or take other actions if a
1275 facility does not have enough staff to meet the residents'
1276 needs.

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1277 ~~(r) Report to the agency any filing for bankruptcy~~
1278 ~~protection by the facility or its parent corporation,~~
1279 ~~divestiture or spin-off of its assets, or corporate~~
1280 ~~reorganization within 30 days after the completion of such~~
1281 ~~activity.~~
1282 (3) A facility may charge a reasonable fee for copying a
1283 resident's records. Such fee may not exceed $1 per page for the
1284 first 25 pages and 25 cents per page for each page in excess of
1285 25 pages.
1286 Section 31. Subsection (3) of section 400.142, Florida
1287 Statutes, is amended to read:
1288 400.142 Emergency medication kits; orders not to
1289 resuscitate.—
1290 (3) Facility staff may withhold or withdraw cardiopulmonary
1291 resuscitation if presented with an order not to resuscitate
1292 executed pursuant to s. 401.45. ~~The agency shall adopt rules~~
1293 ~~providing for the implementation of such orders.~~ Facility staff
1294 and facilities shall not be subject to criminal prosecution or
1295 civil liability, nor be considered to have engaged in negligent
1296 or unprofessional conduct, for withholding or withdrawing
1297 cardiopulmonary resuscitation pursuant to such an order and
1298 rules adopted by the agency. The absence of an order not to
1299 resuscitate executed pursuant to s. 401.45 does not preclude a
1300 physician from withholding or withdrawing cardiopulmonary
1301 resuscitation as otherwise permitted by law.
1302 Section 32. Section 400.145, Florida Statutes, is repealed.
1303 Section 33. Present subsections (9), (11), (12), (13),
1304 (14), and (15) of section 400.147, Florida Statutes, are
1305 renumbered as subsections (8), (9), (10), (11), (12), and (13),

1306 respectively, and present subsections (7), (8), and (10) of that
1307 section are amended to read:
1308 400.147 Internal risk management and quality assurance
1309 program.—
1310 (7) The facility shall initiate an investigation ~~and shall~~
1311 ~~notify the agency~~ within 1 business day after the risk manager
1312 or his or her designee has received a report pursuant to
1313 paragraph (1)(d). <u>Each facility shall complete the investigation</u>
1314 <u>and submit a report to the agency within 15 calendar days if the</u>
1315 <u>incident is determined to be an adverse incident as defined in</u>
1316 <u>subsection (5).</u> ~~The notification must be made in writing and be~~
1317 ~~provided electronically, by facsimile device or overnight mail~~
1318 ~~delivery.~~ The <u>agency shall develop a form for reporting this</u>
1319 <u>information, and the</u> notification must include <u>the name of the</u>
1320 <u>risk manager of the facility,</u> information regarding the identity
1321 of the affected resident, the type of adverse incident, the
1322 initiation of an investigation by the facility, and whether the
1323 events causing or resulting in the adverse incident represent a
1324 potential risk to any other resident. The notification is
1325 confidential as provided by law and is not discoverable or
1326 admissible in any civil or administrative action, except in
1327 disciplinary proceedings by the agency or the appropriate
1328 regulatory board. The agency may investigate, as it deems
1329 appropriate, any such incident and prescribe measures that must
1330 or may be taken in response to the incident. The agency shall
1331 review each <u>report</u> ~~incident~~ and determine whether it potentially
1332 involved conduct by the health care professional who is subject
1333 to disciplinary action, in which case the provisions of s.
1334 456.073 shall apply.

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1335 ~~(8)(a) Each facility shall complete the investigation and~~
1336 ~~submit an adverse incident report to the agency for each adverse~~
1337 ~~incident within 15 calendar days after its occurrence. If, after~~
1338 ~~a complete investigation, the risk manager determines that the~~
1339 ~~incident was not an adverse incident as defined in subsection~~
1340 ~~(5), the facility shall include this information in the report.~~
1341 ~~The agency shall develop a form for reporting this information.~~
1342 ~~(b) The information reported to the agency pursuant to~~
1343 ~~paragraph (a) which relates to persons licensed under chapter~~
1344 ~~458, chapter 459, chapter 461, or chapter 466 shall be reviewed~~
1345 ~~by the agency. The agency shall determine whether any of the~~
1346 ~~incidents potentially involved conduct by a health care~~
1347 ~~professional who is subject to disciplinary action, in which~~
1348 ~~case the provisions of s. 456.073 shall apply.~~
1349 ~~(c) The report submitted to the agency must also contain~~
1350 ~~the name of the risk manager of the facility.~~
1351 ~~(d) The adverse incident report is confidential as provided~~
1352 ~~by law and is not discoverable or admissible in any civil or~~
1353 ~~administrative action, except in disciplinary proceedings by the~~
1354 ~~agency or the appropriate regulatory board.~~
1355 ~~(10) By the 10th of each month, each facility subject to~~
1356 ~~this section shall report any notice received pursuant to s.~~
1357 ~~400.0233(2) and each initial complaint that was filed with the~~
1358 ~~clerk of the court and served on the facility during the~~
1359 ~~previous month by a resident or a resident's family member,~~
1360 ~~guardian, conservator, or personal legal representative. The~~
1361 ~~report must include the name of the resident, the resident's~~
1362 ~~date of birth and social security number, the Medicaid~~
1363 ~~identification number for Medicaid-eligible persons, the date or~~

1364 ~~dates of the incident leading to the claim or dates of~~
1365 ~~residency, if applicable, and the type of injury or violation of~~
1366 ~~rights alleged to have occurred. Each facility shall also submit~~
1367 ~~a copy of the notices received pursuant to s. 400.0233(2) and~~
1368 ~~complaints filed with the clerk of the court. This report is~~
1369 ~~confidential as provided by law and is not discoverable or~~
1370 ~~admissible in any civil or administrative action, except in such~~
1371 ~~actions brought by the agency to enforce the provisions of this~~
1372 ~~part.~~
1373 Section 34. <u>Section 400.148, Florida Statutes, is repealed.</u>
1374 Section 35. Paragraph (e) of subsection (2) of section
1375 400.179, Florida Statutes, is amended to read:
1376 400.179 Liability for Medicaid underpayments and
1377 overpayments.—
1378 (2) Because any transfer of a nursing facility may expose
1379 the fact that Medicaid may have underpaid or overpaid the
1380 transferor, and because in most instances, any such underpayment
1381 or overpayment can only be determined following a formal field
1382 audit, the liabilities for any such underpayments or
1383 overpayments shall be as follows:
1384 ~~(e) For the 2009-2010 fiscal year only, the provisions of~~
1385 ~~paragraph (d) shall not apply. This paragraph expires July 1,~~
1386 ~~2010.~~
1387 Section 36. Subsection (3) of section 400.19, Florida
1388 Statutes, is amended to read:
1389 400.19 Right of entry and inspection.—
1390 (3) The agency shall every 15 months conduct at least one
1391 unannounced inspection to determine compliance by the licensee
1392 with statutes, and with rules promulgated under the provisions

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1393 of those statutes, governing minimum standards of construction,
1394 quality and adequacy of care, and rights of residents. The
1395 survey shall be conducted every 6 months for the next 2-year
1396 period if the facility has been cited for a class I deficiency,
1397 has been cited for two or more class II deficiencies arising
1398 from separate surveys or investigations within a 60-day period,
1399 or has had three or more substantiated complaints within a 6-
1400 month period, each resulting in at least one class I or class II
1401 deficiency. In addition to any other fees or fines in this part,
1402 the agency shall assess a fine for each facility that is subject
1403 to the 6-month survey cycle. The fine for the 2-year period
1404 shall be $6,000, one-half to be paid at the completion of each
1405 survey. The agency may adjust this fine by the change in the
1406 Consumer Price Index, based on the 12 months immediately
1407 preceding the increase, to cover the cost of the additional
1408 surveys. The agency shall verify through subsequent inspection
1409 that any deficiency identified during inspection is corrected.
1410 However, the agency may verify the correction of a class III or
1411 class IV deficiency ~~unrelated to resident rights or resident~~
1412 ~~care~~ without reinspecting the facility if adequate written
1413 documentation has been received from the facility, which
1414 provides assurance that the deficiency has been corrected. The
1415 giving or causing to be given of advance notice of such
1416 unannounced inspections by an employee of the agency to any
1417 unauthorized person shall constitute cause for suspension of not
1418 fewer than 5 working days according to the provisions of chapter
1419 110.
1420 Section 37. Subsection (5) of section 400.23, Florida
1421 Statutes, is amended to read:

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1422 400.23 Rules; evaluation and deficiencies; licensure
1423 status.—
1424 (5)(a) The agency, in collaboration with the Division of
1425 Children's Medical Services Network of the Department of Health,
1426 must, no later than December 31, 1993, adopt rules for minimum
1427 standards of care for persons under 21 years of age who reside
1428 in nursing home facilities. The rules must include a methodology
1429 for reviewing a nursing home facility under ss. 408.031-408.045
1430 which serves only persons under 21 years of age. A facility may
1431 be exempt from these standards for specific persons between 18
1432 and 21 years of age, if the person's physician agrees that
1433 minimum standards of care based on age are not necessary.
1434 (b) The agency, in collaboration with the Division of
1435 Children's Medical Services Network, shall adopt rules for
1436 minimum staffing requirements for nursing home facilities that
1437 serve persons under 21 years of age, which shall apply in lieu
1438 of the standards contained in subsection (3).
1439 1. For persons under 21 years of age who require skilled
1440 care, the requirements shall include a minimum combined average
1441 of licensed nurses, respiratory therapists, respiratory care
1442 practitioners, and certified nursing assistants of 3.9 hours of
1443 direct care per resident per day for each nursing home facility.
1444 2. For persons under 21 years of age who are fragile, the
1445 requirements shall include a minimum combined average of
1446 licensed nurses, respiratory therapists, respiratory care
1447 practitioners, and certified nursing assistants of 5 hours of
1448 direct care per resident per day for each nursing home facility.
1449 Section 38. Subsection (1) of section 400.275, Florida
1450 Statutes, is amended to read:

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1451 400.275 Agency duties.—
1452 (1) ~~The agency shall ensure that each newly hired nursing~~
1453 ~~home surveyor, as a part of basic training, is assigned full-~~
1454 ~~time to a licensed nursing home for at least 2 days within a 7-~~
1455 ~~day period to observe facility operations outside of the survey~~
1456 ~~process before the surveyor begins survey responsibilities. Such~~
1457 ~~observations may not be the sole basis of a deficiency citation~~
1458 ~~against the facility.~~ The agency may not assign an individual to
1459 be a member of a survey team for purposes of a survey,
1460 evaluation, or consultation visit at a nursing home facility in
1461 which the surveyor was an employee within the preceding <u>2</u> ~~5~~
1462 years.
1463 Section 39. Subsection (27) of section 400.462, Florida
1464 Statutes, is amended to read:
1465 400.462 Definitions.—As used in this part, the term:
1466 (27) "Remuneration" means any payment or other benefit made
1467 directly or indirectly, overtly or covertly, in cash or in kind.
1468 <u>However, when the term is used in any provision of law relating</u>
1469 <u>to health care providers, such term does not mean an item that</u>
1470 <u>has an individual value of up to $10, including, but not limited</u>
1471 <u>to, a plaque, a certificate, a trophy, or a novelty item that is</u>
1472 <u>intended solely for presentation or is customarily given away</u>
1473 <u>solely for promotional, recognition, or advertising purposes.</u>
1474 Section 40. Subsection (2) of section 400.484, Florida
1475 Statutes, is amended to read:
1476 400.484 Right of inspection; <u>violations</u> ~~deficiencies~~;
1477 fines.—
1478 (2) The agency shall impose fines for various classes of
1479 <u>violations</u> ~~deficiencies~~ in accordance with the following

1480 schedule:

1481 (a) <u>Class I violations are defined in s. 408.813.</u> ~~A class I~~
1482 ~~deficiency is any act, omission, or practice that results in a~~
1483 ~~patient's death, disablement, or permanent injury, or places a~~
1484 ~~patient at imminent risk of death, disablement, or permanent~~
1485 ~~injury.~~ Upon finding a class I <u>violation</u> ~~deficiency~~, the agency
1486 shall impose an administrative fine in the amount of $15,000 for
1487 each occurrence and each day that the <u>violation</u> ~~deficiency~~
1488 exists.

1489 (b) <u>Class II violations are defined in s. 408.813.</u> ~~A class~~
1490 ~~II deficiency is any act, omission, or practice that has a~~
1491 ~~direct adverse effect on the health, safety, or security of a~~
1492 ~~patient.~~ Upon finding a class II <u>violation</u> ~~deficiency~~, the
1493 agency shall impose an administrative fine in the amount of
1494 $5,000 for each occurrence and each day that the <u>violation</u>
1495 ~~deficiency~~ exists.

1496 (c) <u>Class III violations are defined in s. 408.813.</u> ~~A class~~
1497 ~~III deficiency is any act, omission, or practice that has an~~
1498 ~~indirect, adverse effect on the health, safety, or security of a~~
1499 ~~patient.~~ Upon finding an uncorrected or repeated class III
1500 <u>violation</u> ~~deficiency~~, the agency shall impose an administrative
1501 fine not to exceed $1,000 for each occurrence and each day that
1502 the uncorrected or repeated <u>violation</u> ~~deficiency~~ exists.

1503 (d) <u>Class IV violations are defined in s. 408.813.</u> ~~A class~~
1504 ~~IV deficiency is any act, omission, or practice related to~~
1505 ~~required reports, forms, or documents which does not have the~~
1506 ~~potential of negatively affecting patients. These violations are~~
1507 ~~of a type that the agency determines do not threaten the health,~~
1508 ~~safety, or security of patients.~~ Upon finding an uncorrected or

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1509 repeated class IV violation ~~deficiency~~, the agency shall impose
1510 an administrative fine not to exceed $500 for each occurrence
1511 and each day that the uncorrected or repeated violation
1512 ~~deficiency~~ exists.
1513 Section 41. Paragraph (a) of section (15) of section
1514 400.506, Florida Statutes, is amended, present subsection (17)
1515 of that section is renumbered as subsection (18), and a new
1516 subsection (17) is added to that section, to read:
1517 400.506 Licensure of nurse registries; requirements;
1518 penalties.—
1519 (15)(a) The agency may deny, suspend, or revoke the license
1520 of a nurse registry and shall impose a fine of $5,000 against a
1521 nurse registry that:
1522 1. Provides services to residents in an assisted living
1523 facility for which the nurse registry does not receive fair
1524 market value remuneration.
1525 2. Provides staffing to an assisted living facility for
1526 which the nurse registry does not receive fair market value
1527 remuneration.
1528 3. Fails to provide the agency, upon request, with copies
1529 of all contracts with assisted living facilities which were
1530 executed within the last 5 years.
1531 4. Gives remuneration to a case manager, discharge planner,
1532 facility-based staff member, or third-party vendor who is
1533 involved in the discharge planning process of a facility
1534 licensed under chapter 395 or this chapter and from whom the
1535 nurse registry receives referrals. A nurse registry is exempt
1536 from this subparagraph if it does not bill ~~the Florida Medicaid~~
1537 ~~program or~~ the Medicare program or share a controlling interest

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1538 with any entity licensed, registered, or certified under part II
1539 of chapter 408 that bills ~~the Florida Medicaid program or~~ the
1540 Medicare program.
1541 5. Gives remuneration to a physician, a member of the
1542 physician's office staff, or an immediate family member of the
1543 physician, and the nurse registry received a patient referral in
1544 the last 12 months from that physician or the physician's office
1545 staff. A nurse registry is exempt from this subparagraph if it
1546 does not bill ~~the Florida Medicaid program or~~ the Medicare
1547 program or share a controlling interest with any entity
1548 licensed, registered, or certified under part II of chapter 408
1549 that bills ~~the Florida Medicaid program or~~ the Medicare program.
1550 (17) An administrator may manage only one nurse registry.
1551 However, an administrator may manage up to five nurse registries
1552 if all five registries have identical controlling interests, as
1553 defined in s. 408.803, and are located within one agency
1554 geographic service area or within an immediately contiguous
1555 county. An administrator shall designate, in writing, for each
1556 licensed entity, a qualified alternate administrator to serve
1557 during the administrator's absence.
1558 Section 42. Subsection (1) of section 400.509, Florida
1559 Statutes, is amended to read:
1560 400.509 Registration of particular service providers exempt
1561 from licensure; certificate of registration; regulation of
1562 registrants.—
1563 (1) Any organization that provides companion services or
1564 homemaker services and does not provide a home health service to
1565 a person is exempt from licensure under this part. However, any
1566 organization that provides companion services or homemaker

1567 services must register with the agency. <u>Organizations that</u>
1568 <u>provide companion services only for persons with developmental</u>
1569 <u>disabilities, as defined in s. 393.063, under contract with the</u>
1570 <u>Agency for Persons with Disabilities, are exempt from</u>
1571 <u>registration with the agency.</u>
1572 Section 43. For the purpose of incorporating the amendment
1573 made by this act to section 400.509, Florida Statutes, in a
1574 reference thereto, paragraph (b) of subsection (5) of section
1575 400.464, Florida Statutes, is reenacted to read:
1576 400.464 Home health agencies to be licensed; expiration of
1577 license; exemptions; unlawful acts; penalties.—
1578 (5) The following are exempt from the licensure
1579 requirements of this part:
1580 (b) Home health services provided by a state agency, either
1581 directly or through a contractor with:
1582 1. The Department of Elderly Affairs.
1583 2. The Department of Health, a community health center, or
1584 a rural health network that furnishes home visits for the
1585 purpose of providing environmental assessments, case management,
1586 health education, personal care services, family planning, or
1587 followup treatment, or for the purpose of monitoring and
1588 tracking disease.
1589 3. Services provided to persons with developmental
1590 disabilities, as defined in s. 393.063.
1591 4. Companion and sitter organizations that were registered
1592 under s. 400.509(1) on January 1, 1999, and were authorized to
1593 provide personal services under a developmental services
1594 provider certificate on January 1, 1999, may continue to provide
1595 such services to past, present, and future clients of the

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1596 organization who need such services, notwithstanding the
1597 provisions of this act.
1598 5. The Department of Children and Family Services.
1599 Section 44. For the purpose of incorporating the amendment
1600 made by this act to section 400.509, Florida Statutes, in a
1601 reference thereto, paragraph (a) of subsection (6) of section
1602 400.506, Florida Statutes, is reenacted to read:
1603 400.506 Licensure of nurse registries; requirements;
1604 penalties.—
1605 (6)(a) A nurse registry may refer for contract in private
1606 residences registered nurses and licensed practical nurses
1607 registered and licensed under part I of chapter 464, certified
1608 nursing assistants certified under part II of chapter 464, home
1609 health aides who present documented proof of successful
1610 completion of the training required by rule of the agency, and
1611 companions or homemakers for the purposes of providing those
1612 services authorized under s. 400.509(1). A licensed nurse
1613 registry shall ensure that each certified nursing assistant
1614 referred for contract by the nurse registry and each home health
1615 aide referred for contract by the nurse registry is adequately
1616 trained to perform the tasks of a home health aide in the home
1617 setting. Each person referred by a nurse registry must provide
1618 current documentation that he or she is free from communicable
1619 diseases.
1620 Section 45. Paragraph (i) of subsection (1) and subsection
1621 (4) of section 400.606, Florida Statutes, are amended to read:
1622 400.606 License; application; renewal; conditional license
1623 or permit; certificate of need.—
1624 (1) In addition to the requirements of part II of chapter

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1625 408, the initial application and change of ownership application
1626 must be accompanied by a plan for the delivery of home,
1627 residential, and homelike inpatient hospice services to
1628 terminally ill persons and their families. Such plan must
1629 contain, but need not be limited to:
1630 ~~(i) The projected annual operating cost of the hospice.~~
1631
1632 If the applicant is an existing licensed health care provider,
1633 the application must be accompanied by a copy of the most recent
1634 profit-loss statement and, if applicable, the most recent
1635 licensure inspection report.
1636 (4) A freestanding hospice facility that is ~~primarily~~
1637 engaged in providing inpatient and related services and that is
1638 not otherwise licensed as a health care facility shall be
1639 required to obtain a certificate of need. However, a
1640 freestanding hospice facility with six or fewer beds shall not
1641 be required to comply with institutional standards such as, but
1642 not limited to, standards requiring sprinkler systems, emergency
1643 electrical systems, or special lavatory devices.
1644 Section 46. Subsection (2) of section 400.607, Florida
1645 Statutes, is amended to read:
1646 400.607 Denial, suspension, revocation of license;
1647 emergency actions; imposition of administrative fine; grounds.—
1648 (2) <u>A violation of this part, part II of chapter 408, or</u>
1649 <u>applicable rules</u> ~~Any of the following actions~~ by a licensed
1650 hospice or any of its employees shall be grounds for
1651 <u>administrative</u> action by the agency against a hospice<u>.</u>~~:~~
1652 ~~(a) A violation of the provisions of this part, part II of~~
1653 ~~chapter 408, or applicable rules.~~

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1654 ~~(b) An intentional or negligent act materially affecting~~
1655 ~~the health or safety of a patient.~~
1656 Section 47. Section 400.915, Florida Statutes, is amended
1657 to read:
1658 400.915 Construction and renovation; requirements.—The
1659 requirements for the construction or renovation of a PPEC center
1660 shall comply with:
1661 (1) The provisions of chapter 553, which pertain to
1662 building construction standards, including plumbing, electrical
1663 code, glass, manufactured buildings, accessibility for the
1664 physically disabled;
1665 (2) The provisions of s. 633.022 and applicable rules
1666 pertaining to physical ~~minimum~~ standards for nonresidential
1667 child care ~~physical~~ facilities ~~in rule 10M-12.003, Florida~~
1668 ~~Administrative Code, Child Care Standards~~; and
1669 (3) The standards or rules adopted pursuant to this part
1670 and part II of chapter 408.
1671 Section 48. Subsection (1) of section 400.925, Florida
1672 Statutes, is amended to read:
1673 400.925 Definitions.—As used in this part, the term:
1674 (1) "Accrediting organizations" means the Joint Commission
1675 ~~on Accreditation of Healthcare Organizations~~ or other national
1676 accreditation agencies whose standards for accreditation are
1677 comparable to those required by this part for licensure.
1678 Section 49. Section 400.931, Florida Statutes, is amended
1679 to read:
1680 400.931 Application for license; documentation of
1681 accreditation; fee~~; provisional license; temporary permit~~.—
1682 (1) In addition to the requirements of part II of chapter

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1683 408, the applicant must file with the application satisfactory
1684 proof that the home medical equipment provider is in compliance
1685 with this part and applicable rules, including:
1686 (a) A report, by category, of the equipment to be provided,
1687 indicating those offered either directly by the applicant or
1688 through contractual arrangements with existing providers.
1689 Categories of equipment include:
1690 1. Respiratory modalities.
1691 2. Ambulation aids.
1692 3. Mobility aids.
1693 4. Sickroom setup.
1694 5. Disposables.
1695 (b) A report, by category, of the services to be provided,
1696 indicating those offered either directly by the applicant or
1697 through contractual arrangements with existing providers.
1698 Categories of services include:
1699 1. Intake.
1700 2. Equipment selection.
1701 3. Delivery.
1702 4. Setup and installation.
1703 5. Patient training.
1704 6. Ongoing service and maintenance.
1705 7. Retrieval.
1706 (c) A listing of those with whom the applicant contracts,
1707 both the providers the applicant uses to provide equipment or
1708 services to its consumers and the providers for whom the
1709 applicant provides services or equipment.
1710 (2) An applicant for initial licensure, change of
1711 ownership, or renewal to operate a licensed home medical

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1712 equipment provider at a location outside the state of Florida
1713 must submit documentation of accreditation, or an application
1714 for accreditation, from an accrediting organization that is
1715 recognized by the agency. An applicant that has applied for
1716 accreditation must provide proof of accreditation that is not
1717 conditional or provisional within 120 days after the date of the
1718 agency's receipt of the application for licensure or the
1719 application shall be withdrawn from further consideration. Such
1720 accreditation must be maintained by the home medical equipment
1721 provider in order to maintain licensure. ~~As an alternative to~~
1722 ~~submitting proof of financial ability to operate as required in~~
1723 ~~s. 408.810(8), the applicant may submit a $50,000 surety bond to~~
1724 ~~the agency.~~
1725 (3) As specified in part II of chapter 408, the home
1726 medical equipment provider must also obtain and maintain
1727 professional and commercial liability insurance. Proof of
1728 liability insurance, as defined in s. 624.605, must be submitted
1729 with the application. The agency shall set the required amounts
1730 of liability insurance by rule, but the required amount must not
1731 be less than $250,000 per claim. In the case of contracted
1732 services, it is required that the contractor have liability
1733 insurance not less than $250,000 per claim.
1734 (4) When a change of the general manager of a home medical
1735 equipment provider occurs, the licensee must notify the agency
1736 of the change within 45 days.
1737 (5) In accordance with s. 408.805, an applicant or a
1738 licensee shall pay a fee for each license application submitted
1739 under this part, part II of chapter 408, and applicable rules.
1740 The amount of the fee shall be established by rule and may not

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1741 exceed $300 per biennium. The agency shall set the fees in an
1742 amount that is sufficient to cover its costs in carrying out its
1743 responsibilities under this part. However, state, county, or
1744 municipal governments applying for licenses under this part are
1745 exempt from the payment of license fees.
1746 (6) An applicant for initial licensure, renewal, or change
1747 of ownership shall also pay an inspection fee not to exceed
1748 $400, which shall be paid by all applicants except those not
1749 subject to licensure inspection by the agency as described in s.
1750 400.933.
1751 Section 50. Subsection (2) of section 400.932, Florida
1752 Statutes, is amended to read:
1753 400.932 Administrative penalties.—
1754 (2) A violation of this part, part II of chapter 408, or
1755 applicable rules ~~Any of the following actions~~ by an employee of
1756 a home medical equipment provider shall be ~~are~~ grounds for
1757 administrative action or penalties by the agency.~~:~~
1758 ~~(a) Violation of this part, part II of chapter 408, or~~
1759 ~~applicable rules.~~
1760 ~~(b) An intentional, reckless, or negligent act that~~
1761 ~~materially affects the health or safety of a patient.~~
1762 Section 51. Subsection (3) of section 400.967, Florida
1763 Statutes, is amended to read:
1764 400.967 Rules and classification of violations
1765 ~~deficiencies~~.—
1766 (3) The agency shall adopt rules to provide that, when the
1767 criteria established under this part and part II of chapter 408
1768 are not met, such violations ~~deficiencies~~ shall be classified
1769 according to the nature of the violation ~~deficiency~~. The agency

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1770 shall indicate the classification on the face of the notice of
1771 deficiencies as follows:
1772 (a) Class I violations ~~deficiencies~~ are defined in s.
1773 408.813 ~~those which the agency determines present an imminent~~
1774 ~~danger to the residents or guests of the facility or a~~
1775 ~~substantial probability that death or serious physical harm~~
1776 ~~would result therefrom~~. ~~The condition or practice constituting a~~
1777 ~~class I violation must be abated or eliminated immediately,~~
1778 ~~unless a fixed period of time, as determined by the agency, is~~
1779 ~~required for correction.~~ A class I violation ~~deficiency~~ is
1780 subject to a civil penalty in an amount not less than $5,000 and
1781 not exceeding $10,000 for each violation ~~deficiency~~. A fine may
1782 be levied notwithstanding the correction of the violation
1783 ~~deficiency~~.
1784 (b) Class II violations ~~deficiencies~~ are defined in s.
1785 408.813 ~~those which the agency determines have a direct or~~
1786 ~~immediate relationship to the health, safety, or security of the~~
1787 ~~facility residents, other than class I deficiencies~~. A class II
1788 violation ~~deficiency~~ is subject to a civil penalty in an amount
1789 not less than $1,000 and not exceeding $5,000 for each violation
1790 ~~deficiency~~. A citation for a class II violation ~~deficiency~~ shall
1791 specify the time within which the violation ~~deficiency~~ must be
1792 corrected. If a class II violation ~~deficiency~~ is corrected
1793 within the time specified, no civil penalty shall be imposed,
1794 unless it is a repeated offense.
1795 (c) Class III violations ~~deficiencies~~ are defined in s.
1796 408.813 ~~those which the agency determines to have an indirect or~~
1797 ~~potential relationship to the health, safety, or security of the~~
1798 ~~facility residents, other than class I or class II deficiencies~~.

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1799 A class III violation ~~deficiency~~ is subject to a civil penalty
1800 of not less than $500 and not exceeding $1,000 for each
1801 deficiency. A citation for a class III violation ~~deficiency~~
1802 shall specify the time within which the violation ~~deficiency~~
1803 must be corrected. If a class III violation ~~deficiency~~ is
1804 corrected within the time specified, no civil penalty shall be
1805 imposed, unless it is a repeated offense.
1806 (d) Class IV violations are defined in s. 408.813. Upon
1807 finding an uncorrected or repeated class IV violation, the
1808 agency shall impose an administrative fine not to exceed $500
1809 for each occurrence and each day that the uncorrected or
1810 repeated violation exists.
1811 Section 52. Subsections (4) and (7) of section 400.9905,
1812 Florida Statutes, are amended to read:
1813 400.9905 Definitions.—
1814 (4) "Clinic" means an entity at which health care services
1815 are provided to individuals and which tenders charges for
1816 reimbursement for such services, including a mobile clinic and a
1817 portable health service or equipment provider. For purposes of
1818 this part, the term does not include and the licensure
1819 requirements of this part do not apply to:
1820 (a) Entities licensed or registered by the state under
1821 chapter 395; or entities licensed or registered by the state and
1822 providing only health care services within the scope of services
1823 authorized under their respective licenses granted under ss.
1824 383.30-383.335, chapter 390, chapter 394, chapter 397, this
1825 chapter except part X, chapter 429, chapter 463, chapter 465,
1826 chapter 466, chapter 478, part I of chapter 483, chapter 484, or
1827 chapter 651; end-stage renal disease providers authorized under

1828 42 C.F.R. part 405, subpart U; or providers certified under 42
1829 C.F.R. part 485, subpart B or subpart H; or any entity that
1830 provides neonatal or pediatric hospital-based health care
1831 services or other health care services by licensed practitioners
1832 solely within a hospital licensed under chapter 395.
1833 (b) Entities that own, directly or indirectly, entities
1834 licensed or registered by the state pursuant to chapter 395; or
1835 entities that own, directly or indirectly, entities licensed or
1836 registered by the state and providing only health care services
1837 within the scope of services authorized pursuant to their
1838 respective licenses granted under ss. 383.30-383.335, chapter
1839 390, chapter 394, chapter 397, this chapter except part X,
1840 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
1841 part I of chapter 483, chapter 484, chapter 651; end-stage renal
1842 disease providers authorized under 42 C.F.R. part 405, subpart
1843 U; or providers certified under 42 C.F.R. part 485, subpart B or
1844 subpart H; or any entity that provides neonatal or pediatric
1845 hospital-based health care services by licensed practitioners
1846 solely within a hospital licensed under chapter 395.
1847 (c) Entities that are owned, directly or indirectly, by an
1848 entity licensed or registered by the state pursuant to chapter
1849 395; or entities that are owned, directly or indirectly, by an
1850 entity licensed or registered by the state and providing only
1851 health care services within the scope of services authorized
1852 pursuant to their respective licenses granted under ss. 383.30-
1853 383.335, chapter 390, chapter 394, chapter 397, this chapter
1854 except part X, chapter 429, chapter 463, chapter 465, chapter
1855 466, chapter 478, part I of chapter 483, chapter 484, or chapter
1856 651; end-stage renal disease providers authorized under 42

1857 C.F.R. part 405, subpart U; or providers certified under 42
1858 C.F.R. part 485, subpart B or subpart H; or any entity that
1859 provides neonatal or pediatric hospital-based health care
1860 services by licensed practitioners solely within a hospital
1861 under chapter 395.
1862 (d) Entities that are under common ownership, directly or
1863 indirectly, with an entity licensed or registered by the state
1864 pursuant to chapter 395; or entities that are under common
1865 ownership, directly or indirectly, with an entity licensed or
1866 registered by the state and providing only health care services
1867 within the scope of services authorized pursuant to their
1868 respective licenses granted under ss. 383.30-383.335, chapter
1869 390, chapter 394, chapter 397, this chapter except part X,
1870 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
1871 part I of chapter 483, chapter 484, or chapter 651; end-stage
1872 renal disease providers authorized under 42 C.F.R. part 405,
1873 subpart U; or providers certified under 42 C.F.R. part 485,
1874 subpart B or subpart H; or any entity that provides neonatal or
1875 pediatric hospital-based health care services by licensed
1876 practitioners solely within a hospital licensed under chapter
1877 395.
1878 (e) An entity that is exempt from federal taxation under 26
1879 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan
1880 under 26 U.S.C. s. 409 that has a board of trustees not less
1881 than two-thirds of which are Florida-licensed health care
1882 practitioners and provides only physical therapy services under
1883 physician orders, any community college or university clinic,
1884 and any entity owned or operated by the federal or state
1885 government, including agencies, subdivisions, or municipalities

1886 thereof.
1887 (f) A sole proprietorship, group practice, partnership, or
1888 corporation that provides health care services by physicians
1889 covered by s. 627.419, that is directly supervised by one or
1890 more of such physicians, and that is wholly owned by one or more
1891 of those physicians or by a physician and the spouse, parent,
1892 child, or sibling of that physician.
1893 (g) A sole proprietorship, group practice, partnership, or
1894 corporation that provides health care services by licensed
1895 health care practitioners under chapter 457, chapter 458,
1896 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
1897 chapter 466, chapter 467, chapter 480, chapter 484, chapter 486,
1898 chapter 490, chapter 491, or part I, part III, part X, part
1899 XIII, or part XIV of chapter 468, or s. 464.012, which are
1900 wholly owned by one or more licensed health care practitioners,
1901 or the licensed health care practitioners set forth in this
1902 paragraph and the spouse, parent, child, or sibling of a
1903 licensed health care practitioner, so long as one of the owners
1904 who is a licensed health care practitioner is supervising the
1905 business activities and is legally responsible for the entity's
1906 compliance with all federal and state laws. However, a health
1907 care practitioner may not supervise services beyond the scope of
1908 the practitioner's license, except that, for the purposes of
1909 this part, a clinic owned by a licensee in s. 456.053(3)(b) that
1910 provides only services authorized pursuant to s. 456.053(3)(b)
1911 may be supervised by a licensee specified in s. 456.053(3)(b).
1912 (h) Clinical facilities affiliated with an accredited
1913 medical school at which training is provided for medical
1914 students, residents, or fellows.

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1915 (i) Entities that provide only oncology or radiation
1916 therapy services by physicians licensed under chapter 458 or
1917 chapter 459 or entities that provide oncology or radiation
1918 therapy services by physicians licensed under chapter 458 or
1919 chapter 459 which are owned by a corporation whose shares are
1920 publicly traded on a recognized stock exchange.
1921 (j) Clinical facilities affiliated with a college of
1922 chiropractic accredited by the Council on Chiropractic Education
1923 at which training is provided for chiropractic students.
1924 (k) Entities that provide licensed practitioners to staff
1925 emergency departments or to deliver anesthesia services in
1926 facilities licensed under chapter 395 and that derive at least
1927 90 percent of their gross annual revenues from the provision of
1928 such services. Entities claiming an exemption from licensure
1929 under this paragraph must provide documentation demonstrating
1930 compliance.
1931 (l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or
1932 perinatology clinical facilities that are a publicly traded
1933 corporation or that are wholly owned, directly or indirectly, by
1934 a publicly traded corporation. As used in this paragraph, a
1935 publicly traded corporation is a corporation that issues
1936 securities traded on an exchange registered with the United
1937 States Securities and Exchange Commission as a national
1938 securities exchange.
1939 (m) Entities that are owned by a corporation that has $250
1940 million or more in total annual sales of health care services
1941 provided by licensed health care practitioners if one or more of
1942 the owners of the entity is a health care practitioner who is
1943 licensed in this state, is responsible for supervising the

1944 business activities of the entity, and is legally responsible
1945 for the entity's compliance with state law for purposes of this
1946 section.
1947 (n) Entities that are owned or controlled, directly or
1948 indirectly, by a publicly traded entity with $100 million or
1949 more, in the aggregate, in total annual revenues derived from
1950 providing health care services by licensed health care
1951 practitioners that are employed or contracted by an entity
1952 described in this paragraph.
1953 (o) Entities that employ 50 or more health care
1954 practitioners who are licensed under chapter 458 or chapter 459
1955 if the billing for medical services is under a single corporate
1956 tax identification number. The application for exemption under
1957 this paragraph must contain information that includes the name,
1958 residence address, business address, and telephone number of the
1959 entity that owns the practice; a complete list of the names and
1960 contact information of all the officers and directors of the
1961 entity; the name, residence address, business address, and
1962 medical license number of each health care practitioner who is
1963 licensed to practice in this state and employed by the entity;
1964 the corporate tax identification number of the entity seeking an
1965 exemption; a listing of health care services to be provided by
1966 the entity at the health care clinics owned or operated by the
1967 entity; and a certified statement prepared by an independent
1968 certified public accountant which states that the entity and the
1969 health care clinics owned or operated by the entity have not
1970 received payment for health care services under insurance
1971 coverage for personal injury protection for the preceding year.
1972 If the agency determines that an entity that is exempt under

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1973 this paragraph has received payments for medical services for
1974 insurance coverage for personal injury protection, the agency
1975 may deny or revoke the exemption from licensure under this
1976 paragraph.
1977 (7) "Portable health service or equipment provider" means
1978 an entity that contracts with or employs persons to provide
1979 portable health services or equipment to multiple locations
1980 ~~performing treatment or diagnostic testing of individuals~~, that
1981 bills third-party payors for those services, and that otherwise
1982 meets the definition of a clinic in subsection (4).
1983 Section 53. Paragraph (b) of subsection (1) and paragraph
1984 (c) of subsection (4) of section 400.991, Florida Statutes, are
1985 amended to read:
1986 400.991 License requirements; background screenings;
1987 prohibitions.—
1988 (1)
1989 (b) Each mobile clinic must obtain a separate health care
1990 clinic license and must provide to the agency, at least
1991 quarterly, its projected street location to enable the agency to
1992 locate and inspect such clinic. A portable health service or
1993 equipment provider must obtain a health care clinic license for
1994 a single administrative office and is not required to submit
1995 quarterly projected street locations.
1996 (4) In addition to the requirements of part II of chapter
1997 408, the applicant must file with the application satisfactory
1998 proof that the clinic is in compliance with this part and
1999 applicable rules, including:
2000 (c) Proof of financial ability to operate as required under
2001 ss. ~~s.~~ 408.810(8) and 408.8065. ~~As an alternative to submitting~~

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2002 ~~proof of financial ability to operate as required under s.~~
2003 ~~408.810(8), the applicant may file a surety bond of at least~~
2004 ~~$500,000 which guarantees that the clinic will act in full~~
2005 ~~conformity with all legal requirements for operating a clinic,~~
2006 ~~payable to the agency. The agency may adopt rules to specify~~
2007 ~~related requirements for such surety bond.~~
2008 Section 54. Paragraph (g) of subsection (1) and paragraph
2009 (a) of subsection (7) of section 400.9935, Florida Statutes, are
2010 amended to read:
2011 400.9935 Clinic responsibilities.—
2012 (1) Each clinic shall appoint a medical director or clinic
2013 director who shall agree in writing to accept legal
2014 responsibility for the following activities on behalf of the
2015 clinic. The medical director or the clinic director shall:
2016 (g) Conduct systematic reviews of clinic billings to ensure
2017 that the billings are not fraudulent or unlawful. Upon discovery
2018 of an unlawful charge, the medical director or clinic director
2019 shall take immediate corrective action. If the clinic performs
2020 only the technical component of magnetic resonance imaging,
2021 static radiographs, computed tomography, or positron emission
2022 tomography, and provides the professional interpretation of such
2023 services, in a fixed facility that is accredited by the Joint
2024 Commission ~~on Accreditation of Healthcare Organizations~~ or the
2025 Accreditation Association for Ambulatory Health Care, and the
2026 American College of Radiology; and if, in the preceding quarter,
2027 the percentage of scans performed by that clinic which was
2028 billed to all personal injury protection insurance carriers was
2029 less than 15 percent, the chief financial officer of the clinic
2030 may, in a written acknowledgment provided to the agency, assume

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2031 the responsibility for the conduct of the systematic reviews of
2032 clinic billings to ensure that the billings are not fraudulent
2033 or unlawful.
2034 (7)(a) Each clinic engaged in magnetic resonance imaging
2035 services must be accredited by the Joint Commission ~~on~~
2036 ~~Accreditation of Healthcare Organizations~~, the American College
2037 of Radiology, or the Accreditation Association for Ambulatory
2038 Health Care, within 1 year after licensure. A clinic that is
2039 accredited by the American College of Radiology or is within the
2040 original 1-year period after licensure and replaces its core
2041 magnetic resonance imaging equipment shall be given 1 year after
2042 the date on which the equipment is replaced to attain
2043 accreditation. However, a clinic may request a single, 6-month
2044 extension if it provides evidence to the agency establishing
2045 that, for good cause shown, such clinic cannot be accredited
2046 within 1 year after licensure, and that such accreditation will
2047 be completed within the 6-month extension. After obtaining
2048 accreditation as required by this subsection, each such clinic
2049 must maintain accreditation as a condition of renewal of its
2050 license. A clinic that files a change of ownership application
2051 must comply with the original accreditation timeframe
2052 requirements of the transferor. The agency shall deny a change
2053 of ownership application if the clinic is not in compliance with
2054 the accreditation requirements. When a clinic adds, replaces, or
2055 modifies magnetic resonance imaging equipment and the
2056 accreditation agency requires new accreditation, the clinic must
2057 be accredited within 1 year after the date of the addition,
2058 replacement, or modification but may request a single, 6-month
2059 extension if the clinic provides evidence of good cause to the

2060 agency.
2061 Section 55. Paragraph (a) of subsection (2) of section
2062 408.033, Florida Statutes, is amended to read:
2063 408.033 Local and state health planning.—
2064 (2) FUNDING.—
2065 (a) The Legislature intends that the cost of local health
2066 councils be borne by assessments on selected health care
2067 facilities subject to facility licensure by the Agency for
2068 Health Care Administration, including abortion clinics, assisted
2069 living facilities, ambulatory surgical centers, birthing
2070 centers, clinical laboratories except community nonprofit blood
2071 banks and clinical laboratories operated by practitioners for
2072 exclusive use regulated under s. 483.035, home health agencies,
2073 hospices, hospitals, intermediate care facilities for the
2074 developmentally disabled, nursing homes, health care clinics,
2075 and multiphasic testing centers and by assessments on
2076 organizations subject to certification by the agency pursuant to
2077 chapter 641, part III, including health maintenance
2078 organizations and prepaid health clinics. Any fee that is
2079 assessed may be collected prospectively at the time a facility's
2080 license is renewed and prorated for the licensing period.
2081 Section 56. Subsection (2) of section 408.034, Florida
2082 Statutes, is amended to read:
2083 408.034 Duties and responsibilities of agency; rules.—
2084 (2) In the exercise of its authority to issue licenses to
2085 health care facilities and health service providers, as provided
2086 under chapters 393 and 395 and parts II, ~~and~~ IV, and VIII of
2087 chapter 400, the agency may not issue a license to any health
2088 care facility or health service provider that fails to receive a

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2089 certificate of need or an exemption for the licensed facility or
2090 service.
2091 Section 57. Paragraph (d) of subsection (1) and paragraph
2092 (m) of subsection (3) of section 408.036, Florida Statutes, are
2093 amended to read:
2094 408.036 Projects subject to review; exemptions.—
2095 (1) APPLICABILITY.—Unless exempt under subsection (3), all
2096 health-care-related projects, as described in paragraphs (a)-
2097 (g), are subject to review and must file an application for a
2098 certificate of need with the agency. The agency is exclusively
2099 responsible for determining whether a health-care-related
2100 project is subject to review under ss. 408.031-408.045.
2101 (d) The establishment of a hospice or hospice inpatient
2102 facility~~, except as provided in s. 408.043~~.
2103 (3) EXEMPTIONS.—Upon request, the following projects are
2104 subject to exemption from the provisions of subsection (1):
2105 (m)1. For the provision of adult open-heart services in a
2106 hospital located within the boundaries of a health service
2107 planning district, as defined in s. 408.032(5), which has
2108 experienced an annual net out-migration of at least 600 open-
2109 heart-surgery cases for 3 consecutive years according to the
2110 most recent data reported to the agency, and the district's
2111 population per licensed and operational open-heart programs
2112 exceeds the state average of population per licensed and
2113 operational open-heart programs by at least 25 percent. All
2114 hospitals within a health service planning district which meet
2115 the criteria reference in sub-subparagraphs 2.a.-h. shall be
2116 eligible for this exemption on July 1, 2004, and shall receive
2117 the exemption upon filing for it and subject to the following:

2118 a. A hospital that has received a notice of intent to grant
2119 a certificate of need or a final order of the agency granting a
2120 certificate of need for the establishment of an open-heart-
2121 surgery program is entitled to receive a letter of exemption for
2122 the establishment of an adult open-heart-surgery program upon
2123 filing a request for exemption and complying with the criteria
2124 enumerated in sub-subparagraphs 2.a.-h., and is entitled to
2125 immediately commence operation of the program.
2126 b. An otherwise eligible hospital that has not received a
2127 notice of intent to grant a certificate of need or a final order
2128 of the agency granting a certificate of need for the
2129 establishment of an open-heart-surgery program is entitled to
2130 immediately receive a letter of exemption for the establishment
2131 of an adult open-heart-surgery program upon filing a request for
2132 exemption and complying with the criteria enumerated in sub-
2133 subparagraphs 2.a.-h., but is not entitled to commence operation
2134 of its program until December 31, 2006.
2135 2. A hospital shall be exempt from the certificate-of-need
2136 review for the establishment of an open-heart-surgery program
2137 when the application for exemption submitted under this
2138 paragraph complies with the following criteria:
2139 a. The applicant must certify that it will meet and
2140 continuously maintain the minimum licensure requirements adopted
2141 by the agency governing adult open-heart programs, including the
2142 most current guidelines of the American College of Cardiology
2143 and American Heart Association Guidelines for Adult Open Heart
2144 Programs.
2145 b. The applicant must certify that it will maintain
2146 sufficient appropriate equipment and health personnel to ensure

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2147 quality and safety.
2148 c. The applicant must certify that it will maintain
2149 appropriate times of operation and protocols to ensure
2150 availability and appropriate referrals in the event of
2151 emergencies.
2152 d. The applicant can demonstrate that it has discharged at
2153 least 300 inpatients with a principal diagnosis of ischemic
2154 heart disease for the most recent 12-month period as reported to
2155 the agency.
2156 e. The applicant is a general acute care hospital that is
2157 in operation for 3 years or more.
2158 f. The applicant is performing more than 300 diagnostic
2159 cardiac catheterization procedures per year, combined inpatient
2160 and outpatient.
2161 g. The applicant's payor mix at a minimum reflects the
2162 community average for Medicaid, charity care, and self-pay
2163 patients or the applicant must certify that it will provide a
2164 minimum of 5 percent of Medicaid, charity care, and self-pay to
2165 open-heart-surgery patients.
2166 h. If the applicant fails to meet the established criteria
2167 for open-heart programs or fails to reach 300 surgeries per year
2168 by the end of its third year of operation, it must show cause
2169 why its exemption should not be revoked.
2170 ~~3. By December 31, 2004, and annually thereafter, the~~
2171 ~~agency shall submit a report to the Legislature providing~~
2172 ~~information concerning the number of requests for exemption it~~
2173 ~~has received under this paragraph during the calendar year and~~
2174 ~~the number of exemptions it has granted or denied during the~~
2175 ~~calendar year.~~

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2176 Section 58. Paragraph (c) of subsection (1) of section
2177 408.037, Florida Statutes, is amended to read:
2178 408.037 Application content.—
2179 (1) Except as provided in subsection (2) for a general
2180 hospital, an application for a certificate of need must contain:
2181 (c) An audited financial statement of the applicant or of
2182 the applicant's parent corporation if audited financial
2183 statements of the applicant do not exist. In an application
2184 submitted by an existing health care facility, health
2185 maintenance organization, or hospice, financial condition
2186 documentation must include, but need not be limited to, a
2187 balance sheet and a profit-and-loss statement of the 2 previous
2188 fiscal years' operation.
2189 Section 59. Subsection (2) of section 408.043, Florida
2190 Statutes, is amended to read:
2191 408.043 Special provisions.—
2192 (2) HOSPICES.—When an application is made for a certificate
2193 of need to establish or to expand a hospice, the need for such
2194 hospice shall be determined on the basis of the need for and
2195 availability of hospice services in the community. The formula
2196 on which the certificate of need is based shall discourage
2197 regional monopolies and promote competition. The inpatient
2198 hospice care component of a hospice which is a freestanding
2199 facility, or a part of a facility, ~~which is primarily engaged in~~
2200 ~~providing inpatient care and related services~~ and is not
2201 licensed as a health care facility shall also be required to
2202 obtain a certificate of need. Provision of hospice care by any
2203 current provider of health care is a significant change in
2204 service and therefore requires a certificate of need for such

2205 services.

2206 Section 60. Paragraph (k) of subsection (3) of section
2207 408.05, Florida Statutes, is amended to read:

2208 408.05 Florida Center for Health Information and Policy
2209 Analysis.—

2210 (3) COMPREHENSIVE HEALTH INFORMATION SYSTEM.—In order to
2211 produce comparable and uniform health information and statistics
2212 for the development of policy recommendations, the agency shall
2213 perform the following functions:

2214 (k) Develop, in conjunction with the State Consumer Health
2215 Information and Policy Advisory Council, and implement a long-
2216 range plan for making available health care quality measures and
2217 financial data that will allow consumers to compare health care
2218 services. The health care quality measures and financial data
2219 the agency must make available shall include, but is not limited
2220 to, pharmaceuticals, physicians, health care facilities, and
2221 health plans and managed care entities. The agency shall update
2222 the plan and report on the status of its implementation
2223 annually. The agency shall also make the plan and status report
2224 available to the public on its Internet website. As part of the
2225 plan, the agency shall identify the process and timeframes for
2226 implementation, any barriers to implementation, and
2227 recommendations of changes in the law that may be enacted by the
2228 Legislature to eliminate the barriers. As preliminary elements
2229 of the plan, the agency shall:

2230 1. Make available patient-safety indicators, inpatient
2231 quality indicators, and performance outcome and patient charge
2232 data collected from health care facilities pursuant to s.
2233 408.061(1)(a) and (2). The terms "patient-safety indicators" and

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2234 “inpatient quality indicators” shall be as defined by the
2235 Centers for Medicare and Medicaid Services, the National Quality
2236 Forum, the Joint Commission ~~on Accreditation of Healthcare~~
2237 ~~Organizations~~, the Agency for Healthcare Research and Quality,
2238 the Centers for Disease Control and Prevention, or a similar
2239 national entity that establishes standards to measure the
2240 performance of health care providers, or by other states. The
2241 agency shall determine which conditions, procedures, health care
2242 quality measures, and patient charge data to disclose based upon
2243 input from the council. When determining which conditions and
2244 procedures are to be disclosed, the council and the agency shall
2245 consider variation in costs, variation in outcomes, and
2246 magnitude of variations and other relevant information. When
2247 determining which health care quality measures to disclose, the
2248 agency:
2249 a. Shall consider such factors as volume of cases; average
2250 patient charges; average length of stay; complication rates;
2251 mortality rates; and infection rates, among others, which shall
2252 be adjusted for case mix and severity, if applicable.
2253 b. May consider such additional measures that are adopted
2254 by the Centers for Medicare and Medicaid Studies, National
2255 Quality Forum, the Joint Commission ~~on Accreditation of~~
2256 ~~Healthcare Organizations~~, the Agency for Healthcare Research and
2257 Quality, Centers for Disease Control and Prevention, or a
2258 similar national entity that establishes standards to measure
2259 the performance of health care providers, or by other states.
2260
2261 When determining which patient charge data to disclose, the
2262 agency shall include such measures as the average of

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2263 undiscounted charges on frequently performed procedures and
2264 preventive diagnostic procedures, the range of procedure charges
2265 from highest to lowest, average net revenue per adjusted patient
2266 day, average cost per adjusted patient day, and average cost per
2267 admission, among others.
2268 2. Make available performance measures, benefit design, and
2269 premium cost data from health plans licensed pursuant to chapter
2270 627 or chapter 641. The agency shall determine which health care
2271 quality measures and member and subscriber cost data to
2272 disclose, based upon input from the council. When determining
2273 which data to disclose, the agency shall consider information
2274 that may be required by either individual or group purchasers to
2275 assess the value of the product, which may include membership
2276 satisfaction, quality of care, current enrollment or membership,
2277 coverage areas, accreditation status, premium costs, plan costs,
2278 premium increases, range of benefits, copayments and
2279 deductibles, accuracy and speed of claims payment, credentials
2280 of physicians, number of providers, names of network providers,
2281 and hospitals in the network. Health plans shall make available
2282 to the agency any such data or information that is not currently
2283 reported to the agency or the office.
2284 3. Determine the method and format for public disclosure of
2285 data reported pursuant to this paragraph. The agency shall make
2286 its determination based upon input from the State Consumer
2287 Health Information and Policy Advisory Council. At a minimum,
2288 the data shall be made available on the agency’s Internet
2289 website in a manner that allows consumers to conduct an
2290 interactive search that allows them to view and compare the
2291 information for specific providers. The website must include

2292 such additional information as is determined necessary to ensure
2293 that the website enhances informed decisionmaking among
2294 consumers and health care purchasers, which shall include, at a
2295 minimum, appropriate guidance on how to use the data and an
2296 explanation of why the data may vary from provider to provider.
2297 4. Publish on its website undiscounted charges for no fewer
2298 than 150 of the most commonly performed adult and pediatric
2299 procedures, including outpatient, inpatient, diagnostic, and
2300 preventative procedures.
2301 Section 61. Paragraph (a) of subsection (1) of section
2302 408.061, Florida Statutes, is amended to read:
2303 408.061 Data collection; uniform systems of financial
2304 reporting; information relating to physician charges;
2305 confidential information; immunity.—
2306 (1) The agency shall require the submission by health care
2307 facilities, health care providers, and health insurers of data
2308 necessary to carry out the agency's duties. Specifications for
2309 data to be collected under this section shall be developed by
2310 the agency with the assistance of technical advisory panels
2311 including representatives of affected entities, consumers,
2312 purchasers, and such other interested parties as may be
2313 determined by the agency.
2314 (a) Data submitted by health care facilities, including the
2315 facilities as defined in chapter 395, shall include, but are not
2316 limited to: case-mix data, patient admission and discharge data,
2317 hospital emergency department data which shall include the
2318 number of patients treated in the emergency department of a
2319 licensed hospital reported by patient acuity level, data on
2320 hospital-acquired infections as specified by rule, data on

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2321 complications as specified by rule, data on readmissions as
2322 specified by rule, with patient and provider-specific
2323 identifiers included, actual charge data by diagnostic groups,
2324 financial data, accounting data, operating expenses, expenses
2325 incurred for rendering services to patients who cannot or do not
2326 pay, interest charges, depreciation expenses based on the
2327 expected useful life of the property and equipment involved, and
2328 demographic data. The agency shall adopt nationally recognized
2329 risk adjustment methodologies or software consistent with the
2330 standards of the Agency for Healthcare Research and Quality and
2331 as selected by the agency for all data submitted as required by
2332 this section. Data may be obtained from documents such as, but
2333 not limited to: leases, contracts, debt instruments, itemized
2334 patient bills, medical record abstracts, and related diagnostic
2335 information. Reported data elements shall be reported
2336 electronically and ~~in accordance with rule 59E-7.012, Florida~~
2337 ~~Administrative Code. Data submitted shall be~~ certified by the
2338 chief executive officer or an appropriate and duly authorized
2339 representative or employee of the licensed facility that the
2340 information submitted is true and accurate.
2341 Section 62. Subsection (43) of section 408.07, Florida
2342 Statutes, is amended to read:
2343 408.07 Definitions.—As used in this chapter, with the
2344 exception of ss. 408.031-408.045, the term:
2345 (43) “Rural hospital” means an acute care hospital licensed
2346 under chapter 395, having 100 or fewer licensed beds and an
2347 emergency room, and which is:
2348 (a) The sole provider within a county with a population
2349 density of no greater than 100 persons per square mile;

2350 (b) An acute care hospital, in a county with a population
2351 density of no greater than 100 persons per square mile, which is
2352 at least 30 minutes of travel time, on normally traveled roads
2353 under normal traffic conditions, from another acute care
2354 hospital within the same county;
2355 (c) A hospital supported by a tax district or subdistrict
2356 whose boundaries encompass a population of 100 persons or fewer
2357 per square mile;
2358 (d) A hospital with a service area that has a population of
2359 100 persons or fewer per square mile. As used in this paragraph,
2360 the term "service area" means the fewest number of zip codes
2361 that account for 75 percent of the hospital's discharges for the
2362 most recent 5-year period, based on information available from
2363 the hospital inpatient discharge database in the Florida Center
2364 for Health Information and Policy Analysis at the Agency for
2365 Health Care Administration; or
2366 (e) A critical access hospital.
2367
2368 Population densities used in this subsection must be based upon
2369 the most recently completed United States census. A hospital
2370 that received funds under s. 409.9116 for a quarter beginning no
2371 later than July 1, 2002, is deemed to have been and shall
2372 continue to be a rural hospital from that date through June 30,
2373 2015, if the hospital continues to have 100 or fewer licensed
2374 beds and an emergency room~~, or meets the criteria of s.~~
2375 ~~395.602(2)(e)4~~. An acute care hospital that has not previously
2376 been designated as a rural hospital and that meets the criteria
2377 of this subsection shall be granted such designation upon
2378 application, including supporting documentation, to the Agency

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2379 for Health Care Administration.
2380 Section 63. Section 408.10, Florida Statutes, is amended to
2381 read:
2382 408.10 Consumer complaints.—The agency shall~~:~~
2383 ~~(1)~~ publish and make available to the public a toll-free
2384 telephone number for the purpose of handling consumer complaints
2385 and shall serve as a liaison between consumer entities and other
2386 private entities and governmental entities for the disposition
2387 of problems identified by consumers of health care.
2388 ~~(2) Be empowered to investigate consumer complaints~~
2389 ~~relating to problems with health care facilities' billing~~
2390 ~~practices and issue reports to be made public in any cases where~~
2391 ~~the agency determines the health care facility has engaged in~~
2392 ~~billing practices which are unreasonable and unfair to the~~
2393 ~~consumer.~~
2394 Section 64. Subsections (12) through (30) of section
2395 408.802, Florida Statutes, are renumbered as subsections (11)
2396 through (29), respectively, and present subsection (11) of that
2397 section is amended to read:
2398 408.802 Applicability.—The provisions of this part apply to
2399 the provision of services that require licensure as defined in
2400 this part and to the following entities licensed, registered, or
2401 certified by the agency, as described in chapters 112, 383, 390,
2402 394, 395, 400, 429, 440, 483, and 765:
2403 ~~(11) Private review agents, as provided under part I of~~
2404 ~~chapter 395.~~
2405 Section 65. Subsection (3) is added to section 408.804,
2406 Florida Statutes, to read:
2407 408.804 License required; display.—

2408 (3) Any person who knowingly alters, defaces, or falsifies
2409 a license certificate issued by the agency, or causes or
2410 procures any person to commit such an offense, commits a
2411 misdemeanor of the second degree, punishable as provided in s.
2412 775.082 or s 775.083. Any licensee or provider who displays an
2413 altered, defaced, or falsified license certificate is subject to
2414 the penalties set forth in s. 408.815 and an administrative fine
2415 of $1,000 for each day of illegal display.
2416 Section 66. Paragraph (d) of subsection (2) of section
2417 408.806, Florida Statutes, is amended, to read:
2418 408.806 License application process.—
2419 (2)
2420 (d) ~~The agency shall notify the licensee by mail or~~
2421 ~~electronically at least 90 days before the expiration of a~~
2422 ~~license that a renewal license is necessary to continue~~
2423 ~~operation.~~ The licensee's failure to timely file ~~submit~~ a
2424 renewal application and license application fee with the agency
2425 shall result in a $50 per day late fee charged to the licensee
2426 by the agency; however, the aggregate amount of the late fee may
2427 not exceed 50 percent of the licensure fee or $500, whichever is
2428 less. The agency shall provide a courtesy notice to the licensee
2429 by United States mail, electronically, or by any other manner at
2430 its address of record or mailing address, if provided, at least
2431 90 days prior to the expiration of a license informing the
2432 licensee of the expiration of the license. If the licensee does
2433 not receive the courtesy notice, the licensee continues to be
2434 legally obligated to timely file the renewal application and
2435 license application fee with the agency and is not excused from
2436 the payment of a late fee. If an application is received after

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2437 the required filing date and exhibits a hand-canceled postmark
2438 obtained from a United States post office dated on or before the
2439 required filing date, no fine will be levied. Payment of the
2440 late fee is required in order for a late application to be
2441 considered complete, and failure to pay the late fee is
2442 considered an omission from the application.
2443 Section 67. Paragraph (b) of subsection (1) of section
2444 408.8065, Florida Statutes, is amended to read:
2445 408.8065 Additional licensure requirements for home health
2446 agencies, home medical equipment providers, and health care
2447 clinics.—
2448 (1) An applicant for initial licensure, or initial
2449 licensure due to a change of ownership, as a home health agency,
2450 home medical equipment provider, or health care clinic shall:
2451 (b) Submit projected ~~pro forma~~ financial statements,
2452 including a balance sheet, income and expense statement, and a
2453 statement of cash flows for the first 2 years of operation which
2454 provide evidence that the applicant has sufficient assets,
2455 credit, and projected revenues to cover liabilities and
2456 expenses.
2457
2458 All documents required under this subsection must be prepared in
2459 accordance with generally accepted accounting principles and may
2460 be in a compilation form. The financial statements must be
2461 signed by a certified public accountant.
2462 Section 68. Subsections (4) through (8) of section 408.809,
2463 Florida Statutes, are amended to read:
2464 408.809 Background screening; prohibited offenses.—
2465 (4) In addition to the offenses listed in s. 435.04, all

2466 persons required to undergo background screening pursuant to
2467 this part or authorizing statutes must not have an arrest
2468 awaiting final disposition for, must not have been found guilty
2469 of, regardless of adjudication, or entered a plea of nolo
2470 contendere or guilty to, and must not have been adjudicated
2471 delinquent and the record not have been sealed or expunged for
2472 any of the following offenses or any similar offense of another
2473 jurisdiction:
2474 (a) Any authorizing statutes, if the offense was a felony.
2475 (b) This chapter, if the offense was a felony.
2476 (c) Section 409.920, relating to Medicaid provider fraud.
2477 (d) Section 409.9201, relating to Medicaid fraud.
2478 (e) Section 741.28, relating to domestic violence.
2479 (f) Section 817.034, relating to fraudulent acts through
2480 mail, wire, radio, electromagnetic, photoelectronic, or
2481 photooptical systems.
2482 (g) Section 817.234, relating to false and fraudulent
2483 insurance claims.
2484 (h) Section 817.505, relating to patient brokering.
2485 (i) Section 817.568, relating to criminal use of personal
2486 identification information.
2487 (j) Section 817.60, relating to obtaining a credit card
2488 through fraudulent means.
2489 (k) Section 817.61, relating to fraudulent use of credit
2490 cards, if the offense was a felony.
2491 (l) Section 831.01, relating to forgery.
2492 (m) Section 831.02, relating to uttering forged
2493 instruments.
2494 (n) Section 831.07, relating to forging bank bills, checks,

2495 drafts, or promissory notes.
2496 (o) Section 831.09, relating to uttering forged bank bills,
2497 checks, drafts, or promissory notes.
2498 (p) Section 831.30, relating to fraud in obtaining
2499 medicinal drugs.
2500 (q) Section 831.31, relating to the sale, manufacture,
2501 delivery, or possession with the intent to sell, manufacture, or
2502 deliver any counterfeit controlled substance, if the offense was
2503 a felony.
2504 (5) A person who serves as a controlling interest of, is
2505 employed by, or contracts with a licensee on July 31, 2010, who
2506 has been screened and qualified according to standards specified
2507 in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015,
2508 in accordance with the schedule provided in this subsection. ~~The~~
2509 ~~agency may adopt rules to establish a schedule to stagger the~~
2510 ~~implementation of the required rescreening over the 5-year~~
2511 ~~period, beginning July 31, 2010, through July 31, 2015.~~ If, upon
2512 rescreening, such person has a disqualifying offense that was
2513 not a disqualifying offense at the time of the last screening,
2514 but is a current disqualifying offense and was committed before
2515 the last screening, he or she may apply for an exemption from
2516 the appropriate licensing agency and, if agreed to by the
2517 employer, may continue to perform his or her duties until the
2518 licensing agency renders a decision on the application for
2519 exemption if the person is eligible to apply for an exemption
2520 and the exemption request is received by the agency within 30
2521 days after receipt of the rescreening results by the person. The
2522 rescreening schedule is as follows:
2523 (a) An individual whose last screening was conducted before

2524 December 31, 2003, must be rescreened by July 31, 2013;
2525 (b) An individual whose last screening was conducted
2526 between January 1, 2004, and December 31, 2007, must be
2527 rescreened by July 31, 2014; and
2528 (c) An individual whose last screening was conducted
2529 between January 1, 2008, and July 31, 2010, must be rescreened
2530 by July 31, 2015.
2531 (6)~~(5)~~ The costs associated with obtaining the required
2532 screening must be borne by the licensee or the person subject to
2533 screening. Licensees may reimburse persons for these costs. The
2534 Department of Law Enforcement shall charge the agency for
2535 screening pursuant to s. 943.053(3). The agency shall establish
2536 a schedule of fees to cover the costs of screening.
2537 (7)~~(6)~~(a) As provided in chapter 435, the agency may grant
2538 an exemption from disqualification to a person who is subject to
2539 this section and who:
2540 1. Does not have an active professional license or
2541 certification from the Department of Health; or
2542 2. Has an active professional license or certification from
2543 the Department of Health but is not providing a service within
2544 the scope of that license or certification.
2545 (b) As provided in chapter 435, the appropriate regulatory
2546 board within the Department of Health, or the department itself
2547 if there is no board, may grant an exemption from
2548 disqualification to a person who is subject to this section and
2549 who has received a professional license or certification from
2550 the Department of Health or a regulatory board within that
2551 department and that person is providing a service within the
2552 scope of his or her licensed or certified practice.

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2553 (8)(7) The agency and the Department of Health may adopt
2554 rules pursuant to ss. 120.536(1) and 120.54 to implement this
2555 section, chapter 435, and authorizing statutes requiring
2556 background screening and to implement and adopt criteria
2557 relating to retaining fingerprints pursuant to s. 943.05(2).
2558 (9)(8) There is no unemployment compensation or other
2559 monetary liability on the part of, and no cause of action for
2560 damages arising against, an employer that, upon notice of a
2561 disqualifying offense listed under chapter 435 or this section,
2562 terminates the person against whom the report was issued,
2563 whether or not that person has filed for an exemption with the
2564 Department of Health or the agency.
2565 Section 69. Subsection (3) is added to section 408.813,
2566 Florida Statutes, to read:
2567 408.813 Administrative fines; violations.—As a penalty for
2568 any violation of this part, authorizing statutes, or applicable
2569 rules, the agency may impose an administrative fine.
2570 (3) The agency may impose an administrative fine for a
2571 violation that is not designated as a class I, class II, class
2572 III, or class IV violation. Unless otherwise specified by law,
2573 the amount of the fine shall not exceed $500 for each violation.
2574 Unclassified violations may include:
2575 (a) Violating any term or condition of a license.
2576 (b) Violating any provision of this part, authorizing
2577 statutes, or applicable rules.
2578 (c) Exceeding licensed capacity.
2579 (d) Providing services beyond the scope of the license.
2580 (e) Violating a moratorium imposed pursuant to s. 408.814.
2581 Section 70. Subsection (5) is added to section 408.815,

2582 Florida Statutes, to read:
2583 408.815 License or application denial; revocation.—
2584 (5) In order to ensure the health, safety, and welfare of
2585 clients when a license has been denied, revoked, or is set to
2586 terminate, the agency may extend the license expiration date for
2587 a period of up to 30 days for the sole purpose of allowing the
2588 safe and orderly discharge of clients. The agency may impose
2589 conditions on the extension, including, but not limited to,
2590 prohibiting or limiting admissions, expedited discharge
2591 planning, required status reports, and mandatory monitoring by
2592 the agency or third parties. When imposing these conditions, the
2593 agency shall take into consideration the nature and number of
2594 clients, the availability and location of acceptable alternative
2595 placements, and the ability of the licensee to continue
2596 providing care to the clients. The agency may terminate the
2597 extension or modify the conditions at any time. This authority
2598 is in addition to any other authority granted to the agency
2599 under chapter 120, this part, and authorizing statutes but
2600 creates no right or entitlement to an extension of a license
2601 expiration date.
2602 Section 71. Subsection (1) of section 409.91196, Florida
2603 Statutes, is amended to read:
2604 409.91196 Supplemental rebate agreements; public records
2605 and public meetings exemption.—
2606 (1) The rebate amount, percent of rebate, manufacturer's
2607 pricing, and supplemental rebate, and other trade secrets as
2608 defined in s. 688.002 that the agency has identified for use in
2609 negotiations, held by the Agency for Health Care Administration
2610 under s. 409.912(39)(a)8.~~7.~~ are confidential and exempt from s.

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2611 119.07(1) and s. 24(a), Art. I of the State Constitution.
2612 Section 72. Paragraph (a) of subsection (39) of section
2613 409.912, Florida Statutes, is amended to read:
2614 409.912 Cost-effective purchasing of health care.—The
2615 agency shall purchase goods and services for Medicaid recipients
2616 in the most cost-effective manner consistent with the delivery
2617 of quality medical care. To ensure that medical services are
2618 effectively utilized, the agency may, in any case, require a
2619 confirmation or second physician's opinion of the correct
2620 diagnosis for purposes of authorizing future services under the
2621 Medicaid program. This section does not restrict access to
2622 emergency services or poststabilization care services as defined
2623 in 42 C.F.R. part 438.114. Such confirmation or second opinion
2624 shall be rendered in a manner approved by the agency. The agency
2625 shall maximize the use of prepaid per capita and prepaid
2626 aggregate fixed-sum basis services when appropriate and other
2627 alternative service delivery and reimbursement methodologies,
2628 including competitive bidding pursuant to s. 287.057, designed
2629 to facilitate the cost-effective purchase of a case-managed
2630 continuum of care. The agency shall also require providers to
2631 minimize the exposure of recipients to the need for acute
2632 inpatient, custodial, and other institutional care and the
2633 inappropriate or unnecessary use of high-cost services. The
2634 agency shall contract with a vendor to monitor and evaluate the
2635 clinical practice patterns of providers in order to identify
2636 trends that are outside the normal practice patterns of a
2637 provider's professional peers or the national guidelines of a
2638 provider's professional association. The vendor must be able to
2639 provide information and counseling to a provider whose practice

2640 patterns are outside the norms, in consultation with the agency,
2641 to improve patient care and reduce inappropriate utilization.
2642 The agency may mandate prior authorization, drug therapy
2643 management, or disease management participation for certain
2644 populations of Medicaid beneficiaries, certain drug classes, or
2645 particular drugs to prevent fraud, abuse, overuse, and possible
2646 dangerous drug interactions. The Pharmaceutical and Therapeutics
2647 Committee shall make recommendations to the agency on drugs for
2648 which prior authorization is required. The agency shall inform
2649 the Pharmaceutical and Therapeutics Committee of its decisions
2650 regarding drugs subject to prior authorization. The agency is
2651 authorized to limit the entities it contracts with or enrolls as
2652 Medicaid providers by developing a provider network through
2653 provider credentialing. The agency may competitively bid single-
2654 source-provider contracts if procurement of goods or services
2655 results in demonstrated cost savings to the state without
2656 limiting access to care. The agency may limit its network based
2657 on the assessment of beneficiary access to care, provider
2658 availability, provider quality standards, time and distance
2659 standards for access to care, the cultural competence of the
2660 provider network, demographic characteristics of Medicaid
2661 beneficiaries, practice and provider-to-beneficiary standards,
2662 appointment wait times, beneficiary use of services, provider
2663 turnover, provider profiling, provider licensure history,
2664 previous program integrity investigations and findings, peer
2665 review, provider Medicaid policy and billing compliance records,
2666 clinical and medical record audits, and other factors. Providers
2667 shall not be entitled to enrollment in the Medicaid provider
2668 network. The agency shall determine instances in which allowing

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2669 Medicaid beneficiaries to purchase durable medical equipment and
2670 other goods is less expensive to the Medicaid program than long-
2671 term rental of the equipment or goods. The agency may establish
2672 rules to facilitate purchases in lieu of long-term rentals in
2673 order to protect against fraud and abuse in the Medicaid program
2674 as defined in s. 409.913. The agency may seek federal waivers
2675 necessary to administer these policies.
2676 (39)(a) The agency shall implement a Medicaid prescribed-
2677 drug spending-control program that includes the following
2678 components:
2679 1. A Medicaid preferred drug list, which shall be a listing
2680 of cost-effective therapeutic options recommended by the
2681 Medicaid Pharmacy and Therapeutics Committee established
2682 pursuant to s. 409.91195 and adopted by the agency for each
2683 therapeutic class on the preferred drug list. At the discretion
2684 of the committee, and when feasible, the preferred drug list
2685 should include at least two products in a therapeutic class. The
2686 agency may post the preferred drug list and updates to the
2687 preferred drug list on an Internet website without following the
2688 rulemaking procedures of chapter 120. Antiretroviral agents are
2689 excluded from the preferred drug list. The agency shall also
2690 limit the amount of a prescribed drug dispensed to no more than
2691 a 34-day supply unless the drug products' smallest marketed
2692 package is greater than a 34-day supply, or the drug is
2693 determined by the agency to be a maintenance drug in which case
2694 a 100-day maximum supply may be authorized. The agency is
2695 authorized to seek any federal waivers necessary to implement
2696 these cost-control programs and to continue participation in the
2697 federal Medicaid rebate program, or alternatively to negotiate

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2698 state-only manufacturer rebates. The agency may adopt rules to
2699 implement this subparagraph. The agency shall continue to
2700 provide unlimited contraceptive drugs and items. The agency must
2701 establish procedures to ensure that:
2702 a. There is a response to a request for prior consultation
2703 by telephone or other telecommunication device within 24 hours
2704 after receipt of a request for prior consultation; and
2705 b. A 72-hour supply of the drug prescribed is provided in
2706 an emergency or when the agency does not provide a response
2707 within 24 hours as required by sub-subparagraph a.
2708 2. Reimbursement to pharmacies for Medicaid prescribed
2709 drugs shall be set at the lesser of: the average wholesale price
2710 (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC)
2711 plus 4.75 percent, the federal upper limit (FUL), the state
2712 maximum allowable cost (SMAC), or the usual and customary (UAC)
2713 charge billed by the provider.
2714 3. For a prescribed drug billed as a 340B prescribed
2715 medication, the claim must meet the requirements of the Deficit
2716 Reduction Act of 2005 and the federal 340B program, contain a
2717 national drug code, and be billed at the actual acquisition cost
2718 or payment shall be denied.
2719 4.~~3.~~ The agency shall develop and implement a process for
2720 managing the drug therapies of Medicaid recipients who are using
2721 significant numbers of prescribed drugs each month. The
2722 management process may include, but is not limited to,
2723 comprehensive, physician-directed medical-record reviews, claims
2724 analyses, and case evaluations to determine the medical
2725 necessity and appropriateness of a patient’s treatment plan and
2726 drug therapies. The agency may contract with a private

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2727 organization to provide drug-program-management services. The
2728 Medicaid drug benefit management program shall include
2729 initiatives to manage drug therapies for HIV/AIDS patients,
2730 patients using 20 or more unique prescriptions in a 180-day
2731 period, and the top 1,000 patients in annual spending. The
2732 agency shall enroll any Medicaid recipient in the drug benefit
2733 management program if he or she meets the specifications of this
2734 provision and is not enrolled in a Medicaid health maintenance
2735 organization.

2736 5.~~4.~~ The agency may limit the size of its pharmacy network
2737 based on need, competitive bidding, price negotiations,
2738 credentialing, or similar criteria. The agency shall give
2739 special consideration to rural areas in determining the size and
2740 location of pharmacies included in the Medicaid pharmacy
2741 network. A pharmacy credentialing process may include criteria
2742 such as a pharmacy's full-service status, location, size,
2743 patient educational programs, patient consultation, disease
2744 management services, and other characteristics. The agency may
2745 impose a moratorium on Medicaid pharmacy enrollment when it is
2746 determined that it has a sufficient number of Medicaid-
2747 participating providers. The agency must allow dispensing
2748 practitioners to participate as a part of the Medicaid pharmacy
2749 network regardless of the practitioner's proximity to any other
2750 entity that is dispensing prescription drugs under the Medicaid
2751 program. A dispensing practitioner must meet all credentialing
2752 requirements applicable to his or her practice, as determined by
2753 the agency.

2754 6.~~5.~~ The agency shall develop and implement a program that
2755 requires Medicaid practitioners who prescribe drugs to use a

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2756 counterfeit-proof prescription pad for Medicaid prescriptions.
2757 The agency shall require the use of standardized counterfeit-
2758 proof prescription pads by Medicaid-participating prescribers or
2759 prescribers who write prescriptions for Medicaid recipients. The
2760 agency may implement the program in targeted geographic areas or
2761 statewide.
2762 7.~~6.~~ The agency may enter into arrangements that require
2763 manufacturers of generic drugs prescribed to Medicaid recipients
2764 to provide rebates of at least 15.1 percent of the average
2765 manufacturer price for the manufacturer's generic products.
2766 These arrangements shall require that if a generic-drug
2767 manufacturer pays federal rebates for Medicaid-reimbursed drugs
2768 at a level below 15.1 percent, the manufacturer must provide a
2769 supplemental rebate to the state in an amount necessary to
2770 achieve a 15.1-percent rebate level.
2771 8.~~7.~~ The agency may establish a preferred drug list as
2772 described in this subsection, and, pursuant to the establishment
2773 of such preferred drug list, it is authorized to negotiate
2774 supplemental rebates from manufacturers that are in addition to
2775 those required by Title XIX of the Social Security Act and at no
2776 less than 14 percent of the average manufacturer price as
2777 defined in 42 U.S.C. s. 1936 on the last day of a quarter unless
2778 the federal or supplemental rebate, or both, equals or exceeds
2779 29 percent. There is no upper limit on the supplemental rebates
2780 the agency may negotiate. The agency may determine that specific
2781 products, brand-name or generic, are competitive at lower rebate
2782 percentages. Agreement to pay the minimum supplemental rebate
2783 percentage will guarantee a manufacturer that the Medicaid
2784 Pharmaceutical and Therapeutics Committee will consider a

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2785 product for inclusion on the preferred drug list. However, a
2786 pharmaceutical manufacturer is not guaranteed placement on the
2787 preferred drug list by simply paying the minimum supplemental
2788 rebate. Agency decisions will be made on the clinical efficacy
2789 of a drug and recommendations of the Medicaid Pharmaceutical and
2790 Therapeutics Committee, as well as the price of competing
2791 products minus federal and state rebates. The agency is
2792 authorized to contract with an outside agency or contractor to
2793 conduct negotiations for supplemental rebates. For the purposes
2794 of this section, the term "supplemental rebates" means cash
2795 rebates. Effective July 1, 2004, value-added programs as a
2796 substitution for supplemental rebates are prohibited. The agency
2797 is authorized to seek any federal waivers to implement this
2798 initiative.

2799 <u>9.</u>~~8.~~ The Agency for Health Care Administration shall expand
2800 home delivery of pharmacy products. To assist Medicaid patients
2801 in securing their prescriptions and reduce program costs, the
2802 agency shall expand its current mail-order-pharmacy diabetes-
2803 supply program to include all generic and brand-name drugs used
2804 by Medicaid patients with diabetes. Medicaid recipients in the
2805 current program may obtain nondiabetes drugs on a voluntary
2806 basis. This initiative is limited to the geographic area covered
2807 by the current contract. The agency may seek and implement any
2808 federal waivers necessary to implement this subparagraph.

2809 <u>10.</u>~~9.~~ The agency shall limit to one dose per month any drug
2810 prescribed to treat erectile dysfunction.

2811 <u>11.</u>~~10.~~a. The agency may implement a Medicaid behavioral
2812 drug management system. The agency may contract with a vendor
2813 that has experience in operating behavioral drug management

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2814 systems to implement this program. The agency is authorized to
2815 seek federal waivers to implement this program.
2816 b. The agency, in conjunction with the Department of
2817 Children and Family Services, may implement the Medicaid
2818 behavioral drug management system that is designed to improve
2819 the quality of care and behavioral health prescribing practices
2820 based on best practice guidelines, improve patient adherence to
2821 medication plans, reduce clinical risk, and lower prescribed
2822 drug costs and the rate of inappropriate spending on Medicaid
2823 behavioral drugs. The program may include the following
2824 elements:
2825 (I) Provide for the development and adoption of best
2826 practice guidelines for behavioral health-related drugs such as
2827 antipsychotics, antidepressants, and medications for treating
2828 bipolar disorders and other behavioral conditions; translate
2829 them into practice; review behavioral health prescribers and
2830 compare their prescribing patterns to a number of indicators
2831 that are based on national standards; and determine deviations
2832 from best practice guidelines.
2833 (II) Implement processes for providing feedback to and
2834 educating prescribers using best practice educational materials
2835 and peer-to-peer consultation.
2836 (III) Assess Medicaid beneficiaries who are outliers in
2837 their use of behavioral health drugs with regard to the numbers
2838 and types of drugs taken, drug dosages, combination drug
2839 therapies, and other indicators of improper use of behavioral
2840 health drugs.
2841 (IV) Alert prescribers to patients who fail to refill
2842 prescriptions in a timely fashion, are prescribed multiple same-

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2843 class behavioral health drugs, and may have other potential
2844 medication problems.
2845 (V) Track spending trends for behavioral health drugs and
2846 deviation from best practice guidelines.
2847 (VI) Use educational and technological approaches to
2848 promote best practices, educate consumers, and train prescribers
2849 in the use of practice guidelines.
2850 (VII) Disseminate electronic and published materials.
2851 (VIII) Hold statewide and regional conferences.
2852 (IX) Implement a disease management program with a model
2853 quality-based medication component for severely mentally ill
2854 individuals and emotionally disturbed children who are high
2855 users of care.
2856 12.~~11.~~a. The agency shall implement a Medicaid prescription
2857 drug management system. The agency may contract with a vendor
2858 that has experience in operating prescription drug management
2859 systems in order to implement this system. Any management system
2860 that is implemented in accordance with this subparagraph must
2861 rely on cooperation between physicians and pharmacists to
2862 determine appropriate practice patterns and clinical guidelines
2863 to improve the prescribing, dispensing, and use of drugs in the
2864 Medicaid program. The agency may seek federal waivers to
2865 implement this program.
2866 b. The drug management system must be designed to improve
2867 the quality of care and prescribing practices based on best
2868 practice guidelines, improve patient adherence to medication
2869 plans, reduce clinical risk, and lower prescribed drug costs and
2870 the rate of inappropriate spending on Medicaid prescription
2871 drugs. The program must:

2872 (I) Provide for the development and adoption of best
2873 practice guidelines for the prescribing and use of drugs in the
2874 Medicaid program, including translating best practice guidelines
2875 into practice; reviewing prescriber patterns and comparing them
2876 to indicators that are based on national standards and practice
2877 patterns of clinical peers in their community, statewide, and
2878 nationally; and determine deviations from best practice
2879 guidelines.
2880 (II) Implement processes for providing feedback to and
2881 educating prescribers using best practice educational materials
2882 and peer-to-peer consultation.
2883 (III) Assess Medicaid recipients who are outliers in their
2884 use of a single or multiple prescription drugs with regard to
2885 the numbers and types of drugs taken, drug dosages, combination
2886 drug therapies, and other indicators of improper use of
2887 prescription drugs.
2888 (IV) Alert prescribers to patients who fail to refill
2889 prescriptions in a timely fashion, are prescribed multiple drugs
2890 that may be redundant or contraindicated, or may have other
2891 potential medication problems.
2892 (V) Track spending trends for prescription drugs and
2893 deviation from best practice guidelines.
2894 (VI) Use educational and technological approaches to
2895 promote best practices, educate consumers, and train prescribers
2896 in the use of practice guidelines.
2897 (VII) Disseminate electronic and published materials.
2898 (VIII) Hold statewide and regional conferences.
2899 (IX) Implement disease management programs in cooperation
2900 with physicians and pharmacists, along with a model quality-

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2901 based medication component for individuals having chronic
2902 medical conditions.
2903 13.~~12.~~ The agency is authorized to contract for drug rebate
2904 administration, including, but not limited to, calculating
2905 rebate amounts, invoicing manufacturers, negotiating disputes
2906 with manufacturers, and maintaining a database of rebate
2907 collections.
2908 14.~~13.~~ The agency may specify the preferred daily dosing
2909 form or strength for the purpose of promoting best practices
2910 with regard to the prescribing of certain drugs as specified in
2911 the General Appropriations Act and ensuring cost-effective
2912 prescribing practices.
2913 15.~~14.~~ The agency may require prior authorization for
2914 Medicaid-covered prescribed drugs. The agency may, but is not
2915 required to, prior-authorize the use of a product:
2916 a. For an indication not approved in labeling;
2917 b. To comply with certain clinical guidelines; or
2918 c. If the product has the potential for overuse, misuse, or
2919 abuse.
2920
2921 The agency may require the prescribing professional to provide
2922 information about the rationale and supporting medical evidence
2923 for the use of a drug. The agency may post prior authorization
2924 criteria and protocol and updates to the list of drugs that are
2925 subject to prior authorization on an Internet website without
2926 amending its rule or engaging in additional rulemaking.
2927 16.~~15.~~ The agency, in conjunction with the Pharmaceutical
2928 and Therapeutics Committee, may require age-related prior
2929 authorizations for certain prescribed drugs. The agency may

2930 preauthorize the use of a drug for a recipient who may not meet
2931 the age requirement or may exceed the length of therapy for use
2932 of this product as recommended by the manufacturer and approved
2933 by the Food and Drug Administration. Prior authorization may
2934 require the prescribing professional to provide information
2935 about the rationale and supporting medical evidence for the use
2936 of a drug.

2937 17.~~16.~~ The agency shall implement a step-therapy prior
2938 authorization approval process for medications excluded from the
2939 preferred drug list. Medications listed on the preferred drug
2940 list must be used within the previous 12 months prior to the
2941 alternative medications that are not listed. The step-therapy
2942 prior authorization may require the prescriber to use the
2943 medications of a similar drug class or for a similar medical
2944 indication unless contraindicated in the Food and Drug
2945 Administration labeling. The trial period between the specified
2946 steps may vary according to the medical indication. The step-
2947 therapy approval process shall be developed in accordance with
2948 the committee as stated in s. 409.91195(7) and (8). A drug
2949 product may be approved without meeting the step-therapy prior
2950 authorization criteria if the prescribing physician provides the
2951 agency with additional written medical or clinical documentation
2952 that the product is medically necessary because:

2953 a. There is not a drug on the preferred drug list to treat
2954 the disease or medical condition which is an acceptable clinical
2955 alternative;

2956 b. The alternatives have been ineffective in the treatment
2957 of the beneficiary’s disease; or

2958 c. Based on historic evidence and known characteristics of

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2959 the patient and the drug, the drug is likely to be ineffective,
2960 or the number of doses have been ineffective.
2961
2962 The agency shall work with the physician to determine the best
2963 alternative for the patient. The agency may adopt rules waiving
2964 the requirements for written clinical documentation for specific
2965 drugs in limited clinical situations.
2966 18.~~17.~~ The agency shall implement a return and reuse
2967 program for drugs dispensed by pharmacies to institutional
2968 recipients, which includes payment of a $5 restocking fee for
2969 the implementation and operation of the program. The return and
2970 reuse program shall be implemented electronically and in a
2971 manner that promotes efficiency. The program must permit a
2972 pharmacy to exclude drugs from the program if it is not
2973 practical or cost-effective for the drug to be included and must
2974 provide for the return to inventory of drugs that cannot be
2975 credited or returned in a cost-effective manner. The agency
2976 shall determine if the program has reduced the amount of
2977 Medicaid prescription drugs which are destroyed on an annual
2978 basis and if there are additional ways to ensure more
2979 prescription drugs are not destroyed which could safely be
2980 reused. The agency's conclusion and recommendations shall be
2981 reported to the Legislature by December 1, 2005.
2982 Section 73. Subsections (3) and (4) of section 429.07,
2983 Florida Statutes, are amended, and subsections (6) and (7) are
2984 added to that section, to read:
2985 429.07 License required; fee; inspections.—
2986 (3) In addition to the requirements of s. 408.806, each
2987 license granted by the agency must state the type of care for

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which the license is granted. Licenses shall be issued for one or more of the following categories of care: standard, extended congregate care, ~~limited nursing services,~~ or limited mental health.

(a) A standard license shall be issued to a facility ~~facilities~~ providing one or more of the personal services identified in s. 429.02. Such licensee ~~facilities~~ may also employ or contract with a person ~~licensed under part I of chapter 464~~ to ~~administer medications and~~ perform other tasks as specified in s. 429.255.

(b) An extended congregate care license shall be issued to a licensee ~~facilities~~ providing, directly or through contract, services beyond those authorized in paragraph (a), including services performed by persons licensed under part I of chapter 464 and supportive services, as defined by rule, to persons who would otherwise be disqualified from continued residence in a facility licensed under this part.

1. In order for extended congregate care services to be provided, the agency must first determine that all requirements established in law and rule are met and must specifically designate, on the ~~facility's~~ license, that such services may be provided and whether the designation applies to all or part of the facility. Such designation may be made at the time of initial licensure or relicensure, or upon request in writing by a licensee under this part and part II of chapter 408. The notification of approval or the denial of the request shall be made in accordance with part II of chapter 408. An existing licensee ~~facilities~~ qualifying to provide extended congregate care services must have maintained a standard license and ~~may~~

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3017 not ~~have~~ been subject to administrative sanctions during the
3018 previous 2 years, or since initial licensure if ~~the facility has~~
3019 ~~been~~ licensed for less than 2 years, for any of the following
3020 reasons:
3021 a. A class I or class II violation;
3022 b. Three or more repeat or recurring class III violations
3023 of identical or similar resident care standards from which a
3024 pattern of noncompliance is found by the agency;
3025 c. Three or more class III violations that were not
3026 corrected in accordance with the corrective action plan approved
3027 by the agency;
3028 d. Violation of resident care standards which results in
3029 requiring the facility to employ the services of a consultant
3030 pharmacist or consultant dietitian;
3031 e. Denial, suspension, or revocation of a license for
3032 another facility licensed under this part in which the applicant
3033 for an extended congregate care license has at least 25 percent
3034 ownership interest; or
3035 f. Imposition of a moratorium pursuant to this part or part
3036 II of chapter 408 or initiation of injunctive proceedings.
3037 2. A facility that is licensed to provide extended
3038 congregate care services shall maintain a written progress
3039 report for ~~on~~ each person who receives services which describes
3040 the type, amount, duration, scope, and outcome of services that
3041 are rendered and the general status of the resident's health. ~~A~~
3042 ~~registered nurse, or appropriate designee, representing the~~
3043 ~~agency shall visit the facility at least quarterly to monitor~~
3044 ~~residents who are receiving extended congregate care services~~
3045 ~~and to determine if the facility is in compliance with this~~

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3046 ~~part, part II of chapter 408, and relevant rules. One of the~~
3047 ~~visits may be in conjunction with the regular survey. The~~
3048 ~~monitoring visits may be provided through contractual~~
3049 ~~arrangements with appropriate community agencies. A registered~~
3050 ~~nurse shall serve as part of the team that inspects the~~
3051 ~~facility. The agency may waive one of the required yearly~~
3052 ~~monitoring visits for a facility that has been licensed for at~~
3053 ~~least 24 months to provide extended congregate care services,~~
3054 ~~if, during the inspection, the registered nurse determines that~~
3055 ~~extended congregate care services are being provided~~
3056 ~~appropriately, and if the facility has no class I or class II~~
3057 ~~violations and no uncorrected class III violations. The agency~~
3058 ~~must first consult with the long-term care ombudsman council for~~
3059 ~~the area in which the facility is located to determine if any~~
3060 ~~complaints have been made and substantiated about the quality of~~
3061 ~~services or care. The agency may not waive one of the required~~
3062 ~~yearly monitoring visits if complaints have been made and~~
3063 ~~substantiated.~~
3064 3. A facility that is licensed to provide extended
3065 congregate care services must:
3066 a. Demonstrate the capability to meet unanticipated
3067 resident service needs.
3068 b. Offer a physical environment that promotes a homelike
3069 setting, provides for resident privacy, promotes resident
3070 independence, and allows sufficient congregate space as defined
3071 by rule.
3072 c. Have sufficient staff available, taking into account the
3073 physical plant and firesafety features of the building, to
3074 assist with the evacuation of residents in an emergency.

3075 d. Adopt and follow policies and procedures that maximize
3076 resident independence, dignity, choice, and decisionmaking to
3077 permit residents to age in place, so that moves due to changes
3078 in functional status are minimized or avoided.
3079 e. Allow residents or, if applicable, a resident's
3080 representative, designee, surrogate, guardian, or attorney in
3081 fact to make a variety of personal choices, participate in
3082 developing service plans, and share responsibility in
3083 decisionmaking.
3084 f. Implement the concept of managed risk.
3085 g. Provide, directly or through contract, the services of a
3086 person licensed under part I of chapter 464.
3087 h. In addition to the training mandated in s. 429.52,
3088 provide specialized training as defined by rule for facility
3089 staff.
3090 4. A facility that is licensed to provide extended
3091 congregate care services is exempt from the criteria for
3092 continued residency set forth in rules adopted under s. 429.41.
3093 A licensed facility must adopt its own requirements within
3094 guidelines for continued residency set forth by rule. However,
3095 the facility may not serve residents who require 24-hour nursing
3096 supervision. A licensed facility that provides extended
3097 congregate care services must also provide each resident with a
3098 written copy of facility policies governing admission and
3099 retention.
3100 5. The primary purpose of extended congregate care services
3101 is to allow residents, as they become more impaired, the option
3102 of remaining in a familiar setting from which they would
3103 otherwise be disqualified for continued residency. A facility

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3104 licensed to provide extended congregate care services may also
3105 admit an individual who exceeds the admission criteria for a
3106 facility with a standard license, if the individual is
3107 determined appropriate for admission to the extended congregate
3108 care facility.
3109 6. Before the admission of an individual to a facility
3110 licensed to provide extended congregate care services, the
3111 individual must undergo a medical examination as provided in s.
3112 429.26(4) and the facility must develop a preliminary service
3113 plan for the individual.
3114 7. When a licensee facility can no longer provide or
3115 arrange for services in accordance with the resident's service
3116 plan and needs and the licensee's facility's policy, the
3117 licensee facility shall make arrangements for relocating the
3118 person in accordance with s. 429.28(1)(k).
3119 8. Failure to provide extended congregate care services may
3120 result in denial of extended congregate care license renewal.
3121 (c) A limited nursing services license shall be issued to a
3122 facility that provides services beyond those authorized in
3123 paragraph (a) and as specified in this paragraph.
3124 1. In order for limited nursing services to be provided in
3125 a facility licensed under this part, the agency must first
3126 determine that all requirements established in law and rule are
3127 met and must specifically designate, on the facility's license,
3128 that such services may be provided. Such designation may be made
3129 at the time of initial licensure or relicensure, or upon request
3130 in writing by a licensee under this part and part II of chapter
3131 408. Notification of approval or denial of such request shall be
3132 made in accordance with part II of chapter 408. Existing

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3133 ~~facilities qualifying to provide limited nursing services shall~~
3134 ~~have maintained a standard license and may not have been subject~~
3135 ~~to administrative sanctions that affect the health, safety, and~~
3136 ~~welfare of residents for the previous 2 years or since initial~~
3137 ~~licensure if the facility has been licensed for less than 2~~
3138 ~~years.~~
3139 ~~2. Facilities that are licensed to provide limited nursing~~
3140 ~~services shall maintain a written progress report on each person~~
3141 ~~who receives such nursing services, which report describes the~~
3142 ~~type, amount, duration, scope, and outcome of services that are~~
3143 ~~rendered and the general status of the resident's health. A~~
3144 ~~registered nurse representing the agency shall visit such~~
3145 ~~facilities at least twice a year to monitor residents who are~~
3146 ~~receiving limited nursing services and to determine if the~~
3147 ~~facility is in compliance with applicable provisions of this~~
3148 ~~part, part II of chapter 408, and related rules. The monitoring~~
3149 ~~visits may be provided through contractual arrangements with~~
3150 ~~appropriate community agencies. A registered nurse shall also~~
3151 ~~serve as part of the team that inspects such facility.~~
3152 ~~3. A person who receives limited nursing services under~~
3153 ~~this part must meet the admission criteria established by the~~
3154 ~~agency for assisted living facilities. When a resident no longer~~
3155 ~~meets the admission criteria for a facility licensed under this~~
3156 ~~part, arrangements for relocating the person shall be made in~~
3157 ~~accordance with s. 429.28(1)(k), unless the facility is licensed~~
3158 ~~to provide extended congregate care services.~~
3159 (4) In accordance with s. 408.805, an applicant or licensee
3160 shall pay a fee for each license application submitted under
3161 this part, part II of chapter 408, and applicable rules. The

3162 amount of the fee shall be established by rule.
3163 (a) The biennial license fee required of a facility is $300
3164 per license, with an additional fee of $71 ~~$50~~ per resident
3165 based on the total licensed resident capacity of the facility,
3166 except that no additional fee will be assessed for beds
3167 designated for recipients of optional state supplementation
3168 payments provided for in s. 409.212. The total fee may not
3169 exceed $10,000.
3170 (b) In addition to the total fee assessed under paragraph
3171 (a), the agency shall require facilities that are licensed to
3172 provide extended congregate care services under this part to pay
3173 an additional fee per licensed facility. The amount of the
3174 biennial fee shall be $400 per license, with an additional fee
3175 of $10 per resident based on the total licensed resident
3176 capacity of the facility.
3177 ~~(c) In addition to the total fee assessed under paragraph~~
3178 ~~(a), the agency shall require facilities that are licensed to~~
3179 ~~provide limited nursing services under this part to pay an~~
3180 ~~additional fee per licensed facility. The amount of the biennial~~
3181 ~~fee shall be $250 per license, with an additional fee of $10 per~~
3182 ~~resident based on the total licensed resident capacity of the~~
3183 ~~facility.~~
3184 (6) In order to determine whether the facility is
3185 adequately protecting residents’ rights as provided in s.
3186 429.28, the agency’s standard license survey shall include
3187 private informal conversations with a sample of residents and
3188 consultation with the ombudsman council in the planning and
3189 service area in which the facility is located to discuss
3190 residents’ experiences within the facility.

3191 (7) An assisted living facility that has been cited within
3192 the previous 24-month period for a class I or class II
3193 violation, regardless of the status of any enforcement or
3194 disciplinary action, is subject to periodic unannounced
3195 monitoring to determine if the facility is in compliance with
3196 this part, part II of chapter 408, and applicable rules.
3197 Monitoring may occur through a desk review or an onsite
3198 assessment. If the class I or class II violation relates to
3199 providing or failing to provide nursing care, a registered nurse
3200 must participate in monitoring activities during the 12-month
3201 period following the violation.
3202 Section 74. Subsection (7) of section 429.11, Florida
3203 Statutes, is renumbered as subsection (6), and present
3204 subsection (6) of that section is amended to read:
3205 429.11 Initial application for license; provisional
3206 license.—
3207 (6) In addition to the license categories available in s.
3208 408.808, a provisional license may be issued to an applicant
3209 making initial application for licensure or making application
3210 for a change of ownership. A provisional license shall be
3211 limited in duration to a specific period of time not to exceed 6
3212 months, as determined by the agency.
3213 Section 75. Section 429.12, Florida Statutes, is amended to
3214 read:
3215 429.12 Sale or transfer of ownership of a facility.—It is
3216 the intent of the Legislature to protect the rights of the
3217 residents of an assisted living facility when the facility is
3218 sold or the ownership thereof is transferred. Therefore, in
3219 addition to the requirements of part II of chapter 408, whenever

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3220 a facility is sold or the ownership thereof is transferred,
3221 including leasing, ~~:~~
3222 ~~(1)~~ the transferee shall notify the residents, in writing,
3223 of the change of ownership within 7 days after receipt of the
3224 new license.
3225 ~~(2) The transferor of a facility the license of which is~~
3226 ~~denied pending an administrative hearing shall, as a part of the~~
3227 ~~written change-of-ownership contract, advise the transferee that~~
3228 ~~a plan of correction must be submitted by the transferee and~~
3229 ~~approved by the agency at least 7 days before the change of~~
3230 ~~ownership and that failure to correct the condition which~~
3231 ~~resulted in the moratorium pursuant to part II of chapter 408 or~~
3232 ~~denial of licensure is grounds for denial of the transferee's~~
3233 ~~license.~~
3234 Section 76. Subsections (1), (4), and (5) of section
3235 429.17, Florida Statutes, are amended to read:
3236 429.17 Expiration of license; renewal; conditional
3237 license.—
3238 (1) ~~Limited nursing,~~ Extended congregate care~~,~~ and limited
3239 mental health licenses shall expire at the same time as the
3240 facility's standard license, regardless of when issued.
3241 (4) In addition to the license categories available in s.
3242 408.808, a conditional license may be issued to an applicant for
3243 license renewal if the applicant fails to meet all standards and
3244 requirements for licensure. A conditional license issued under
3245 this subsection shall be limited in duration to a specific
3246 period of time not to exceed 6 months, as determined by the
3247 agency~~, and shall be accompanied by an agency-approved plan of~~
3248 ~~correction~~.

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3249 (5) When an extended congregate care ~~or limited nursing~~
3250 license is requested during a facility's biennial license
3251 period, the fee shall be prorated in order to permit the
3252 additional license to expire at the end of the biennial license
3253 period. The fee shall be calculated as of the date the
3254 additional license application is received by the agency.
3255 Section 77. Section 429.195, Florida Statutes, is amended
3256 to read:
3257 429.195 Rebates prohibited; penalties.—
3258 (1) It is unlawful for any assisted living facility
3259 licensed under this part to contract or promise to pay or
3260 receive any commission, bonus, kickback, or rebate or engage in
3261 any split-fee arrangement in any form whatsoever with any health
3262 care provider or health care facility under s. 817.505
3263 ~~physician, surgeon, organization, agency, or person, either~~
3264 ~~directly or indirectly, for residents referred to an assisted~~
3265 ~~living facility licensed under this part~~. ~~A facility may employ~~
3266 ~~or contract with persons to market the facility, provided the~~
3267 ~~employee or contract provider clearly indicates that he or she~~
3268 ~~represents the facility. A person or agency independent of the~~
3269 ~~facility may provide placement or referral services for a fee to~~
3270 ~~individuals seeking assistance in finding a suitable facility;~~
3271 ~~however, any fee paid for placement or referral services must be~~
3272 ~~paid by the individual looking for a facility, not by the~~
3273 ~~facility.~~
3274 (2) A violation of this section shall be considered patient
3275 brokering and is punishable as provided in s. 817.505.
3276 (3) This section does not apply to:
3277 (a) An individual with whom the facility employs or

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3278 contracts with to market the facility if the individual clearly
3279 indicates that he or she works with or for the facility.
3280 (b) A referral service that provides information,
3281 consultation, or referrals to consumers to assist them in
3282 finding appropriate care or housing options for senior citizens
3283 or disabled adults if such referred consumers are not Medicaid
3284 recipients.
3285 (c) A resident of an assisted living facility who refers to
3286 the assisted living facility a friend, family member, or other
3287 individual with whom the resident has a personal relationship,
3288 and the assisted living facility is not prohibited from
3289 providing a monetary reward to the resident for making such a
3290 referral.
3291 Section 78. Subsections (6) through (10) of section 429.23,
3292 Florida Statutes, are renumbered as subsections (5) through (9),
3293 respectively, and present subsection (5) of that section is
3294 amended to read:
3295 429.23 Internal risk management and quality assurance
3296 program; adverse incidents and reporting requirements.—
3297 (5) Each facility shall report monthly to the agency any
3298 liability claim filed against it. The report must include the
3299 name of the resident, the dates of the incident leading to the
3300 claim, if applicable, and the type of injury or violation of
3301 rights alleged to have occurred. This report is not discoverable
3302 in any civil or administrative action, except in such actions
3303 brought by the agency to enforce the provisions of this part.
3304 Section 79. Paragraph (a) of subsection (1) and subsection
3305 (2) of section 429.255, Florida Statutes, are amended to read:
3306 429.255 Use of personnel; emergency care.—

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3307 (1)(a) Persons under contract to the facility or, facility
3308 staff, or volunteers, who are licensed according to part I of
3309 chapter 464, or those persons exempt under s. 464.022(1), and
3310 others as defined by rule, may administer medications to
3311 residents, take residents' vital signs, manage individual weekly
3312 pill organizers for residents who self-administer medication,
3313 give prepackaged enemas ordered by a physician, observe
3314 residents, document observations on the appropriate resident's
3315 record, report observations to the resident's physician, and
3316 contract or allow residents or a resident's representative,
3317 designee, surrogate, guardian, or attorney in fact to contract
3318 with a third party, provided residents meet the criteria for
3319 appropriate placement as defined in s. 429.26. Persons under
3320 contract to the facility or facility staff who are licensed
3321 according to part I of chapter 464 may provide limited nursing
3322 services. Nursing assistants certified pursuant to part II of
3323 chapter 464 may take residents' vital signs as directed by a
3324 licensed nurse or physician. The facility is responsible for
3325 maintaining documentation of services provided under this
3326 paragraph and as required by rule and ensuring that staff are
3327 adequately trained to monitor residents receiving these
3328 services.
3329 (2) In facilities licensed to provide extended congregate
3330 care, persons under contract to the facility or, facility staff,
3331 or volunteers, who are licensed according to part I of chapter
3332 464, or those persons exempt under s. 464.022(1), or those
3333 persons certified as nursing assistants pursuant to part II of
3334 chapter 464, may also perform all duties within the scope of
3335 their license or certification, as approved by the facility

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3336 administrator and pursuant to this part.

3337 Section 80. Subsections (4), (5), (6), and (7) of section
3338 429.28, Florida Statutes, are renumbered as subsections (3),
3339 (4), (5), and (6), respectively, and present subsections (3) and
3340 (6) of that section are amended to read:

3341 429.28 Resident bill of rights.—

3342 ~~(3)(a) The agency shall conduct a survey to determine~~
3343 ~~general compliance with facility standards and compliance with~~
3344 ~~residents' rights as a prerequisite to initial licensure or~~
3345 ~~licensure renewal.~~

3346 ~~(b) In order to determine whether the facility is~~
3347 ~~adequately protecting residents' rights, the biennial survey~~
3348 ~~shall include private informal conversations with a sample of~~
3349 ~~residents and consultation with the ombudsman council in the~~
3350 ~~planning and service area in which the facility is located to~~
3351 ~~discuss residents' experiences within the facility.~~

3352 ~~(c) During any calendar year in which no survey is~~
3353 ~~conducted, the agency shall conduct at least one monitoring~~
3354 ~~visit of each facility cited in the previous year for a class I~~
3355 ~~or class II violation, or more than three uncorrected class III~~
3356 ~~violations.~~

3357 ~~(d) The agency may conduct periodic followup inspections as~~
3358 ~~necessary to monitor the compliance of facilities with a history~~
3359 ~~of any class I, class II, or class III violations that threaten~~
3360 ~~the health, safety, or security of residents.~~

3361 ~~(e) The agency may conduct complaint investigations as~~
3362 ~~warranted to investigate any allegations of noncompliance with~~
3363 ~~requirements required under this part or rules adopted under~~
3364 ~~this part.~~

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3365 (5)~~(6)~~ Any facility which terminates the residency of an
3366 individual who participated in activities specified in
3367 subsection (4) ~~(5)~~ shall show good cause in a court of competent
3368 jurisdiction.
3369 Section 81. Subsection (1) of section 429.294, Florida
3370 Statutes, is amended to read:
3371 429.294 Availability of facility records for investigation
3372 of resident's rights violations and defenses; penalty.—
3373 (1) Failure to provide complete copies of a resident's
3374 records, including, but not limited to, all medical records and
3375 the resident's chart, within the control or possession of the
3376 facility within 10 days, constitutes ~~in accordance with the~~
3377 ~~provisions of s. 400.145, shall constitute~~ evidence of failure
3378 of that party to comply with good faith discovery requirements
3379 and waives ~~shall waive~~ the good faith certificate and presuit
3380 notice requirements under this part by the requesting party.
3381 Section 82. Paragraphs (i) and (j) of subsection (1) and
3382 subsection (3) of section 429.41, Florida Statutes, are amended,
3383 and present subsections (4) and (5) of that section are
3384 renumbered subsections (3) and (4), respectively, to read:
3385 429.41 Rules establishing standards.—
3386 (1) It is the intent of the Legislature that rules
3387 published and enforced pursuant to this section shall include
3388 criteria by which a reasonable and consistent quality of
3389 resident care and quality of life may be ensured and the results
3390 of such resident care may be demonstrated. Such rules shall also
3391 ensure a safe and sanitary environment that is residential and
3392 noninstitutional in design or nature. It is further intended
3393 that reasonable efforts be made to accommodate the needs and

3394 preferences of residents to enhance the quality of life in a
3395 facility. The agency, in consultation with the department, may
3396 adopt rules to administer the requirements of part II of chapter
3397 408. In order to provide safe and sanitary facilities and the
3398 highest quality of resident care accommodating the needs and
3399 preferences of residents, the department, in consultation with
3400 the agency, the Department of Children and Family Services, and
3401 the Department of Health, shall adopt rules, policies, and
3402 procedures to administer this part, which must include
3403 reasonable and fair minimum standards in relation to:
3404 (i) Facilities holding an ~~a limited nursing,~~ extended
3405 congregate care, or limited mental health license.
3406 (j) The establishment of specific criteria to define
3407 appropriateness of resident admission and continued residency in
3408 a facility holding a standard, ~~limited nursing,~~ extended
3409 congregate care, and limited mental health license.
3410 ~~(3) The department shall submit a copy of proposed rules to~~
3411 ~~the Speaker of the House of Representatives, the President of~~
3412 ~~the Senate, and appropriate committees of substance for review~~
3413 ~~and comment prior to the promulgation thereof. Rules promulgated~~
3414 ~~by the department shall encourage the development of homelike~~
3415 ~~facilities which promote the dignity, individuality, personal~~
3416 ~~strengths, and decisionmaking ability of residents.~~
3417 Section 83. Subsections (1) and (2) of section 429.53,
3418 Florida Statutes, are amended to read:
3419 429.53 Consultation by the agency.—
3420 (1) The ~~area offices of licensure and certification of the~~
3421 agency shall provide consultation to the following upon request:
3422 (a) A licensee of a facility.

3423 (b) A person interested in obtaining a license to operate a
3424 facility under this part.
3425 (2) As used in this section, “consultation” includes:
3426 (a) An explanation of the requirements of this part and
3427 rules adopted pursuant thereto;
3428 (b) An explanation of the license application and renewal
3429 procedures; and
3430 ~~(c) The provision of a checklist of general local and state~~
3431 ~~approvals required prior to constructing or developing a~~
3432 ~~facility and a listing of the types of agencies responsible for~~
3433 ~~such approvals;~~
3434 ~~(d) An explanation of benefits and financial assistance~~
3435 ~~available to a recipient of supplemental security income~~
3436 ~~residing in a facility;~~
3437 (c)~~(e)~~ Any other information which the agency deems
3438 necessary to promote compliance with the requirements of this
3439 part~~; and~~
3440 ~~(f) A preconstruction review of a facility to ensure~~
3441 ~~compliance with agency rules and this part~~.
3442 Section 84. Subsections (1) and (2) of section 429.54,
3443 Florida Statutes, are renumbered as subsections (2) and (3),
3444 respectively, and a new subsection (1) is added to that section
3445 to read:
3446 429.54 Collection of information; local subsidy.—
3447 (1) A facility that is licensed under this part must report
3448 electronically to the agency semiannually data related to the
3449 facility, including, but not limited to, the total number of
3450 residents, the number of residents who are receiving limited
3451 mental health services, the number of residents who are

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3452 receiving extended congregate care services, the number of
3453 residents who are receiving limited nursing services, and
3454 professional staffing employed by or under contract with the
3455 licensee to provide resident services. The department, in
3456 consultation with the agency, shall adopt rules to administer
3457 this subsection.
3458 Section 85. Subsections (1) and (5) of section 429.71,
3459 Florida Statutes, are amended to read:
3460 429.71 Classification of violations ~~deficiencies~~;
3461 administrative fines.—
3462 (1) In addition to the requirements of part II of chapter
3463 408 and in addition to any other liability or penalty provided
3464 by law, the agency may impose an administrative fine on a
3465 provider according to the following classification:
3466 (a) Class I violations are defined in s. 408.813 ~~those~~
3467 ~~conditions or practices related to the operation and maintenance~~
3468 ~~of an adult family-care home or to the care of residents which~~
3469 ~~the agency determines present an imminent danger to the~~
3470 ~~residents or guests of the facility or a substantial probability~~
3471 ~~that death or serious physical or emotional harm would result~~
3472 ~~therefrom. The condition or practice that constitutes a class I~~
3473 ~~violation must be abated or eliminated within 24 hours, unless a~~
3474 ~~fixed period, as determined by the agency, is required for~~
3475 ~~correction~~. A class I violation ~~deficiency~~ is subject to an
3476 administrative fine in an amount not less than $500 and not
3477 exceeding $1,000 for each violation. ~~A fine may be levied~~
3478 ~~notwithstanding the correction of the deficiency.~~
3479 (b) Class II violations are defined in s. 408.813 ~~those~~
3480 ~~conditions or practices related to the operation and maintenance~~

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3481 ~~of an adult family-care home or to the care of residents which~~
3482 ~~the agency determines directly threaten the physical or~~
3483 ~~emotional health, safety, or security of the residents, other~~
3484 ~~than class I violations~~. A class II violation is subject to an
3485 administrative fine in an amount not less than $250 and not
3486 exceeding $500 for each violation. ~~A citation for a class II~~
3487 ~~violation must specify the time within which the violation is~~
3488 ~~required to be corrected. If a class II violation is corrected~~
3489 ~~within the time specified, no civil penalty shall be imposed,~~
3490 ~~unless it is a repeated offense.~~
3491 (c) Class III violations are defined in s. 408.813 ~~those~~
3492 ~~conditions or practices related to the operation and maintenance~~
3493 ~~of an adult family-care home or to the care of residents which~~
3494 ~~the agency determines indirectly or potentially threaten the~~
3495 ~~physical or emotional health, safety, or security of residents,~~
3496 ~~other than class I or class II violations~~. A class III violation
3497 is subject to an administrative fine in an amount not less than
3498 $100 and not exceeding $250 for each violation. ~~A citation for a~~
3499 ~~class III violation shall specify the time within which the~~
3500 ~~violation is required to be corrected.~~ If a class III violation
3501 is corrected within the time specified, no civil penalty shall
3502 be imposed, unless it is a repeated violation ~~offense~~.
3503 (d) Class IV violations are defined in s. 408.813 ~~those~~
3504 ~~conditions or occurrences related to the operation and~~
3505 ~~maintenance of an adult family-care home, or related to the~~
3506 ~~required reports, forms, or documents, which do not have the~~
3507 ~~potential of negatively affecting the residents~~. ~~A provider that~~
3508 ~~does not correct~~ A class IV violation ~~within the time limit~~
3509 ~~specified by the agency~~ is subject to an administrative fine in

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3510 an amount not less than $50 and not exceeding $100 for each
3511 violation. Any class IV violation that is corrected during the
3512 time the agency survey is conducted will be identified as an
3513 agency finding and not as a violation<u>, unless it is a repeat</u>
3514 <u>violation</u>.
3515 ~~(5) As an alternative to or in conjunction with an~~
3516 ~~administrative action against a provider, the agency may request~~
3517 ~~a plan of corrective action that demonstrates a good faith~~
3518 ~~effort to remedy each violation by a specific date, subject to~~
3519 ~~the approval of the agency.~~
3520 Section 86. Section 429.915, Florida Statutes, is amended
3521 to read:
3522 429.915 Conditional license.—In addition to the license
3523 categories available in part II of chapter 408, the agency may
3524 issue a conditional license to an applicant for license renewal
3525 or change of ownership if the applicant fails to meet all
3526 standards and requirements for licensure. A conditional license
3527 issued under this subsection must be limited to a specific
3528 period not exceeding 6 months, as determined by the agency~~, and~~
3529 ~~must be accompanied by an approved plan of correction~~.
3530 Section 87. Paragraphs (b) and (g) of subsection (3) of
3531 section 430.80, Florida Statutes, are amended to read:
3532 430.80 Implementation of a teaching nursing home pilot
3533 project.—
3534 (3) To be designated as a teaching nursing home, a nursing
3535 home licensee must, at a minimum:
3536 (b) Participate in a nationally recognized accreditation
3537 program and hold a valid accreditation, such as the
3538 accreditation awarded by the Joint Commission ~~on Accreditation~~

3539 ~~of Healthcare Organizations~~, or, at the time of initial
3540 designation, possess a Gold Seal Award as conferred by the state
3541 on its licensed nursing home;
3542 (g) Maintain insurance coverage pursuant to s.
3543 400.141(1)(q)~~(s)~~ or proof of financial responsibility in a
3544 minimum amount of $750,000. Such proof of financial
3545 responsibility may include:
3546 1. Maintaining an escrow account consisting of cash or
3547 assets eligible for deposit in accordance with s. 625.52; or
3548 2. Obtaining and maintaining pursuant to chapter 675 an
3549 unexpired, irrevocable, nontransferable and nonassignable letter
3550 of credit issued by any bank or savings association organized
3551 and existing under the laws of this state or any bank or savings
3552 association organized under the laws of the United States that
3553 has its principal place of business in this state or has a
3554 branch office which is authorized to receive deposits in this
3555 state. The letter of credit shall be used to satisfy the
3556 obligation of the facility to the claimant upon presentment of a
3557 final judgment indicating liability and awarding damages to be
3558 paid by the facility or upon presentment of a settlement
3559 agreement signed by all parties to the agreement when such final
3560 judgment or settlement is a result of a liability claim against
3561 the facility.
3562 Section 88. Paragraph (d) of subsection (9) of section
3563 440.102, Florida Statutes, is repealed.
3564 Section 89. Paragraph (a) of subsection (2) of section
3565 440.13, Florida Statutes, is amended to read:
3566 440.13 Medical services and supplies; penalty for
3567 violations; limitations.—

3568 (2) MEDICAL TREATMENT; DUTY OF EMPLOYER TO FURNISH.—
3569 (a) Subject to the limitations specified elsewhere in this
3570 chapter, the employer shall furnish to the employee such
3571 medically necessary remedial treatment, care, and attendance for
3572 such period as the nature of the injury or the process of
3573 recovery may require, which is in accordance with established
3574 practice parameters and protocols of treatment as provided for
3575 in this chapter, including medicines, medical supplies, durable
3576 medical equipment, orthoses, prostheses, and other medically
3577 necessary apparatus. Remedial treatment, care, and attendance,
3578 including work-hardening programs or pain-management programs
3579 accredited by the Commission on Accreditation of Rehabilitation
3580 Facilities or the Joint Commission ~~on the Accreditation of~~
3581 ~~Health Organizations~~ or pain-management programs affiliated with
3582 medical schools, shall be considered as covered treatment only
3583 when such care is given based on a referral by a physician as
3584 defined in this chapter. Medically necessary treatment, care,
3585 and attendance does not include chiropractic services in excess
3586 of 24 treatments or rendered 12 weeks beyond the date of the
3587 initial chiropractic treatment, whichever comes first, unless
3588 the carrier authorizes additional treatment or the employee is
3589 catastrophically injured.
3590
3591 Failure of the carrier to timely comply with this subsection
3592 shall be a violation of this chapter and the carrier shall be
3593 subject to penalties as provided for in s. 440.525.
3594 Section 90. Subsection (1) of section 483.035, Florida
3595 Statutes, is amended to read:
3596 483.035 Clinical laboratories operated by practitioners for

3597 exclusive use; licensure and regulation.—
3598 (1) A clinical laboratory operated by one or more
3599 practitioners licensed under chapter 458, chapter 459, chapter
3600 460, chapter 461, chapter 462, part I of chapter 464, or chapter
3601 466, exclusively in connection with the diagnosis and treatment
3602 of their own patients, must be licensed under this part and must
3603 comply with the provisions of this part, except that the agency
3604 shall adopt rules for staffing, for personnel, including
3605 education and training of personnel, for proficiency testing,
3606 and for construction standards relating to the licensure and
3607 operation of the laboratory based upon and not exceeding the
3608 same standards contained in the federal Clinical Laboratory
3609 Improvement Amendments of 1988 and the federal regulations
3610 adopted thereunder.
3611 Section 91. Subsections (1) and (9) of section 483.051,
3612 Florida Statutes, are amended to read:
3613 483.051 Powers and duties of the agency.—The agency shall
3614 adopt rules to implement this part, which rules must include,
3615 but are not limited to, the following:
3616 (1) LICENSING; QUALIFICATIONS.—The agency shall provide for
3617 biennial licensure of all nonwaived clinical laboratories
3618 meeting the requirements of this part and shall prescribe the
3619 qualifications necessary for such licensure, including, but not
3620 limited to, an application for or proof of a certificate under
3621 Clinical Laboratory Improvement Amendments of 1988. A nonwaived
3622 laboratory is a laboratory that has not been granted a
3623 certificate of waiver by the Centers for Medicare and Medicaid
3624 Services under the Clinical Laboratory Improvement Amendments of
3625 1988 and the federal rules adopted thereunder.

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3626 (9) ALTERNATE-SITE TESTING.—The agency, in consultation
3627 with the Board of Clinical Laboratory Personnel, shall adopt, by
3628 rule, the criteria for alternate-site testing to be performed
3629 under the supervision of a clinical laboratory director. The
3630 elements to be addressed in the rule include, but are not
3631 limited to: a hospital internal needs assessment; a protocol of
3632 implementation including tests to be performed and who will
3633 perform the tests; criteria to be used in selecting the method
3634 of testing to be used for alternate-site testing; minimum
3635 training and education requirements for those who will perform
3636 alternate-site testing, such as documented training, licensure,
3637 certification, or other medical professional background not
3638 limited to laboratory professionals; documented inservice
3639 training as well as initial and ongoing competency validation;
3640 an appropriate internal and external quality control protocol;
3641 an internal mechanism for identifying and tracking alternate-
3642 site testing by the central laboratory; and recordkeeping
3643 requirements. ~~Alternate-site testing locations must register~~
3644 ~~when the clinical laboratory applies to renew its license.~~ For
3645 purposes of this subsection, the term "alternate-site testing"
3646 means any laboratory testing done under the administrative
3647 control of a hospital, but performed out of the physical or
3648 administrative confines of the central laboratory.
3649 Section 92. Section 483.294, Florida Statutes, is amended
3650 to read:
3651 483.294 Inspection of centers.—In accordance with s.
3652 408.811, the agency shall biennially~~, at least once annually,~~
3653 inspect the premises and operations of all centers subject to
3654 licensure under this part.

3655 Section 93. Subsection (4) is added to section 626.9541,
3656 Florida Statutes, to read:
3657 626.9541 Unfair methods of competition and unfair or
3658 deceptive acts or practices defined; alternative rates of
3659 payment; wellness programs.—
3660 (4) WELLNESS PROGRAMS.—An insurer issuing a group or
3661 individual health benefit plan may offer a voluntary wellness or
3662 health-improvement program that allows for rewards or
3663 incentives, including, but not limited to, merchandise, gift
3664 cards, debit cards, premium discounts or rebates, contributions
3665 towards a member's health savings account, modifications to
3666 copayment, deductible, or coinsurance amounts, or any
3667 combination of these incentives, to encourage or reward
3668 participation in the program. The health plan member may be
3669 required to provide verification, such as a statement from his
3670 or her physician, that a medical condition makes it unreasonably
3671 difficult or medically inadvisable for the individual to
3672 participate in the wellness program. Any reward or incentive
3673 established under this subsection is not an insurance benefit
3674 and does not violate this section. This subsection does not
3675 prohibit an insurer from offering incentives or rewards to
3676 members for adherence to wellness or health improvement programs
3677 if otherwise allowed by state or federal law. Notwithstanding
3678 any provision of this subsection, no insurer, nor its agent, may
3679 use any incentive authorized by this subsection for the purpose
3680 of redirecting patients from one health care insurance plan to
3681 another.
3682 Section 94. Subsection (1) of section 627.645, Florida
3683 Statutes, is amended to read:

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3684 627.645 Denial of health insurance claims restricted.—
3685 (1) No claim for payment under a health insurance policy or
3686 self-insured program of health benefits for treatment, care, or
3687 services in a licensed hospital which is accredited by the Joint
3688 Commission ~~on the Accreditation of Hospitals~~, the American
3689 Osteopathic Association, or the Commission on the Accreditation
3690 of Rehabilitative Facilities shall be denied because such
3691 hospital lacks major surgical facilities and is primarily of a
3692 rehabilitative nature, if such rehabilitation is specifically
3693 for treatment of physical disability.
3694 Section 95. Paragraph (c) of subsection (2) of section
3695 627.668, Florida Statutes, is amended to read:
3696 627.668 Optional coverage for mental and nervous disorders
3697 required; exception.—
3698 (2) Under group policies or contracts, inpatient hospital
3699 benefits, partial hospitalization benefits, and outpatient
3700 benefits consisting of durational limits, dollar amounts,
3701 deductibles, and coinsurance factors shall not be less favorable
3702 than for physical illness generally, except that:
3703 (c) Partial hospitalization benefits shall be provided
3704 under the direction of a licensed physician. For purposes of
3705 this part, the term “partial hospitalization services” is
3706 defined as those services offered by a program accredited by the
3707 Joint Commission ~~on Accreditation of Hospitals (JCAH)~~ or in
3708 compliance with equivalent standards. Alcohol rehabilitation
3709 programs accredited by the Joint Commission ~~on Accreditation of~~
3710 ~~Hospitals~~ or approved by the state and licensed drug abuse
3711 rehabilitation programs shall also be qualified providers under
3712 this section. In any benefit year, if partial hospitalization

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3713 services or a combination of inpatient and partial
3714 hospitalization are utilized, the total benefits paid for all
3715 such services shall not exceed the cost of 30 days of inpatient
3716 hospitalization for psychiatric services, including physician
3717 fees, which prevail in the community in which the partial
3718 hospitalization services are rendered. If partial
3719 hospitalization services benefits are provided beyond the limits
3720 set forth in this paragraph, the durational limits, dollar
3721 amounts, and coinsurance factors thereof need not be the same as
3722 those applicable to physical illness generally.
3723 Section 96. Subsection (3) of section 627.669, Florida
3724 Statutes, is amended to read:
3725 627.669 Optional coverage required for substance abuse
3726 impaired persons; exception.—
3727 (3) The benefits provided under this section shall be
3728 applicable only if treatment is provided by, or under the
3729 supervision of, or is prescribed by, a licensed physician or
3730 licensed psychologist and if services are provided in a program
3731 accredited by the Joint Commission ~~on Accreditation of Hospitals~~
3732 or approved by the state.
3733 Section 97. Paragraph (a) of subsection (1) of section
3734 627.736, Florida Statutes, is amended to read:
3735 627.736 Required personal injury protection benefits;
3736 exclusions; priority; claims.—
3737 (1) REQUIRED BENEFITS.—Every insurance policy complying
3738 with the security requirements of s. 627.733 shall provide
3739 personal injury protection to the named insured, relatives
3740 residing in the same household, persons operating the insured
3741 motor vehicle, passengers in such motor vehicle, and other

3742 persons struck by such motor vehicle and suffering bodily injury
3743 while not an occupant of a self-propelled vehicle, subject to
3744 the provisions of subsection (2) and paragraph (4)(e), to a
3745 limit of $10,000 for loss sustained by any such person as a
3746 result of bodily injury, sickness, disease, or death arising out
3747 of the ownership, maintenance, or use of a motor vehicle as
3748 follows:
3749 (a) *Medical benefits.*—Eighty percent of all reasonable
3750 expenses for medically necessary medical, surgical, X-ray,
3751 dental, and rehabilitative services, including prosthetic
3752 devices, and medically necessary ambulance, hospital, and
3753 nursing services. However, the medical benefits shall provide
3754 reimbursement only for such services and care that are lawfully
3755 provided, supervised, ordered, or prescribed by a physician
3756 licensed under chapter 458 or chapter 459, a dentist licensed
3757 under chapter 466, or a chiropractic physician licensed under
3758 chapter 460 or that are provided by any of the following persons
3759 or entities:
3760 1. A hospital or ambulatory surgical center licensed under
3761 chapter 395.
3762 2. A person or entity licensed under ss. 401.2101-401.45
3763 that provides emergency transportation and treatment.
3764 3. An entity wholly owned by one or more physicians
3765 licensed under chapter 458 or chapter 459, chiropractic
3766 physicians licensed under chapter 460, or dentists licensed
3767 under chapter 466 or by such practitioner or practitioners and
3768 the spouse, parent, child, or sibling of that practitioner or
3769 those practitioners.
3770 4. An entity wholly owned, directly or indirectly, by a

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3771 hospital or hospitals.
3772 5. A health care clinic licensed under ss. 400.990-400.995
3773 that is:
3774 a. Accredited by the Joint Commission on Accreditation of
3775 Healthcare Organizations, the American Osteopathic Association,
3776 the Commission on Accreditation of Rehabilitation Facilities, or
3777 the Accreditation Association for Ambulatory Health Care, Inc.;
3778 or
3779 b. A health care clinic that:
3780 (I) Has a medical director licensed under chapter 458,
3781 chapter 459, or chapter 460;
3782 (II) Has been continuously licensed for more than 3 years
3783 or is a publicly traded corporation that issues securities
3784 traded on an exchange registered with the United States
3785 Securities and Exchange Commission as a national securities
3786 exchange; and
3787 (III) Provides at least four of the following medical
3788 specialties:
3789 (A) General medicine.
3790 (B) Radiography.
3791 (C) Orthopedic medicine.
3792 (D) Physical medicine.
3793 (E) Physical therapy.
3794 (F) Physical rehabilitation.
3795 (G) Prescribing or dispensing outpatient prescription
3796 medication.
3797 (H) Laboratory services.
3798
3799 The Financial Services Commission shall adopt by rule the form

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3800 that must be used by an insurer and a health care provider
3801 specified in subparagraph 3., subparagraph 4., or subparagraph
3802 5. to document that the health care provider meets the criteria
3803 of this paragraph, which rule must include a requirement for a
3804 sworn statement or affidavit.
3805
3806 Only insurers writing motor vehicle liability insurance in this
3807 state may provide the required benefits of this section, and no
3808 such insurer shall require the purchase of any other motor
3809 vehicle coverage other than the purchase of property damage
3810 liability coverage as required by s. 627.7275 as a condition for
3811 providing such required benefits. Insurers may not require that
3812 property damage liability insurance in an amount greater than
3813 $10,000 be purchased in conjunction with personal injury
3814 protection. Such insurers shall make benefits and required
3815 property damage liability insurance coverage available through
3816 normal marketing channels. Any insurer writing motor vehicle
3817 liability insurance in this state who fails to comply with such
3818 availability requirement as a general business practice shall be
3819 deemed to have violated part IX of chapter 626, and such
3820 violation shall constitute an unfair method of competition or an
3821 unfair or deceptive act or practice involving the business of
3822 insurance; and any such insurer committing such violation shall
3823 be subject to the penalties afforded in such part, as well as
3824 those which may be afforded elsewhere in the insurance code.
3825 Section 98. Subsection (12) of section 641.495, Florida
3826 Statutes, is amended to read:
3827 641.495 Requirements for issuance and maintenance of
3828 certificate.—

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3829 (12) The provisions of part I of chapter 395 do not apply
3830 to a health maintenance organization that, on or before January
3831 1, 1991, provides not more than 10 outpatient holding beds for
3832 short-term and hospice-type patients in an ambulatory care
3833 facility for its members, provided that such health maintenance
3834 organization maintains current accreditation by the Joint
3835 Commission ~~on Accreditation of Health Care Organizations~~, the
3836 Accreditation Association for Ambulatory Health Care, or the
3837 National Committee for Quality Assurance.
3838 Section 99. Subsection (13) of section 651.118, Florida
3839 Statutes, is amended to read:
3840 651.118 Agency for Health Care Administration; certificates
3841 of need; sheltered beds; community beds.—
3842 (13) Residents, as defined in this chapter, are not
3843 considered new admissions for the purpose of s.
3844 400.141(1)(n)~~(o)~~1.d.
3845 Section 100. Subsection (2) of section 766.1015, Florida
3846 Statutes, is amended to read:
3847 766.1015 Civil immunity for members of or consultants to
3848 certain boards, committees, or other entities.—
3849 (2) Such committee, board, group, commission, or other
3850 entity must be established in accordance with state law or in
3851 accordance with requirements of the Joint Commission ~~on~~
3852 ~~Accreditation of Healthcare Organizations~~, established and duly
3853 constituted by one or more public or licensed private hospitals
3854 or behavioral health agencies, or established by a governmental
3855 agency. To be protected by this section, the act, decision,
3856 omission, or utterance may not be made or done in bad faith or
3857 with malicious intent.

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3858 Section 101. Subsection (4) of section 766.202, Florida
3859 Statutes, is amended to read:
3860 766.202 Definitions; ss. 766.201-766.212.—As used in ss.
3861 766.201-766.212, the term:
3862 (4) "Health care provider" means any hospital, ambulatory
3863 surgical center, or mobile surgical facility as defined and
3864 licensed under chapter 395; a birth center licensed under
3865 chapter 383; any person licensed under chapter 458, chapter 459,
3866 chapter 460, chapter 461, chapter 462, chapter 463, part I of
3867 chapter 464, chapter 466, chapter 467, part XIV of chapter 468,
3868 or chapter 486; a clinical lab licensed under chapter 483; a
3869 health maintenance organization certificated under part I of
3870 chapter 641; a blood bank; a plasma center; an industrial
3871 clinic; a renal dialysis facility; or a professional association
3872 partnership, corporation, joint venture, or other association
3873 for professional activity by health care providers.
3874 Section 102. Paragraph (j) is added to subsection (3) of
3875 section 817.505, Florida Statutes, to read:
3876 817.505 Patient brokering prohibited; exceptions;
3877 penalties.—
3878 (3) This section shall not apply to:
3879 (j) Any payment by an assisted living facility, as defined
3880 in s. 429.02, which is permitted under s. 429.195(3).
3881 Section 103. Section 381.06014, Florida Statutes, is
3882 amended to read:
3883 381.06014 Blood establishments.—
3884 (1) As used in this section, the term:
3885 (a) "Blood establishment" means any person, entity, or
3886 organization, operating within the state, which examines an

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3887 individual for the purpose of blood donation or which collects,
3888 processes, stores, tests, or distributes blood or blood
3889 components collected from the human body for the purpose of
3890 transfusion, for any other medical purpose, or for the
3891 production of any biological product. A person, entity, or
3892 organization that uses a mobile unit to conduct such activities
3893 within the state is also a blood establishment.
3894 (b) "Volunteer donor" means a person who does not receive
3895 remuneration, other than an incentive, for a blood donation
3896 intended for transfusion, and the product container of the
3897 donation from the person qualifies for labeling with the
3898 statement "volunteer donor" under 21 C.F.R. s. 606.121.
3899 (2) Any blood establishment operating in the state may not
3900 conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~
3901 unless that blood establishment is operated in a manner
3902 consistent with the provisions of Title 21 C.F.R. parts 211 and
3903 600-640~~, Code of Federal Regulations~~.
3904 (3) Any blood establishment determined to be operating in
3905 the state in a manner not consistent with the provisions of
3906 Title 21 C.F.R. parts 211 and 600-640~~, Code of Federal~~
3907 ~~Regulations,~~ and in a manner that constitutes a danger to the
3908 health or well-being of donors or recipients as evidenced by the
3909 federal Food and Drug Administration's inspection reports and
3910 the revocation of the blood establishment's license or
3911 registration is ~~shall be~~ in violation of this chapter and must
3912 ~~shall~~ immediately cease all operations in the state.
3913 (4) The operation of a blood establishment in a manner not
3914 consistent with the provisions of Title 21 C.F.R. parts 211 and
3915 600-640~~, Code of Federal Regulations,~~ and in a manner that

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3916 constitutes a danger to the health or well-being of blood donors
3917 or recipients as evidenced by the federal Food and Drug
3918 Administration's inspection process is declared a nuisance and
3919 inimical to the public health, welfare, and safety. The Agency
3920 for Health Care Administration or any state attorney may bring
3921 an action for an injunction to restrain such operations or
3922 enjoin the future operation of the blood establishment.
3923 (5) A local government may not restrict the access to or
3924 use of any public facility or infrastructure for the collection
3925 of blood or blood components from volunteer donors based on
3926 whether the blood establishment is operating as a for-profit
3927 organization or not-for-profit organization.
3928 (6) In determining the service fee of blood or blood
3929 components received from volunteer donors and sold to hospitals
3930 or other health care providers, a blood establishment may not
3931 base the service fee of the blood or blood component solely on
3932 whether the purchasing entity is a for-profit organization or
3933 not-for-profit organization.
3934 (7) A blood establishment that collects blood or blood
3935 components from volunteer donors must disclose on the Internet
3936 the information required under this subsection to educate and
3937 inform donors and the public about the blood establishment's
3938 activities. A hospital that collects blood or blood components
3939 to be used only by that hospital's licensed facilities or by a
3940 health care provider that is a part of the hospital's business
3941 entity is exempt from the disclosure requirements in this
3942 subsection. The information required to be disclosed under this
3943 subsection may be cumulative for all blood establishments within
3944 a business entity. A blood establishment must disclose on its

3945 website all of the following information:
3946 (a) A description of the steps involved in collecting,
3947 processing, and distributing volunteer donations.
3948 (b) By March 1 of each year, the number of units of blood
3949 components which were:
3950 1. Produced by the blood establishment during the preceding
3951 calendar year;
3952 2. Obtained from other sources during the preceding
3953 calendar year;
3954 3. Distributed during the preceding calendar year to health
3955 care providers located outside this state. However, if the blood
3956 establishment collects donations in a county outside this state,
3957 distributions to health care providers in that county shall be
3958 excluded. Such information shall be reported in the aggregate
3959 for health care providers located within the United States and
3960 its territories or outside the United States and its
3961 territories; and
3962 4. Distributed during the preceding calendar year to
3963 entities that are not health care providers. Such information
3964 shall be reported in the aggregate for purchasers located within
3965 the United States and its territories or outside the United
3966 States and its territories.
3967 (c) The blood establishment's conflict-of-interest policy,
3968 policy concerning related-party transactions, whistleblower
3969 policy, and policy for determining executive compensation. If a
3970 change occurs to any of these documents, the revised document
3971 must be available on the blood establishment's website by the
3972 following March 1.
3973 (d) Except for a hospital that collects blood or blood

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3974 components from volunteer donors:

3975 1. The most recent 3 years of the Return of Organization
3976 Exempt from Income Tax, Internal Revenue Service Form 990, if
3977 the business entity for the blood establishment is eligible to
3978 file such return. The Form 990 must be available on the blood
3979 establishment's website within 60 calendar days after it is
3980 filed with the Internal Revenue Service; or

3981 2. If the business entity for the blood establishment is
3982 not eligible to file the Form 990 return, a balance sheet,
3983 income statement, and statement of changes in cash flow, along
3984 with the expression of an opinion thereon by an independent
3985 certified public accountant who audited or reviewed such
3986 financial statements. Such documents must be available on the
3987 blood establishment's website within 120 days after the end of
3988 the blood establishment's fiscal year and must remain on the
3989 blood establishment's website for at least 36 months.

3990 (8) A blood establishment is liable for a civil penalty for
3991 failing to make the disclosures required under subsection (7).
3992 The Department of Legal Affairs may assess the civil penalty
3993 against the blood establishment for each day that it fails to
3994 make such required disclosures, but the penalty may not exceed
3995 $10,000 per year. If multiple blood establishments operated by a
3996 single business entity fail to meet such disclosure
3997 requirements, the civil penalty may be assessed against only one
3998 of the business entity's blood establishments. The Department of
3999 Legal Affairs may terminate an action if the blood establishment
4000 agrees to pay a stipulated civil penalty. A civil penalty so
4001 collected accrues to the state and shall be deposited as
4002 received into the General Revenue Fund unallocated. The

4003 Department of Legal Affairs may terminate the action and waive
4004 the civil penalty upon a showing of good cause by the blood
4005 establishment as to why the required disclosures were not made.
4006 Section 104. Subsection (23) of section 499.003, Florida
4007 Statutes, is amended to read:
4008 499.003 Definitions of terms used in this part.—As used in
4009 this part, the term:
4010 (23) “Health care entity” means a closed pharmacy or any
4011 person, organization, or business entity that provides
4012 diagnostic, medical, surgical, or dental treatment or care, or
4013 chronic or rehabilitative care, but does not include any
4014 wholesale distributor or retail pharmacy licensed under state
4015 law to deal in prescription drugs. However, a blood
4016 establishment is a health care entity that may engage in the
4017 wholesale distribution of prescription drugs under s.
4018 499.01(2)(g)1.c.
4019 Section 105. Subsection (21) of section 499.005, Florida
4020 Statutes, is amended to read:
4021 499.005 Prohibited acts.—It is unlawful for a person to
4022 perform or cause the performance of any of the following acts in
4023 this state:
4024 (21) The wholesale distribution of any prescription drug
4025 that was:
4026 (a) Purchased by a public or private hospital or other
4027 health care entity; or
4028 (b) Donated or supplied at a reduced price to a charitable
4029 organization,
4030
4031 unless the wholesale distribution of the prescription drug is

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4032 authorized in s. 499.01(2)(g)1.c.

4033 Section 106. Paragraphs (a) and (g) of subsection (2) of
4034 section 499.01, Florida Statutes, are amended to read:

4035 499.01 Permits.—

4036 (2) The following permits are established:

4037 (a) *Prescription drug manufacturer permit.*—A prescription
4038 drug manufacturer permit is required for any person that is a
4039 manufacturer of a prescription drug and that manufactures or
4040 distributes such prescription drugs in this state.

4041 1. A person that operates an establishment permitted as a
4042 prescription drug manufacturer may engage in wholesale
4043 distribution of prescription drugs manufactured at that
4044 establishment and must comply with all of the provisions of this
4045 part, except s. 499.01212, and the rules adopted under this
4046 part, except s. 499.01212, which ~~that~~ apply to a wholesale
4047 distributor.

4048 2. A prescription drug manufacturer must comply with all
4049 appropriate state and federal good manufacturing practices.

4050 3. A blood establishment, as defined in s. 381.06014,
4051 operating in a manner consistent with the provisions of Title 21
4052 C.F.R. parts 211 and 600-640, and manufacturing only the
4053 prescription drugs described in s. 499.003(54)(d) is not
4054 required to be permitted as a prescription drug manufacturer
4055 under this paragraph or to register products under s. 499.015.

4056 (g) *Restricted prescription drug distributor permit.*—

4057 1. A restricted prescription drug distributor permit is
4058 required for:

4059 a. Any person located in this state that engages in the
4060 distribution of a prescription drug, which distribution is not

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4061 considered “wholesale distribution” under s. 499.003(54)(a).
4062 b.~~1.~~ Any ~~A~~ person located in this state who engages in the
4063 receipt or distribution of a prescription drug in this state for
4064 the purpose of processing its return or its destruction ~~must~~
4065 ~~obtain a permit as a restricted prescription drug distributor~~ if
4066 such person is not the person initiating the return, the
4067 prescription drug wholesale supplier of the person initiating
4068 the return, or the manufacturer of the drug.
4069 c. A blood establishment located in this state which
4070 collects blood and blood components only from volunteer donors
4071 as defined in s. 381.06014 or pursuant to an authorized
4072 practitioner’s order for medical treatment or therapy and
4073 engages in the wholesale distribution of a prescription drug not
4074 described in s. 499.003(54)(d) to a health care entity. The
4075 health care entity receiving a prescription drug distributed
4076 under this sub-subparagraph must be licensed as a closed
4077 pharmacy or provide health care services at that establishment.
4078 The blood establishment must operate in accordance with s.
4079 381.06014 and may distribute only:
4080 (I) Prescription drugs indicated for a bleeding or clotting
4081 disorder or anemia;
4082 (II) Blood-collection containers approved under s. 505 of
4083 the federal act;
4084 (III) Drugs that are blood derivatives, or a recombinant or
4085 synthetic form of a blood derivative;
4086 (IV) Prescription drugs that are identified in rules
4087 adopted by the department and that are essential to services
4088 performed or provided by blood establishments and authorized for
4089 distribution by blood establishments under federal law; or

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4090 (V) To the extent authorized by federal law, drugs
4091 necessary to collect blood or blood components from volunteer
4092 blood donors; for blood establishment personnel to perform
4093 therapeutic procedures under the direction and supervision of a
4094 licensed physician; and to diagnose, treat, manage, and prevent
4095 any reaction of either a volunteer blood donor or a patient
4096 undergoing a therapeutic procedure performed under the direction
4097 and supervision of a licensed physician,
4098
4099 as long as all of the health care services provided by the blood
4100 establishment are related to its activities as a registered
4101 blood establishment or the health care services consist of
4102 collecting, processing, storing, or administering human
4103 hematopoietic stem cells or progenitor cells or performing
4104 diagnostic testing of specimens if such specimens are tested
4105 together with specimens undergoing routine donor testing.
4106 2. Storage, handling, and recordkeeping of these
4107 distributions by a person required to be permitted as a
4108 restricted prescription drug distributor must comply with the
4109 requirements for wholesale distributors under s. 499.0121, but
4110 not those set forth in s. 499.01212 if the distribution occurs
4111 pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.
4112 3. A person who applies for a permit as a restricted
4113 prescription drug distributor, or for the renewal of such a
4114 permit, must provide to the department the information required
4115 under s. 499.012.
4116 4. The department may adopt rules regarding the
4117 distribution of prescription drugs by hospitals, health care
4118 entities, charitable organizations, ~~or~~ other persons not

4119 involved in wholesale distribution, and blood establishments,
4120 which rules are necessary for the protection of the public
4121 health, safety, and welfare.
4122 Section 107. This act shall take effect July 1, 2011.

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