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By the Policy and Steering Committee on Ways and Means; the Committee on Health Regulation; and Senator Gardiner

576-05334-10 20102434c2 A bill to be entitled

An act relating to health care; amending s. 112.0455, F.S., relating to the Drug-Free Workplace Act; deleting an obsolete provision; amending s. 318.21, F.S.; revising distribution of funds from civil penalties imposed for traffic infractions by county courts; amending s. 381.00315, F.S.; directing the Department of Health to accept funds from counties, municipalities, and certain other entities for the purchase of certain products made available under a contract of the United States Department of Health and Human Services for the manufacture and delivery of such products in response to a public health emergency; amending s. 381.0072, F.S.; limiting Department of Health food service inspections in nursing homes; requiring the department to coordinate inspections with the Agency for Health Care Administration; amending s. 381.06014, F.S.; defining the term "volunteer donor"; requiring that certain blood establishments disclose specified information on the Internet; repealing s. 383.325, F.S., relating to confidentiality of inspection reports of licensed birth center facilities; amending s. 395.002, F.S.; revising and deleting definitions applicable to regulation of hospitals and other licensed facilities; conforming a cross-reference; amending s. 395.003, F.S.; deleting an obsolete provision; conforming a cross-reference; amending s. 395.0193, F.S.; requiring a licensed facility to report certain peer review

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576-05334-10 20102434c2

information and final disciplinary actions to the Division of Medical Quality Assurance of the Department of Health rather than the Division of Health Quality Assurance of the Agency for Health Care Administration; amending s. 395.1023, F.S.; providing for the Department of Children and Family Services rather than the Department of Health to perform certain functions with respect to child protection cases; requiring certain hospitals to notify the Department of Children and Family Services of compliance; amending s. 395.1041, F.S., relating to hospital emergency services and care; deleting obsolete provisions; repealing s. 395.1046, F.S., relating to complaint investigation procedures; amending s. 395.1055, F.S.; requiring licensed facility beds to conform to standards specified by the Agency for Health Care Administration, the Florida Building Code, and the Florida Fire Prevention Code; amending s. 395.10972, F.S.; revising a reference to the Florida Society of Healthcare Risk Management to conform to the current designation; amending s. 395.2050, F.S.; revising a reference to the federal Health Care Financing Administration to conform to the current designation; amending s. 395.3036, F.S.; correcting a reference; repealing s. 395.3037, F.S., relating to redundant definitions; amending ss. 154.11, 394.741, 395.3038, 400.925, 400.9935, 408.05, 440.13, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S.; revising references to the Joint

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576-05334-10 20102434c2

Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, and the Council on Accreditation to conform to their current designations; amending s. 395.602, F.S.; revising the definition of the term "rural hospital" to delete an obsolete provision; amending s. 400.021, F.S.; revising the definition of the term "geriatric outpatient clinic"; amending s. 400.0255, F.S.; correcting an obsolete cross-reference to administrative rules; amending s. 400.063, F.S.; deleting an obsolete provision; amending ss. 400.071 and 400.0712, F.S.; revising applicability of general licensure requirements under part II of ch. 408, F.S., to applications for nursing home licensure; revising provisions governing inactive licenses; amending s. 400.111, F.S.; providing for disclosure of controlling interest of a nursing home facility upon request by the Agency for Health Care Administration; amending s. 400.1183, F.S.; revising grievance record maintenance and reporting requirements for nursing homes; amending s. 400.141, F.S.; providing criteria for the provision of respite services by nursing homes; requiring a written plan of care; requiring a contract for services; requiring resident release to caregivers to be designated in writing; providing an exemption to the application of discharge planning rules; providing for residents' rights; providing for use of personal medications; providing terms of respite stay;

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576-05334-10 20102434c2

providing for communication of patient information; requiring a physician order for care and proof of a physical examination; providing for services for respite patients and duties of facilities with respect to such patients; conforming a cross-reference; requiring facilities to maintain clinical records that meet specified standards; providing a fine relating to an admissions moratorium; deleting requirement for facilities to submit certain information related to management companies to the agency; deleting a requirement for facilities to notify the agency of certain bankruptcy filings to conform to changes made by the act; amending s. 400.142, F.S.; deleting language relating to agency adoption of rules; amending 400.147, F.S.; revising reporting requirements for licensed nursing home facilities relating to adverse incidents; repealing s. 400.148, F.S., relating to the Medicaid "Up-or-Out" Quality of Care Contract Management Program; amending s. 400.162, F.S., requiring nursing homes to provide a resident property statement annually and upon request; amending s. 400.179, F.S.; revising requirements for nursing home lease bond alternative fees; deleting an obsolete provision; amending s. 400.19, F.S.; revising inspection requirements; repealing s. 400.195, F.S., relating to agency reporting requirements; amending s. 400.23, F.S.; deleting an obsolete provision; correcting a reference; directing the agency to adopt rules for minimum staffing standards in nursing homes

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576-05334-10 20102434c2

that serve persons under 21 years of age; providing minimum staffing standards; amending s. 400.275, F.S.; revising agency duties with regard to training nursing home surveyor teams; revising requirements for team members; amending s. 400.484, F.S.; revising the schedule of home health agency inspection violations; amending s. 400.606, F.S.; revising the content requirements of the plan accompanying an initial or change-of-ownership application for licensure of a hospice; revising requirements relating to certificates of need for certain hospice facilities; amending s. 400.607, F.S.; revising grounds for agency action against a hospice; amending s. 400.915, F.S.; correcting an obsolete cross-reference to administrative rules; amending s. 400.931, F.S.; deleting a requirement that an applicant for a home medical equipment provider license submit a surety bond to the agency; amending s. 400.932, F.S.; revising grounds for the imposition of administrative penalties for certain violations by an employee of a home medical equipment provider; amending s. 400.967, F.S.; revising the schedule of inspection violations for intermediate care facilities for the developmentally disabled; providing a penalty for certain violations; amending s. 400.9905, F.S.; providing that part X of ch, 400, F.S., the Health Care Clinic Act, does not apply to an entity owned by a corporation with a specified amount of annual sales of health care services under certain circumstances or

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576-05334-10 20102434c2

to an entity owned or controlled by a publicly traded entity with a specified amount of annual revenues; amending s. 400.991, F.S.; conforming terminology; revising application requirements relating to documentation of financial ability to operate a mobile clinic; amending s. 408.034, F.S.; revising agency authority relating to licensing of intermediate care facilities for the developmentally disabled; amending s. 408.036, F.S.; deleting an exemption from certain certificate-of-need review requirements for a hospice or a hospice inpatient facility; amending s. 408.043, F.S.; revising requirements for certain freestanding inpatient hospice care facilities to obtain a certificate of need; amending s. 408.061, F.S.; revising health care facility data reporting requirements; amending s. 408.10, F.S.; removing agency authority to investigate certain consumer complaints; amending s. 408.802, F.S.; removing applicability of part II of ch. 408, F.S., relating to general licensure requirements, to private review agents; amending s. 408.804, F.S.; providing penalties for altering, defacing, or falsifying a license certificate issued by the agency or displaying such an altered, defaced, or falsified certificate; amending s. 408.806, F.S.; revising agency responsibilities for notification of licensees of impending expiration of a license; requiring payment of a late fee for a license application to be considered complete under certain circumstances; amending s. 408.810, F.S.; revising

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576-05334-10 20102434c2

provisions relating to information required for licensure; requiring proof of submission of notice to a mortgagor or landlord regarding provision of services requiring licensure; requiring disclosure of information by a controlling interest of certain court actions relating to financial instability within a specified time period; amending s. 408.813, F.S.; authorizing the agency to impose fines for unclassified violations of part II of ch. 408, F.S.; amending s. 408.815, F.S.; authorizing the agency to extend a license expiration date under certain circumstances; amending s. 409.221, F.S.; deleting a reporting requirement relating to the consumerdirected care program; amending s. 409.91196, F.S.; conforming a cross-reference; amending s. 409.912, F.S.; revising procedures for implementation of a Medicaid prescribed-drug spending-control program; amending s. 429.07, F.S.; deleting the requirement for an assisted living facility to obtain an additional license in order to provide limited nursing services; deleting the requirement for the agency to conduct quarterly monitoring visits of facilities that hold a license to provide extended congregate care services; deleting the requirement for the department to report annually on the status of and recommendations related to extended congregate care; deleting the requirement for the agency to conduct monitoring visits at least twice a year to facilities providing limited nursing services; increasing the licensure fees and the

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576-05334-10 20102434c2

maximum fee required for the standard license; increasing the licensure fees for the extended congregate care license; eliminating the license fee for the limited nursing services license; transferring from another provision of law the requirement that a biennial survey of an assisted living facility include specific actions to determine whether the facility is adequately protecting residents' rights; providing that an assisted living facility that has a class I or class II violation is subject to monitoring visits; requiring a registered nurse to participate in certain monitoring visits; amending s. 429.11, F.S.; revising licensure application requirements for assisted living facilities to eliminate provisional licenses; amending s. 429.12, F.S.; revising notification requirements for the sale or transfer of ownership of an assisted living facility; amending s. 429.14, F.S.; removing a ground for the imposition of an administrative penalty; clarifying provisions relating to a facility's request for a hearing under certain circumstances; authorizing the agency to provide certain information relating to the licensure status of assisted living facilities electronically or through the agency's Internet website; amending s. 429.17, F.S.; deleting provisions relating to the limited nursing services license; revising agency responsibilities regarding the issuance of conditional licenses; amending s. 429.19, F.S.; clarifying that a monitoring fee may be assessed in addition to an

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576-05334-10 20102434c2

administrative fine; amending s. 429.23, F.S.; deleting reporting requirements for assisted living facilities relating to liability claims; amending s. 429.255, F.S.; eliminating provisions authorizing the use of volunteers to provide certain health-carerelated services in assisted living facilities; authorizing assisted living facilities to provide limited nursing services; requiring an assisted living facility to be responsible for certain recordkeeping and staff to be trained to monitor residents receiving certain health-care-related services; amending s. 429.28, F.S.; deleting a requirement for a biennial survey of an assisted living facility, to conform to changes made by the act; amending s. 429.35, F.S.; authorizing the agency to provide certain information relating to the inspections of assisted living facilities electronically or through the agency's Internet website; amending s. 429.41, F.S., relating to rulemaking; conforming provisions to changes made by the act; amending s. 429.53, F.S.; revising provisions relating to consultation by the agency; revising a definition; amending s. 429.54, F.S.; requiring licensed assisted living facilities to electronically report certain data semiannually to the agency in accordance with rules adopted by the department; amending s. 429.71, F.S.; revising schedule of inspection violations for adult familycare homes; amending s. 429.911, F.S.; deleting a ground for agency action against an adult day care

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576-05334-10 20102434c2

center; amending s. 429.915, F.S.; revising agency responsibilities regarding the issuance of conditional licenses; amending s. 483.201, F.S.; providing for disciplinary action against clinical laboratories failing to disclose specified information on the Internet; providing a maximum annual administrative fine that may be imposed annually against certain clinical laboratories for failure to comply with such disclosure requirement; amending s. 483.294, F.S.; revising frequency of agency inspections of multiphasic health testing centers; amending s. 499.003, F.S.; revising the definition of the term "health care entity" to clarify that a blood establishment may be a health care entity and engage in certain activities; removing a requirement that certain prescription drug purchasers maintain a separate inventory of certain prescription drugs; amending s. 499.005, F.S.; clarifying provisions prohibiting the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity, to conform to changes made by the act; amending s. 499.01, F.S.; exempting certain blood establishments from the requirements to be permitted as a prescription drug manufacturer and register products; requiring that certain blood establishments obtain a restricted prescription drug distributor permit under specified conditions; limiting the prescription drugs that a blood establishment may distribute with the restricted

576-05334-10 20102434c2

prescription drug distributor permit; authorizing the Department of Health to adopt rules; amending s. 499.01212, F.S.; exempting prescription drugs contained in sealed medical convenience kits from the pedigree paper requirements under specified circumstances; amending s. 633.081, F.S.; limiting Fire Marshal inspections of nursing homes to once a year; providing for additional inspections based on complaints and violations identified in the course of orientation or training activities; amending s. 766.202, F.S.; adding persons licensed under part XIV of ch. 468, F.S., to the definition of "health care provider"; amending ss. 394.4787, 400.0239, 408.07, 430.80, and 651.118, F.S.; conforming terminology and cross-references; revising a reference; providing an effective date.

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

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Section 1. Present paragraph (e) of subsection (10) and paragraph (e) of subsection (14) of section 112.0455, Florida Statutes, are amended, and paragraphs (f) through (k) of subsection (10) of that section are redesignated as paragraphs (e) through (j), respectively, to read:

- 112.0455 Drug-Free Workplace Act.-
- (10) EMPLOYER PROTECTION. -
- (e) Nothing in this section shall be construed to operate retroactively, and nothing in this section shall abrogate the right of an employer under state law to conduct drug tests prior

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576-05334-10 20102434c2

to January 1, 1990. A drug test conducted by an employer prior to January 1, 1990, is not subject to this section.

- (14) DISCIPLINE REMEDIES.-
- (e) Upon resolving an appeal filed pursuant to paragraph(c), and finding a violation of this section, the commission may order the following relief:
- 1. Rescind the disciplinary action, expunse related records from the personnel file of the employee or job applicant and reinstate the employee.
  - 2. Order compliance with paragraph  $(10)(f)\frac{(g)}{(g)}$ .
  - 3. Award back pay and benefits.
- 4. Award the prevailing employee or job applicant the necessary costs of the appeal, reasonable attorney's fees, and expert witness fees.
- Section 2. Paragraph (n) of subsection (1) of section 154.11, Florida Statutes, is amended to read:
  - 154.11 Powers of board of trustees.-
- (1) The board of trustees of each public health trust shall be deemed to exercise a public and essential governmental function of both the state and the county and in furtherance thereof it shall, subject to limitation by the governing body of the county in which such board is located, have all of the powers necessary or convenient to carry out the operation and governance of designated health care facilities, including, but without limiting the generality of, the foregoing:
- (n) To appoint originally the staff of physicians to practice in any designated facility owned or operated by the board and to approve the bylaws and rules to be adopted by the medical staff of any designated facility owned and operated by

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576-05334-10 20102434c2

the board, such governing regulations to be in accordance with the standards of The Joint Commission on the Accreditation of Hospitals which provide, among other things, for the method of appointing additional staff members and for the removal of staff members.

Section 3. Subsection (15) of section 318.21, Florida Statutes, is amended to read:

318.21 Disposition of civil penalties by county courts.—All civil penalties received by a county court pursuant to the provisions of this chapter shall be distributed and paid monthly as follows:

(15) Of the additional fine assessed under s. 318.18(3)(e) for a violation of s. 316.1893, 50 percent of the moneys received from the fines shall be remitted to the Department of Revenue and deposited into the Brain and Spinal Cord Injury Trust Fund of Department of Health and shall be appropriated to the Department of Health Agency for Health Care Administration as general revenue to provide an enhanced Medicaid payment to nursing homes that serve Medicaid recipients with spinal cord injuries that are medically complex and who are technologically and respiratory dependent with brain and spinal cord injuries. The remaining 50 percent of the moneys received from the enhanced fine imposed under s. 318.18(3)(e) shall be remitted to the Department of Revenue and deposited into the Department of Health Administrative Trust Fund to provide financial support to certified trauma centers in the counties where enhanced penalty zones are established to ensure the availability and accessibility of trauma services. Funds deposited into the Administrative Trust Fund under this subsection shall be

576-05334-10 20102434c2

378 allocated as follows:

(a) Fifty percent shall be allocated equally among all Level I, Level II, and pediatric trauma centers in recognition of readiness costs for maintaining trauma services.

- (b) Fifty percent shall be allocated among Level I, Level II, and pediatric trauma centers based on each center's relative volume of trauma cases as reported in the Department of Health Trauma Registry.
- Section 4. Subsection (3) is added to section 381.00315, Florida Statutes, to read:
- 381.00315 Public health advisories; public health emergencies.—The State Health Officer is responsible for declaring public health emergencies and issuing public health advisories.
- (3) To facilitate effective emergency management, when the United States Department of Health and Human Services contracts for the manufacture and delivery of licensable products in response to a public health emergency and the terms of those contracts are made available to the states, the department shall accept funds provided by counties, municipalities, and other entities designated in the state emergency management plan required under s. 252.35(2)(a) for the purpose of participation in such contracts. The department shall deposit the funds into the Grants and Donations Trust Fund and expend the funds on behalf of the donor county, municipality, or other entity for the purchase the licensable products made available under the contract.
- Section 5. Paragraph (e) is added to subsection (2) of section 381.0072, Florida Statutes, to read:

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576-05334-10 20102434c2

381.0072 Food service protection.—It shall be the duty of the Department of Health to adopt and enforce sanitation rules consistent with law to ensure the protection of the public from food-borne illness. These rules shall provide the standards and requirements for the storage, preparation, serving, or display of food in food service establishments as defined in this section and which are not permitted or licensed under chapter 500 or chapter 509.

- (2) DUTIES.-
- (e) The department shall inspect food service
  establishments in nursing homes licensed under part II of
  chapter 400 twice each year. The department may make additional
  inspections only in response to complaints. The department shall
  coordinate inspections with the Agency for Health Care
  Administration, such that the department's inspection is at
  least 60 days after a recertification visit by the Agency for
  Health Care Administration.

Section 6. Section 381.06014, Florida Statutes, is amended to read:

- 381.06014 Blood establishments.-
- (1) As used in this section, the term:
- (a) "Blood establishment" means any person, entity, or organization, operating within the state, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.
  - (b) "Volunteer donor" means a person who does not receive

576-05334-10 20102434c2

remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. 606.121.

- (2) Any blood establishment operating in the state may not conduct any activity defined in subsection (1) unless that blood establishment is operated in a manner consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations.
- (3) Any blood establishment determined to be operating in the state in a manner not consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of donors or recipients as evidenced by the federal Food and Drug Administration's inspection reports and the revocation of the blood establishment's license or registration shall be in violation of this chapter and shall immediately cease all operations in the state.
- (4) The operation of a blood establishment in a manner not consistent with the provisions of Title 21 parts 211 and 600-640, Code of Federal Regulations, and in a manner that constitutes a danger to the health or well-being of blood donors or recipients as evidenced by the federal Food and Drug Administration's inspection process is declared a nuisance and inimical to the public health, welfare, and safety. The Agency for Health Care Administration or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the blood establishment.
  - (5) A blood establishment that collects blood or blood

576-05334-10 20102434c2

components from volunteer donors must disclose on the Internet information to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components from volunteer donors for its own use or for health care providers that are part of its business entity is exempt from the disclosure requirements in this subsection. The information required to be disclosed under this subsection may be cumulative for all blood establishments within a business entity. Disciplinary action against the blood establishment's clinical laboratory license may be taken as provided in s. 483.201 for a blood establishment that is required to disclose but fails to disclose on its website all of the following information:

- (a) A description of the steps involved in collecting, processing, and distributing volunteer donations, presented in a manner appropriate for the donating public.
- (b) By March 1 of each year, the number of units of blood components, identified by component, that were:
- 1. Produced by the blood establishment during the preceding calendar year;
- 2. Obtained from other sources during the preceding
  calendar year;
- 3. Distributed during the preceding year to health care providers located outside this state. However, if the blood establishment collects donations in a county outside this state, distributions to health care providers in that county shall be excluded. Such information shall be aggregated by health care providers located within the United States and its territories or outside the United States and its territories; and

576-05334-10 20102434c2

4. Distributed to entities that are not health care providers during the preceding year. Such information shall be aggregated by purchasers located within the United States and its territories or outside the United States and its territories.

- For purposes of this paragraph, the components that must be reported include whole blood, red blood cells, leukoreduced red blood cells, fresh frozen plasma or the equivalent, recovered plasma, platelets, and cryoprecipitated antihemophilic factor.
- (c) The blood establishment's conflict-of-interest policy, policy concerning related-party transactions, whistleblower policy, and policy for determining executive compensation. If a change to any of these documents occurs, the revised document must be available on the blood establishment's website by the following March 1.
- (d)1. The most recent 3 years of the Return of Organization Exempt from Income Tax, Internal Revenue Service Form 990, if the business entity for the blood establishment is eligible to file such return. The Form 990 must be available on the blood establishment's website within 30 calendar days after filing it with the Internal Revenue Service; or
- 2. If the business entity for the blood establishment is not eligible to file the Form 990 return, a balance sheet, income statement, statement of changes in cash flow, and the expression of an opinion thereon by an independent certified public accountant who audited or reviewed such financial statements. Such documents must be available on the blood establishment's website within 120 days after the end of the

Statutes, is amended to read:

576-05334-10 20102434c2

blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

Section 7. <u>Section 383.325</u>, <u>Florida Statutes</u>, <u>is repealed</u>. Section 8. Subsection (7) of section 394.4787, Florida

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s.  $395.002\underline{(26)}\underline{(28)}$  and part II of chapter 408 as a specialty psychiatric hospital.

Section 9. Subsection (2) of section 394.741, Florida Statutes, is amended to read:

394.741 Accreditation requirements for providers of behavioral health care services.—

- (2) Notwithstanding any provision of law to the contrary, accreditation shall be accepted by the agency and department in lieu of the agency's and department's facility licensure onsite review requirements and shall be accepted as a substitute for the department's administrative and program monitoring requirements, except as required by subsections (3) and (4), for:
- (a) Any organization from which the department purchases behavioral health care services that is accredited by The Joint Commission on Accreditation of Healthcare Organizations or the Council on Accreditation for Children and Family Services, or has those services that are being purchased by the department accredited by the Commission on Accreditation of Rehabilitation Facilities CARF—the Rehabilitation Accreditation Commission.

576-05334-10 20102434c2

(b) Any mental health facility licensed by the agency or any substance abuse component licensed by the department that is accredited by The Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities CARF—the Rehabilitation Accreditation Commission, or the Council on Accreditation of Children and Family Services.

(c) Any network of providers from which the department or the agency purchases behavioral health care services accredited by The Joint Commission on Accreditation of Healthcare

Organizations, the Commission on Accreditation of Rehabilitation

Facilities CARF—the Rehabilitation Accreditation Commission, the Council on Accreditation of Children and Family Services, or the National Committee for Quality Assurance. A provider organization, which is part of an accredited network, is afforded the same rights under this part.

Section 10. Present subsections (15) through (32) of section 395.002, Florida Statutes, are renumbered as subsections (14) through (28), respectively, and present subsections (1), (14), (24), (30), and (31), and paragraph (c) of present subsection (28) of that section are amended to read:

395.002 Definitions.—As used in this chapter:

(1) "Accrediting organizations" means <u>nationally recognized</u> or approved accrediting organizations whose standards incorporate comparable licensure requirements as determined by the agency the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc.

576-05334-10 20102434c2

(14) "Initial denial determination" means a determination by a private review agent that the health care services furnished or proposed to be furnished to a patient are inappropriate, not medically necessary, or not reasonable.

- (24) "Private review agent" means any person or entity which performs utilization review services for third-party payors on a contractual basis for outpatient or inpatient services. However, the term shall not include full-time employees, personnel, or staff of health insurers, health maintenance organizations, or hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, when performing utilization review for their respective hospitals, health maintenance organizations, or insureds of the same insurance group. For this purpose, health insurers, health maintenance organizations, and hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, include such entities engaged as administrators of self-insurance as defined in s. 624.031.
- (26) (28) "Specialty hospital" means any facility which meets the provisions of subsection (12), and which regularly makes available either:
- (c) Intensive residential treatment programs for children and adolescents as defined in subsection (14) (15).
- (30) "Utilization review" means a system for reviewing the medical necessity or appropriateness in the allocation of health care resources of hospital services given or proposed to be given to a patient or group of patients.
- (31) "Utilization review plan" means a description of the policies and procedures governing utilization review activities

576-05334-10 20102434c2

performed by a private review agent.

Section 11. Paragraph (c) of subsection (1) and paragraph (b) of subsection (2) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.—

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(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.

(2)

(b) The agency shall, at the request of a licensee that is a teaching hospital as defined in s. 408.07(45), issue a single license to a licensee for facilities that have been previously licensed as separate premises, provided such separately licensed facilities, taken together, constitute the same premises as defined in s. 395.002(22)(23). Such license for the single premises shall include all of the beds, services, and programs that were previously included on the licenses for the separate premises. The granting of a single license under this paragraph shall not in any manner reduce the number of beds, services, or programs operated by the licensee.

Section 12. Paragraph (e) of subsection (2) and subsection (4) of section 395.0193, Florida Statutes, are amended to read:

395.0193 Licensed facilities; peer review; disciplinary powers; agency or partnership with physicians.—

(2) Each licensed facility, as a condition of licensure, shall provide for peer review of physicians who deliver health care services at the facility. Each licensed facility shall develop written, binding procedures by which such peer review

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576-05334-10 20102434c2

shall be conducted. Such procedures shall include:

- (e) Recording of agendas and minutes which do not contain confidential material, for review by the Division of <u>Medical</u>

  <u>Quality Assurance of the department</u> <u>Health Quality Assurance of the agency</u>.
- (4) Pursuant to ss. 458.337 and 459.016, any disciplinary actions taken under subsection (3) shall be reported in writing to the Division of Medical Quality Assurance of the department Health Quality Assurance of the agency within 30 working days after its initial occurrence, regardless of the pendency of appeals to the governing board of the hospital. The notification shall identify the disciplined practitioner, the action taken, and the reason for such action. All final disciplinary actions taken under subsection (3), if different from those which were reported to the department agency within 30 days after the initial occurrence, shall be reported within 10 working days to the Division of Medical Quality Assurance of the department Health Quality Assurance of the agency in writing and shall specify the disciplinary action taken and the specific grounds therefor. The division shall review each report and determine whether it potentially involved conduct by the licensee that is subject to disciplinary action, in which case s. 456.073 shall apply. The reports are not subject to inspection under s. 119.07(1) even if the division's investigation results in a finding of probable cause.

Section 13. Section 395.1023, Florida Statutes, is amended to read:

395.1023 Child abuse and neglect cases; duties.—Each licensed facility shall adopt a protocol that, at a minimum,

576-05334-10 20102434c2

requires the facility to:

(1) Incorporate a facility policy that every staff member has an affirmative duty to report, pursuant to chapter 39, any actual or suspected case of child abuse, abandonment, or neglect; and

(2) In any case involving suspected child abuse, abandonment, or neglect, designate, at the request of the Department of Children and Family Services, a staff physician to act as a liaison between the hospital and the Department of Children and Family Services office which is investigating the suspected abuse, abandonment, or neglect, and the child protection team, as defined in s. 39.01, when the case is referred to such a team.

Each general hospital and appropriate specialty hospital shall comply with the provisions of this section and shall notify the agency and the Department of Children and Family Services of its compliance by sending a copy of its policy to the agency and the Department of Children and Family Services as required by rule. The failure by a general hospital or appropriate specialty hospital to comply shall be punished by a fine not exceeding \$1,000, to be fixed, imposed, and collected by the agency. Each day in violation is considered a separate offense.

Section 14. Subsection (2) and paragraph (d) of subsection (3) of section 395.1041, Florida Statutes, are amended to read: 395.1041 Access to emergency services and care.—

(2) INVENTORY OF HOSPITAL EMERGENCY SERVICES.—The agency shall establish and maintain an inventory of hospitals with emergency services. The inventory shall list all services within

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576-05334-10 20102434c2

the service capability of the hospital, and such services shall appear on the face of the hospital license. Each hospital having emergency services shall notify the agency of its service capability in the manner and form prescribed by the agency. The agency shall use the inventory to assist emergency medical services providers and others in locating appropriate emergency medical care. The inventory shall also be made available to the general public. On or before August 1, 1992, the agency shall request that each hospital identify the services which are within its service capability. On or before November 1, 1992, the agency shall notify each hospital of the service capability to be included in the inventory. The hospital has 15 days from the date of receipt to respond to the notice. By December 1, 1992, the agency shall publish a final inventory. Each hospital shall reaffirm its service capability when its license is renewed and shall notify the agency of the addition of a new service or the termination of a service prior to a change in its service capability.

- (3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—
- (d)1. Every hospital shall ensure the provision of services within the service capability of the hospital, at all times, either directly or indirectly through an arrangement with another hospital, through an arrangement with one or more physicians, or as otherwise made through prior arrangements. A hospital may enter into an agreement with another hospital for purposes of meeting its service capability requirement, and appropriate compensation or other reasonable conditions may be negotiated for these backup services.

576-05334-10 20102434c2

2. If any arrangement requires the provision of emergency medical transportation, such arrangement must be made in consultation with the applicable provider and may not require the emergency medical service provider to provide transportation that is outside the routine service area of that provider or in a manner that impairs the ability of the emergency medical service provider to timely respond to prehospital emergency calls.

- 3. A hospital shall not be required to ensure service capability at all times as required in subparagraph 1. if, prior to the receiving of any patient needing such service capability, such hospital has demonstrated to the agency that it lacks the ability to ensure such capability and it has exhausted all reasonable efforts to ensure such capability through backup arrangements. In reviewing a hospital's demonstration of lack of ability to ensure service capability, the agency shall consider factors relevant to the particular case, including the following:
- a. Number and proximity of hospitals with the same service capability.
- b. Number, type, credentials, and privileges of specialists.
  - c. Frequency of procedures.
  - d. Size of hospital.
- 4. The agency shall publish proposed rules implementing a reasonable exemption procedure by November 1, 1992. Subparagraph 1. shall become effective upon the effective date of said rules or January 31, 1993, whichever is earlier. For a period not to exceed 1 year from the effective date of subparagraph 1., a

576-05334-10 20102434c2

hospital requesting an exemption shall be deemed to be exempt from offering the service until the agency initially acts to deny or grant the original request. The agency has 45 days from the date of receipt of the request to approve or deny the request. After the first year from the effective date of subparagraph 1., If the agency fails to initially act within the time period, the hospital is deemed to be exempt from offering the service until the agency initially acts to deny the request.

Section 15. <u>Section 395.1046</u>, <u>Florida Statutes</u>, is repealed.

Section 16. Paragraph (e) of subsection (1) of section 395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.

- (1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:
- (e) Licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by the <a href="agency">agency</a>, the Florida Building Code, and the Florida Fire Prevention Code department.

Section 17. Subsection (1) of section 395.10972, Florida Statutes, is amended to read:

395.10972 Health Care Risk Manager Advisory Council.—The Secretary of Health Care Administration may appoint a seven-member advisory council to advise the agency on matters pertaining to health care risk managers. The members of the council shall serve at the pleasure of the secretary. The council shall designate a chair. The council shall meet at the call of the secretary or at those times as may be required by

576-05334-10 20102434c2

rule of the agency. The members of the advisory council shall receive no compensation for their services, but shall be reimbursed for travel expenses as provided in s. 112.061. The council shall consist of individuals representing the following areas:

(1) Two shall be active health care risk managers, including one risk manager who is recommended by and a member of the Florida Society  $\underline{\text{for}}$  of Healthcare Risk Management  $\underline{\text{and}}$  Patient Safety.

Section 18. Subsection (3) of section 395.2050, Florida Statutes, is amended to read:

395.2050 Routine inquiry for organ and tissue donation; certification for procurement activities; death records review.—

(3) Each organ procurement organization designated by the federal Centers for Medicare and Medicaid Services Health Care Financing Administration and licensed by the state shall conduct an annual death records review in the organ procurement organization's affiliated donor hospitals. The organ procurement organization shall enlist the services of every Florida licensed tissue bank and eye bank affiliated with or providing service to the donor hospital and operating in the same service area to participate in the death records review.

Section 19. Subsection (2) of section 395.3036, Florida Statutes, is amended to read:

395.3036 Confidentiality of records and meetings of corporations that lease public hospitals or other public health care facilities.—The records of a private corporation that leases a public hospital or other public health care facility are confidential and exempt from the provisions of s. 119.07(1)

576-05334-10 20102434c2

and s. 24(a), Art. I of the State Constitution, and the meetings of the governing board of a private corporation are exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution when the public lessor complies with the public finance accountability provisions of s. 155.40(5) with respect to the transfer of any public funds to the private lessee and when the private lessee meets at least three of the five following criteria:

(2) The public lessor and the private lessee do not commingle any of their funds in any account maintained by either of them, other than the payment of the rent and administrative fees or the transfer of funds pursuant to  $\underline{s. 155.40(2)}$  subsection (2).

Section 20. <u>Section 395.3037</u>, Florida Statutes, is repealed.

Section 21. Subsections (1), (4), and (5) of section 395.3038, Florida Statutes, are amended to read:

395.3038 State-listed primary stroke centers and comprehensive stroke centers; notification of hospitals.—

(1) The agency shall make available on its website and to the department a list of the name and address of each hospital that meets the criteria for a primary stroke center and the name and address of each hospital that meets the criteria for a comprehensive stroke center. The list of primary and comprehensive stroke centers shall include only those hospitals that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as a primary or a comprehensive stroke center by

576-05334-10 20102434c2

The Joint Commission on Accreditation of Healthcare Organizations.

- (4) The agency shall adopt by rule criteria for a primary stroke center which are substantially similar to the certification standards for primary stroke centers of The Joint Commission on Accreditation of Healthcare Organizations.
- (5) The agency shall adopt by rule criteria for a comprehensive stroke center. However, if The Joint Commission on Accreditation of Healthcare Organizations establishes criteria for a comprehensive stroke center, the agency shall establish criteria for a comprehensive stroke center which are substantially similar to those criteria established by The Joint Commission on Accreditation of Healthcare Organizations.

Section 22. Paragraph (e) of subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.-

- (2) DEFINITIONS.—As used in this part:
- (e) "Rural hospital" means an acute care hospital licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:
- 1. The sole provider within a county with a population density of no greater than 100 persons per square mile;
- 2. An acute care hospital, in a county with a population density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;
- 3. A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer

576-05334-10 20102434c2

871 per square mile;

4. A hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax pursuant to law and in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency pursuant to chapter 125, and has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits and a Medicaid inpatient utilization rate greater than 15 percent;

4.5. A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Policy Analysis at the Agency for Health Care Administration; or

5.6. A hospital designated as a critical access hospital, as defined in s. 408.07(15).

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2015, if the hospital continues to have 100 or fewer licensed beds and an emergency room, or meets the criteria of subparagraph 4. An acute care hospital that has not previously

576-05334-10 20102434c2

been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation to the Agency for Health Care Administration.

Section 23. Subsection (8) of section 400.021, Florida Statutes, is amended to read:

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

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

Section 24. Paragraph (g) of subsection (2) of section 400.0239, Florida Statutes, is amended to read:

400.0239 Quality of Long-Term Care Facility Improvement Trust Fund.—

- (2) Expenditures from the trust fund shall be allowable for direct support of the following:
- (g) Other initiatives authorized by the Centers for Medicare and Medicaid Services for the use of federal civil monetary penalties, including projects recommended through the Medicaid "Up-or-Out" Quality of Care Contract Management Program pursuant to s. 400.148.

Section 25. Subsection (15) of section 400.0255, Florida Statutes, is amended to read

400.0255 Resident transfer or discharge; requirements and procedures; hearings.—

576-05334-10 20102434c2

(15)(a) The department's Office of Appeals Hearings shall conduct hearings under this section. The office shall notify the facility of a resident's request for a hearing.

- (b) The department shall, by rule, establish procedures to be used for fair hearings requested by residents. These procedures shall be equivalent to the procedures used for fair hearings for other Medicaid cases appearing in s. 409.285 and applicable rules, chapter 10-2, part VI, Florida Administrative Code. The burden of proof must be clear and convincing evidence. A hearing decision must be rendered within 90 days after receipt of the request for hearing.
- (c) If the hearing decision is favorable to the resident who has been transferred or discharged, the resident must be readmitted to the facility's first available bed.
- (d) The decision of the hearing officer shall be final. Any aggrieved party may appeal the decision to the district court of appeal in the appellate district where the facility is located. Review procedures shall be conducted in accordance with the Florida Rules of Appellate Procedure.

Section 26. Subsection (2) of section 400.063, Florida Statutes, is amended to read:

400.063 Resident protection.-

(2) The agency is authorized to establish for each facility, subject to intervention by the agency, a separate bank account for the deposit to the credit of the agency of any moneys received from the Health Care Trust Fund or any other moneys received for the maintenance and care of residents in the facility, and the agency is authorized to disburse moneys from such account to pay obligations incurred for the purposes of

576-05334-10 20102434c2

this section. The agency is authorized to requisition moneys from the Health Care Trust Fund in advance of an actual need for cash on the basis of an estimate by the agency of moneys to be spent under the authority of this section. Any bank account established under this section need not be approved in advance of its creation as required by s. 17.58, but shall be secured by depository insurance equal to or greater than the balance of such account or by the pledge of collateral security in conformance with criteria established in s. 18.11. The agency shall notify the Chief Financial Officer of any such account so established and shall make a quarterly accounting to the Chief Financial Officer for all moneys deposited in such account.

Section 27. Subsections (1) and (5) of section 400.071, Florida Statutes, are amended to read:

400.071 Application for license.

- (1) In addition to the requirements of part II of chapter 408, the application for a license shall be under oath and must contain the following:
- (a) The location of the facility for which a license is sought and an indication, as in the original application, that such location conforms to the local zoning ordinances.
- (b) A signed affidavit disclosing any financial or ownership interest that a controlling interest as defined in part II of chapter 408 has held in the last 5 years in any entity licensed by this state or any other state to provide health or residential care which has closed voluntarily or involuntarily; has filed for bankruptcy; has had a receiver appointed; has had a license denied, suspended, or revoked; or has had an injunction issued against it which was initiated by a

576-05334-10 20102434c2

regulatory agency. The affidavit must disclose the reason any such entity was closed, whether voluntarily or involuntarily.

- (c) The total number of beds and the total number of Medicare and Medicaid certified beds.
- (b)(d) Information relating to the applicant and employees which the agency requires by rule. The applicant must demonstrate that sufficient numbers of qualified staff, by training or experience, will be employed to properly care for the type and number of residents who will reside in the facility.
- (c) (e) Copies of any civil verdict or judgment involving the applicant rendered within the 10 years preceding the application, relating to medical negligence, violation of residents' rights, or wrongful death. As a condition of licensure, the licensee agrees to provide to the agency copies of any new verdict or judgment involving the applicant, relating to such matters, within 30 days after filing with the clerk of the court. The information required in this paragraph shall be maintained in the facility's licensure file and in an agency database which is available as a public record.
- (5) As a condition of licensure, each facility must establish and submit with its application a plan for quality assurance and for conducting risk management.
- Section 28. Section 400.0712, Florida Statutes, is amended to read:
  - 400.0712 Application for inactive license.-
- (1) As specified in this section, the agency may issue an inactive license to a nursing home facility for all or a portion of its beds. Any request by a licensee that a nursing home or

576-05334-10 20102434c2

portion of a nursing home become inactive must be submitted to the agency in the approved format. The facility may not initiate any suspension of services, notify residents, or initiate inactivity before receiving approval from the agency; and a licensee that violates this provision may not be issued an inactive license.

- (1) (2) In addition to the powers granted under part II of chapter 408, the agency may issue an inactive license to a nursing home that chooses to use an unoccupied contiguous portion of the facility for an alternative use to meet the needs of elderly persons through the use of less restrictive, less institutional services.
- (a) An inactive license issued under this subsection may be granted for a period not to exceed the current licensure expiration date but may be renewed by the agency at the time of licensure renewal.
- (b) A request to extend the inactive license must be submitted to the agency in the approved format and approved by the agency in writing.
- (c) Nursing homes that receive an inactive license to provide alternative services shall not receive preference for participation in the Assisted Living for the Elderly Medicaid waiver.
- $\underline{(2)}$  (3) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.
- Section 29. Section 400.111, Florida Statutes, is amended to read:
- 400.111 Disclosure of controlling interest.—In addition to the requirements of part II of chapter 408, when requested by

576-05334-10 20102434c2

the agency, the licensee shall submit a signed affidavit disclosing any financial or ownership interest that a controlling interest has held within the last 5 years in any entity licensed by the state or any other state to provide health or residential care which entity has closed voluntarily or involuntarily; has filed for bankruptcy; has had a receiver appointed; has had a license denied, suspended, or revoked; or has had an injunction issued against it which was initiated by a regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntarily or involuntarily.

Section 30. Subsection (2) of section 400.1183, Florida Statutes, is amended to read:

400.1183 Resident grievance procedures.-

(2) Each facility shall maintain records of all grievances for agency inspection and shall report to the agency at the time of relicensure the total number of grievances handled during the prior licensure period, a categorization of the cases underlying the grievances, and the final disposition of the grievances.

Section 31. Paragraphs (o) through (w) of subsection (1) of section 400.141, Florida Statutes, are redesignated as paragraphs (n) through (u), respectively, and present paragraphs (f), (g), (j), (n), (o), and (r) of that subsection are amended, to read:

400.141 Administration and management of nursing home facilities.—

- (1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:
- (f) Be allowed and encouraged by the agency to provide other needed services under certain conditions. If the facility

576-05334-10 20102434c2

has a standard licensure status, and has had no class I or class II deficiencies during the past 2 years or has been awarded a Gold Seal under the program established in s. 400.235, it may be encouraged by the agency to provide services, including, but not limited to, respite and adult day services, which enable individuals to move in and out of the facility. A facility is not subject to any additional licensure requirements for providing these services.

- 1. Respite care may be offered to persons in need of short-term or temporary nursing home services. For each person admitted under the respite care program, the facility licensee must:
- a. Have a written abbreviated plan of care that, at a minimum, includes nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. The nursing or physician assessments may take the place of all other assessments required for full-time residents.
- b. Have a contract that, at a minimum, specifies the services to be provided to the respite resident, including charges for services, activities, equipment, emergency medical services, and the administration of medications. If multiple respite admissions for a single person are anticipated, the original contract is valid for 1 year after the date of execution.
- c. Ensure that each resident is released to his or her caregiver or an individual designated in writing by the caregiver.
  - 2. A person admitted under the respite care program is:
  - a. Exempt from requirements in rule related to discharge

576-05334-10 20102434c2

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b. Covered by the resident's rights set forth in s.

400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident

shall not be considered trust funds subject to the requirements

of s. 400.022(1)(h) until the resident has been in the facility

for more than 14 consecutive days.

- c. Allowed to use his or her personal medications for the respite stay if permitted by facility policy. The facility must obtain a physician's orders for the medications. The caregiver may provide information regarding the medications as part of the nursing assessment, which must agree with the physician's orders. Medications shall be released with the resident upon discharge in accordance with current orders.
- 3. A person receiving respite care is entitled to a total of 60 days in the facility within a contract year or a calendar year if the contract is for less than 12 months. However, each single stay may not exceed 14 days. If a stay exceeds 14 consecutive days, the facility must comply with all assessment and care planning requirements applicable to nursing home residents.
- 4. A person receiving respite care must reside in a licensed nursing home bed.
- 5. A prospective respite resident must provide medical information from a physician, a physician assistant, or a nurse practitioner and other information from the primary caregiver as may be required by the facility prior to or at the time of admission to receive respite care. The medical information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician

576-05334-10 20102434c2

assistant, or nurse practitioner. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

6. The facility must assume the duties of the primary caregiver. To ensure continuity of care and services, the resident is entitled to retain his or her personal physician and must have access to medically necessary services such as physical therapy, occupational therapy, or speech therapy, as needed. The facility must arrange for transportation to these services if necessary. Respite care must be provided in accordance with this part and rules adopted by the agency. However, the agency shall, by rule, adopt modified requirements for resident assessment, resident care plans, resident contracts, physician orders, and other provisions, as appropriate, for short-term or temporary nursing home services.

7. The agency shall allow for shared programming and staff in a facility which meets minimum standards and offers services pursuant to this paragraph, but, if the facility is cited for deficiencies in patient care, may require additional staff and programs appropriate to the needs of service recipients. A person who receives respite care may not be counted as a resident of the facility for purposes of the facility's licensed capacity unless that person receives 24-hour respite care. A person receiving either respite care for 24 hours or longer or adult day services must be included when calculating minimum staffing for the facility. Any costs and revenues generated by a nursing home facility from nonresidential programs or services shall be excluded from the calculations of Medicaid per diems for nursing home institutional care reimbursement.

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576-05334-10 20102434c2

(g) If the facility has a standard license or is a Gold Seal facility, exceeds the minimum required hours of licensed nursing and certified nursing assistant direct care per resident per day, and is part of a continuing care facility licensed under chapter 651 or a retirement community that offers other services pursuant to part III of this chapter or part I or part III of chapter 429 on a single campus, be allowed to share programming and staff. At the time of inspection and in the semiannual report required pursuant to paragraph (n) <del>(o)</del>, a continuing care facility or retirement community that uses this option must demonstrate through staffing records that minimum staffing requirements for the facility were met. Licensed nurses and certified nursing assistants who work in the nursing home facility may be used to provide services elsewhere on campus if the facility exceeds the minimum number of direct care hours required per resident per day and the total number of residents receiving direct care services from a licensed nurse or a certified nursing assistant does not cause the facility to violate the staffing ratios required under s. 400.23(3)(a). Compliance with the minimum staffing ratios shall be based on total number of residents receiving direct care services, regardless of where they reside on campus. If the facility receives a conditional license, it may not share staff until the conditional license status ends. This paragraph does not restrict the agency's authority under federal or state law to require additional staff if a facility is cited for deficiencies in care which are caused by an insufficient number of certified nursing assistants or licensed nurses. The agency may adopt rules for the documentation necessary to determine compliance

576-05334-10 20102434c2

1190 with this provision.

- (j) Keep full records of resident admissions and discharges; medical and general health status, including medical records, personal and social history, and identity and address of next of kin or other persons who may have responsibility for the affairs of the residents; and individual resident care plans including, but not limited to, prescribed services, service frequency and duration, and service goals. The records shall be open to inspection by the agency. The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.
- (n) Submit to the agency the information specified in s. 400.071(1)(b) for a management company within 30 days after the effective date of the management agreement.
- (n) (o) 1. Submit semiannually to the agency, or more frequently if requested by the agency, information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. For purposes of this reporting:
- a. Staff-to-resident ratios must be reported in the categories specified in s. 400.23(3)(a) and applicable rules. The ratio must be reported as an average for the most recent calendar quarter.
- b. Staff turnover must be reported for the most recent 12-month period ending on the last workday of the most recent calendar quarter prior to the date the information is submitted.

576-05334-10 20102434c2

The turnover rate must be computed quarterly, with the annual rate being the cumulative sum of the quarterly rates. The turnover rate is the total number of terminations or separations experienced during the quarter, excluding any employee terminated during a probationary period of 3 months or less, divided by the total number of staff employed at the end of the period for which the rate is computed, and expressed as a percentage.

- c. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.
- d. A nursing facility that has failed to comply with state minimum-staffing requirements for 2 consecutive days is prohibited from accepting new admissions until the facility has achieved the minimum-staffing requirements for a period of 6 consecutive days. For the purposes of this sub-subparagraph, any person who was a resident of the facility and was absent from the facility for the purpose of receiving medical care at a separate location or was on a leave of absence is not considered a new admission. Failure to impose such an admissions moratorium is subject to a \$1,000 fine constitutes a class II deficiency.
- e. A nursing facility which does not have a conditional license may be cited for failure to comply with the standards in s. 400.23(3)(a)1.a. only if it has failed to meet those standards on 2 consecutive days or if it has failed to meet at least 97 percent of those standards on any one day.
  - f. A facility which has a conditional license must be in

576-05334-10 20102434c2

compliance with the standards in s. 400.23(3)(a) at all times.

- 2. This paragraph does not limit the agency's ability to impose a deficiency or take other actions if a facility does not have enough staff to meet the residents' needs.
- (r) Report to the agency any filing for bankruptcy protection by the facility or its parent corporation, divestiture or spin-off of its assets, or corporate reorganization within 30 days after the completion of such activity.

Section 32. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate.—

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

Section 33. Subsections (11) through (15) of section 400.147, Florida Statutes, are renumbered as subsections (10) through (14), respectively, and present subsection (10) is amended to read:

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576-05334-10 20102434c2

400.147 Internal risk management and quality assurance program.—

(10) By the 10th of each month, each facility subject to this section shall report any notice received pursuant to s. 400.0233(2) and each initial complaint that was filed with the clerk of the court and served on the facility during the previous month by a resident or a resident's family member, quardian, conservator, or personal legal representative. The report must include the name of the resident, the resident's date of birth and social security number, the Medicaid identification number for Medicaid-eligible persons, the date or dates of the incident leading to the claim or dates of residency, if applicable, and the type of injury or violation of rights alleged to have occurred. Each facility shall also submit a copy of the notices received pursuant to s. 400.0233(2) and complaints filed with the clerk of the court. This report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in such actions brought by the agency to enforce the provisions of this <del>part.</del>

Section 34. Section 400.148, Florida Statutes, is repealed.

Section 35. Paragraph (f) of subsection (5) of section

400.162, Florida Statutes, is amended to read:

400.162 Property and personal affairs of residents.—
(5)

(f) At least every 3 months, the licensee shall furnish the resident and the guardian, trustee, or conservator, if any, for the resident a complete and verified statement of all funds and

other property to which this subsection applies, detailing the

576-05334-10 20102434c2

amounts and items received, together with their sources and disposition. For resident property, the licensee shall furnish such a statement annually and within 7 calendar days after a request for a statement. In any event, the licensee shall furnish such statements a statement annually and upon the discharge or transfer of a resident. Any governmental agency or private charitable agency contributing funds or other property on account of a resident also shall be entitled to receive such statements statement annually and upon discharge or transfer and such other report as it may require pursuant to law.

Section 36. Paragraphs (d) and (e) of subsection (2) of section 400.179, Florida Statutes, are amended to read:

400.179 Liability for Medicaid underpayments and overpayments.—

- (2) Because any transfer of a nursing facility may expose the fact that Medicaid may have underpaid or overpaid the transferor, and because in most instances, any such underpayment or overpayment can only be determined following a formal field audit, the liabilities for any such underpayments or overpayments shall be as follows:
- (d) Where the transfer involves a facility that has been leased by the transferor:
- 1. The transferee shall, as a condition to being issued a license by the agency, acquire, maintain, and provide proof to the agency of a bond with a term of 30 months, renewable annually, in an amount not less than the total of 3 months' Medicaid payments to the facility computed on the basis of the preceding 12-month average Medicaid payments to the facility.
  - 2. A leasehold licensee may meet the requirements of

576-05334-10 20102434c2

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

576-05334-10 20102434c2

subparagraph, minus any amounts used to repay nursing home
Medicaid overpayments and amounts transferred to contribute to
the General Revenue Fund pursuant to s. 215.20. If the net
cumulative collections, minus amounts utilized to repay nursing
home Medicaid overpayments, exceed \$25 million, the provisions
of this paragraph shall not apply for the subsequent fiscal
year.

- 3. The leasehold licensee may meet the bond requirement through other arrangements acceptable to the agency. The agency is herein granted specific authority to promulgate rules pertaining to lease bond arrangements.
- 4. All existing nursing facility licensees, operating the facility as a leasehold, shall acquire, maintain, and provide proof to the agency of the 30-month bond required in subparagraph 1., above, on and after July 1, 1993, for each license renewal.
- 5. It shall be the responsibility of all nursing facility operators, operating the facility as a leasehold, to renew the 30-month bond and to provide proof of such renewal to the agency annually.
- 6. Any failure of the nursing facility operator to acquire, maintain, renew annually, or provide proof to the agency shall be grounds for the agency to deny, revoke, and suspend the facility license to operate such facility and to take any further action, including, but not limited to, enjoining the facility, asserting a moratorium pursuant to part II of chapter 408, or applying for a receiver, deemed necessary to ensure compliance with this section and to safeguard and protect the health, safety, and welfare of the facility's residents. A lease

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576-05334-10 20102434c2

agreement required as a condition of bond financing or refinancing under s. 154.213 by a health facilities authority or required under s. 159.30 by a county or municipality is not a leasehold for purposes of this paragraph and is not subject to the bond requirement of this paragraph.

(e) For the 2009-2010 fiscal year only, the provisions of paragraph (d) shall not apply. This paragraph expires July 1, 2010.

Section 37. Subsection (3) of section 400.19, Florida Statutes, is amended to read:

400.19 Right of entry and inspection.

(3) The agency shall every 15 months conduct at least one unannounced inspection to determine compliance by the licensee with statutes, and with rules promulgated under the provisions of those statutes, governing minimum standards of construction, quality and adequacy of care, and rights of residents. The survey shall be conducted every 6 months for the next 2-year period if the facility has been cited for a class I deficiency, has been cited for two or more class II deficiencies arising from separate surveys or investigations within a 60-day period, or has had three or more substantiated complaints within a 6month period, each resulting in at least one class I or class II deficiency. In addition to any other fees or fines in this part, the agency shall assess a fine for each facility that is subject to the 6-month survey cycle. The fine for the 2-year period shall be \$6,000, one-half to be paid at the completion of each survey. The agency may adjust this fine by the change in the Consumer Price Index, based on the 12 months immediately preceding the increase, to cover the cost of the additional

576-05334-10 20102434c2

surveys. The agency shall verify through subsequent inspection that any deficiency identified during inspection is corrected. However, the agency may verify the correction of a class III or class IV deficiency unrelated to resident rights or resident care without reinspecting the facility if adequate written documentation has been received from the facility, which provides assurance that the deficiency has been corrected. The giving or causing to be given of advance notice of such unannounced inspections by an employee of the agency to any unauthorized person shall constitute cause for suspension of not fewer than 5 working days according to the provisions of chapter 110.

Section 38. Section 400.195, Florida Statutes, is repealed.

Section 39. Subsection (5) of section 400.23, Florida

Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

- (5) (a) The agency, in collaboration with the Division of Children's Medical Services Network of the Department of Health, must, no later than December 31, 1993, adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. The rules must include a methodology for reviewing a nursing home facility under ss. 408.031-408.045 which serves only persons under 21 years of age. A facility may be exempt from these standards for specific persons between 18 and 21 years of age, if the person's physician agrees that minimum standards of care based on age are not necessary.
- (b) The agency, in collaboration with the Division of Children's Medical Services Network, shall adopt rules for

576-05334-10 20102434c2

minimum staffing requirements for nursing home facilities that serve persons under 21 years of age, which shall apply in lieu of the standards contained in subsection (3).

- 1. For persons under 21 years of age who require skilled care, the requirements shall include a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants of 3.9 hours of direct care per resident per day for each nursing home facility.
- 2. For persons under 21 years of age who are fragile, the requirements shall include a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants of 5 hours of direct care per resident per day for each nursing home facility.

Section 40. Subsection (1) of section 400.275, Florida Statutes, is amended to read:

400.275 Agency duties.-

(1) The agency shall ensure that each newly hired nursing home surveyor, as a part of basic training, is assigned full—time to a licensed nursing home for at least 2 days within a 7-day period to observe facility operations outside of the survey process before the surveyor begins survey responsibilities. Such observations may not be the sole basis of a deficiency citation against the facility. The agency may not assign an individual to be a member of a survey team for purposes of a survey, evaluation, or consultation visit at a nursing home facility in which the surveyor was an employee within the preceding  $\frac{2}{5}$  years.

Section 41. Subsection (2) of section 400.484, Florida Statutes, is amended to read:

576-05334-10 20102434c2

400.484 Right of inspection;  $\underline{\text{violations}}$  deficiencies; fines.—

- (2) The agency shall impose fines for various classes of <u>violations</u> deficiencies in accordance with the following schedule:
- (a) Class I violations are defined in s. 408.813. A class I deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury. Upon finding a class I violation deficiency, the agency shall impose an administrative fine in the amount of \$15,000 for each occurrence and each day that the violation deficiency exists.
- (b) Class II violations are defined in s. 408.813. A class II deficiency is any act, omission, or practice that has a direct adverse effect on the health, safety, or security of a patient. Upon finding a class II violation deficiency, the agency shall impose an administrative fine in the amount of \$5,000 for each occurrence and each day that the violation deficiency exists.
- (c) Class III violations are defined in s. 408.813. A class III deficiency is any act, omission, or practice that has an indirect, adverse effect on the health, safety, or security of a patient. Upon finding an uncorrected or repeated class III violation deficiency, the agency shall impose an administrative fine not to exceed \$1,000 for each occurrence and each day that the uncorrected or repeated violation deficiency exists.
- (d) Class IV violations are defined in s. 408.813. A class IV deficiency is any act, omission, or practice related to

576-05334-10 20102434c2

required reports, forms, or documents which does not have the potential of negatively affecting patients. These violations are of a type that the agency determines do not threaten the health, safety, or security of patients. Upon finding an uncorrected or repeated class IV violation deficiency, the agency shall impose an administrative fine not to exceed \$500 for each occurrence and each day that the uncorrected or repeated violation deficiency exists.

- Section 42. Paragraph (i) of subsection (1) and subsection (4) of section 400.606, Florida Statutes, are amended to read:
  400.606 License; application; renewal; conditional license or permit; certificate of need.—
- (1) In addition to the requirements of part II of chapter 408, the initial application and change of ownership application must be accompanied by a plan for the delivery of home, residential, and homelike inpatient hospice services to terminally ill persons and their families. Such plan must contain, but need not be limited to:
  - (i) The projected annual operating cost of the hospice.

If the applicant is an existing licensed health care provider, the application must be accompanied by a copy of the most recent profit-loss statement and, if applicable, the most recent licensure inspection report.

(4) A freestanding hospice facility that is primarily engaged in providing inpatient and related services and that is not otherwise licensed as a health care facility shall be required to obtain a certificate of need. However, a freestanding hospice facility with six or fewer beds shall not

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576-05334-10 20102434c2

be required to comply with institutional standards such as, but not limited to, standards requiring sprinkler systems, emergency electrical systems, or special lavatory devices.

Section 43. Subsection (2) of section 400.607, Florida Statutes, is amended to read:

400.607 Denial, suspension, revocation of license; emergency actions; imposition of administrative fine; grounds.—

- (2) A violation of this part, part II of chapter 408, or applicable rules Any of the following actions by a licensed hospice or any of its employees shall be grounds for administrative action by the agency against a hospice.÷
- (a) A violation of the provisions of this part, part II of chapter 408, or applicable rules.
- $\hspace{1cm}$  (b) An intentional or negligent act materially affecting the health or safety of a patient.

Section 44. Section 400.915, Florida Statutes, is amended to read:

- 400.915 Construction and renovation; requirements.—The requirements for the construction or renovation of a PPEC center shall comply with:
- (1) The provisions of chapter 553, which pertain to building construction standards, including plumbing, electrical code, glass, manufactured buildings, accessibility for the physically disabled;
- (2) The provisions of s. 633.022 and applicable rules pertaining to physical minimum standards for nonresidential child care physical facilities in rule 10M-12.003, Florida Administrative Code, Child Care Standards; and
  - (3) The standards or rules adopted pursuant to this part

576-05334-10 20102434c2

1567 and part II of chapter 408.

Section 45. Subsection (1) of section 400.925, Florida Statutes, is amended to read:

400.925 Definitions.—As used in this part, the term:

(1) "Accrediting organizations" means The Joint Commission on Accreditation of Healthcare Organizations or other national accreditation agencies whose standards for accreditation are comparable to those required by this part for licensure.

Section 46. Subsections (3) through (6) of section 400.931, Florida Statutes, are renumbered as subsections (2) through (5), respectively, and present subsection (2) of that section is amended to read:

400.931 Application for license; fee; provisional license; temporary permit.—

(2) As an alternative to submitting proof of financial ability to operate as required in s. 408.810(8), the applicant may submit a \$50,000 surety bond to the agency.

Section 47. Subsection (2) of section 400.932, Florida Statutes, is amended to read:

400.932 Administrative penalties.-

- (2) A violation of this part, part II of chapter 408, or applicable rules Any of the following actions by an employee of a home medical equipment provider shall be are grounds for administrative action or penalties by the agency.÷
- (a) Violation of this part, part II of chapter 408, or applicable rules.
- (b) An intentional, reckless, or negligent act that materially affects the health or safety of a patient.
  - Section 48. Subsection (3) of section 400.967, Florida

Page 55 of 132

576-05334-10 20102434c2

1596 Statutes, is amended to read:

400.967 Rules and classification of <u>violations</u> deficiencies.—

- (3) The agency shall adopt rules to provide that, when the criteria established under this part and part II of chapter 408 are not met, such <u>violations</u> deficiencies shall be classified according to the nature of the <u>violation</u> deficiency. The agency shall indicate the classification on the face of the notice of deficiencies as follows:
- (a) Class I <u>violations</u> deficiencies are <u>defined in s.</u>

  408.813 those which the agency determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical harm would result therefrom. The condition or practice constituting a class I violation must be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class I <u>violation</u> deficiency is subject to a civil penalty in an amount not less than \$5,000 and not exceeding \$10,000 for each <u>violation</u> deficiency. A fine may be levied notwithstanding the correction of the <u>violation</u> deficiency.
- (b) Class II <u>violations</u> deficiencies are <u>defined in s.</u>

  408.813 those which the agency determines have a direct or immediate relationship to the health, safety, or security of the facility residents, other than class I deficiencies. A class II <u>violation</u> deficiency is subject to a civil penalty in an amount not less than \$1,000 and not exceeding \$5,000 for each <u>violation</u> deficiency. A citation for a class II <u>violation</u> deficiency shall specify the time within which the violation deficiency must be

576-05334-10 20102434c2

corrected. If a class II <u>violation</u> deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

- (c) Class III violations deficiencies are defined in s.

  408.813 those which the agency determines to have an indirect or potential relationship to the health, safety, or security of the facility residents, other than class I or class II deficiencies. A class III violation deficiency is subject to a civil penalty of not less than \$500 and not exceeding \$1,000 for each deficiency. A citation for a class III violation deficiency shall specify the time within which the violation deficiency must be corrected. If a class III violation deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.
- (d) Class IV violations are defined in s. 408.813. Upon finding an uncorrected or repeated class IV violation, the agency shall impose an administrative fine not to exceed \$500 for each occurrence and each day that the uncorrected or repeated violation exists.

Section 49. Subsections (4) and (7) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.-

- (4) "Clinic" means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable <a href="health service or">health service or</a> equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:
  - (a) Entities licensed or registered by the state under

576-05334-10 20102434c2

chapter 395; or entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

- (b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; or entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.
- (c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; or entities that are owned, directly or indirectly, by an

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576-05334-10 20102434c2

entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

- (d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; or entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses granted under ss. 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; or providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.
  - (e) An entity that is exempt from federal taxation under 26

576-05334-10 20102434c2

U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan under 26 U.S.C. s. 409 that has a board of trustees not less than two-thirds of which are Florida-licensed health care practitioners and provides only physical therapy services under physician orders, any community college or university clinic, and any entity owned or operated by the federal or state government, including agencies, subdivisions, or municipalities thereof.

- (f) A sole proprietorship, group practice, partnership, or corporation that provides health care services by physicians covered by s. 627.419, that is directly supervised by one or more of such physicians, and that is wholly owned by one or more of those physicians or by a physician and the spouse, parent, child, or sibling of that physician.
- (g) A sole proprietorship, group practice, partnership, or corporation that provides health care services by licensed health care practitioners under chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 466, chapter 467, chapter 480, chapter 484, chapter 486, chapter 490, chapter 491, or part I, part III, part X, part XIII, or part XIV of chapter 468, or s. 464.012, which are wholly owned by one or more licensed health care practitioners, or the licensed health care practitioners set forth in this paragraph and the spouse, parent, child, or sibling of a licensed health care practitioner, so long as one of the owners who is a licensed health care practitioner is supervising the business activities and is legally responsible for the entity's compliance with all federal and state laws. However, a health care practitioner may not supervise services beyond the scope of

576-05334-10 20102434c2

the practitioner's license, except that, for the purposes of this part, a clinic owned by a licensee in s. 456.053(3)(b) that provides only services authorized pursuant to s. 456.053(3)(b) may be supervised by a licensee specified in s. 456.053(3)(b).

- (h) Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows.
- (i) Entities that provide only oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 or entities that provide oncology or radiation therapy services by physicians licensed under chapter 458 or chapter 459 which are owned by a corporation whose shares are publicly traded on a recognized stock exchange.
- (j) Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.
- (k) Entities that provide licensed practitioners to staff emergency departments or to deliver anesthesia services in facilities licensed under chapter 395 and that derive at least 90 percent of their gross annual revenues from the provision of such services. Entities claiming an exemption from licensure under this paragraph must provide documentation demonstrating compliance.
- (1) Orthotic, or prosthetic, pediatric cardiology, or perinatology clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United

576-05334-10 20102434c2

1770 States Securities and Exchange Commission as a national securities exchange.

- (m) Entities that are owned by a corporation that has \$250 million or more in total annual sales of health care services provided by licensed health care practitioners if one or more of the owners of the entity is a health care practitioner who is licensed in this state, is responsible for supervising the business activities of the entity, and is legally responsible for the entity's compliance with state law for purposes of this section.
- (n) Entities that are owned or controlled, directly or indirectly, by a publicly traded entity with \$100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care practitioners that are employed or contracted by an entity described in this paragraph.
- (7) "Portable <u>health service or</u> equipment provider" means an entity that contracts with or employs persons to provide portable <u>health care services or</u> equipment to multiple locations <del>performing treatment or diagnostic testing of individuals</del>, that bills third-party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).
- Section 50. Paragraph (b) of subsection (1) and paragraph (c) of subsection (4) of section 400.991, Florida Statutes, are amended to read:
- 400.991 License requirements; background screenings; prohibitions.—
  - (1)
  - (b) Each mobile clinic must obtain a separate health care

576-05334-10 20102434c2

clinic license and must provide to the agency, at least quarterly, its projected street location to enable the agency to locate and inspect such clinic. A portable <u>health service or</u> equipment provider must obtain a health care clinic license for a single administrative office and is not required to submit quarterly projected street locations.

- (4) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the clinic is in compliance with this part and applicable rules, including:
- (c) Proof of financial ability to operate as required under <u>ss. s.</u> 408.810(8) <u>and 408.8065</u>. As an alternative to submitting proof of financial ability to operate as required under s. 408.810(8), the applicant may file a surety bond of at least \$500,000 which guarantees that the clinic will act in full conformity with all legal requirements for operating a clinic, payable to the agency. The agency may adopt rules to specify related requirements for such surety bond.

Section 51. Paragraph (g) of subsection (1) and paragraph (a) of subsection (7) of section 400.9935, Florida Statutes, are amended to read:

400.9935 Clinic responsibilities.-

- (1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:
- (g) Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful. Upon discovery of an unlawful charge, the medical director or clinic director

576-05334-10 20102434c2

shall take immediate corrective action. If the clinic performs only the technical component of magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography, and provides the professional interpretation of such services, in a fixed facility that is accredited by The Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care, and the American College of Radiology; and if, in the preceding quarter, the percentage of scans performed by that clinic which was billed to all personal injury protection insurance carriers was less than 15 percent, the chief financial officer of the clinic may, in a written acknowledgment provided to the agency, assume the responsibility for the conduct of the systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful.

(7) (a) Each clinic engaged in magnetic resonance imaging services must be accredited by The Joint Commission on Accreditation of Healthcare Organizations, the American College of Radiology, or the Accreditation Association for Ambulatory Health Care, within 1 year after licensure. A clinic that is accredited by the American College of Radiology or is within the original 1-year period after licensure and replaces its core magnetic resonance imaging equipment shall be given 1 year after the date on which the equipment is replaced to attain accreditation. However, a clinic may request a single, 6-month extension if it provides evidence to the agency establishing that, for good cause shown, such clinic cannot be accredited within 1 year after licensure, and that such accreditation will be completed within the 6-month extension. After obtaining

576-05334-10 20102434c2

accreditation as required by this subsection, each such clinic must maintain accreditation as a condition of renewal of its license. A clinic that files a change of ownership application must comply with the original accreditation timeframe requirements of the transferor. The agency shall deny a change of ownership application if the clinic is not in compliance with the accreditation requirements. When a clinic adds, replaces, or modifies magnetic resonance imaging equipment and the accreditation agency requires new accreditation, the clinic must be accredited within 1 year after the date of the addition, replacement, or modification but may request a single, 6-month extension if the clinic provides evidence of good cause to the agency.

Section 52. Subsection (2) of section 408.034, Florida Statutes, is amended to read:

408.034 Duties and responsibilities of agency; rules.-

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under chapters 393 and 395 and parts II, and IV, and VIII of chapter 400, the agency may not issue a license to any health care facility or health service provider that fails to receive a certificate of need or an exemption for the licensed facility or service.

Section 53. Paragraph (d) of subsection (1) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.-

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)—(g), are subject to review and must file an application for a

576-05334-10 20102434c2

certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(d) The establishment of a hospice or hospice inpatient facility, except as provided in s. 408.043.

Section 54. Subsection (2) of section 408.043, Florida Statutes, is amended to read:

408.043 Special provisions.

(2) HOSPICES.—When an application is made for a certificate of need to establish or to expand a hospice, the need for such hospice shall be determined on the basis of the need for and availability of hospice services in the community. The formula on which the certificate of need is based shall discourage regional monopolies and promote competition. The inpatient hospice care component of a hospice which is a freestanding facility, or a part of a facility, which is primarily engaged in providing inpatient care and related services and is not licensed as a health care facility shall also be required to obtain a certificate of need. Provision of hospice care by any current provider of health care is a significant change in service and therefore requires a certificate of need for such services.

Section 55. Paragraph (k) of subsection (3) of section 408.05, Florida Statutes, is amended to read:

408.05 Florida Center for Health Information and Policy Analysis.—

(3) COMPREHENSIVE HEALTH INFORMATION SYSTEM.—In order to produce comparable and uniform health information and statistics for the development of policy recommendations, the agency shall

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576-05334-10 20102434c2

perform the following functions:

- (k) Develop, in conjunction with the State Consumer Health Information and Policy Advisory Council, and implement a longrange plan for making available health care quality measures and financial data that will allow consumers to compare health care services. The health care quality measures and financial data the agency must make available shall include, but is not limited to, pharmaceuticals, physicians, health care facilities, and health plans and managed care entities. The agency shall submit the initial plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2006, and shall update the plan and report on the status of its implementation annually thereafter. The agency shall also make the plan and status report available to the public on its Internet website. As part of the plan, the agency shall identify the process and timeframes for implementation, any barriers to implementation, and recommendations of changes in the law that may be enacted by the Legislature to eliminate the barriers. As preliminary elements of the plan, the agency shall:
- 1. Make available patient-safety indicators, inpatient quality indicators, and performance outcome and patient charge data collected from health care facilities pursuant to s. 408.061(1)(a) and (2). The terms "patient-safety indicators" and "inpatient quality indicators" shall be as defined by the Centers for Medicare and Medicaid Services, the National Quality Forum, The Joint Commission on Accreditation of Healthcare Organizations, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or a similar national entity that establishes standards to measure the

576-05334-10 20102434c2

performance of health care providers, or by other states. The agency shall determine which conditions, procedures, health care quality measures, and patient charge data to disclose based upon input from the council. When determining which conditions and procedures are to be disclosed, the council and the agency shall consider variation in costs, variation in outcomes, and magnitude of variations and other relevant information. When determining which health care quality measures to disclose, the agency:

- a. Shall consider such factors as volume of cases; average patient charges; average length of stay; complication rates; mortality rates; and infection rates, among others, which shall be adjusted for case mix and severity, if applicable.
- b. May consider such additional measures that are adopted by the Centers for Medicare and Medicaid Studies, National Quality Forum, The Joint Commission on Accreditation of Healthcare Organizations, the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, or a similar national entity that establishes standards to measure the performance of health care providers, or by other states.

When determining which patient charge data to disclose, the agency shall include such measures as the average of undiscounted charges on frequently performed procedures and preventive diagnostic procedures, the range of procedure charges from highest to lowest, average net revenue per adjusted patient day, average cost per adjusted patient day, and average cost per admission, among others.

2. Make available performance measures, benefit design, and

576-05334-10 20102434c2

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

3. Determine the method and format for public disclosure of data reported pursuant to this paragraph. The agency shall make its determination based upon input from the State Consumer Health Information and Policy Advisory Council. At a minimum, the data shall be made available on the agency's Internet website in a manner that allows consumers to conduct an interactive search that allows them to view and compare the information for specific providers. The website must include such additional information as is determined necessary to ensure that the website enhances informed decisionmaking among consumers and health care purchasers, which shall include, at a minimum, appropriate guidance on how to use the data and an explanation of why the data may vary from provider to provider. The data specified in subparagraph 1. shall be released no later

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576-05334-10 20102434c2

than January 1, 2006, for the reporting of infection rates, and no later than October 1, 2005, for mortality rates and complication rates. The data specified in subparagraph 2. shall be released no later than October 1, 2006.

4. Publish on its website undiscounted charges for no fewer than 150 of the most commonly performed adult and pediatric procedures, including outpatient, inpatient, diagnostic, and preventative procedures.

Section 56. Paragraph (a) of subsection (1) of section 408.061, Florida Statutes, is amended to read:

- 408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—
- (1) The agency shall require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties. Specifications for data to be collected under this section shall be developed by the agency with the assistance of technical advisory panels including representatives of affected entities, consumers, purchasers, and such other interested parties as may be determined by the agency.
- (a) Data submitted by health care facilities, including the facilities as defined in chapter 395, shall include, but are not limited to: case-mix data, patient admission and discharge data, hospital emergency department data which shall include the number of patients treated in the emergency department of a licensed hospital reported by patient acuity level, data on hospital-acquired infections as specified by rule, data on complications as specified by rule, data on readmissions as

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576-05334-10 20102434c2

specified by rule, with patient and provider-specific identifiers included, actual charge data by diagnostic groups, financial data, accounting data, operating expenses, expenses incurred for rendering services to patients who cannot or do not pay, interest charges, depreciation expenses based on the expected useful life of the property and equipment involved, and demographic data. The agency shall adopt nationally recognized risk adjustment methodologies or software consistent with the standards of the Agency for Healthcare Research and Quality and as selected by the agency for all data submitted as required by this section. Data may be obtained from documents such as, but not limited to: leases, contracts, debt instruments, itemized patient bills, medical record abstracts, and related diagnostic information. Reported data elements shall be reported electronically and in accordance with rule 59E-7.012, Florida Administrative Code. Data submitted shall be certified by the chief executive officer or an appropriate and duly authorized representative or employee of the licensed facility that the information submitted is true and accurate.

Section 57. Subsection (43) of section 408.07, Florida Statutes, is amended to read:

- 408.07 Definitions.—As used in this chapter, with the exception of ss. 408.031-408.045, the term:
- (43) "Rural hospital" means an acute care hospital licensed under chapter 395, having 100 or fewer licensed beds and an emergency room, and which is:
- (a) The sole provider within a county with a population density of no greater than 100 persons per square mile;
  - (b) An acute care hospital, in a county with a population

576-05334-10 20102434c2

density of no greater than 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from another acute care hospital within the same county;

- (c) A hospital supported by a tax district or subdistrict whose boundaries encompass a population of 100 persons or fewer per square mile;
- (d) A hospital with a service area that has a population of 100 persons or fewer per square mile. As used in this paragraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Policy Analysis at the Agency for Health Care Administration; or
  - (e) A critical access hospital.

Population densities used in this subsection must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2015, if the hospital continues to have 100 or fewer licensed beds and an emergency room, or meets the criteria of s. 395.602(2)(e)4. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this subsection shall be granted such designation upon application, including supporting documentation, to the Agency for Health Care Administration.

576-05334-10 20102434c2

Section 58. Section 408.10, Florida Statutes, is amended to read:

408.10 Consumer complaints.—The agency shall÷

(1) publish and make available to the public a toll-free telephone number for the purpose of handling consumer complaints and shall serve as a liaison between consumer entities and other private entities and governmental entities for the disposition of problems identified by consumers of health care.

(2) Be empowered to investigate consumer complaints relating to problems with health care facilities' billing practices and issue reports to be made public in any cases where the agency determines the health care facility has engaged in billing practices which are unreasonable and unfair to the consumer.

Section 59. Subsections (12) through (30) of section 408.802, Florida Statutes, are renumbered as subsections (11) through (29), respectively, and present subsection (11) of that section is amended to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

(11) Private review agents, as provided under part I of chapter 395.

Section 60. Subsection (3) is added to section 408.804, Florida Statutes, to read:

408.804 License required; display.-

(3) Any person who knowingly alters, defaces, or falsifies

576-05334-10 20102434c2

a license certificate issued by the agency, or causes or procures any person to commit such an offense, commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s 775.083. Any licensee or provider who displays an altered, defaced, or falsified license certificate is subject to the penalties set forth in s. 408.815 and an administrative fine of \$1,000 for each day of illegal display.

Section 61. Paragraph (d) of subsection (2) of section 408.806, Florida Statutes, is amended, present subsections (3) through (8) are renumbered as subsections (4) through (9), respectively, and a new subsection (3) is added to that section, to read:

408.806 License application process.-

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electronically at least 90 days before the expiration of a license that a renewal license is necessary to continue operation. The licensee's failure to timely file submit a renewal application and license application fee with the agency shall result in a \$50 per day late fee charged to the licensee by the agency; however, the aggregate amount of the late fee may not exceed 50 percent of the licensure fee or \$500, whichever is less. The agency shall provide a courtesy notice to the licensee by United States mail, electronically, or by any other manner at its address of record or mailing address, if provided, at least 90 days prior to the expiration of a license informing the licensee of the expiration of the licensee does not receive the courtesy notice, the licensee continues to be legally

576-05334-10 20102434c2

application fee with the agency and is not excused from the payment of a late fee. If an application is received after the required filing date and exhibits a hand-canceled postmark obtained from a United States post office dated on or before the required filing date, no fine will be levied.

(3) Payment of the late fee is required to consider any late application complete, and failure to pay the late fee is considered an omission from the application.

Section 62. Subsections (6) and (9) of section 408.810, Florida Statutes, are amended to read:

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

- (6) (a) An applicant must provide the agency with proof of the applicant's legal right to occupy the property before a license may be issued. Proof may include, but need not be limited to, copies of warranty deeds, lease or rental agreements, contracts for deeds, quitclaim deeds, or other such documentation.
- (b) In the event the property is encumbered by a mortgage or is leased, an applicant must provide the agency with proof that the mortgagor or landlord has been provided written notice of the applicant's intent as mortgagee or tenant to provide services that require licensure and instruct the mortgagor or landlord to serve the agency by certified mail with copies of any foreclosure or eviction actions initiated by the mortgagor

576-05334-10 20102434c2

2176 or landlord against the applicant.

(9) A controlling interest may not withhold from the agency any evidence of financial instability, including, but not limited to, checks returned due to insufficient funds, delinquent accounts, nonpayment of withholding taxes, unpaid utility expenses, nonpayment for essential services, or adverse court action concerning the financial viability of the provider or any other provider licensed under this part that is under the control of the controlling interest. A controlling interest shall notify the agency within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings concerning the provider, in which the controlling interest is a petitioner or defendant. Any person who violates this subsection commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation is a separate offense.

Section 63. Subsection (3) is added to section 408.813, Florida Statutes, to read:

- 408.813 Administrative fines; violations.—As a penalty for any violation of this part, authorizing statutes, or applicable rules, the agency may impose an administrative fine.
- (3) The agency may impose an administrative fine for a violation that does not qualify as a class I, class II, class III, or class IV violation. Unless otherwise specified by law, the amount of the fine shall not exceed \$500 for each violation. Unclassified violations may include:
  - (a) Violating any term or condition of a license.
- (b) Violating any provision of this part, authorizing statutes, or applicable rules.

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576-05334-10 20102434c2

(c) Exceeding licensed capacity.

Florida Statutes, to read:

- (d) Providing services beyond the scope of the license.
- 2207 (e) Violating a moratorium imposed pursuant to s. 408.814.

  2208 Section 64. Subsection (5) is added to section 408.815,
  - 408.815 License or application denial; revocation.-
  - (5) In order to ensure the health, safety, and welfare of clients when a license has been denied, revoked, or is set to terminate, the agency may extend the license expiration date for a period of up to 30 days for the sole purpose of allowing the safe and orderly discharge of clients. The agency may impose conditions on the extension, including, but not limited to, prohibiting or limiting admissions, expedited discharge planning, required status reports, and mandatory monitoring by the agency or third parties. In imposing these conditions, the agency shall take into consideration the nature and number of clients, the availability and location of acceptable alternative placements, and the ability of the licensee to continue providing care to the clients. The agency may terminate the extension or modify the conditions at any time. This authority is in addition to any other authority granted to the agency under chapter 120, this part, and authorizing statutes but creates no right or entitlement to an extension of a license expiration date.

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

- 409.221 Consumer-directed care program.-
- (4) CONSUMER-DIRECTED CARE.
- (k) Reviews and reports. The agency and the Departments of

576-05334-10 20102434c2

Elderly Affairs, Health, and Children and Family Services and the Agency for Persons with Disabilities shall each, on an ongoing basis, review and assess the implementation of the consumer-directed care program. By January 15 of each year, the agency shall submit a written report to the Legislature that includes each department's review of the program and contains recommendations for improvements to the program.

Section 66. Subsection (1) of section 409.91196, Florida Statutes, is amended to read:

409.91196 Supplemental rebate agreements; public records and public meetings exemption.—

(1) The rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebate, and other trade secrets as defined in s. 688.002 that the agency has identified for use in negotiations, held by the Agency for Health Care Administration under s. 409.912(39) (a) 8.7 are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

Section 67. Paragraph (a) of subsection (39) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion

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576-05334-10 20102434c2

shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through

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576-05334-10 20102434c2

provider credentialing. The agency may competitively bid singlesource-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than longterm rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

- (39) (a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:
- 1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established

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576-05334-10 20102434c2

pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the preferred drug list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency is authorized to seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to implement this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

- a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and
- b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.
- 2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lesser of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC)

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576-05334-10 20102434c2

plus 4.75 percent, the federal upper limit (FUL), the state
maximum allowable cost (SMAC), or the usual and customary (UAC)
charge billed by the provider.

- 3. For a prescribed drug billed as a 340B prescribed medication, the claim must meet the requirements of the Deficit Reduction Act of 2005 and the federal 340B program, contain a national drug code, and be billed at the actual acquisition cost or payment shall be denied.
- 4.3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.
- $\underline{5.4.}$  The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and

576-05334-10 20102434c2

location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

 $\underline{6.5.}$  The agency shall develop and implement a program that requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by Medicaid-participating prescribers or prescribers who write prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

7.6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a

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576-05334-10 20102434c2

supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

8.7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not quaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Effective July 1, 2004, value-added programs as a substitution for supplemental rebates are prohibited. The agency is authorized to seek any federal waivers to implement this

576-05334-10 20102434c2

2437 initiative.

9.8. The Agency for Health Care Administration shall expand home delivery of pharmacy products. To assist Medicaid patients in securing their prescriptions and reduce program costs, the agency shall expand its current mail-order-pharmacy diabetes-supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered by the current contract. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

- 10.9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.
- 11.10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency is authorized to seek federal waivers to implement this program.
- b. The agency, in conjunction with the Department of Children and Family Services, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:
- (I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as

576-05334-10 20102434c2

antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

- (II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.
- (III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.
- (IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.
- (V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.
- (VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.
  - (VII) Disseminate electronic and published materials.
  - (VIII) Hold statewide and regional conferences.
- (IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

576-05334-10 20102434c2

12.11.a. The agency shall implement a Medicaid prescription drug management system. The agency may contract with a vendor that has experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

- b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:
- (I) Provide for the development and adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.
- (II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.
- (III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to

576-05334-10 20102434c2

the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

- (IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.
- (V) Track spending trends for prescription drugs and deviation from best practice guidelines.
- (VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.
  - (VII) Disseminate electronic and published materials.
  - (VIII) Hold statewide and regional conferences.
- (IX) Implement disease management programs in cooperation with physicians and pharmacists, along with a model quality-based medication component for individuals having chronic medical conditions.
- 13.12. The agency is authorized to contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.
- 14.13. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.
  - 15.14. The agency may require prior authorization for

576-05334-10 20102434c2

Medicaid-covered prescribed drugs. The agency may, but is not required to, prior-authorize the use of a product:

- a. For an indication not approved in labeling;
- b. To comply with certain clinical guidelines; or
- c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency may post prior authorization criteria and protocol and updates to the list of drugs that are subject to prior authorization on an Internet website without amending its rule or engaging in additional rulemaking.

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

17.16. The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months prior to the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the

576-05334-10 20102434c2

medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The steptherapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

- a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;
- b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or
- c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

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

18.17. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a \$5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a

576-05334-10 20102434c2

pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused. The agency's conclusion and recommendations shall be reported to the Legislature by December 1, 2005.

Section 68. Subsections (3) and (4) of section 429.07, Florida Statutes, are amended, and subsections (6) and (7) are added to that section, to read:

429.07 License required; fee; inspections.-

- (3) In addition to the requirements of s. 408.806, each license granted by the agency must state the type of care for 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 <u>a facility</u> facilities providing one or more of the personal services identified in s. 429.02. Such <u>licensee</u> facilities may also employ or contract with a person <del>licensed under part I of chapter 464</del> to <del>administer medications and</del> 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

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576-05334-10 20102434c2

acts performed pursuant to part I of chapter 464 by persons licensed thereunder, and supportive services defined by rule to persons who otherwise would be disqualified from continued residence in a facility licensed under this part.

- 1. In order for extended congregate care services to be provided in a facility licensed under this part, 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 a 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. Notification of approval or denial of such 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  $\frac{may}{may}$  not  $\frac{have}{may}$  been subject to administrative sanctions during the previous 2 years, or since initial licensure if the facility has been licensed for less than 2 years, for any of the following reasons:
  - a. A class I or class II violation;
- b. Three or more repeat or recurring class III violations of identical or similar resident care standards as specified in rule from which a pattern of noncompliance is found by the agency;
- c. Three or more class III violations that were not corrected in accordance with the corrective action plan approved by the agency;
  - d. Violation of resident care standards resulting in a

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576-05334-10 20102434c2

requirement to employ the services of a consultant pharmacist or consultant dietitian;

- e. Denial, suspension, or revocation of a license for another facility under this part in which the applicant for an extended congregate care license has at least 25 percent ownership interest; or
- f. Imposition of a moratorium pursuant to this part or part II of chapter 408 or initiation of injunctive proceedings.
- 2. A licensee Facilities that is are licensed to provide extended congregate care services shall maintain a written progress report for on each person who receives such services, and the which report must describe describes the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A registered nurse, or appropriate designee, representing the agency shall visit such facilities at least quarterly to monitor residents who are receiving extended congregate care services and to determine the facility is in compliance with this part, part II of chapter 408, and rules that relate to extended congregate care. One of these visits may be in conjunction with the regular survey. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall serve as part of the team that inspects such facility. The agency may waive one of the required yearly monitoring visits for a facility that has been licensed for at least 24 months to provide extended congregate care services, if, during the inspection, the registered nurse determines that extended congregate care services are being provided appropriately, and if the facility has no class I or class II

576-05334-10 20102434c2

violations and no uncorrected class III violations. Before such decision is made, the agency shall consult with the long-term care ombudsman council for the area in which the facility is located to determine if any complaints have been made and substantiated about the quality of services or care. The agency may not waive one of the required yearly monitoring visits if complaints have been made and substantiated.

- 3. <u>Licensees</u> Facilities that are licensed to provide extended congregate care services shall:
- a. Demonstrate the capability to meet unanticipated resident service needs.
- b. Offer a physical environment that promotes a homelike setting, provides for resident privacy, promotes resident independence, and allows sufficient congregate space as defined by rule.
- c. Have sufficient staff available, taking into account the physical plant and firesafety features of the building, to assist with the evacuation of residents in an emergency, as necessary.
- d. Adopt and follow policies and procedures that maximize resident independence, dignity, choice, and decisionmaking to permit residents to age in place to the extent possible, so that moves due to changes in functional status are minimized or avoided.
- e. Allow residents or, if applicable, a resident's representative, designee, surrogate, guardian, or attorney in fact to make a variety of personal choices, participate in developing service plans, and share responsibility in decisionmaking.

576-05334-10 20102434c2

- f. Implement the concept of managed risk.
- g. Provide, either directly or through contract, the services of a person licensed pursuant to part I of chapter 464.
- h. In addition to the training mandated in s. 429.52, provide specialized training as defined by rule for facility staff.
- 4. <u>Licensees</u> Facilities licensed to provide extended congregate care services are exempt from the criteria for continued residency as set forth in rules adopted under s. 429.41. <u>Licensees</u> Facilities so licensed shall adopt their own requirements within guidelines for continued residency set forth by rule. However, such <u>licensees</u> facilities may not serve residents who require 24-hour nursing supervision. <u>Licensees</u> Facilities licensed to provide extended congregate care services shall provide each resident with a written copy of facility policies governing admission and retention.
- 5. The primary purpose of extended congregate care services is to allow residents, as they become more impaired, the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency. A facility licensed to provide extended congregate care services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the extended congregate care facility.
- 6. Before admission of an individual to a facility licensed to provide extended congregate care services, the individual must undergo a medical examination as provided in s. 429.26(4) and the facility must develop a preliminary service plan for the

576-05334-10 20102434c2

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- 7. When a <u>licensee facility</u> can no longer provide or arrange for services in accordance with the resident's service plan and needs and the <u>licensee's facility's</u> policy, the <u>licensee facility</u> shall make arrangements for relocating the person in accordance with s. 429.28(1)(k).
- 8. Failure to provide extended congregate care services may result in denial of extended congregate care license renewal.
- 9. No later than January 1 of each year, the department, in consultation with the agency, shall prepare and submit to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the chairs of appropriate legislative committees, a report on the status of, and recommendations related to, extended congregate care services. The status report must include, but need not be limited to, the following information:
- a. A description of the facilities licensed to provide such services, including total number of beds licensed under this part.
- b. The number and characteristics of residents receiving such services.
- c. The types of services rendered that could not be provided through a standard license.
- d. An analysis of deficiencies cited during licensure inspections.
- e. The number of residents who required extended congregate care services at admission and the source of admission.
  - f. Recommendations for statutory or regulatory changes.
  - g. The availability of extended congregate care to state

576-05334-10 20102434c2

clients residing in facilities licensed under this part and in need of additional services, and recommendations for appropriations to subsidize extended congregate care services for such persons.

h. Such other information as the department considers appropriate.

(c) A limited nursing services license shall be issued to a facility that provides services beyond those authorized in paragraph (a) and as specified in this paragraph.

1. In order for limited nursing services to be provided in a facility licensed under this part, 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. 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. Notification of approval or denial of such request shall be made in accordance with part II of chapter 408. Existing facilities qualifying to provide limited nursing services shall have maintained a standard license and may not have been subject to administrative sanctions that affect the health, safety, and welfare of residents for the previous 2 years or since initial licensure if the facility has been licensed for less than 2 years.

2. Facilities that are licensed to provide limited nursing services shall maintain a written progress report on each person who receives such nursing services, which report describes the type, amount, duration, scope, and outcome of services that are rendered and the general status of the resident's health. A

576-05334-10 20102434c2

registered nurse representing the agency shall visit such facilities at least twice a year to monitor residents who are receiving limited nursing services and to determine if the facility is in compliance with applicable provisions of this part, part II of chapter 408, and related rules. The monitoring visits may be provided through contractual arrangements with appropriate community agencies. A registered nurse shall also serve as part of the team that inspects such facility.

- 3. A person who receives limited nursing services under this part must meet the admission criteria established by the agency for assisted living facilities. When a resident no longer meets the admission criteria for a facility licensed under this part, arrangements for relocating the person shall be made in accordance with s. 429.28(1)(k), unless the facility is licensed to provide extended congregate care services.
- (4) In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted under this part, part II of chapter 408, and applicable rules. The amount of the fee shall be established by rule.
- (a) The biennial license fee required of a facility is \$356 \$300 per license, with an additional fee of \$67.50 \$50 per resident based on the total licensed resident capacity of the facility, except that no additional fee will be assessed for beds designated for recipients of optional state supplementation payments provided for in s. 409.212. The total fee may not exceed \$18,000 \$10,000.
- (b) In addition to the total fee assessed under paragraph(a), the agency shall require facilities that are licensed toprovide extended congregate care services under this part to pay

576-05334-10 20102434c2

an additional fee per licensed facility. The amount of the biennial fee shall be  $\frac{$501}{$400}$  per license, with an additional fee of \$10 per resident based on the total licensed resident capacity of the facility.

- (c) In addition to the total fee assessed under paragraph (a), the agency shall require facilities that are licensed to provide limited nursing services under this part to pay an additional fee per licensed facility. The amount of the biennial fee shall be \$250 per license, with an additional fee of \$10 per resident based on the total licensed resident capacity of the facility.
- (6) In order to determine whether the facility is adequately protecting residents' rights as provided in s.

  429.28, the biennial survey shall include private informal conversations with a sample of residents and consultation with the ombudsman council in the planning and service area in which the facility is located to discuss residents' experiences within the facility.
- (7) An assisted living facility that has been cited within the previous 24-month period for a class I or class II violation, regardless of the status of any enforcement or disciplinary action, is subject to periodic unannounced monitoring to determine if the facility is in compliance with this part, part II of chapter 408, and applicable rules.

  Monitoring may occur through a desk review or an onsite assessment. If the class I or class II violation relates to providing or failing to provide nursing care, a registered nurse must participate in at least two onsite monitoring visits within a 12-month period.

576-05334-10 20102434c2

Section 69. Subsection (7) of section 429.11, Florida Statutes, is renumbered as subsection (6), and present subsection (6) of that section is amended to read:

429.11 Initial application for license; provisional license.

(6) In addition to the license categories available in s.
408.808, a provisional license may be issued to an applicant
making initial application for licensure or making application
for a change of ownership. A provisional license shall be
limited in duration to a specific period of time not to exceed 6
months, as determined by the agency.

Section 70. Section 429.12, Florida Statutes, is amended to read:

429.12 Sale or transfer of ownership of a facility.—It is the intent of the Legislature to protect the rights of the residents of an assisted living facility when the facility is sold or the ownership thereof is transferred. Therefore, in addition to the requirements of part II of chapter 408, whenever a facility is sold or the ownership thereof is transferred, including leasing:.

(1) The transferee shall notify the residents, in writing, of the change of ownership within 7 days after receipt of the new license.

(2) The transferor of a facility the license of which is denied pending an administrative hearing shall, as a part of the written change-of-ownership contract, advise the transferee that a plan of correction must be submitted by the transferee and approved by the agency at least 7 days before the change of ownership and that failure to correct the condition which

576-05334-10 20102434c2

resulted in the moratorium pursuant to part II of chapter 408 or denial of licensure is grounds for denial of the transferee's license.

Section 71. Paragraphs (b) through (l) of subsection (l) of section 429.14, Florida Statutes, are redesignated as paragraphs (a) through (k), respectively, and present paragraph (a) of subsection (l) and subsections (5) and (6) of that section are amended to read:

429.14 Administrative penalties.-

- (1) In addition to the requirements of part II of chapter 408, the agency may deny, revoke, and suspend any license issued under this part and impose an administrative fine in the manner provided in chapter 120 against a licensee of an assisted living facility for a violation of any provision of this part, part II of chapter 408, or applicable rules, or for any of the following actions by a licensee of an assisted living facility, for the actions of any person subject to level 2 background screening under s. 408.809, or for the actions of any facility employee:
- (a) An intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility.
- (5) An action taken by the agency to suspend, deny, or revoke a facility's license under this part or part II of chapter 408, in which the agency claims that the facility owner or an employee of the facility has threatened the health, safety, or welfare of a resident of the facility shall be heard by the Division of Administrative Hearings of the Department of Management Services within 120 days after receipt of the facility's request for a hearing, unless that time limitation is waived by both parties. The administrative law judge must render

576-05334-10 20102434c2

a decision within 30 days after receipt of a proposed recommended order.

(6) The agency shall provide to the Division of Hotels and Restaurants of the Department of Business and Professional Regulation, on a monthly basis, a list of those assisted living facilities that have had their licenses denied, suspended, or revoked or that are involved in an appellate proceeding pursuant to s. 120.60 related to the denial, suspension, or revocation of a license. This information may be provided electronically or through the agency's Internet website.

Section 72. Subsections (1), (4), and (5) of section 429.17, Florida Statutes, are amended to read:

429.17 Expiration of license; renewal; conditional license.—

- (1) Limited nursing, Extended congregate care, and limited mental health licenses shall expire at the same time as the facility's standard license, regardless of when issued.
- (4) In addition to the license categories available in s. 408.808, a conditional license may be issued to an applicant for license renewal if the applicant fails to meet all standards and requirements for licensure. A conditional license issued under this subsection shall be limited in duration to a specific period of time not to exceed 6 months, as determined by the agency, and shall be accompanied by an agency-approved plan of correction.
- (5) When an extended <u>congregate</u> care <del>or limited nursing</del> <del>license</del> is requested during a facility's biennial license period, the fee shall be prorated in order to permit the additional license to expire at the end of the biennial license

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576-05334-10 20102434c2

period. The fee shall be calculated as of the date the additional license application is received by the agency.

Section 73. Subsection (7) of section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

(7) In addition to any administrative fines imposed, the agency may assess a survey or monitoring fee, equal to the lesser of one half of the facility's biennial license and bed fee or \$500, to cover the cost of conducting initial complaint investigations that result in the finding of a violation that was the subject of the complaint or to monitor the health, safety, or security of residents under s. 429.07(7) monitoring visits conducted under s. 429.28(3)(c) to verify the correction of the violations.

Section 74. Subsections (6) through (10) of section 429.23, Florida Statutes, are renumbered as subsections (5) through (9), respectively, and present subsection (5) of that section is amended to read:

429.23 Internal risk management and quality assurance program; adverse incidents and reporting requirements.—

(5) Each facility shall report monthly to the agency any liability claim filed against it. The report must include the name of the resident, the dates of the incident leading to the claim, if applicable, and the type of injury or violation of rights alleged to have occurred. This report is not discoverable in any civil or administrative action, except in such actions brought by the agency to enforce the provisions of this part.

Section 75. Paragraph (a) of subsection (1) and subsection

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576-05334-10 20102434c2

(2) of section 429.255, Florida Statutes, are amended to read: 429.255 Use of personnel; emergency care.—

- (1)(a) Persons under contract to the facility or  $\tau$  facility staff, or volunteers, who are licensed according to part I of chapter 464, or those persons exempt under s. 464.022(1), and others as defined by rule, may administer medications to residents, take residents' vital signs, manage individual weekly pill organizers for residents who self-administer medication, give prepackaged enemas ordered by a physician, observe residents, document observations on the appropriate resident's record, report observations to the resident's physician, and contract or allow residents or a resident's representative, designee, surrogate, quardian, or attorney in fact to contract with a third party, provided residents meet the criteria for appropriate placement as defined in s. 429.26. Persons under contract to the facility or facility staff who are licensed according to part I of chapter 464 may provide limited nursing services. Nursing assistants certified pursuant to part II of chapter 464 may take residents' vital signs as directed by a licensed nurse or physician. The facility is responsible for maintaining documentation of services provided under this paragraph as required by rule and ensuring that staff are adequately trained to monitor residents receiving these services.
- (2) In facilities licensed to provide extended congregate care, persons under contract to the facility or, facility staff, or volunteers, who are licensed according to part I of chapter 464, or those persons exempt under s. 464.022(1), or those persons certified as nursing assistants pursuant to part II of

576-05334-10 20102434c2

chapter 464, may also perform all duties within the scope of their license or certification, as approved by the facility administrator and pursuant to this part.

Section 76. Subsection (3) of section 429.28, Florida Statutes, is amended to read:

429.28 Resident bill of rights.-

- (3) (a) The agency shall conduct a survey to determine general compliance with facility standards and compliance with residents' rights as a prerequisite to initial licensure or licensure renewal.
- (b) In order to determine whether the facility is adequately protecting residents' rights, the biennial survey shall include private informal conversations with a sample of residents and consultation with the ombudsman council in the planning and service area in which the facility is located to discuss residents' experiences within the facility.
- (c) During any calendar year in which no survey is conducted, the agency shall conduct at least one monitoring visit of each facility cited in the previous year for a class I or class II violation, or more than three uncorrected class III violations.
- (d) The agency may conduct periodic followup inspections as necessary to monitor the compliance of facilities with a history of any class I, class II, or class III violations that threaten the health, safety, or security of residents.
- (e) The agency may conduct complaint investigations as warranted to investigate any allegations of noncompliance with requirements required under this part or rules adopted under this part.

576-05334-10 20102434c2

Section 77. Subsection (2) of section 429.35, Florida Statutes, is amended to read:

429.35 Maintenance of records; reports.-

(2) Within 60 days after the date of the biennial inspection visit required under s. 408.811 or within 30 days after the date of any interim visit, the agency shall forward the results of the inspection to the local ombudsman council in whose planning and service area, as defined in part II of chapter 400, the facility is located; to at least one public library or, in the absence of a public library, the county seat in the county in which the inspected assisted living facility is located; and, when appropriate, to the district Adult Services and Mental Health Program Offices. This information may be provided electronically or through the agency's Internet website.

Section 78. Paragraphs (i) and (j) of subsection (1) of section 429.41, Florida Statutes, are amended to read:

429.41 Rules establishing standards.-

(1) It is the intent of the Legislature that rules published and enforced pursuant to this section shall include criteria by which a reasonable and consistent quality of resident care and quality of life may be ensured and the results of such resident care may be demonstrated. Such rules shall also ensure a safe and sanitary environment that is residential and noninstitutional in design or nature. It is further intended that reasonable efforts be made to accommodate the needs and preferences of residents to enhance the quality of life in a facility. The agency, in consultation with the department, may adopt rules to administer the requirements of part II of chapter

576-05334-10 20102434c2

408. In order to provide safe and sanitary facilities and the highest quality of resident care accommodating the needs and preferences of residents, the department, in consultation with the agency, the Department of Children and Family Services, and the Department of Health, shall adopt rules, policies, and procedures to administer this part, which must include reasonable and fair minimum standards in relation to:

- (i) Facilities holding an a limited nursing, extended congregate care, or limited mental health license.
- (j) The establishment of specific criteria to define appropriateness of resident admission and continued residency in a facility holding a standard, limited nursing, extended congregate care, and limited mental health license.

Section 79. Subsections (1) and (2) of section 429.53, Florida Statutes, are amended to read:

429.53 Consultation by the agency.-

- (1) The area offices of licensure and certification of the agency shall provide consultation to the following upon request:
  - (a) A licensee of a facility.
- (b) A person interested in obtaining a license to operate a facility under this part.
  - (2) As used in this section, "consultation" includes:
- (a) An explanation of the requirements of this part and rules adopted pursuant thereto;
- (b) An explanation of the license application and renewal procedures;
- (c) The provision of a checklist of general local and state approvals required prior to constructing or developing a facility and a listing of the types of agencies responsible for

576-05334-10

20102434c2

3104 such approvals; 3105 (d) An explanation of benefits and financial assistance 3106 available to a recipient of supplemental security income 3107 residing in a facility; 3108 (c) (e) Any other information which the agency deems 3109 necessary to promote compliance with the requirements of this 3110 part; and 3111 (f) A preconstruction review of a facility to ensure 3112 compliance with agency rules and this part. 3113 Section 80. Subsections (1) and (2) of section 429.54, Florida Statutes, are renumbered as subsections (2) and (3), 3114 3115 respectively, and a new subsection (1) is added to that section 3116 to read: 3117 429.54 Collection of information; local subsidy. 3118 (1) A facility that is licensed under this part must report 3119 electronically to the agency semiannually data related to the 3120 facility, including, but not limited to, the total number of 3121 residents, the number of residents who are receiving limited 3122 mental health services, the number of residents who are 3123 receiving extended congregate care services, the number of 3124 residents who are receiving limited nursing services, and 3125 professional staffing employed by or under contract with the licensee to provide resident services. The department, in 3126 3127 consultation with the agency, shall adopt rules to administer 3128 this subsection. Section 81. Subsections (1) and (5) of section 429.71, 3129 3130 Florida Statutes, are amended to read: 3131 429.71 Classification of violations deficiencies; 3132 administrative fines.-

 576-05334-10 20102434c2

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

- (a) Class I violations are <u>defined in s. 408.813</u> those conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical or emotional harm would result therefrom. The condition or practice that constitutes a class I violation must be abated or eliminated within 24 hours, unless a fixed period, as determined by the agency, is required for correction. A class I violation deficiency is subject to an administrative fine in an amount not less than \$500 and not exceeding \$1,000 for each violation. A fine may be levied notwithstanding the correction of the deficiency.
- (b) Class II violations are <u>defined in s. 408.813</u> those conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines directly threaten the physical or emotional health, safety, or security of the residents, other than class I violations. A class II violation is subject to an administrative fine in an amount not less than \$250 and not exceeding \$500 for each violation. A citation for a class II violation must specify the time within which the violation is required to be corrected. If a class II violation is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

576-05334-10 20102434c2

conditions or practices related to the operation and maintenance of an adult family-care home or to the care of residents which the agency determines indirectly or potentially threaten the physical or emotional health, safety, or security of residents, other than class I or class II violations. A class III violation is subject to an administrative fine in an amount not less than \$100 and not exceeding \$250 for each violation. A citation for a class III violation shall specify the time within which the violation is required to be corrected. If a class III violation is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated violation offense.

- (d) Class IV violations are <u>defined in s. 408.813</u> those conditions or occurrences related to the operation and maintenance of an adult family-care home, or related to the required reports, forms, or documents, which do not have the potential of negatively affecting the residents. A provider that does not correct A class IV violation within the time limit specified by the agency is subject to an administrative fine in an amount not less than \$50 and not exceeding \$100 for each violation. Any class IV violation that is corrected during the time the agency survey is conducted will be identified as an agency finding and not as a violation, unless it is a repeat violation.
- (5) As an alternative to or in conjunction with an administrative action against a provider, the agency may request a plan of corrective action that demonstrates a good faith effort to remedy each violation by a specific date, subject to the approval of the agency.

576-05334-10 20102434c2

Section 82. Paragraphs (b) through (e) of subsection (2) of section 429.911, Florida Statutes, are redesignated as paragraphs (a) through (d), respectively, and present paragraph (a) of that subsection is amended to read:

- 429.911 Denial, suspension, revocation of license; emergency action; administrative fines; investigations and inspections.—
- (2) Each of the following actions by the owner of an adult day care center or by its operator or employee is a ground for action by the agency against the owner of the center or its operator or employee:
- (a) An intentional or negligent act materially affecting the health or safety of center participants.

Section 83. Section 429.915, Florida Statutes, is amended to read:

429.915 Conditional license.—In addition to the license categories available in part II of chapter 408, the agency may issue a conditional license to an applicant for license renewal or change of ownership if the applicant fails to meet all standards and requirements for licensure. A conditional license issued under this subsection must be limited to a specific period not exceeding 6 months, as determined by the agency, and must be accompanied by an approved plan of correction.

Section 84. Paragraphs (b) and (h) of subsection (3) of section 430.80, Florida Statutes, are amended to read:

- 430.80 Implementation of a teaching nursing home pilot project.—
- (3) To be designated as a teaching nursing home, a nursing home licensee must, at a minimum:

576-05334-10 20102434c2

(b) Participate in a nationally recognized accreditation program and hold a valid accreditation, such as the accreditation awarded by The Joint Commission on Accreditation of Healthcare Organizations;

- (h) Maintain insurance coverage pursuant to s. 400.141(1) (q) (s) or proof of financial responsibility in a minimum amount of \$750,000. Such proof of financial responsibility may include:
- 1. Maintaining an escrow account consisting of cash or assets eligible for deposit in accordance with s. 625.52; or
- 2. Obtaining and maintaining pursuant to chapter 675 an unexpired, irrevocable, nontransferable and nonassignable letter of credit issued by any bank or savings association organized and existing under the laws of this state or any bank or savings association organized under the laws of the United States that has its principal place of business in this state or has a branch office which is authorized to receive deposits in this state. The letter of credit shall be used to satisfy the obligation of the facility to the claimant upon presentment of a final judgment indicating liability and awarding damages to be paid by the facility or upon presentment of a settlement agreement signed by all parties to the agreement when such final judgment or settlement is a result of a liability claim against the facility.

Section 85. Paragraph (a) of subsection (2) of section 440.13, Florida Statutes, is amended to read:

440.13 Medical services and supplies; penalty for violations; limitations.—

(2) MEDICAL TREATMENT; DUTY OF EMPLOYER TO FURNISH.-

576-05334-10 20102434c2

(a) Subject to the limitations specified elsewhere in this chapter, the employer shall furnish to the employee such medically necessary remedial treatment, care, and attendance for such period as the nature of the injury or the process of recovery may require, which is in accordance with established practice parameters and protocols of treatment as provided for in this chapter, including medicines, medical supplies, durable medical equipment, orthoses, prostheses, and other medically necessary apparatus. Remedial treatment, care, and attendance, including work-hardening programs or pain-management programs accredited by the Commission on Accreditation of Rehabilitation Facilities or The Joint Commission on the Accreditation of Health Organizations or pain-management programs affiliated with medical schools, shall be considered as covered treatment only when such care is given based on a referral by a physician as defined in this chapter. Medically necessary treatment, care, and attendance does not include chiropractic services in excess of 24 treatments or rendered 12 weeks beyond the date of the initial chiropractic treatment, whichever comes first, unless the carrier authorizes additional treatment or the employee is catastrophically injured.

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Failure of the carrier to timely comply with this subsection shall be a violation of this chapter and the carrier shall be subject to penalties as provided for in s. 440.525.

Section 86. Subsection (11) is added to section 483.201, Florida Statutes, to read:

483.201 Grounds for disciplinary action against clinical laboratories.—In addition to the requirements of part II of

576-05334-10 20102434c2

chapter 408, the following acts constitute grounds for which a disciplinary action specified in s. 483.221 may be taken against a clinical laboratory:

(11) A blood establishment that collects blood or blood components from volunteer donors failing to disclose information concerning its activities as required by s. 381.06014. Each day of violation constitutes a separate violation and each separate violation is subject to a separate fine. If multiple licensed establishments operated by a single business entity fail to meet such disclosure requirements, the agency may assess fines against only one of the business entity's clinical laboratory licenses. The total administrative fine may not exceed \$10,000 for each annual reporting period.

Section 87. Section 483.294, Florida Statutes, is amended to read:

483.294 Inspection of centers.—In accordance with s. 408.811, the agency shall biennially, at least once annually, inspect the premises and operations of all centers subject to licensure under this part.

Section 88. Subsection (23) and paragraph (a) of subsection (53) of section 499.003, Florida Statutes, are amended to read: 499.003 Definitions of terms used in this part.—As used in

3300 this part, the term:

(23) "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood

576-05334-10 20102434c2

establishment may be a health care entity and engage in the wholesale distribution of prescription drugs under s.

499.01(2)(g)1.c.

- (53) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
- (a) Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):
- 1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.
- 2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
- 3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.
  - 4. The sale, purchase, trade, or other transfer of a

576-05334-10 20102434c2

prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

- a. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.
- b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.
- c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.
- d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.
- d.e. The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

576-05334-10 20102434c2

e.f. The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph  $\underline{d}$ .

 $\underline{\text{f.g.}}$  In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

Section 89. Subsection (21) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

- (21) The wholesale distribution of any prescription drug that was:
- (a) Purchased by a public or private hospital or other health care entity, except as authorized in s. 499.01(2)(g)1.c.; or
  - (b) Donated or supplied at a reduced price to a charitable

576-05334-10 20102434c2

3394 organization.

Section 90. Paragraphs (a) and (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.-

- (2) The following permits are established:
- (a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.
- 1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, that apply to a wholesale distributor.
- 2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.
- 3. A blood establishment as defined in s. 381.06014, operating in a manner consistent with the provisions of Title 21 C.F.R. Parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(53)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or register products under s. 499.015.
  - (g) Restricted prescription drug distributor permit.-
- 1. A restricted prescription drug distributor permit is required for:
  - $\underline{a}$ . Any person that engages in the distribution of a prescription drug, which distribution is not considered

576-05334-10 20102434c2

3423 "wholesale distribution" under s. 499.003(53)(a).

<u>b.1.</u> Any A person who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction  $\frac{\text{must obtain}}{\text{a permit as a restricted prescription drug distributor}}$  if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

- c. A blood establishment located in this state that collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(53)(d) to a health care entity. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:
- (I) Prescription drugs indicated for a bleeding or clotting disorder or anemia;
- (II) Blood-collection containers approved under s. 505 of the federal act;
- (III) Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative; or
- (IV) Prescription drugs identified in rules adopted by the department which are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law,

576-05334-10 20102434c2

- as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing.
- 2. Storage, handling, and recordkeeping of these distributions by a person permitted as a restricted prescription drug distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to subsubparagraph 1.a. or sub-subparagraph 1.b.
- 3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.
- 4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, and blood establishments; which rules are necessary for the protection of the public health, safety, and welfare. The department may adopt rules related to the transportation, storage, and recordkeeping of prescription drugs which are essential to services performed or provided by a blood establishment, including requirements for the use of prescription drugs in mobile blood-collection vehicles.

576-05334-10 20102434c2

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

499.01212 Pedigree paper.-

- (3) EXCEPTIONS.—A pedigree paper is not required for:
- (i) The wholesale distribution of prescription drugs contained within a sealed medical convenience kit if the kit:
- 1. Is assembled in an establishment that is registered as a medical device manufacturer with the Food and Drug
  Administration; and
- 2. Does not contain any controlled substance that appears in any schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

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

627.645 Denial of health insurance claims restricted.-

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

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

627.668 Optional coverage for mental and nervous disorders required; exception.—

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576-05334-10 20102434c2

(2) Under group policies or contracts, inpatient hospital benefits, partial hospitalization benefits, and outpatient benefits consisting of durational limits, dollar amounts, deductibles, and coinsurance factors shall not be less favorable than for physical illness generally, except that:

- (c) Partial hospitalization benefits shall be provided under the direction of a licensed physician. For purposes of this part, the term "partial hospitalization services" is defined as those services offered by a program accredited by The Joint Commission on Accreditation of Hospitals (JCAH) or in compliance with equivalent standards. Alcohol rehabilitation programs accredited by The Joint Commission on Accreditation of Hospitals or approved by the state and licensed drug abuse rehabilitation programs shall also be qualified providers under this section. In any benefit year, if partial hospitalization services or a combination of inpatient and partial hospitalization are utilized, the total benefits paid for all such services shall not exceed the cost of 30 days of inpatient hospitalization for psychiatric services, including physician fees, which prevail in the community in which the partial hospitalization services are rendered. If partial hospitalization services benefits are provided beyond the limits set forth in this paragraph, the durational limits, dollar amounts, and coinsurance factors thereof need not be the same as those applicable to physical illness generally.
- Section 94. Subsection (3) of section 627.669, Florida Statutes, is amended to read:
- 627.669 Optional coverage required for substance abuse impaired persons; exception.—

576-05334-10 20102434c2

(3) The benefits provided under this section shall be applicable only if treatment is provided by, or under the supervision of, or is prescribed by, a licensed physician or licensed psychologist and if services are provided in a program accredited by The Joint Commission on Accreditation of Hospitals or approved by the state.

Section 95. Paragraph (a) of subsection (1) of section 627.736, Florida Statutes, is amended to read:

627.736 Required personal injury protection benefits; exclusions; priority; claims.—

- (1) REQUIRED BENEFITS.—Every insurance policy complying with the security requirements of s. 627.733 shall provide personal injury protection to the named insured, relatives residing in the same household, persons operating the insured motor vehicle, passengers in such motor vehicle, and other persons struck by such motor vehicle and suffering bodily injury while not an occupant of a self-propelled vehicle, subject to the provisions of subsection (2) and paragraph (4)(e), to a limit of \$10,000 for loss sustained by any such person as a result of bodily injury, sickness, disease, or death arising out of the ownership, maintenance, or use of a motor vehicle as follows:
- (a) Medical benefits.—Eighty percent of all reasonable expenses for medically necessary medical, surgical, X-ray, dental, and rehabilitative services, including prosthetic devices, and medically necessary ambulance, hospital, and nursing services. However, the medical benefits shall provide reimbursement only for such services and care that are lawfully provided, supervised, ordered, or prescribed by a physician

576-05334-10 20102434c2

licensed under chapter 458 or chapter 459, a dentist licensed under chapter 466, or a chiropractic physician licensed under chapter 460 or that are provided by any of the following persons or entities:

- 1. A hospital or ambulatory surgical center licensed under chapter 395.
- 2. A person or entity licensed under ss. 401.2101-401.45 that provides emergency transportation and treatment.
- 3. An entity wholly owned by one or more physicians licensed under chapter 458 or chapter 459, chiropractic physicians licensed under chapter 460, or dentists licensed under chapter 466 or by such practitioner or practitioners and the spouse, parent, child, or sibling of that practitioner or those practitioners.
- 4. An entity wholly owned, directly or indirectly, by a hospital or hospitals.
- 5. A health care clinic licensed under ss. 400.990-400.995 that is:
- a. Accredited by The Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, or the Accreditation Association for Ambulatory Health Care, Inc.; or
  - b. A health care clinic that:
- (I) Has a medical director licensed under chapter 458, chapter 459, or chapter 460;
- (II) Has been continuously licensed for more than 3 years or is a publicly traded corporation that issues securities traded on an exchange registered with the United States

576-05334-10 20102434c2

Securities and Exchange Commission as a national securities exchange; and

- (III) Provides at least four of the following medical specialties:
  - (A) General medicine.
  - (B) Radiography.
  - (C) Orthopedic medicine.
  - (D) Physical medicine.
  - (E) Physical therapy.
  - (F) Physical rehabilitation.
- (G) Prescribing or dispensing outpatient prescription medication.
  - (H) Laboratory services.

The Financial Services Commission shall adopt by rule the form that must be used by an insurer and a health care provider specified in subparagraph 3., subparagraph 4., or subparagraph 5. to document that the health care provider meets the criteria of this paragraph, which rule must include a requirement for a sworn statement or affidavit.

Only insurers writing motor vehicle liability insurance in this state may provide the required benefits of this section, and no such insurer shall require the purchase of any other motor vehicle coverage other than the purchase of property damage liability coverage as required by s. 627.7275 as a condition for providing such required benefits. Insurers may not require that property damage liability insurance in an amount greater than \$10,000 be purchased in conjunction with personal injury

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576-05334-10 20102434c2

protection. Such insurers shall make benefits and required property damage liability insurance coverage available through normal marketing channels. Any insurer writing motor vehicle liability insurance in this state who fails to comply with such availability requirement as a general business practice shall be deemed to have violated part IX of chapter 626, and such violation shall constitute an unfair method of competition or an unfair or deceptive act or practice involving the business of insurance; and any such insurer committing such violation shall be subject to the penalties afforded in such part, as well as those which may be afforded elsewhere in the insurance code.

Section 96. Section 633.081, Florida Statutes, is amended to read:

633.081 Inspection of buildings and equipment; orders; firesafety inspection training requirements; certification; disciplinary action.-The State Fire Marshal and her or his agents shall, at any reasonable hour, when the department has reasonable cause to believe that a violation of this chapter or s. 509.215, or a rule promulgated thereunder, or a minimum firesafety code adopted by a local authority, may exist, inspect any and all buildings and structures which are subject to the requirements of this chapter or s. 509.215 and rules promulgated thereunder. The authority to inspect shall extend to all equipment, vehicles, and chemicals which are located within the premises of any such building or structure. The State Fire Marshal and her or his agents shall inspect nursing homes licensed under part II of chapter 400 only once every calendar year and upon receiving a complaint forming the basis of a reasonable cause to believe that a violation of this chapter or

576-05334-10 20102434c2

s. 509.215, or a rule promulgated thereunder, or a minimum firesafety code adopted by a local authority may exist and upon identifying such a violation in the course of conducting orientation or training activities within a nursing home.

- (1) Each county, municipality, and special district that has firesafety enforcement responsibilities shall employ or contract with a firesafety inspector. The firesafety inspector must conduct all firesafety inspections that are required by law. The governing body of a county, municipality, or special district that has firesafety enforcement responsibilities may provide a schedule of fees to pay only the costs of inspections conducted pursuant to this subsection and related administrative expenses. Two or more counties, municipalities, or special districts that have firesafety enforcement responsibilities may jointly employ or contract with a firesafety inspector.
- (2) Every firesafety inspection conducted pursuant to state or local firesafety requirements shall be by a person certified as having met the inspection training requirements set by the State Fire Marshal. Such person shall:
- (a) Be a high school graduate or the equivalent as determined by the department;
- (b) Not have been found guilty of, or having pleaded guilty or nolo contendere to, a felony or a crime punishable by imprisonment of 1 year or more under the law of the United States, or of any state thereof, which involves moral turpitude, without regard to whether a judgment of conviction has been entered by the court having jurisdiction of such cases;
- (c) Have her or his fingerprints on file with the department or with an agency designated by the department;

576-05334-10 20102434c2

(d) Have good moral character as determined by the
department;

- (e) Be at least 18 years of age;
- (f) Have satisfactorily completed the firesafety inspector certification examination as prescribed by the department; and
- (g)1. Have satisfactorily completed, as determined by the department, a firesafety inspector training program of not less than 200 hours established by the department and administered by agencies and institutions approved by the department for the purpose of providing basic certification training for firesafety inspectors; or
- 2. Have received in another state training which is determined by the department to be at least equivalent to that required by the department for approved firesafety inspector education and training programs in this state.
- (3) Each special state firesafety inspection which is required by law and is conducted by or on behalf of an agency of the state must be performed by an individual who has met the provision of subsection (2), except that the duration of the training program shall not exceed 120 hours of specific training for the type of property that such special state firesafety inspectors are assigned to inspect.
- (4) A firefighter certified pursuant to s. 633.35 may conduct firesafety inspections, under the supervision of a certified firesafety inspector, while on duty as a member of a fire department company conducting inservice firesafety inspections without being certified as a firesafety inspector, if such firefighter has satisfactorily completed an inservice fire department company inspector training program of at least

576-05334-10 20102434c2

24 hours' duration as provided by rule of the department.

- (5) Every firesafety inspector or special state firesafety inspector certificate is valid for a period of 3 years from the date of issuance. Renewal of certification shall be subject to the affected person's completing proper application for renewal and meeting all of the requirements for renewal as established under this chapter or by rule promulgated thereunder, which shall include completion of at least 40 hours during the preceding 3-year period of continuing education as required by the rule of the department or, in lieu thereof, successful passage of an examination as established by the department.
- (6) The State Fire Marshal may deny, refuse to renew, suspend, or revoke the certificate of a firesafety inspector or special state firesafety inspector if it finds that any of the following grounds exist:
- (a) Any cause for which issuance of a certificate could have been refused had it then existed and been known to the State Fire Marshal.
- (b) Violation of this chapter or any rule or order of the State Fire Marshal.
  - (c) Falsification of records relating to the certificate.
- (d) Having been found guilty of or having pleaded guilty or nolo contendere to a felony, whether or not a judgment of conviction has been entered.
  - (e) Failure to meet any of the renewal requirements.
- (f) Having been convicted of a crime in any jurisdiction which directly relates to the practice of fire code inspection, plan review, or administration.
  - (g) Making or filing a report or record that the

576-05334-10 20102434c2

certificateholder knows to be false, or knowingly inducing another to file a false report or record, or knowingly failing to file a report or record required by state or local law, or knowingly impeding or obstructing such filing, or knowingly inducing another person to impede or obstruct such filing.

- (h) Failing to properly enforce applicable fire codes or permit requirements within this state which the certificateholder knows are applicable by committing willful misconduct, gross negligence, gross misconduct, repeated negligence, or negligence resulting in a significant danger to life or property.
- (i) Accepting labor, services, or materials at no charge or at a noncompetitive rate from any person who performs work that is under the enforcement authority of the certificateholder and who is not an immediate family member of the certificateholder. For the purpose of this paragraph, the term "immediate family member" means a spouse, child, parent, sibling, grandparent, aunt, uncle, or first cousin of the person or the person's spouse or any person who resides in the primary residence of the certificateholder.
- (7) The department shall provide by rule for the certification of firesafety inspectors.
- Section 97. Subsection (12) of section 641.495, Florida Statutes, is amended to read:
- 641.495 Requirements for issuance and maintenance of certificate.—
- (12) The provisions of part I of chapter 395 do not apply to a health maintenance organization that, on or before January 1, 1991, provides not more than 10 outpatient holding beds for

576-05334-10 20102434c2

short-term and hospice-type patients in an ambulatory care facility for its members, provided that such health maintenance organization maintains current accreditation by The Joint Commission on Accreditation of Health Care Organizations, the Accreditation Association for Ambulatory Health Care, or the National Committee for Quality Assurance.

Section 98. Subsection (13) of section 651.118, Florida Statutes, is amended to read:

- 651.118 Agency for Health Care Administration; certificates of need; sheltered beds; community beds.—
- (13) Residents, as defined in this chapter, are not considered new admissions for the purpose of s.  $400.141(1)(n) \frac{(0)}{1.d}$ .

Section 99. Subsection (2) of section 766.1015, Florida Statutes, is amended to read:

766.1015 Civil immunity for members of or consultants to certain boards, committees, or other entities.—

(2) Such committee, board, group, commission, or other entity must be established in accordance with state law or in accordance with requirements of The Joint Commission on Accreditation of Healthcare Organizations, established and duly constituted by one or more public or licensed private hospitals or behavioral health agencies, or established by a governmental agency. To be protected by this section, the act, decision, omission, or utterance may not be made or done in bad faith or with malicious intent.

Section 100. Subsection (4) of section 766.202, Florida Statutes, is amended to read:

766.202 Definitions; ss. 766.201-766.212.—As used in ss.

576-05334-10 20102434c2

3800 766.201-766.212, the term:

(4) "Health care provider" means any hospital, ambulatory surgical center, or mobile surgical facility as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; a clinical lab licensed under chapter 483; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Section 101. This act shall take effect July 1, 2010.