LEGISLATIVE ACTION

Senate	.	House
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05/06/2011 08:39 PM	.	05/06/2011 10:49 PM
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Senator Latvala moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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

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

(1) Residency or detention in a facility, whether public or private, when residence or detention is incidental to the provision of medical, geriatric, educational, counseling, religious, or similar services. For residents of a facility licensed under part II of chapter 400, the provisions of s.

400.0255 are the exclusive procedures for all transfers and discharges.

Section 2. Paragraphs (f) through (k) of subsection (10) of section 112.0455, Florida Statutes, are redesignated as paragraphs (e) through (j), respectively, paragraph (e) of subsection (12) is redesignated as paragraph (d), and present paragraph (e) of subsection (10), present paragraph (d) of subsection (12), and paragraph (e) of subsection (14) of that section are amended 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 to January 1, 1990. A drug test conducted by an employer prior to January 1, 1990, is not subject to this section.~~

(12) DRUG-TESTING STANDARDS; LABORATORIES.—

~~(d) The laboratory shall submit to the Agency for Health Care Administration a monthly report with statistical information regarding the testing of employees and job applicants. The reports shall include information on the methods of analyses conducted, the drugs tested for, the number of positive and negative results for both initial and confirmation tests, and any other information deemed appropriate by the Agency for Health Care Administration. No monthly report shall identify specific employees or job applicants.~~

(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, expunge related records from the personnel file of the employee or job applicant and reinstate the employee.

2. Order compliance with paragraph (10)(f) ~~(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 3. 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 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.


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Section 4. 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 brain and spinal cord injuries that are medically complex and who are technologically and respiratory dependent. 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 Emergency Medical Services 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 Emergency Medical Services Trust Fund under this subsection shall be 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 5. Section 383.325, Florida Statutes, is repealed.

Section 6. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

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(26) ~~(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 7. 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~~.

(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 8. 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 nationally recognized 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~~.

~~(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 performed by a private review agent.~~

Section 9. 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.—

(1)

~~(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 10. Subsection (3) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.—

(3) 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. With the exception of state-operated licensed facilities, each

facility licensed under this part shall pay to the agency~~, at the time of inspection,~~ the following fees:

(a) *Inspection for licensure.*—A fee shall be paid which is not less than $8 per hospital bed, nor more than $12 per hospital bed, except that the minimum fee shall be $400 per facility.

(b) *Inspection for lifesafety only.*—A fee shall be paid which is not less than 75 cents per hospital bed, nor more than $1.50 per hospital bed, except that the minimum fee shall be $40 per facility.

Section 11. 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 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 Medical Quality Assurance of the department ~~Health Quality Assurance of the agency~~.

(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 12. 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, 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 13. 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 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.

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 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 after ~~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 that ~~the~~ time period, the hospital is deemed to be exempt from offering the service until the agency initially acts to deny the request.

Section 14. Section 395.1046, Florida Statutes, is repealed.

Section 15. Paragraphs (b) and (e) of subsection (1) of section 395.1055, Florida Statutes, are 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:

(b) Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patient care and safety are established and implemented. These procedures shall require housekeeping and sanitation staff to wear masks and gloves when cleaning patient rooms and disinfecting environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used by the hospital. The agency may impose an administrative fine for each day that a violation of this paragraph occurs.

(e) Licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by the agency, the Florida Building Code, and the Florida Fire Prevention Code ~~department~~.

Section 16. 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

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 for ~~of~~ Healthcare Risk Management and Patient Safety.

Section 17. 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 18. 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)

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 s. 155.40 ~~subsection (2)~~.

Section 19. Section 395.3037, Florida Statutes, is repealed.

Section 20. 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

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 21. Paragraph (d) of subsection (2) of section 395.4025, Florida Statutes, is amended to read:

395.4025 Trauma centers; selection; quality assurance; records.—

(2)

(d)1. Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, as provided by rule of the department. An applicant that is granted additional time pursuant to this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. Any applicant that demonstrates

an ongoing effort to complete the activities within the timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center. An applicant that has received an additional 18 months pursuant to this paragraph shall be granted up to two additional 6-month extensions to meet all requirements as provided in paragraph (c), if construction related to a critical element is delayed as a result of governmental action or inaction with respect to regulations or permitting, and the applicant has made a good faith effort to comply with the applicable regulations or obtain the required permits.

2. Timeframes provided in subsections (1)-(8) shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center.

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 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 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. Subsections (8) and (16) of section 400.021, Florida Statutes, are 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, physician assistant, or physician.

(16) "Resident care plan" means a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, with participation from other facility staff and the resident or his or her designee or legal representative, which includes a comprehensive assessment of the needs of an individual resident; the type and frequency of services required to provide the necessary care for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being; a listing of services provided within or outside the facility to meet those needs; and an explanation

of service goals. ~~The resident care plan must be signed by the director of nursing or another registered nurse employed by the facility to whom institutional responsibilities have been delegated and by the resident, the resident's designee, or the resident's legal representative. The facility may not use an agency or temporary registered nurse to satisfy the foregoing requirement and must document the institutional responsibilities that have been delegated to the registered nurse.~~

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.—

(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 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 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) 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 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 for a portion of the total beds 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.

(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 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 and shall retain a log for agency inspection of ~~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. Section 400.141, Florida Statutes, is 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:

(a) Be under the administrative direction and charge of a licensed administrator.

(b) Appoint a medical director licensed pursuant to chapter 458 or chapter 459. The agency may establish by rule more specific criteria for the appointment of a medical director.

(c) Have available the regular, consultative, and emergency services of physicians licensed by the state.

(d) Provide for resident use of a community pharmacy as specified in s. 400.022(1)(q). Any other law to the contrary notwithstanding, a registered pharmacist licensed in Florida,

that is under contract with a facility licensed under this chapter or chapter 429, shall repackage a nursing facility resident's bulk prescription medication which has been packaged by another pharmacist licensed in any state in the United States into a unit dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. In order to be eligible for the repackaging, a resident or the resident's spouse must receive prescription medication benefits provided through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. s. 831, or a long-term care policy as defined in s. 627.9404(1). A pharmacist who correctly repackages and relabels the medication and the nursing facility which correctly administers such repackaged medication under this paragraph may not be held liable in any civil or administrative action arising from the repackaging. In order to be eligible for the repackaging, a nursing facility resident for whom the medication is to be repackaged shall sign an informed consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided in this paragraph. A pharmacist who repackages and relabels prescription medications, as authorized under this paragraph, may charge a reasonable fee for costs resulting from the implementation of this provision.

(e) Provide for the access of the facility residents to dental and other health-related services, recreational services, rehabilitative services, and social work services appropriate to

their needs and conditions and not directly furnished by the licensee. When a geriatric outpatient nurse clinic is conducted in accordance with rules adopted by the agency, outpatients attending such clinic shall not be counted as part of the general resident population of the nursing home facility, nor shall the nursing staff of the geriatric outpatient clinic be counted as part of the nursing staff of the facility, until the outpatient clinic load exceeds 15 a day.

(f) Be allowed and encouraged by the agency to provide other needed services under certain conditions. If the facility 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, under the following conditions:~~.~~

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 planning.

b. Covered by the residents' 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 order for the medications. The caregiver may provide information regarding the medications as part of the nursing assessment and that information must agree with the physician's order. Medications shall be released with the resident upon discharge in accordance with current physician's orders.

3. A person receiving respite care is entitled to reside in the facility for a total of 60 days within a contract year or within 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, physician assistant, or nurse practitioner and other information from the primary caregiver as may be required by the facility before 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 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.

(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 (o)~~, 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

884 violate the staffing ratios required under s. 400.23(3)(a).
885 Compliance with the minimum staffing ratios shall be based on
886 total number of residents receiving direct care services,
887 regardless of where they reside on campus. If the facility
888 receives a conditional license, it may not share staff until the
889 conditional license status ends. This paragraph does not
890 restrict the agency's authority under federal or state law to
891 require additional staff if a facility is cited for deficiencies
892 in care which are caused by an insufficient number of certified
893 nursing assistants or licensed nurses. The agency may adopt
894 rules for the documentation necessary to determine compliance
895 with this provision.
896 (h) Maintain the facility premises and equipment and
897 conduct its operations in a safe and sanitary manner.
898 (i) If the licensee furnishes food service, provide a
899 wholesome and nourishing diet sufficient to meet generally
900 accepted standards of proper nutrition for its residents and
901 provide such therapeutic diets as may be prescribed by attending
902 physicians. In making rules to implement this paragraph, the
903 agency shall be guided by standards recommended by nationally
904 recognized professional groups and associations with knowledge
905 of dietetics.
906 (j) Keep full records of resident admissions and
907 discharges; medical and general health status, including medical
908 records, personal and social history, and identity and address
909 of next of kin or other persons who may have responsibility for
910 the affairs of the residents; and individual resident care plans
911 including, but not limited to, prescribed services, service
912 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.

(k) Keep such fiscal records of its operations and conditions as may be necessary to provide information pursuant to this part.

(l) Furnish copies of personnel records for employees affiliated with such facility, to any other facility licensed by this state requesting this information pursuant to this part. Such information contained in the records may include, but is not limited to, disciplinary matters and any reason for termination. Any facility releasing such records pursuant to this part shall be considered to be acting in good faith and may not be held liable for information contained in such records, absent a showing that the facility maliciously falsified such records.

(m) Publicly display a poster provided by the agency containing the names, addresses, and telephone numbers for the state's abuse hotline, the State Long-Term Care Ombudsman, the Agency for Health Care Administration consumer hotline, the Advocacy Center for Persons with Disabilities, the Florida Statewide Advocacy Council, and the Medicaid Fraud Control Unit, with a clear description of the assistance to be expected from each.

~~(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. 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

971 achieved the minimum-staffing requirements for a period of 6
972 consecutive days. For the purposes of this sub-subparagraph, any
973 person who was a resident of the facility and was absent from
974 the facility for the purpose of receiving medical care at a
975 separate location or was on a leave of absence is not considered
976 a new admission. Failure to impose such an admissions moratorium
977 is subject to a $1,000 fine ~~constitutes a class II deficiency~~.
978 2.~~e.~~ A nursing facility which does not have a conditional
979 license may be cited for failure to comply with the standards in
980 s. 400.23(3)(a)1.b. and c. only if it has failed to meet those
981 standards on 2 consecutive days or if it has failed to meet at
982 least 97 percent of those standards on any one day.
983 3.~~f.~~ A facility which has a conditional license must be in
984 compliance with the standards in s. 400.23(3)(a) at all times.
985 ~~2. This paragraph does not limit the agency's ability to~~
986 ~~impose a deficiency or take other actions if a facility does not~~
987 ~~have enough staff to meet the residents' needs.~~
988 (o)~~(p)~~ Notify a licensed physician when a resident exhibits
989 signs of dementia or cognitive impairment or has a change of
990 condition in order to rule out the presence of an underlying
991 physiological condition that may be contributing to such
992 dementia or impairment. The notification must occur within 30
993 days after the acknowledgment of such signs by facility staff.
994 If an underlying condition is determined to exist, the facility
995 shall arrange, with the appropriate health care provider, the
996 necessary care and services to treat the condition.
997 (p)~~(q)~~ If the facility implements a dining and hospitality
998 attendant program, ensure that the program is developed and
999 implemented under the supervision of the facility director of

nursing. A licensed nurse, licensed speech or occupational therapist, or a registered dietitian must conduct training of dining and hospitality attendants. A person employed by a facility as a dining and hospitality attendant must perform tasks under the direct supervision of a licensed nurse.

~~(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.~~

(q) ~~(s)~~ Maintain general and professional liability insurance coverage that is in force at all times. In lieu of general and professional liability insurance coverage, a state-designated teaching nursing home and its affiliated assisted living facilities created under s. 430.80 may demonstrate proof of financial responsibility as provided in s. 430.80(3)(g).

(r) ~~(t)~~ Maintain in the medical record for each resident a daily chart of certified nursing assistant services provided to the resident. The certified nursing assistant who is caring for the resident must complete this record by the end of his or her shift. This record must indicate assistance with activities of daily living, assistance with eating, and assistance with drinking, and must record each offering of nutrition and hydration for those residents whose plan of care or assessment indicates a risk for malnutrition or dehydration.

(s) ~~(u)~~ Before November 30 of each year, subject to the availability of an adequate supply of the necessary vaccine, provide for immunizations against influenza viruses to all its consenting residents in accordance with the recommendations of

the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Subject to these exemptions, any consenting person who becomes a resident of the facility after November 30 but before March 31 of the following year must be immunized within 5 working days after becoming a resident. Immunization shall not be provided to any resident who provides documentation that he or she has been immunized as required by this paragraph. This paragraph does not prohibit a resident from receiving the immunization from his or her personal physician if he or she so chooses. A resident who chooses to receive the immunization from his or her personal physician shall provide proof of immunization to the facility. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

(t) ~~(v)~~ Assess all residents for eligibility for pneumococcal polysaccharide vaccination (PPV) and vaccinate residents when indicated within 60 days after the effective date of this act in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Residents admitted after the effective date of this act shall be assessed within 5 working days of admission and, when indicated, vaccinated within 60 days in accordance with the recommendations of the United States Centers for Disease Control and Prevention, subject to exemptions for medical contraindications and religious or personal beliefs. Immunization shall not be provided to any resident who provides documentation that he or she has been immunized as required by

this paragraph. This paragraph does not prohibit a resident from receiving the immunization from his or her personal physician if he or she so chooses. A resident who chooses to receive the immunization from his or her personal physician shall provide proof of immunization to the facility. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

(u) ~~(w)~~ Annually encourage and promote to its employees the benefits associated with immunizations against influenza viruses in accordance with the recommendations of the United States Centers for Disease Control and Prevention. The agency may adopt and enforce any rules necessary to comply with or implement this paragraph.

This subsection 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.

(2) Facilities that have been awarded a Gold Seal under the program established in s. 400.235 may develop a plan to provide certified nursing assistant training as prescribed by federal regulations and state rules and may apply to the agency for approval of their program.

(3) A facility may charge a reasonable fee for the copying of resident records. The fee may not exceed $1 per page for the first 25 pages and 25 cents per page for each page in excess of 25 pages.

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. Sections 400.0234, 400.145, and 429.294, Florida Statutes, are repealed.

Section 34. Subsection (9) and subsections (11) through (15) of section 400.147, Florida Statutes, are renumbered as subsections (8) through (13), respectively, and present subsections (7), (8), and (10) of that section are amended to read:

400.147 Internal risk management and quality assurance program.—

(7) The facility shall initiate an investigation ~~and shall notify the agency~~ within 1 business day after the risk manager or his or her designee has received a report pursuant to paragraph (1)(d). Each facility shall complete the investigation and submit a report to the agency within 15 calendar days after an incident is determined to be an adverse incident. ~~The notification must be made in writing and be provided~~

~~electronically, by facsimile device or overnight mail delivery.~~ The agency shall develop a form for reporting this information and the notification must include the name of the risk manager of the facility, information regarding the identity of the affected resident, the type of adverse incident, the initiation of an investigation by the facility, and whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The notification is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each report ~~incident~~ and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

~~(8)(a) Each facility shall complete the investigation and submit an adverse incident report to the agency for each adverse incident within 15 calendar days after its occurrence. If, after a complete investigation, the risk manager determines that the incident was not an adverse incident as defined in subsection (5), the facility shall include this information in the report. The agency shall develop a form for reporting this information.~~

~~(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the~~

~~incidents potentially involved conduct by a health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.~~

~~(c) The report submitted to the agency must also contain the name of the risk manager of the facility.~~

~~(d) The adverse incident report is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board.~~

~~(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, guardian, 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 part.~~

Section 35. Section 400.148, Florida Statutes, is repealed.

Section 36. Paragraph (e) of subsection (2) of section

400.179, Florida Statutes, is 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:

~~(c) 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 6-month 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 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. 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 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 39. 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 2 ~~5~~

years.

Section 40. Subsection (27) of section 400.462, Florida Statutes, is amended to read:

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

(27) "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. However, when the term is used in any provision of law relating to a health care provider, such term does not mean an item with an individual value of up to $15, including, but not limited to, plaques, certificates, trophies, or novelties that are intended solely for presentation or are customarily given away solely for promotional, recognition, or advertising purposes.

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

400.484 Right of inspection; violations ~~deficiencies~~; fines.—

(2) The agency shall impose fines for various classes of violations ~~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 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. Subsections (16) and (17) of section 400.506, Florida Statutes, are renumbered as subsections (17) and (18), respectively, paragraph (a) of subsection (15) is amended, and a new subsection (16) is added to that section, to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(15)(a) The agency may deny, suspend, or revoke the license

of a nurse registry and shall impose a fine of $5,000 against a nurse registry that:

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

2. Provides staffing to an assisted living facility for which the nurse registry does not receive fair market value remuneration.

3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within the last 5 years.

4. Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395 or this chapter and from whom the nurse registry receives referrals. A nurse registry is exempt from this subparagraph if it does not bill the ~~Florida Medicaid program or the~~ Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the ~~Florida Medicaid program or the~~ Medicare program.

5. Gives remuneration to a physician, a member of the physician’s office staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician’s office staff. A nurse registry is exempt from this subparagraph if it does not bill the ~~Florida Medicaid program or the~~ Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408

that bills the ~~Florida Medicaid program or the~~ Medicare program.

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

Section 43. Subsection (1) of section 400.509, Florida Statutes, is amended to read:

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

(1) Any organization that provides companion services or homemaker services and does not provide a home health service to a person is exempt from licensure under this part. However, any organization that provides companion services or homemaker services must register with the agency. An organization under contract with the Agency for Persons with Disabilities that provides companion services only for persons with a developmental disability, as defined in s. 393.063, is exempt from registration.

Section 44. 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 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 45. 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.~~

~~(b) An intentional or negligent act materially affecting the health or safety of a patient.~~

Section 46. 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 and part II of chapter 408.

Section 47. 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 48. Subsection (2) of section 400.931, Florida Statutes, is amended to read:

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

(2) An applicant for initial licensure, change of ownership, or renewal to operate a licensed home medical equipment provider at a location outside the state must submit

documentation of accreditation or an application for accreditation from an accrediting organization that is recognized by the agency. An applicant that has applied for accreditation must provide proof of accreditation that is not conditional or provisional within 120 days after the date the agency receives the application for licensure or the application shall be withdrawn from further consideration. Such accreditation must be maintained by the home medical equipment provider to maintain licensure. ~~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 49. 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 50. Subsection (3) of section 400.967, Florida Statutes, is amended to read:

400.967 Rules and classification of violations ~~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 violations ~~deficiencies~~ shall be classified according to the nature of the violation ~~deficiency~~. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) Class I violations ~~deficiencies~~ are defined in s. 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 violation ~~deficiency~~ is subject to a civil penalty in an amount not less than $5,000 and not exceeding $10,000 for each violation ~~deficiency~~. A fine may be levied notwithstanding the correction of the violation ~~deficiency~~.

(b) Class II violations ~~deficiencies~~ are defined in s. 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 violation ~~deficiency~~ is subject to a civil penalty in an amount not less than $1,000 and not exceeding $5,000 for each violation ~~deficiency~~. A citation for a class II violation ~~deficiency~~ shall specify the time within which the violation ~~deficiency~~ must be corrected. If a class II violation ~~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 51. 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 health service or 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 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 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 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 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.

(l) 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 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

1638 the owners of the entity is a health care practitioner who is
1639 licensed in this state, is responsible for supervising the
1640 business activities of the entity, and is legally responsible
1641 for the entity's compliance with state law for purposes of this
1642 section.
1643 (n) Entities that are owned or controlled, directly or
1644 indirectly, by a publicly traded entity with $100 million or
1645 more, in the aggregate, in total annual revenues derived from
1646 providing health care services by licensed health care
1647 practitioners that are employed or contracted by an entity
1648 described in this paragraph.
1649 (o) Entities that employ 50 or more health care
1650 practitioners licensed under chapter 458 or chapter 459 when the
1651 billing for medical services is under a single tax
1652 identification number. The application for exemption under this
1653 paragraph shall contain information that includes the name,
1654 residence address, business address, and phone number of the
1655 entity that owns the practice; a complete list of the names and
1656 contact information of all the officers and directors of the
1657 entity; the name, residence address, business address, and
1658 medical license number of each licensed Florida health care
1659 practitioner employed by the entity; the corporate tax
1660 identification number of the entity seeking an exemption; a
1661 listing of health care services to be provided by the entity at
1662 the health care clinics owned or operated by the entity and a
1663 certified statement prepared by an independent certified public
1664 accountant which states that the entity and the health care
1665 clinics owned or operated by the entity have not received
1666 payment for health care services under personal injury

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protection insurance coverage for the previous year. If the agency determines that an entity that is exempt under this paragraph has received payments for medical services under personal injury protection insurance coverage the agency may deny or revoke the exemption from licensure under this paragraph.

(7) "Portable health service or equipment provider" means an entity that contracts with or employs persons to provide portable health services or equipment to multiple locations ~~performing treatment or diagnostic testing of individuals~~, that bills third-party payors for those services, and that otherwise meets the definition of a clinic in subsection (4).

Section 52. 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 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 health service or 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 ss. ~~s.~~ 408.810(8) and 408.8065. ~~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 53. 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 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 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 54. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Section 55. 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 56. Paragraph (d) of subsection (1) and paragraph (m) of subsection (3) of section 408.036, Florida Statutes, are 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 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~~.

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(m)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be

eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:

a. A hospital that has received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., and is entitled to immediately commence operation of the program.

b. An otherwise eligible hospital that has not received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to immediately receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., but is not entitled to commence operation of its program until December 31, 2006.

2. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:

a. The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.

b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.

c. The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

d. The applicant can demonstrate that it has discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period as reported to the agency.

e. The applicant is a general acute care hospital that is in operation for 3 years or more.

f. The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.

g. The applicant’s payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.

h. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.

~~3. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption it has received under this paragraph during the calendar year and~~

~~the number of exemptions it has granted or denied during the calendar year.~~

Section 57. Paragraph (c) of subsection (1) of section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

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

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

Section 58. 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 59. 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 perform the following functions:

(k) Develop, in conjunction with the State Consumer Health Information and Policy Advisory Council, and implement a long-range 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 update the plan and report on the status of its implementation annually. 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 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 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.

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 60. 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 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 61. 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 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.

Section 62. 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 63. 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 64. 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 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 65. Paragraph (d) of subsection (2) of section 408.806, Florida Statutes, is amended, and paragraph (e) is added to that subsection, to read:

408.806 License application process.—

(2)

(d) ~~The agency shall notify the licensee by mail or 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 license. If the licensee does not receive the courtesy notice, the licensee continues to be legally obligated to timely file the renewal application and

license 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.

(e) The applicant must pay the late fee before a late application is considered complete and failure to pay the late fee is considered an omission from the application for licensure pursuant to paragraph (3)(b).

Section 66. Paragraph (b) of subsection (1) of section 408.8065, Florida Statutes, is amended to read:

408.8065 Additional licensure requirements for home health agencies, home medical equipment providers, and health care clinics.—

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

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

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

Section 67. Subsections (5) through (8) of section 408.809,

Florida Statutes are renumbered as subsections (6) through (9), respectively, and subsection (4) of that section is amended to read:

408.809 Background screening; prohibited offenses.—

(4) In addition to the offenses listed in s. 435.04, all persons required to undergo background screening pursuant to this part or authorizing statutes must not have an arrest awaiting final disposition for, must not have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, and must not have been adjudicated delinquent and the record not have been sealed or expunged for any of the following offenses or any similar offense of another jurisdiction:

(a) Any authorizing statutes, if the offense was a felony.

(b) This chapter, if the offense was a felony.

(c) Section 409.920, relating to Medicaid provider fraud.

(d) Section 409.9201, relating to Medicaid fraud.

(e) Section 741.28, relating to domestic violence.

(f) Section 817.034, relating to fraudulent acts through mail, wire, radio, electromagnetic, photoelectronic, or photooptical systems.

(g) Section 817.234, relating to false and fraudulent insurance claims.

(h) Section 817.505, relating to patient brokering.

(i) Section 817.568, relating to criminal use of personal identification information.

(j) Section 817.60, relating to obtaining a credit card through fraudulent means.

(k) Section 817.61, relating to fraudulent use of credit

cards, if the offense was a felony.

(l) Section 831.01, relating to forgery.

(m) Section 831.02, relating to uttering forged instruments.

(n) Section 831.07, relating to forging bank bills, checks, drafts, or promissory notes.

(o) Section 831.09, relating to uttering forged bank bills, checks, drafts, or promissory notes.

(p) Section 831.30, relating to fraud in obtaining medicinal drugs.

(q) Section 831.31, relating to the sale, manufacture, delivery, or possession with the intent to sell, manufacture, or deliver any counterfeit controlled substance, if the offense was a felony.

(5) A person who serves as a controlling interest of, is employed by, or contracts with a licensee on July 31, 2010, who has been screened and qualified according to standards specified in s. 435.03 or s. 435.04 must be rescreened by July 31, 2015, in accordance with the schedule provided in paragraphs (a)-(c). ~~The agency may adopt rules to establish a schedule to stagger the implementation of the required rescreening over the 5-year period, beginning July 31, 2010, through July 31, 2015.~~ If, upon rescreening, such person has a disqualifying offense that was not a disqualifying offense at the time of the last screening, but is a current disqualifying offense and was committed before the last screening, he or she may apply for an exemption from the appropriate licensing agency and, if agreed to by the employer, may continue to perform his or her duties until the licensing agency renders a decision on the application for

exemption if the person is eligible to apply for an exemption and the exemption request is received by the agency within 30 days after receipt of the rescreening results by the person. The rescreening schedule shall be:

(a) Individuals whose last screening was conducted before December 31, 2003, must be rescreened by July 31, 2013.

(b) Individuals whose last screening was conducted between January 1, 2004, through December 31, 2007, must be rescreened by July 31, 2014.

(c) Individuals whose last screening was conducted between January 1, 2008, through July 31, 2010, must be rescreened by July 31, 2015.

Section 68. Subsection (9) of section 408.810, Florida Statutes, is 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.

(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 69. 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 is not designated 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.

(c) Exceeding licensed capacity.

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

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

Section 70. Subsection (4) of section 408.815, Florida Statutes, is amended, and subsections (5) and (6) are added to that section, to read:

408.815 License or application denial; revocation.—

(4) Unless an applicant is determined by the agency to satisfy the provisions of subsection (5) for the action in question, the agency shall deny an application for a license or license renewal based upon any of the following actions of an

applicant, a controlling interest of the applicant, or any entity in which a controlling interest of the applicant was an owner or officer when the following actions occurred ~~In addition to the grounds provided in authorizing statutes, the agency shall deny an application for a license or license renewal if the applicant or a person having a controlling interest in an applicant has been~~:

(a) Conviction ~~Convicted~~ of~~,~~ or ~~enters~~ a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, Medicare fraud, Medicaid fraud, or insurance fraud, unless the sentence and any subsequent period of probation for such convictions or plea ended more than 15 years prior to the date of the application;

(b) Termination ~~Terminated~~ for cause from the Medicare program or a state ~~Florida~~ Medicaid program ~~pursuant to s. 409.913~~, unless the applicant has been in good standing with the Medicare program or a state ~~Florida~~ Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.~~; or~~

~~(c) Terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from the federal Medicare program or from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to the date of the application.~~

(5) For any application subject to denial under subsection (4), the agency may consider mitigating circumstances, as

applicable, including, but not limited to:

(a) Completion or lawful release from confinement, supervision, or sanction, including any terms of probation, and full restitution;

(b) Execution of a compliance plan with the agency;

(c) Compliance with any integrity agreement or compliance plan with any other government agency;

(d) Determination by the Medicare program or a state Medicaid program that the controlling interest or entity in which the controlling interest was an owner or officer is currently allowed to participate in the Medicare program or a state Medicaid program, either directly as a provider or indirectly as an owner or officer of a provider entity;

(e) Continuation of licensure by the controlling interest or entity in which the controlling interest was an owner or officer, either directly as a licensee or indirectly as an owner or officer of a licensed entity in the state where the action occurred;

(f) Overall impact upon the public health, safety, or welfare; or

(g) Determination that license denial is not commensurate with the prior action taken by the Medicare program or a state Medicaid program.

After considering the circumstances set forth in this subsection, the agency shall grant the license, with or without conditions, grant a provisional license for a period of no more than the licensure cycle, with or without conditions, or deny the license.

(6) 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. When 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 71. Paragraph (c) of subsection (4) of section 409.212, Florida Statutes, is amended to read:

409.212 Optional supplementation.—

(4) In addition to the amount of optional supplementation provided by the state, a person may receive additional supplementation from third parties to contribute to his or her cost of care. Additional supplementation may be provided under the following conditions:

(c) The additional supplementation shall not exceed three ~~two~~ times the provider rate recognized under the optional state supplementation program.

Section 72. 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 73. Paragraph (b) of subsection (4), paragraph (a) of subsection (39), and subsection (41) of section 409.912, Florida Statutes, are 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 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 provider credentialing. The agency may competitively bid single-source-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 long-term 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.

(4) The agency may contract with:

(b) An entity that is providing comprehensive behavioral health care services to certain Medicaid recipients through a capitated, prepaid arrangement pursuant to the federal waiver provided for by s. 409.905(5). Such entity must be licensed under chapter 624, chapter 636, or chapter 641, or authorized under paragraph (c) or paragraph (d), and must possess the clinical systems and operational competence to manage risk and provide comprehensive behavioral health care to Medicaid recipients. As used in this paragraph, the term "comprehensive behavioral health care services" means covered mental health and substance abuse treatment services that are available to

Medicaid recipients. The secretary of the Department of Children and Family Services shall approve provisions of procurements related to children in the department's care or custody before enrolling such children in a prepaid behavioral health plan. Any contract awarded under this paragraph must be competitively procured. In developing the behavioral health care prepaid plan procurement document, the agency shall ensure that the procurement document requires the contractor to develop and implement a plan to ensure compliance with s. 394.4574 related to services provided to residents of licensed assisted living facilities that hold a limited mental health license. Except as provided in subparagraph 8., and except in counties where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211, the agency shall seek federal approval to contract with a single entity meeting these requirements to provide comprehensive behavioral health care services to all Medicaid recipients not enrolled in a Medicaid managed care plan authorized under s. 409.91211, a provider service network authorized under paragraph (d), or a Medicaid health maintenance organization in an AHCA area. In an AHCA area where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211 in one or more counties, the agency may procure a contract with a single entity to serve the remaining counties as an AHCA area or the remaining counties may be included with an adjacent AHCA area and are subject to this paragraph. Each entity must offer a sufficient choice of providers in its network to ensure recipient access to care and the opportunity to select a provider with whom they are satisfied. The network shall include all public mental health hospitals. To ensure

unimpaired access to behavioral health care services by Medicaid recipients, all contracts issued pursuant to this paragraph must require 80 percent of the capitation paid to the managed care plan, including health maintenance organizations and capitated provider service networks, to be expended for the provision of behavioral health care services. If the managed care plan expends less than 80 percent of the capitation paid for the provision of behavioral health care services, the difference shall be returned to the agency. The agency shall provide the plan with a certification letter indicating the amount of capitation paid during each calendar year for behavioral health care services pursuant to this section. The agency may reimburse for substance abuse treatment services on a fee-for-service basis until the agency finds that adequate funds are available for capitated, prepaid arrangements.

1. By January 1, 2001, the agency shall modify the contracts with the entities providing comprehensive inpatient and outpatient mental health care services to Medicaid recipients in Hillsborough, Highlands, Hardee, Manatee, and Polk Counties, to include substance abuse treatment services.

2. By July 1, 2003, the agency and the Department of Children and Family Services shall execute a written agreement that requires collaboration and joint development of all policy, budgets, procurement documents, contracts, and monitoring plans that have an impact on the state and Medicaid community mental health and targeted case management programs.

3. Except as provided in subparagraph 8., by July 1, 2006, the agency and the Department of Children and Family Services shall contract with managed care entities in each AHCA area

except area 6 or arrange to provide comprehensive inpatient and outpatient mental health and substance abuse services through capitated prepaid arrangements to all Medicaid recipients who are eligible to participate in such plans under federal law and regulation. In AHCA areas where eligible individuals number less than 150,000, the agency shall contract with a single managed care plan to provide comprehensive behavioral health services to all recipients who are not enrolled in a Medicaid health maintenance organization, a provider service network authorized under paragraph (d), or a Medicaid capitated managed care plan authorized under s. 409.91211. The agency may contract with more than one comprehensive behavioral health provider to provide care to recipients who are not enrolled in a Medicaid capitated managed care plan authorized under s. 409.91211, a provider service network authorized under paragraph (d), or a Medicaid health maintenance organization in AHCA areas where the eligible population exceeds 150,000. In an AHCA area where the Medicaid managed care pilot program is authorized pursuant to s. 409.91211 in one or more counties, the agency may procure a contract with a single entity to serve the remaining counties as an AHCA area or the remaining counties may be included with an adjacent AHCA area and shall be subject to this paragraph. Contracts for comprehensive behavioral health providers awarded pursuant to this section shall be competitively procured. Both for-profit and not-for-profit corporations are eligible to compete. Managed care plans contracting with the agency under subsection (3) or paragraph (d), shall provide and receive payment for the same comprehensive behavioral health benefits as provided in AHCA rules, including handbooks incorporated by

reference. In AHCA area 11, the agency shall contract with at least two comprehensive behavioral health care providers to provide behavioral health care to recipients in that area who are enrolled in, or assigned to, the MediPass program. One of the behavioral health care contracts must be with the existing provider service network pilot project, as described in paragraph (d), for the purpose of demonstrating the cost-effectiveness of the provision of quality mental health services through a public hospital-operated managed care model. Payment shall be at an agreed-upon capitated rate to ensure cost savings. Of the recipients in area 11 who are assigned to MediPass under s. 409.9122(2)(k), a minimum of 50,000 of those MediPass-enrolled recipients shall be assigned to the existing provider service network in area 11 for their behavioral care.

4. By October 1, 2003, the agency and the department shall submit a plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives which provides for the full implementation of capitated prepaid behavioral health care in all areas of the state.

a. Implementation shall begin in 2003 in those AHCA areas of the state where the agency is able to establish sufficient capitation rates.

b. If the agency determines that the proposed capitation rate in any area is insufficient to provide appropriate services, the agency may adjust the capitation rate to ensure that care will be available. The agency and the department may use existing general revenue to address any additional required match but may not over-obligate existing funds on an annualized basis.

c. Subject to any limitations provided in the General Appropriations Act, the agency, in compliance with appropriate federal authorization, shall develop policies and procedures that allow for certification of local and state funds.

5. Children residing in a statewide inpatient psychiatric program, or in a Department of Juvenile Justice or a Department of Children and Family Services residential program approved as a Medicaid behavioral health overlay services provider may not be included in a behavioral health care prepaid health plan or any other Medicaid managed care plan pursuant to this paragraph.

6. In converting to a prepaid system of delivery, the agency shall in its procurement document require an entity providing only comprehensive behavioral health care services to prevent the displacement of indigent care patients by enrollees in the Medicaid prepaid health plan providing behavioral health care services from facilities receiving state funding to provide indigent behavioral health care, to facilities licensed under chapter 395 which do not receive state funding for indigent behavioral health care, or reimburse the unsubsidized facility for the cost of behavioral health care provided to the displaced indigent care patient.

7. Traditional community mental health providers under contract with the Department of Children and Family Services pursuant to part IV of chapter 394, child welfare providers under contract with the Department of Children and Family Services in areas 1 and 6, and inpatient mental health providers licensed pursuant to chapter 395 must be offered an opportunity to accept or decline a contract to participate in any provider network for prepaid behavioral health services.

8. All Medicaid-eligible children, except children in area 1 and children in Highlands County, Hardee County, Polk County, or Manatee County of area 6, that are open for child welfare services in the HomeSafeNet system, shall receive their behavioral health care services through a specialty prepaid plan operated by community-based lead agencies through a single agency or formal agreements among several agencies. The agency shall work with the specialty plan to develop clinically effective, evidence-based alternatives as a downward substitution for the statewide inpatient psychiatric program and similar residential care and institutional services. The specialty prepaid plan must result in savings to the state comparable to savings achieved in other Medicaid managed care and prepaid programs. Such plan must provide mechanisms to maximize state and local revenues. The specialty prepaid plan shall be developed by the agency and the Department of Children and Family Services. The agency may seek federal waivers to implement this initiative. Medicaid-eligible children whose cases are open for child welfare services in the HomeSafeNet system and who reside in AHCA area 10 are exempt from the specialty prepaid plan upon the development of a service delivery mechanism for children who reside in area 10 as specified in s. 409.91211(3)(dd).

(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

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)

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.

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

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.

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

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 guaranteed 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

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

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.

2798 12.~~11.~~a. The agency shall implement a Medicaid prescription
2799 drug management system. The agency may contract with a vendor
2800 that has experience in operating prescription drug management
2801 systems in order to implement this system. Any management system
2802 that is implemented in accordance with this subparagraph must
2803 rely on cooperation between physicians and pharmacists to
2804 determine appropriate practice patterns and clinical guidelines
2805 to improve the prescribing, dispensing, and use of drugs in the
2806 Medicaid program. The agency may seek federal waivers to
2807 implement this program.
2808 b. The drug management system must be designed to improve
2809 the quality of care and prescribing practices based on best
2810 practice guidelines, improve patient adherence to medication
2811 plans, reduce clinical risk, and lower prescribed drug costs and
2812 the rate of inappropriate spending on Medicaid prescription
2813 drugs. The program must:
2814 (I) Provide for the development and adoption of best
2815 practice guidelines for the prescribing and use of drugs in the
2816 Medicaid program, including translating best practice guidelines
2817 into practice; reviewing prescriber patterns and comparing them
2818 to indicators that are based on national standards and practice
2819 patterns of clinical peers in their community, statewide, and
2820 nationally; and determine deviations from best practice
2821 guidelines.
2822 (II) Implement processes for providing feedback to and
2823 educating prescribers using best practice educational materials
2824 and peer-to-peer consultation.
2825 (III) Assess Medicaid recipients who are outliers in their
2826 use of a single or multiple prescription drugs with regard to

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

(IV) Alert prescribers to 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

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 shall accept electronic prior authorization requests from prescribers or pharmacists for any drug requiring prior authorization and ~~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 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 step-therapy 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 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.

(41) The agency shall establish ~~provide for the development of~~ a demonstration project ~~by establishment~~ in Miami-Dade County of a long-term-care facility licensed and a psychiatric facility pursuant to chapter 395 to improve access to health care for a predominantly minority, medically underserved, and medically complex population and to evaluate alternatives to nursing home care and general acute care for such population. Such project is to be located in a health care condominium and collocated ~~colocated~~ with licensed facilities providing a continuum of care. These projects are ~~The establishment of this project is~~ not subject to the provisions of s. 408.036 or s. 408.039.

Section 74. Subsection (3) and paragraph (c) of subsection (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 a facility ~~facilities~~ providing one or more of the personal services identified in s. 429.02. Such licensee ~~facilities~~ may also employ or contract with a person ~~licensed under part I of chapter 464~~ to ~~administer medications and~~ perform other tasks as specified in s. 429.255.

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

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

care services must have maintained a standard license and ~~may~~ not ~~have~~ 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 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 which results in requiring the facility to employ the services of a consultant pharmacist or consultant dietitian;

e. Denial, suspension, or revocation of a license for another facility licensed 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 facility that is licensed to provide extended congregate care services shall maintain a written progress report for ~~on~~ each person who receives services which 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 the facility at least quarterly to monitor residents who are receiving extended congregate care services~~

~~and to determine if the facility is in compliance with this part, part II of chapter 408, and relevant rules. One of the 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 the 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 violations and no uncorrected class III violations. The agency must first 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. A facility that is licensed to provide extended congregate care services must:

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.

d. Adopt and follow policies and procedures that maximize resident independence, dignity, choice, and decisionmaking to permit residents to age in place, 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.

f. Implement the concept of managed risk.

g. Provide, directly or through contract, the services of a person licensed under 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. A facility that is licensed to provide extended congregate care services is exempt from the criteria for continued residency set forth in rules adopted under s. 429.41. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, the facility may not serve residents who require 24-hour nursing supervision. A licensed facility that provides extended congregate care services must also 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 the 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 individual.

7. When a licensee ~~facility~~ can no longer provide or arrange for services in accordance with the resident's service plan and needs and the licensee's ~~facility's~~ policy, the licensee ~~facility~~ 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.

~~(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 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.

~~(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 agency's standard licensure 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 monitoring activities during the 12-month period following the violation.

Section 75. Subsection (2) of section 429.075, Florida Statutes, is amended to read:

429.075 Limited mental health license.—An assisted living facility that serves three or more mental health residents must obtain a limited mental health license.

(2) Facilities licensed to provide services to mental health residents shall provide appropriate supervision and staffing to provide for the health, safety, and welfare of such residents. In a municipality having a population of more than 300,000 residents, an assisted living facility or a community residential home located within an area zoned as a residential area must maintain 24-hour security services if the assisted living facility or a community residential home has:

(a) Residents who are identified as being part of a priority population; and

(b) Adult residents and adolescent residents who have severe and persistent mental illnesses or substance abuse disorders as described in s. 394.674.

Section 76. 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 77. 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 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 78. Subsection (5) of section 429.14, Florida Statutes, is amended to read:

429.14 Administrative penalties.—

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

Section 79. 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 congregate care ~~or limited nursing license~~ 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 period. The fee shall be calculated as of the date the additional license application is received by the agency.

Section 80. Section 429.195, Florida Statutes, is amended to read:

429.195 Rebates prohibited; penalties.—

(1) It is unlawful for any assisted living facility

licensed under this part to contract or promise to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any health care provider or health care facility pursuant to s. 817.505 ~~physician, surgeon, organization, agency, or person, either directly or indirectly, for residents referred to an assisted living facility licensed under this part~~. ~~A facility may employ or contract with persons to market the facility, provided the employee or contract provider clearly indicates that he or she represents the facility. A person or agency independent of the facility may provide placement or referral services for a fee to individuals seeking assistance in finding a suitable facility; however, any fee paid for placement or referral services must be paid by the individual looking for a facility, not by the facility.~~

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

(3) This section does not apply to:

(a) An individual employed by the facility, or with whom the facility contracts to market the facility, if the employee or contract provider clearly indicates that he or she works with or for the facility.

(b) A referral service that provides information, consultation, or referrals to consumers to assist them in finding appropriate care or housing options for seniors or disabled adults, provided that such referred consumers are not Medicaid recipients.

(c) Residents of an assisted living facility who refer friends, family members, or other individuals with whom they

have a personal relationship to the assisted living facility, and does not prohibit the assisted living facility from providing a monetary reward to the resident for making such a referral.

Section 81. 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 82. Paragraph (a) of subsection (1) and subsection (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~~,~~ 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, guardian, 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 and as required by rule and for 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 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 83. Subsections (4), (5), (6), and (7) of section 429.28, Florida Statutes, are renumbered as subsections (3), (4), (5), and (6), respectively, and present subsections (3) and (6) of that section are 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.~~

(5) ~~(6)~~ Any facility which terminates the residency of an individual who participated in activities specified in subsection (4) ~~(5)~~ shall show good cause in a court of competent jurisdiction.

Section 84. Subsections (4) and (5) of section 429.41, Florida Statutes, are renumbered as subsections (3) and (4), respectively, and paragraphs (i) and (j) of subsection (1) and present subsection (3) of that section 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 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.

~~(3) The department shall submit a copy of proposed rules to the Speaker of the House of Representatives, the President of the Senate, and appropriate committees of substance for review and comment prior to the promulgation thereof. Rules promulgated by the department shall encourage the development of homelike~~

~~facilities which promote the dignity, individuality, personal strengths, and decisionmaking ability of residents.~~

Section 85. 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; and

~~(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 such approvals;~~

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

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

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

Section 86. Subsections (1) and (2) of section 429.54, Florida Statutes, are renumbered as subsections (2) and (3),

respectively, and subsection (1) is added to that section, to read:

429.54 Collection of information; local subsidy.—

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

Section 87. Subsection (6) of section 429.71, Florida Statutes, is renumbered as subsection (5), and subsection (1) and present subsection (5) of that section are amended to read:

429.71 Classification of violations ~~deficiencies~~; administrative fines.—

(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 defined in s. 408.813 ~~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 defined in s. 408.813 ~~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.~~

(c) Class III violations are defined in s. 408.813 ~~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 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 defined in s. 408.813 ~~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.~~

Section 88. 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 89. Paragraphs (b) and (g) 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:

(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~~, or, at the time of initial designation, possess a Gold Seal Award as conferred by the state on its licensed nursing home;

(g) 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 90. Paragraph (d) of subsection (9) of section 440.102, Florida Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(9) DRUG-TESTING STANDARDS FOR LABORATORIES.—

~~(d) The laboratory shall submit to the Agency for Health Care Administration a monthly report with statistical information regarding the testing of employees and job applicants. The report must include information on the methods of analysis conducted, the drugs tested for, the number of positive and negative results for both initial tests and confirmation tests, and any other information deemed appropriate by the Agency for Health Care Administration. A monthly report must not identify specific employees or job applicants.~~

Section 91. 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.—

(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.

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 92. Paragraph (h) of subsection (3) of section 456.053, Florida Statutes, is amended to read:

456.053 Financial arrangements between referring health care providers and providers of health care services.—

(3) DEFINITIONS.—For the purpose of this section, the word, phrase, or term:

(h) "Group practice" means a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:

1.a. In which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

b.~~2.~~ For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and

c.~~3.~~ In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.

2. If the group provides radiation therapy services:

a. The group accepts and treats cancer patients under provider contracts for medical services under s. 409.912 for Medicaid;

b. The group provides the full range of radiation therapy services such that no single type of cancer, either as a primary or secondary diagnosis and as described by the International Statistical Classification of Diseases, shall constitute 40 percent or more of the group's cases for professional and technical services for radiation therapy services, where a case is defined as an individual patient's radiation treatment course; and

c. The health care providers other than physicians specializing in the provision of radiation therapy services or medical oncology services shall not own 50 percent or more of the group practice.

Section 93. Subsection (1) of section 483.035, Florida Statutes, is amended to read:

483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—

(1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.

Section 94. Subsections (1) and (9) of section 483.051, Florida Statutes, are amended to read:

483.051 Powers and duties of the agency.—The agency shall adopt rules to implement this part, which rules must include, but are not limited to, the following:

(1) LICENSING; QUALIFICATIONS.—The agency shall provide for biennial licensure of all nonwaived clinical laboratories meeting the requirements of this part and shall prescribe the qualifications necessary for such licensure, including, but not limited to, application for or proof of a federal Clinical Laboratory Improvement Amendment (CLIA) certificate. For purposes of this section, the term "nonwaived clinical

laboratories" means laboratories that perform any test that the Centers for Medicare and Medicaid Services has determined does not qualify for a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 and the federal rules adopted thereunder.

(9) ALTERNATE-SITE TESTING.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt, by rule, the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The elements to be addressed in the rule include, but are not limited to: a hospital internal needs assessment; a protocol of implementation including tests to be performed and who will perform the tests; criteria to be used in selecting the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training as well as initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for identifying and tracking alternate-site testing by the central laboratory; and recordkeeping requirements. ~~Alternate-site testing locations must register when the clinical laboratory applies to renew its license.~~ For purposes of this subsection, the term "alternate-site testing" means any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

Section 95. 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 96. Paragraph (a) of subsection (54) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(54) "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 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.

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 e.

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 97. 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 98. 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.—

(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 99. Subsection (3) of section 627.669, Florida Statutes, is amended to read:

627.669 Optional coverage required for substance abuse impaired persons; exception.—

(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 100. 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 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 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 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 101. 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 State Fire Marshal 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 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. Except as provided in s. 633.082(2), 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) Except as provided in s. 633.082(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;

(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 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 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 Division of State Fire Marshal and the Florida Building Code Administrators and Inspectors Board, established pursuant to s. 468.605, shall enter into a reciprocity agreement to facilitate joint recognition of continuing education recertification hours for certificateholders licensed under s. 468.609 and firesafety inspectors certified under subsection (2).

(8) The State Fire Marshal shall develop by rule an advanced training and certification program for firesafety inspectors having fire code management responsibilities. The program must be consistent with the appropriate provisions of NFPA 1037, or similar standards adopted by the division, and establish minimum training, education, and experience levels for firesafety inspectors having fire code management responsibilities.

(9) The department shall provide by rule for the certification of firesafety inspectors.

Section 102. 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 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 103. 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) ~~(o)~~1.~~d.~~

Section 104. 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 105. Subsection (4) of section 766.202, Florida Statutes, is amended to read:

766.202 Definitions; ss. 766.201-766.212.—As used in ss. 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 106. Paragraph (j) is added to subsection (3) of section 817.505, Florida Statutes, to read:

817.505 Patient brokering prohibited; exceptions; penalties.—

(3) This section shall not apply to:

(j) Any payments by an assisted living facility, as defined in s. 429.02, or any agreement for or solicitation, offer, or receipt of such payment by a referral service, which is permitted under s. 429.195(3).

Section 107. The per-bed standard assisted living facility licensure fees, including the total fee, have been adjusted by the Consumer Price Index annually since 1998 and are not intended to be reset by this act. In addition to the Consumer Price Index adjustment, the per-bed fee is increased by $9 to neutralize the elimination of the limited nursing services specialty license fee.

Section 108. Section 381.06014, Florida Statutes, is amended to read:

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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. A person, entity, or organization that uses a mobile unit to conduct such activities within the state is also a blood establishment.

(b) "Volunteer donor" means a person who does not receive 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. s. 606.121.

(2) Any blood establishment operating in the state may not conduct any activity defined in paragraph (1)(a) ~~subsection (1)~~ unless that blood establishment is operated in a manner consistent with the provisions of Title 21 C.F.R. 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 C.F.R. 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 is ~~shall be~~ in violation of this chapter and must

~~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 C.F.R. 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 local government may not restrict the access to or use of any public facility or infrastructure for the collection of blood or blood components from volunteer donors based on whether the blood establishment is operating as a for-profit organization or not-for-profit organization.

(6) In determining the service fee of blood or blood components received from volunteer donors and sold to hospitals or other health care providers, a blood establishment may not base the service fee of the blood or blood component solely on whether the purchasing entity is a for-profit organization or not-for-profit organization.

(7) A blood establishment that collects blood or blood components from volunteer donors must disclose on the Internet the information required under this subsection to educate and inform donors and the public about the blood establishment's activities. A hospital that collects blood or blood components to be used only by that hospital's licensed facilities or by a health care provider that is a part of the hospital's 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. A blood establishment must disclose on its website all of the following information:

(a) A description of the steps involved in collecting, processing, and distributing volunteer donations.

(b) By March 1 of each year, the number of units of blood components which 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 calendar 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 reported in the aggregate for health care providers located within the United States and its territories or outside the United States and its territories; and

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

(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 occurs to any of these documents, the revised document must be available on the blood establishment's website by the following March 1.

(d) Except for a hospital that collects blood or blood components from volunteer donors:

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 60 calendar days after it is filed 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, and statement of changes in cash flow, along with 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 blood establishment's fiscal year and must remain on the blood establishment's website for at least 36 months.

(8) A blood establishment is liable for a civil penalty for failing to make the disclosures required under subsection (7). The Department of Legal Affairs may assess the civil penalty against the blood establishment for each day that it fails to make such required disclosures, but the penalty may not exceed $10,000 per year. If multiple blood establishments operated by a single business entity fail to meet such disclosure requirements, the civil penalty may be assessed against only one of the business entity's blood establishments. The Department of

Legal Affairs may terminate an action if the blood establishment agrees to pay a stipulated civil penalty. A civil penalty so collected accrues to the state and shall be deposited as received into the General Revenue Fund unallocated. The Department of Legal Affairs may terminate the action and waive the civil penalty upon a showing of good cause by the blood establishment as to why the required disclosures were not made.

Section 109. Subsection (23) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in 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 establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

Section 110. 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; or

(b) Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

Section 111. Paragraphs (a), (g), and (t) 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, which ~~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(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

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

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

a. Any person located in this state that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.~~1.~~ Any ~~A~~ person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction ~~must obtain 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 which 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(54)(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;

(IV) Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V) To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of either a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

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 required to be 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 sub-subparagraph 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.

(t) *Health care clinic establishment permit.*—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the

health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license. A professional corporation or limited liability company composed of dentists and operating as authorized in s. 466.0285 may pay for prescription drugs obtained by a practitioner licensed under chapter 466, and the licensed practitioner is deemed the purchaser and owner of the prescription drugs.

Section 112. Subsection (6) of section 474.202, Florida Statutes, is amended to read:

474.202 Definitions.—As used in this chapter:

(6) "Limited-service veterinary vaccination clinic ~~medical practice~~" means a veterinary practice at which a veterinarian performs vaccinations or immunizations on multiple animals at a temporary location and operates for a limited time ~~offering or providing veterinary services at any location that has a primary purpose other than that of providing veterinary medical service at a permanent or mobile establishment permitted by the board; provides veterinary medical services for privately owned animals that do not reside at that location; operates for a limited time; and provides limited types of veterinary medical services~~.

Section 113. Subsection (7) of section 474.215, Florida Statutes, is amended to read:

474.215 Premises permits.—

(7) The board by rule shall establish minimum standards for the operation of limited service veterinary vaccination clinics ~~medical practices~~. Such rules shall ~~not restrict limited service veterinary medical practices and shall~~ be consistent with the type of limited veterinary vaccination and immunization services ~~medical service~~ provided.

(a) Any person that offers or provides limited service veterinary vaccination clinics ~~medical practice~~ shall obtain a biennial permit from the board the cost of which shall not exceed $250. The limited service permittee shall register each location where a limited service veterinary vaccination clinic is held and shall pay a fee set by rule not to exceed $25 to register each such location.

(b) All permits issued under this subsection are subject to the provisions of ss. 474.213 and 474.214.

(c) Notwithstanding any provision of this subsection to the contrary, any temporary rabies vaccination effort operated by a county health department in response to a public health threat, as declared by the State Health Officer in consultation with the State Veterinarian, is not subject to any preregistration, time limitation, or fee requirements, but must adhere to all other requirements for limited service veterinary vaccination clinics ~~medical practice~~ as prescribed by rule. The fee charged to the public for a rabies vaccination administered during such temporary rabies vaccination effort may not exceed the actual cost of administering the rabies vaccine. Such rabies vaccination efforts may not be used for any purpose other than to address the public health consequences of the rabies outbreak. The board shall be immediately notified in writing of any temporary rabies vaccination effort operated under this paragraph.

Section 114. Section 455.2185, Florida Statutes, is amended to read:

455.2185 Exemption for certain out-of-state or foreign professionals; limited practice permitted.—

(1) A professional of any other state or of any territory or other jurisdiction of the United States or of any other nation or foreign jurisdiction is exempt from the requirements of licensure under this chapter and the applicable professional practice act under the agency with regulatory jurisdiction over the profession if that profession is regulated in this state under the agency with regulatory jurisdiction over the profession and if that person:

(a) Holds, if so required in the jurisdiction in which that

person practices, an active license to practice that profession.

(b) Engages in the active practice of that profession outside the state.

(c) Is employed or designated in that professional capacity by a sports entity visiting the state for a specific sporting event.

(2) A professional's practice under this section is limited to the members, coaches, and staff of the team for which that professional is employed or designated ~~and to any animals used if the sporting event for which that professional is employed or designated involves animals~~. ~~A professional practicing under authority of this section shall not have practice privileges in any licensed veterinary facility without the approval of that facility.~~

Section 115. Section 456.023, Florida Statutes, is amended to read:

456.023 Exemption for certain out-of-state or foreign professionals; limited practice permitted.—

(1) A professional of any other state or of any territory or other jurisdiction of the United States or of any other nation or foreign jurisdiction is exempt from the requirements of licensure under this chapter and the applicable professional practice act under the agency with regulatory jurisdiction over the profession if that profession is regulated in this state under the agency with regulatory jurisdiction over the profession and if that person:

(a) Holds, if so required in the jurisdiction in which that person practices, an active license to practice that profession.

(b) Engages in the active practice of that profession

outside the state.

(c) Is employed or designated in that professional capacity by a sports entity visiting the state for a specific sporting event.

(2) A professional's practice under this section is limited to the members, coaches, and staff of the team for which that professional is employed or designated ~~and to any animals used if the sporting event for which that professional is employed or designated involves animals~~. A professional practicing under authority of this section shall not have practice privileges in any licensed health care facility ~~or veterinary facility without the approval of that facility~~.

Section 116. Section 456.0635, Florida Statutes, is amended to read:

456.0635 Health care ~~Medicaid~~ fraud; disqualification for license, certificate, or registration.—

(1) ~~Medicaid~~ Fraud in the practice of a health care profession is prohibited.

(2) Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue ~~or renew~~ a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant~~, has been~~:

(a) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction ~~21 U.S.C. ss.~~

~~801-970, or 42 U.S.C. ss. 1395-1396~~, unless the sentence and any subsequent period of probation for such conviction or plea ~~pleas~~ ended: ~~more than 15 years prior to the date of the application;~~

1. For felonies of the first or second degree, more than 15 years before the date of application.

2. For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3. For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application.

Notwithstanding s. 120.60, for felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the board, or the department if there is no board, may not approve or deny the application for a license, certificate, or registration until the final resolution of the case;

(b) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c) ~~(b)~~ Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d) ~~(c)~~ Has been terminated for cause, pursuant to the appeals procedures established by the state ~~or Federal~~

4538 ~~Government~~, from any other state Medicaid program ~~or the federal~~
4539 ~~Medicare program~~, unless the applicant has been in good standing
4540 with a state Medicaid program ~~or the federal Medicare program~~
4541 for the most recent 5 years and the termination occurred at
4542 least 20 years before ~~prior to~~ the date of the application; or~~.~~
4543 (e) Is currently listed on the United States Department of
4544 Health and Human Services Office of Inspector General's List of
4545 Excluded Individuals and Entities.
4546
4547 This subsection does not apply to applicants for initial
4548 licensure or certification who were enrolled in an educational
4549 or training program on or before July 1, 2010, which was
4550 recognized by a board or, if there is no board, recognized by
4551 the department, and who applied for licensure after July 1,
4552 2010.
4553 (3) The department shall refuse to renew a license,
4554 certificate, or registration of any applicant if the candidate
4555 or applicant or any principal, officer, agent, managing
4556 employee, or affiliated person of the applicant:
4557 (a) Has been convicted of, or entered a plea of guilty or
4558 nolo contendere to, regardless of adjudication, a felony under:
4559 chapter 409, chapter 817, or chapter 893, or a similar felony
4560 offense committed in another state or jurisdiction since July 1,
4561 2010.
4562 (b) Has been convicted of, or entered a plea of guilty or
4563 nolo contendere to, regardless of adjudication, a felony under
4564 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1,
4565 2010.
4566 (c) Has been terminated for cause from the Florida Medicaid

program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department may not approve or deny the application for a renewal of a license, certificate, or registration until the final resolution of the case.

(4) ~~(3)~~ Licensed health care practitioners shall report allegations of health care ~~Medicaid~~ fraud to the department, regardless of the practice setting in which the alleged Medicaid fraud occurred.

(5) ~~(4)~~ The acceptance by a licensing authority of a candidate's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care ~~Medicaid~~ fraud or similar charges constitutes the permanent revocation of the license.

Section 117. Subsection (6) of section 456.036, Florida

Statutes, is amended to read:

456.036 Licenses; active and inactive status; delinquency.—

(6)(a) Except as provided in paragraph (b), a delinquent licensee must affirmatively apply with a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle in which a licensee becomes delinquent. Failure by a delinquent licensee to become active or inactive before the expiration of the current licensure cycle renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on an applicant for new licensure.

(b) A delinquent licensee whose license becomes delinquent before the final resolution of a case under s. 456.0635(3) must affirmatively apply by submitting a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle in which the case achieves final resolution by order of the court. Failure by a delinquent licensee to become active or inactive before the expiration of that licensure cycle renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on an applicant for new licensure.

Section 118. Subsection (9) is added to section 465.014, Florida Statutes, to read:

465.014 Pharmacy technician.—

(9) This section does not apply to a practitioner

authorized to dispense drugs under s. 465.0276 or a medical assistant or licensed health care professional under the direct supervision of such practitioner if the practitioner is treating a patient who provides proof of insurance through a public-payer or private-payer source. The exemption provided by this subsection applies only to medical personnel under the direct supervision of the dispensing practitioner while dispensing in the practitioner's office.

Section 119. Section 627.6011, Florida Statutes, is created to read:

627.6011 Mandated coverages.—Mandatory health benefits regulated by this chapter which must be covered by an insurer are intended to apply only to the types of health benefit plans defined in s. 627.6699(3)(k), issued in any market, unless specifically designated. As used in this section, the term "mandatory health benefits" means benefits provided in ss. 627.6401-627.64193 and any cross-references to such sections, or any other mandatory treatments, health coverages, or benefits enacted after the effective date of this act.

Section 120. Subsection (3) is added to section 766.110, Florida Statutes, to read:

766.110 Liability of health care facilities.—

(3) To ensure comprehensive risk management for diagnosis of disease, a health care facility, including a hospital or ambulatory surgical center, as defined in chapter 395, may use scientific diagnostic disease methodologies that use information regarding specific diseases in health care facilities and that are adopted by the facility's medical review committee.

Section 121. This act shall take effect July 1, 2011.

4654
4655 ================ T I T L E A M E N D M E N T ================
4656 And the title is amended as follows:
4657 Delete everything before the enacting clause
4658 and insert:
4659 A bill to be entitled
4660 An act relating to health care; amending s. 83.42,
4661 F.S., establishing that s. 400.0255, F.S., provides
4662 exclusive procedures for resident transfer and
4663 discharge; amending s. 112.0455, F.S., relating to the
4664 Drug-Free Workplace Act; deleting an obsolete
4665 provision; deleting a requirement that a laboratory
4666 that conducts drug tests submit certain reports to the
4667 Agency for Health Care Administration; amending s.
4668 318.21, F.S.; revising distribution of funds from
4669 civil penalties imposed for traffic infractions by
4670 county courts; repealing s. 383.325, F.S., relating to
4671 confidentiality of inspection reports of licensed
4672 birth center facilities; amending s. 395.002, F.S.;
4673 revising and deleting definitions applicable to
4674 regulation of hospitals and other licensed facilities;
4675 conforming a cross-reference; amending s. 395.003,
4676 F.S.; deleting an obsolete provision; conforming a
4677 cross-reference; amending s. 395.0161, F.S.; deleting
4678 a provision requiring licensure inspection fees for
4679 hospitals, ambulatory surgical centers, and mobile
4680 surgical facilities to be paid at the time of the
4681 inspection; amending s. 395.0193, F.S.; requiring a
4682 licensed facility to report certain peer review

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 additional housekeeping and sanitation procedures in licensed facilities for infection control purposes; 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,

4712 400.925, 400.9935, 408.05, 440.13, 627.645, 627.668,
4713 627.669, 627.736, 641.495, and 766.1015, F.S.;
4714 revising references to the Joint Commission on
4715 Accreditation of Healthcare Organizations, the
4716 Commission on Accreditation of Rehabilitation
4717 Facilities, and the Council on Accreditation to
4718 conform to their current designations; amending s.
4719 395.4025, F.S.; authorizing the Department of Health
4720 to grant additional extensions for trauma center
4721 applicants under certain circumstances; amending s.
4722 395.602, F.S.; revising the definition of the term
4723 "rural hospital" to delete an obsolete provision;
4724 amending s. 400.021, F.S.; revising the definition of
4725 the term "geriatric outpatient clinic" to include
4726 additional staff; revising the term "resident care
4727 plan"; removing a provision that requires certain
4728 signatures on the plan; amending s. 400.0255, F.S.;
4729 correcting an obsolete cross-reference to
4730 administrative rules; amending s. 400.063, F.S.;
4731 deleting an obsolete provision; amending ss. 400.071
4732 and 400.0712, F.S.; revising applicability of general
4733 licensure requirements under part II of ch. 408, F.S.,
4734 the Health Care Licensing Procedures Act, to
4735 applications for nursing home licensure; revising
4736 provisions governing inactive licenses; amending s.
4737 400.111, F.S.; providing for disclosure of controlling
4738 interest of a nursing home facility upon request by
4739 the Agency for Health Care Administration; amending s.
4740 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; providing for communication of patient information; requiring a physician's 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; providing a limit on fees charged by a facility for copies of patient records; amending s. 400.142, F.S.; deleting language relating to agency adoption of rules; repealing s. 400.145, F.S., relating to records of care and treatment of residents; repealing ss. 400.0234 and 429.294, F.S., relating to availability of facility records for investigation of resident's rights violations and

defenses; amending 400.147, F.S.; removing a requirement for nursing homes and related health care facilities to notify the agency within a specified period of time after receipt of an adverse incident report; 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. 400.179, F.S.; deleting an obsolete provision; amending s. 400.19, F.S.; revising inspection 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 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. 400.462, F.S.; revising the definition of the term "remuneration" as it applies to home health agencies; amending s. 400.484, F.S.; revising the schedule of home health agency inspection violations; amending s. 400.506, F.S.; deleting language relating to exemptions from penalties imposed on nurse registries if a nurse registry does not bill the Florida Medicaid Program; providing criteria for an administrator to manage a nurse registry; amending s. 400.509, F.S.; revising the service providers exempt from licensure registration to include

organizations that provide companion services only for persons with developmental disabilities; 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; requiring applicants to submit documentation of accreditation within a specified period of time; 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.; revising the definitions of the terms “clinic” and “portable equipment provider”; providing that part X of ch. 400, F.S., the Health Care Clinic Act, does not apply to certain clinical facilities, an entity owned by a corporation with a specified amount of annual sales of health care services under certain circumstances, an entity owned or controlled by a

publicly traded entity with a specified amount of annual revenues, or an entity that employs a specified number of licensed health care practitioners under certain conditions; amending s. 400.991, F.S.; conforming terminology; revising application requirements relating to documentation of financial ability to operate a mobile clinic; amending s. 408.033, F.S.; permitting fees assessed on certain health care facilities to be collected prospectively at the time of licensure renewal and prorated for the licensure period; 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; deleting a requirement that the agency submit a report regarding requests for exemption; amending s. 408.037, F.S.; revising certificate-of-need requirements for general hospital applicants to evaluate the applicant's parent corporation if audited financial statements of the applicant do not exist; 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. 408.8065, F.S.; requiring home health agencies, home medical equipment providers, and health care clinics to submit projected financial statements; amending s. 408.809, F.S., relating to background screening of specified employees of health care providers; revising provisions for required rescreening; removing provisions authorizing the agency to adopt rules establishing a rescreening schedule; establishing a rescreening schedule; amending s. 408.810, F.S.; 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.; providing for certain mitigating circumstances to be considered for any application subject to denial; authorizing the agency to extend a license expiration date under

certain circumstances; amending s. s. 409.212, F.S.; increasing the limit on the amount of additional supplementation provided by a third party under the optional state supplementation program; amending s. 409.91196, F.S.; revising components of a Medicaid prescribed-drug spending-control program; conforming a cross-reference; amending s. 409.912, F.S.; requiring the Agency for Health Care Administration to work with the specialty prepaid plan that provides behavioral health care services for certain Medicaid-eligible children to develop evidence-based alternatives for the statewide inpatient psychiatric program and other similar services; revising procedures for implementation of a Medicaid prescribed-drug spending-control program; requiring that the agency establish a demonstration project in Miami-Dade County of a psychiatric facility; 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; eliminating the license fee for the limited

nursing services license; transferring from another provision of law the requirement that the standard survey of an assisted living facility include specific actions to determine whether the facility is adequately protecting residents' rights; providing that under specified conditions an assisted living facility that has a class I or class II violation is subject to periodic unannounced monitoring; requiring a registered nurse to participate in certain monitoring visits; amending s. 429.075, F.S.; requiring certain facilities that have a limited mental health license to maintain 24-hour security services; amending s. 429.11, F.S.; revising licensure application requirements for assisted living facilities to eliminate provisional licenses; amending s. 429.12, F.S.; deleting a requirement that a transferor of an assisted living facility advise the transferee to submit a plan for correction of certain deficiencies to the Agency for Health Care Administration before ownership of the facility is transferred; amending s. 429.14, F.S.; clarifying provisions relating to a facility's request for a hearing under certain circumstances; 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. 429.195, F.S.; revising the list of entities prohibited from providing rebates; providing exceptions to prohibited patient brokering

for assisted living facilities; 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-care-related 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; conforming a cross-reference; amending s. 429.41, F.S., relating to rulemaking; conforming provisions to changes made by the act; deleting the requirement for the Department of Elderly Affairs to submit a copy of proposed rules to the Legislature; 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 to the agency in accordance with rules adopted by the department; amending s. 429.71, F.S.; revising schedule of inspection violations for adult family-care homes; amending s. 429.915, F.S.; revising agency responsibilities regarding the issuance of conditional licenses; amending s. 440.102, F.S.; deleting the

requirement for laboratories to submit a monthly report to the agency with statistical information regarding the testing of employees and job applicants; amending s. 456.053, F.S.; revising the definition of the term "group practice" as it relates to financial arrangements of referring health care providers and providers of health care services to include group practices that provide radiation therapy services under certain circumstances; amending s. 483.035, F.S.; requiring certain clinical laboratories operated by one or more practitioners licensed under part I of ch. 464, F.S., the Nurse Practice Act, and ch. 463, F.S., the Optometry Practice Act, to be licensed under part I of ch. 483, F.S., the Florida Clinical Laboratory Law; amending s. 483.051, F.S.; establishing qualifications necessary for clinical laboratory licensure; amending s. 483.294, F.S.; revising frequency of agency inspections of multiphasic health testing centers; amending s. 499.003, F.S.; removing the requirement for certain prescription drug purchasers to maintain a separate inventory of certain prescription drugs; amending s. 633.081, F.S.; limiting State 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., relating to orthotics, prosthetics, and pedorthics, to

the definition of "health care provider"; amending s. 817.505, F.S.; creating an exception to the patient brokering prohibition for assisted living facilities; amending ss. 394.4787, 400.0239, 408.07, 430.80, and 651.118, F.S.; conforming terminology and references to changes made by the act; revising a reference; establishing that assisted living facility licensure fees have been adjusted by Consumer Price Index since 1998 and are not intended to be reset by this act; amending s. 381.06014, F.S.; redefining the term "blood establishment" and defining the term "volunteer donor"; prohibiting local governments from restricting access to public facilities or infrastructure for certain activities based on whether a blood establishment is operating as a for-profit organization or not-for-profit organization; prohibiting a blood establishment from considering whether certain customers are operating as for-profit organizations or not-for-profit organizations when determining service fees for selling blood or blood components; requiring that certain blood establishments disclose specified information on the Internet; authorizing the Department of Legal Affairs to assess a civil penalty against a blood establishment that fails to disclose specified information on the Internet; providing that the civil penalty accrues to the state and requiring that it be deposited as received into the General Revenue Fund; amending s. 499.003, F.S.; redefining the term "health

care entity" to clarify that a blood establishment is a health care entity that may engage in certain activities; amending s. 499.005, F.S.; clarifying provisions that prohibit the unauthorized wholesale distribution of a prescription drug that was purchased by a hospital or other health care entity or donated or supplied at a reduced price to a charitable organization, 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 under a restricted prescription drug distributor permit; authorizing the Department of Health to adopt rules regarding the distribution of prescription drugs by blood establishments; authorizing certain business entities to pay for prescription drugs obtained by practitioners licensed under ch. 466, F.S.; amending s. 474.202, F.S.; defining the term "limited service veterinary vaccination clinic"; amending s. 474.215, F.S.; revising terminology; requiring that the Board of Veterinary Medicine establish minimum standards for limited service veterinary vaccination clinics rather than limited service veterinary medical practices; amending ss. 455.2185 and 456.023, F.S.; deleting

provisions that limit the practice privileges of out-of-state or foreign health care professionals or veterinarians who are in this state for a specific sporting event; amending s. 456.0635, F.S.; revising the grounds under which the Department of Health or corresponding board is required to refuse to admit a candidate to an examination and to refuse to issue or renew a license, certificate, or registration of a health care practitioner; providing an exception; amending s. 456.036, F.S.; requiring a delinquent licensee whose license becomes delinquent before the final resolution of a case regarding Medicaid fraud to affirmatively apply by submitting a complete application for active or inactive status during the licensure cycle in which the case achieves final resolution by order of the court; providing that failure by a delinquent licensee to become active or inactive before the expiration of that licensure cycle renders the license null; requiring that any subsequent licensure be as a result of applying for and meeting all requirements imposed on an applicant for new licensure; amending s. 465.014, F.S.; providing that state law regarding pharmacy technicians does not apply to a practitioner authorized to dispense drugs or a medical assistant or licensed health care professional under the direct supervision of such practitioner if the practitioner is treating a patient who provides proof of insurance through a public-payer or private-payer source;

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providing that this exemption applies only to medical personnel under the direct supervision of the dispensing practitioner while dispensing in the practitioner’s office; creating s. 627.6011, F.S.; providing clarification regarding the types of coverage that must be included in mandatory benefits; providing a definition; amending s. 766.110, F.S.; authorizing health care facilities to use scientific diagnostic disease methodologies that use information regarding specific diseases in health care facilities and that are adopted by the facility’s medical review committee; providing an effective date.