By the Committee on Health Regulation; and Senator Garcia

588-02736A-12 20121884c1

A bill to be entitled

An act relating to health regulation by the Agency for Health Care Administration; amending s. 83.42, F.S., relating to exclusions from part II of ch. 83, F.S., the Florida Residential Landlord and Tenant Act; clarifying that the procedures in s. 400.0255, F.S., for transfers and discharges are exclusive to residents of a nursing home licensed under part II of ch. 400, F.S.; amending s. 112.0455, F.S., relating to the Drug-Free Workplace Act; deleting a provision regarding retroactivity of the act; deleting a provision specifying that the act does not abrogate the right of an employer under state law to conduct drug tests before a certain date; deleting a provision that requires a laboratory to submit to the Agency for Health Care Administration a monthly report containing statistical information regarding the testing of employees and job applicants; amending s. 318.21, F.S.; providing that a portion of the additional fines assessed for traffic violations within an enhanced penalty zone be remitted to the Department of Revenue and deposited into the Brain and Spinal Cord Injury Trust Fund of the Department of Health to serve certain Medicaid recipients; repealing s. 383.325, F.S., relating to confidentiality of inspection reports of licensed birth center facilities; creating s. 385.2031, F.S.; designating the Florida Hospital/Sandford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource

for research in the prevention and treatment of diabetes; amending s. 395.002, F.S.; redefining the term "accrediting organizations" as it applies to the regulation of hospitals and other licensed facilities; conforming a cross-reference; amending s. 395.003, F.S.; deleting an obsolete provision; authorizing a specialty-licensed children's hospital that has at least a specified number of licensed neonatal intensive care unit beds to provide obstetrical services that are restricted to the diagnosis, care, and treatment of certain pregnant women; authorizing the Agency for Health Care Administration to adopt rules; amending s. 395.0161, F.S.; deleting a requirement that facilities licensed under part I of ch. 395, F.S., pay licensing fees at the time of inspection; amending s. 395.0193, F.S.; requiring a 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 that licensed facility beds conform to standards specified by the Agency for Health Care Administration, the Florida Building Code, and the Florida Fire Prevention Code; amending s. 395.3025, F.S.; authorizing the disclosure of patient records to the Department of Health rather than the Agency for Health Care Administration in accordance with an issued subpoena; requiring the department, rather than the agency, to make available, upon written request by a practitioner against whom probable cause has been found, any patient records that form the basis of the determination of probable cause; amending s. 395.3036, F.S.; correcting a cross-reference; repealing s. 395.3037, F.S., relating to redundant definitions for the Department of Health and the Agency for Health Care Administration; amending s. 395.602, F.S.; revising the definition of the term "rural hospital" to delete an obsolete provision; amending s. 400.021, F.S.; revising the definitions of the terms "geriatric outpatient clinic" and "resident care plan"; amending s. 400.275, F.S.; revising agency duties with regard to training nursing home surveyor teams; revising requirements for team members; amending s. 400.474, F.S.; revising the requirements for a quarterly report submitted to the Agency for Health Care Administration by each home health agency; amending s. 400.484, F.S.; revising the classification

of violations by a home health agency for which the agency imposes an administrative fine; amending and reenacting s. 400.506, F.S., relating to licensure of nurse registries, to incorporate the amendment made to s. 400.509, F.S., in a reference thereto; authorizing an administrator to manage up to five nurse registries under certain circumstances; requiring an administrator to designate, in writing, for each licensed entity, a qualified alternate administrator to serve during the administrator's absence; amending s. 400.509, F.S.; providing that organizations that provide companion services only to persons with developmental disabilities, under contract with the Agency for Persons with Disabilities, are exempt from registration with the Agency for Health Care Administration; amending s. 400.601, F.S.; redefining the term "hospice" to include a limited liability company as it relates to nursing homes and related health care facilities; 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. 400.915, F.S.; correcting an obsolete cross-reference to administrative rules; amending s. 400.931, F.S.; requiring each applicant for initial licensure, change of ownership, or license renewal to operate a licensed home medical equipment provider at a location outside

the state to submit documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the Agency for Health Care Administration; requiring an applicant that has applied for accreditation to provide proof of accreditation within a specified time; deleting a requirement that an applicant for a home medical equipment provider license submit a surety bond to the agency; amending s. 400.967, F.S.; revising the classification of violations by 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"; authorizing the Agency for Health Care Administration to deny or revoke an exemption from licensure based on certain criteria if a health care clinic receives payment for health care services under personal injury protection insurance coverage; including health services provided at multiple locations within the definition of the term "portable health service or equipment provider"; 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.; providing that fees assessed on selected health care facilities and organizations may be collected prospectively at the time of licensure renewal and prorated for the licensing 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; amending s. 408.037, F.S.; revising requirements for the financial information to be included in an application for a certificate of need; 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 data reporting requirements for health care facilities; amending s. 408.07, F.S.; deleting a cross-reference; amending s. 408.10, F.S.; removing agency authority to investigate certain consumer complaints; amending s. 408.7056, F.S.; providing that the Subscriber Assistance Program applies to health plans that meet certain requirements; repealing s. 408.802(11), 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.; revising the requirements for becoming licensed as a home health agency, home medical equipment provider, or health care clinic; amending s. 408.809, F.S.; revising provisions to include a schedule for background rescreenings of certain employees; amending s. 408.810, F.S.; requiring that the controlling interest of a health care licensee notify the agency of certain court proceedings; providing a penalty; 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. 409.912, F.S.; revising the components of the Medicaid prescribed-drug spending-control program; amending s. 409.91195, F.S.; revising the membership of the Medicaid Pharmaceutical and Therapeutics Committee; providing the requirements for the members; providing terms of membership; requiring the Agency for Health Care Administration to serve as staff for the committee and assist the committee with its duties; providing additional requirements for presenting public testimony to include a product on a preferred drug list; requiring that the committee be informed in writing of the agency's action when the agency does not follow the recommendation of the committee; amending s. 409.975, F.S.; providing that an essential provider and a hospital that is necessary for a managed care plan to demonstrate an adequate network as determined by the Agency for Health Care Administration is part of that managed care plan's

network for purposes of the provider's or hospital's application for enrollment or expansion in the Medicaid program; requiring that a managed care plan's payment under this provision to an essential provider be made in accordance with s. 409.975, F.S., regarding managed care plan accountability; repealing s. 429.11(6), F.S., relating to provisional licenses for assisted living facilities; amending s. 429.294, F.S.; revising a cross-reference; amending s. 429.71, F.S.; revising the classification of violations; amending s. 429.915, F.S.; revising agency responsibilities regarding the issuance of conditional licenses; amending ss. 430.80 and 430.81, F.S.; conforming cross-references; repealing s. 440.102(9)(d), F.S., relating to a requirement that laboratories submit to the Agency for Health Care Administration a monthly report containing statistical information regarding the testing of employees and job applicants; amending s. 483.035, F.S.; providing for a clinical laboratory to be operated by certain nurses; amending s. 483.051, F.S.; requiring the Agency for Health Care Administration to provide for biennial licensure of all nonwaived laboratories that meet certain requirements; requiring the agency to prescribe qualifications for such licensure; defining nonwaived laboratories as laboratories that do not have a certificate of waiver from the Centers for Medicare and Medicaid Services; deleting requirements for the registration of an alternate site testing location

when the clinical laboratory applies to renew its license; amending s. 483.245, F.S.; prohibiting a clinical laboratory from placing a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the same entity; authorizing a person who is aggrieved by a violation to bring a civil action for appropriate relief; amending s. 483.294, F.S.; revising the frequency of agency inspections of multiphasic health testing centers; amending s. 499.003, F.S.; redefining the term "wholesale distribution" with regard to the Florida Drug and Cosmetic Act to remove certain requirements governing prescription drug inventories; amending and creating, respectively, ss. 627.602 and 627.6513, F.S.; providing that the Uniform Health Carrier External Review Model Act and the Employee Retirement Income Security Act apply to individual and group health insurance policies except those subject to the Subscriber Assistance Program under s. 408.7056, F.S.; creating s. 641.312, F.S.; requiring the Office of Insurance Regulation within the Department of Financial Services to administer the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act; providing that the Uniform Health Carrier External Review Model Act does not apply to a health maintenance contract that is subject to the Subscriber Assistance Program under s. 408.7056, F.S.; amending s. 651.118, F.S.; conforming

a cross-reference; providing a directive to the Division of Statutory Revision; providing effective dates.

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

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. Present paragraphs (f) through (k) of subsection (10) of section 112.0455, Florida Statutes, are redesignated as paragraphs (e) through (j), respectively, and present paragraph (e) of subsection (10), 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.—

(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this section and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to this section. A license issued by the agency is required in order to operate a laboratory.

(b) A laboratory may analyze initial or confirmation drug specimens only if:

1. The laboratory is licensed and approved by the Agency for Health Care Administration using criteria established by the United States Department of Health and Human Services as general guidelines for modeling the state drug testing program and in accordance with part II of chapter 408. Each applicant for licensure and licensee must comply with all requirements of part II of chapter 408.

2. The laboratory has written procedures to ensure chain of custody.

3. The laboratory follows proper quality control procedures, including, but not limited to:

a. The use of internal quality controls including the use of samples of known concentrations which are used to check the performance and calibration of testing equipment, and periodic use of blind samples for overall accuracy.

b. An internal review and certification process for drug test results, conducted by a person qualified to perform that function in the testing laboratory.

c. Security measures implemented by the testing laboratory to preclude adulteration of specimens and drug test results.

d. Other necessary and proper actions taken to ensure reliable and accurate drug test results.

(c) A laboratory shall disclose to the employer a written test result report within 7 working days after receipt of the sample. All laboratory reports of a drug test result shall, at a minimum, state:

1. The name and address of the laboratory which performed the test and the positive identification of the person tested.

2. Positive results on confirmation tests only, or negative results, as applicable.

3. A list of the drugs for which the drug analyses were conducted.

4. The type of tests conducted for both initial and confirmation tests and the minimum cutoff levels of the tests.

5. Any correlation between medication reported by the employee or job applicant pursuant to subparagraph (8)(b)2. and a positive confirmed drug test result.

A ~~No~~ report may not ~~shall~~ disclose the presence or absence of any drug other than a specific drug and its metabolites listed pursuant to this section.

~~(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.~~

(d) ~~(e)~~ Laboratories shall provide technical assistance to the employer, employee, or job applicant for the purpose of interpreting any positive confirmed test results which could have been caused by prescription or nonprescription medication taken by the employee or job applicant.

(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) ~~(10)(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. 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 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 who have ~~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 4. Section 383.325, Florida Statutes, is repealed.

Section 5. Section 385.2031, Florida Statutes, is created to read:

385.2031 Resource for research in the prevention and treatment of diabetes.—The Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes is designated as a resource in this state for research in the prevention and treatment of diabetes.

Section 6. Subsection (1) of section 395.002, Florida Statutes, is amended to read:

395.002 Definitions.—As used in this chapter:

(1) "Accrediting organizations" means national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by the state ~~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~~.

Section 7. Paragraph (c) of subsection (1) and subsection (6) 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.~~

(6) A specialty hospital may not provide any service or regularly serve any population group beyond those services or groups specified in its license. A specialty-licensed children's hospital that is authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery services may provide cardiovascular service to adults who, as children, were previously served by the hospital for congenital heart disease, or to those patients who are referred for a specialized procedure only for congenital heart disease by an adult hospital, without obtaining additional licensure as a provider of adult cardiovascular services. The agency may request

documentation as needed to support patient selection and treatment. This subsection does not apply to a specialty-licensed children's hospital that is already licensed to provide adult cardiovascular services. A specialty-licensed children's hospital that has at least 50 licensed neonatal intensive care unit beds may provide obstetrical services, including labor and delivery, which are restricted to the diagnosis, care, and treatment of pregnant women of any age who have:

(a) At least one maternal or fetal characteristic or condition that would characterize the pregnancy or delivery as high-risk; or

(b) Received medical advice or a diagnosis indicating their fetus will require at least one perinatal intervention.

The agency shall adopt rules that establish standards and guidelines for admission to any program that qualifies under this subsection.

Section 8. 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 9. Subsections (2) and (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 must ~~shall~~ include:

(a) Mechanism for choosing the membership of the body or bodies that conduct peer review.

(b) Adoption of rules of order for the peer review process.

(c) Fair review of the case with the physician involved.

(d) Mechanism to identify and avoid conflict of interest on the part of the peer review panel members.

(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~~.

(f) Review, at least annually, of the peer review procedures by the governing board of the licensed facility.

(g) Focus of the peer review process on review of professional practices at the facility to reduce morbidity and mortality and to improve patient care.

(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 10. 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 11. 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 is ~~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 12. Section 395.1046, Florida Statutes, is repealed.

Section 13. Paragraph (e) of subsection (1) of section 395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

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

Section 14. Paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.—

(4) Patient records are confidential and must not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:

(e) The department ~~agency~~ upon subpoena issued pursuant to s. 456.071.~~, but~~ The records obtained thereby must be used solely for the purpose of the agency, the department, and the appropriate professional board in an ~~its~~ investigation, prosecution, and appeal of disciplinary proceedings. If the

department ~~agency~~ requests copies of the records, the facility shall charge a fee pursuant to this section ~~no more than its actual copying costs, including reasonable staff time~~. The records must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency, the department, or the appropriate regulatory board. However, the department ~~agency~~ must make available, upon written request by a practitioner against whom probable cause has been found, any such records that form the basis of the determination of probable cause.

Section 15. 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 16. Section 395.3037, Florida Statutes, is repealed.

Section 17. 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 18. 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 by a licensed practical nurse who is under the direct supervision of a registered nurse, an advanced registered nurse practitioner, a physician assistant, or a 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 19. 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 20. Subsection (6) of section 400.474, Florida Statutes, is amended, present subsection (7) is redesignated as subsection (8), and a new subsection (7) is added to that section, to read:

400.474 Administrative penalties.—

(6) The agency may deny, revoke, or suspend the license of a home health agency and shall impose a fine of $5,000 against a home health agency that:

(a) Gives remuneration for staffing services to:

1. Another home health agency with which it has formal or informal patient-referral transactions or arrangements; or

2. A health services pool with which it has formal or informal patient-referral transactions or arrangements,

unless the home health agency has activated its comprehensive emergency management plan in accordance with s. 400.492. This paragraph does not apply to a Medicare-certified home health agency that provides fair market value remuneration for staffing services to a non-Medicare-certified home health agency that is

part of a continuing care facility licensed under chapter 651 for providing services to its own residents if each resident receiving home health services pursuant to this arrangement attests in writing that he or she made a decision without influence from staff of the facility to select, from a list of Medicare-certified home health agencies provided by the facility, that Medicare-certified home health agency to provide the services.

(b) Provides services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration.

(c) Provides staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

(d) Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within 5 years before the request.

(e) 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, chapter 429, or this chapter from whom the home health agency receives referrals.

~~(f) Fails to submit to the agency, within 15 days after the end of each calendar quarter, a written report that includes the following data based on data as it existed on the last day of the quarter:~~

~~1. The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;~~

~~2. The number of patients receiving both home health services from the home health agency and hospice services;~~

~~3. The number of patients receiving home health services from that home health agency; and~~

~~4. The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.~~

(f) ~~(g)~~ Gives cash, or its equivalent, to a Medicare or Medicaid beneficiary.

(g) ~~(h)~~ Has more than one medical director contract in effect at one time or more than one medical director contract and one contract with a physician-specialist whose services are mandated for the home health agency in order to qualify to participate in a federal or state health care program at one time.

(h) ~~(i)~~ Gives remuneration to a physician without a medical director contract being in effect. The contract must:

1. Be in writing and signed by both parties;

2. Provide for remuneration that is at fair market value for an hourly rate, which must be supported by invoices submitted by the medical director describing the work performed, the dates on which that work was performed, and the duration of that work; and

3. Be for a term of at least 1 year.

The hourly rate specified in the contract may not be increased during the term of the contract. The home health agency may not execute a subsequent contract with that physician which has an

increased hourly rate and covers any portion of the term that was in the original contract.

(i) ~~(j)~~ Gives remuneration to:

1. A physician, and the home health agency is in violation of paragraph (g) ~~(h)~~ or paragraph (h) ~~(i)~~;

2. A member of the physician's office staff; or

3. An immediate family member of the physician,

if the home health agency has received a patient referral in the preceding 12 months from that physician or physician's office staff.

(j) ~~(k)~~ Fails to provide to the agency, upon request, copies of all contracts with a medical director which were executed within 5 years before the request.

(k) ~~(l)~~ Demonstrates a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period.

Nothing in paragraph (e) or paragraph (i) ~~(j)~~ shall be interpreted as applying to or precluding any discount, compensation, waiver of payment, or payment practice permitted by 42 U.S.C. s. 1320a-7(b) or regulations adopted thereunder, including 42 C.F.R. s. 1001.952 or s. 1395nn or regulations adopted thereunder.

(7) Each home health agency shall submit to the agency, within 15 days after the end of each calendar quarter, a written

report that includes the following data as it existed on the last day of the quarter:

(a) The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency.

(b) The number of patients receiving home health services from the home health agency who are also receiving hospice services.

(c) The number of patients receiving home health services from the home health agency.

(d) The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

(e) The number of physicians who were paid by the home health agency for professional services of any kind during the calendar quarter, the amount paid to each physician, and the number of hours each physician spent performing those services.

If the quarterly report is not received by the agency on or before the deadline, the agency shall impose a fine in the amount of $200 for each day that the report is late, which may not exceed $5,000 per quarter.

Section 21. Section 400.484, Florida Statutes, is amended to read:

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

(1) In addition to the requirements of s. 408.811, the agency may make such inspections and investigations as are

necessary in order to determine the state of compliance with this part, part II of chapter 408, and applicable rules.

(2) The agency shall impose fines for various classes of violations ~~deficiencies~~ in accordance with the following schedule:

(a) A class I violation is defined in s. 408.813 ~~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) A class II violation is defined in s. 408.813 ~~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) A class III violation is defined in s. 408.813 ~~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) A class IV violation is defined in s. 408.813 ~~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.

(3) In addition to any other penalties imposed pursuant to this section or part, the agency may assess costs related to an investigation that results in a successful prosecution, excluding costs associated with an attorney's time.

Section 22. For the purpose of incorporating the amendment made by this act to section 400.509, Florida Statutes, in a reference thereto, paragraph (a) of subsection (6) of section 400.506 is reenacted, present subsection (17) of that section is renumbered as subsection (18), and a new subsection (17) is added to that section, to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(6)(a) A nurse registry may refer for contract in private residences registered nurses and licensed practical nurses registered and licensed under part I of chapter 464, certified nursing assistants certified under part II of chapter 464, home health aides who present documented proof of successful completion of the training required by rule of the agency, and companions or homemakers for the purposes of providing those services authorized under s. 400.509(1). A licensed nurse registry shall ensure that each certified nursing assistant referred for contract by the nurse registry and each home health aide referred for contract by the nurse registry is adequately

trained to perform the tasks of a home health aide in the home setting. Each person referred by a nurse registry must provide current documentation that he or she is free from communicable diseases.

(17) 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 23. 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 which provides companion services only for persons with a developmental disability, as defined in s. 393.063, is exempt from registration.

Section 24. Subsection (3) of section 400.601, Florida Statutes, is amended to read:

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

(3) "Hospice" means a centrally administered corporation or a limited liability company that provides ~~providing~~ a continuum of palliative and supportive care for the terminally ill patient and his or her family.

Section 25. 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 that has ~~with~~ six or fewer beds is ~~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 26. 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 27. Section 400.931, Florida Statutes, is amended to read:

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

(1) In addition to the requirements of part II of chapter 408, the applicant must file with the application satisfactory proof that the home medical equipment provider is in compliance with this part and applicable rules, including:

(a) A report, by category, of the equipment to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of equipment include:

1. Respiratory modalities.

2. Ambulation aids.

3. Mobility aids.

4. Sickroom setup.

5. Disposables.

(b) A report, by category, of the services to be provided, indicating those offered either directly by the applicant or through contractual arrangements with existing providers. Categories of services include:

1. Intake.

2. Equipment selection.

3. Delivery.

4. Setup and installation.

5. Patient training.

6. Ongoing service and maintenance.

7. Retrieval.

(c) A listing of those with whom the applicant contracts, both the providers the applicant uses to provide equipment or services to its consumers and the providers for whom the applicant provides services or equipment.

(2) An applicant for initial licensure, change of ownership, or license 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 in order 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.~~

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

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

(5) In accordance with s. 408.805, an applicant or a 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 and may not exceed $300 per biennium. The agency shall set the fees in an amount that is sufficient to cover its costs in carrying out its responsibilities under this part. However, state, county, or municipal governments applying for licenses under this part are exempt from the payment of license fees.

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

400.933.

Section 28. Section 400.967, Florida Statutes, is amended to read:

400.967 Rules and classification of violations ~~deficiencies~~.—

(1) It is the intent of the Legislature that rules adopted and enforced under this part and part II of chapter 408 include criteria by which a reasonable and consistent quality of resident care may be ensured, the results of such resident care can be demonstrated, and safe and sanitary facilities can be provided.

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Agency for Persons with Disabilities and the Department of Elderly Affairs, shall adopt and enforce rules to administer this part and part II of chapter 408, which shall include reasonable and fair criteria governing:

(a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The agency shall update or revise the criteria as the need arises. All facilities must comply with those lifesafety code requirements and building code standards applicable at the time

of approval of their construction plans. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. The agency shall adopt fair and reasonable rules setting forth conditions under which existing facilities undergoing additions, alterations, conversions, renovations, or repairs are required to comply with the most recent updated or revised standards.

(b) The number and qualifications of all personnel, including management, medical nursing, and other personnel, having responsibility for any part of the care given to residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof.

(g) The preparation and annual update of a comprehensive emergency management plan. The agency shall adopt rules establishing minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing;

emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(h) The use of restraint and seclusion. Such rules must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff during an incident of restraint or seclusion; establish procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

(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 violation ~~deficiencies~~ as follows:

(a) A class I violation is defined in s. 408.813 ~~deficiencies are 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) A class II violation is defined in s. 408.813 ~~deficiencies are 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) A class III violation is defined in s. 408.813 ~~deficiencies are 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 violation ~~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) A class IV violation is 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.

(4) The agency shall approve or disapprove the plans and specifications within 60 days after receipt of the final plans and specifications. The agency may be granted one 15-day extension for the review period, if the secretary of the agency so approves. If the agency fails to act within the specified time, it is deemed to have approved the plans and specifications. When the agency disapproves plans and specifications, it must set forth in writing the reasons for disapproval. Conferences and consultations may be provided as necessary.

(5) The agency may charge an initial fee of $2,000 for review of plans and construction on all projects, no part of which is refundable. The agency may also collect a fee, not to

exceed 1 percent of the estimated construction cost or the actual cost of review, whichever is less, for the portion of the review which encompasses initial review through the initial revised construction document review. The agency may collect its actual costs on all subsequent portions of the review and construction inspections. Initial fee payment must accompany the initial submission of plans and specifications. Any subsequent payment that is due is payable upon receipt of the invoice from the agency. Notwithstanding any other provision of law, all money received by the agency under this section shall be deemed to be trust funds, to be held and applied solely for the operations required under this section.

Section 29. 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 <u>health service or</u> 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 or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and 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 or controlled, directly or indirectly, by a publicly traded entity with $100 million or more, in the aggregate, in total annual revenues derived from providing health care services by licensed health care

practitioners that are employed or contracted by an entity described in this paragraph.

(n) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners if one or more of the owners of the entity is a health care practitioner who is licensed in this state, is responsible for supervising the business activities of the entity, and is legally responsible for the entity's compliance with state law for purposes of this section.

(o) Entities that employ 50 or more health care practitioners who are licensed under chapter 458 or chapter 459 if the billing for medical services is under a single corporate tax identification number. The application for exemption under this paragraph must contain information that includes the name, residence address, business address, and telephone number of the entity that owns the practice; a complete list of the names and contact information of all the officers and directors of the entity; the name, residence address, business address, and medical license number of each health care practitioner who is licensed to practice in this state and employed by the entity; the corporate tax identification number of the entity seeking an exemption; a listing of health care services to be provided by the entity at the health care clinics owned or operated by the entity; and a certified statement prepared by an independent certified public accountant which states that the entity and the health care clinics owned or operated by the entity have not received payment for health care services under insurance coverage for personal injury protection for the preceding year.

If the agency determines that an entity that is exempt under this paragraph has received payments for medical services for insurance coverage for personal injury protection, 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 at 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 30. Paragraph (b) of subsection (1) and 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:

(a) A listing of services to be provided either directly by the applicant or through contractual arrangements with existing

providers;

(b) The number and discipline of each professional staff member to be employed; and

(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 31. 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 32. 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 33. Paragraph (d) of subsection (1) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(g), are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

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

Section 34. 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 35. 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 36. 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 37. 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 38. 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 39. Effective May 1, 2012, subsection (15) is added to section 408.7056, Florida Statutes, to read:

408.7056 Subscriber Assistance Program.—

(15) This section applies only to prepaid health clinics certified under chapter 641, Florida Healthy Kids health plans, and health plans that meet the requirements of 45 C.F.R. 147.140.

Section 40. Subsection (11) of section 408.802, Florida Statutes, is repealed.

Section 41. 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 42. 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 before the expiration of a license. This courtesy notice must inform the licensee of the expiration of the license. If the agency does not provide the courtesy notice or 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 43. 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 44. Section 408.809, Florida Statutes, is amended to read:

408.809 Background screening; prohibited offenses.—

(1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who are considered employees for the purposes of conducting screening under chapter 435:

(a) The licensee, if an individual.

(b) The administrator or a similarly titled person who is responsible for the day-to-day operation of the provider.

(c) The financial officer or similarly titled individual who is responsible for the financial operation of the licensee or provider.

(d) Any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the

conviction at the time of license application.

(e) Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients. Evidence of contractor screening may be retained by the contractor's employer or the licensee.

(2) Every 5 years following his or her licensure, employment, or entry into a contract in a capacity that under subsection (1) would require level 2 background screening under chapter 435, each such person must submit to level 2 background rescreening as a condition of retaining such license or continuing in such employment or contractual status. For any such rescreening, the agency shall request the Department of Law Enforcement to forward the person's fingerprints to the Federal Bureau of Investigation for a national criminal history record check. If the fingerprints of such a person are not retained by the Department of Law Enforcement under s. 943.05(2)(g), the person must file a complete set of fingerprints with the agency and the agency shall forward the fingerprints to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check. The fingerprints may be retained by the Department of Law Enforcement under s. 943.05(2)(g). The cost of the state and

national criminal history records checks required by level 2 screening may be borne by the licensee or the person fingerprinted. Proof of compliance with level 2 screening standards submitted within the previous 5 years to meet any provider or professional licensure requirements of the Agency, the Department of Health, the Agency for Persons with Disabilities, the Department of Children and Family Services, the Department of Elderly Affairs, or the Department of Financial Services for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under chapter 651 satisfies the requirements of this section if the screening standards and disqualifying offenses are equivalent to those specified in s. 453.04 and this section, and the person subject to screening has not been unemployed for more than 90 days and such proof is accompanied, under penalty of perjury, by an affidavit of compliance with the provisions of chapter 435 and this section using forms provided by the agency.

(3) All fingerprints must be provided in electronic format. Screening results shall be reviewed by the agency with respect to the offenses specified in s. 435.04 and this section, and the qualifying or disqualifying status of the person named in the request shall be maintained in a database. The qualifying or disqualifying status of the person named in the request shall be posted on a secure website for retrieval by the licensee or designated agent on the licensee’s behalf.

(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 as follows:

(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.

(6) ~~(5)~~ The costs associated with obtaining the required screening must be borne by the licensee or the person subject to screening. Licensees may reimburse persons for these costs. The Department of Law Enforcement shall charge the agency for screening pursuant to s. 943.053(3). The agency shall establish a schedule of fees to cover the costs of screening.

(7) ~~(6)~~(a) As provided in chapter 435, the agency may grant an exemption from disqualification to a person who is subject to this section and who:

1. Does not have an active professional license or certification from the Department of Health; or

2. Has an active professional license or certification from the Department of Health but is not providing a service within the scope of that license or certification.

(b) As provided in chapter 435, the appropriate regulatory board within the Department of Health, or the department itself if there is no board, may grant an exemption from disqualification to a person who is subject to this section and who has received a professional license or certification from the Department of Health or a regulatory board within that department and that person is providing a service within the scope of his or her licensed or certified practice.

(8) ~~(7)~~ The agency and the Department of Health may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this

section, chapter 435, and authorizing statutes requiring background screening and to implement and adopt criteria relating to retaining fingerprints pursuant to s. 943.05(2).

(9)~~(8)~~ There is no unemployment compensation or other monetary liability on the part of, and no cause of action for damages arising against, an employer that, upon notice of a disqualifying offense listed under chapter 435 or this section, terminates the person against whom the report was issued, whether or not that person has filed for an exemption with the Department of Health or the agency.

Section 45. 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 46. 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 may not exceed $500 for each violation. Unclassified violations 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 47. Paragraph (a) of subsection (37) of section 409.912, Florida Statutes, is amended to read:

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

emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion 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 are not 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.

(37)(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 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 may 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 administer 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 lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

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

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 if 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.

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.

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.

7. The agency may establish a preferred drug list as

described in this subsection, and, pursuant to the establishment of such preferred drug list, 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 guarantees 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 may 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. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or

pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

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

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

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.

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

a. The agency may contract with a vendor that has

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

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

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

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

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

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

12. The agency may 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.

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.

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

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

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

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency may post prior authorization and step-edit criteria, ~~and~~ protocol, and updates to the list of drugs that are subject to prior authorization on the agency's ~~an~~ Internet website within 21 days after the prior authorization criteria, protocol, or updates are approved by the agency ~~without amending its rule or engaging in additional rulemaking~~.

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.

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 before 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.

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.

Section 48. Subsections (1), (7), and (8) of section 409.91195, Florida Statutes, are amended to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.—There is created a Medicaid Pharmaceutical and

Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(1)(a) The committee shall be composed of 11 members appointed by the Governor as follows: one member licensed under chapter 458 or chapter 459 who is nominated by the Florida Medical Association; one member licensed under chapter 459 who is nominated by the Florida Osteopathic Medical Association; one member licensed under chapter 458 or chapter 459 who is nominated by the American Academy of Family Physicians, Florida Chapter; one member licensed under chapter 458 or chapter 459 who is nominated by the American Academy of Pediatrics, Florida Chapter; one member licensed under chapter 458 or chapter 459 nominated by the Florida Psychiatric Society; one member licensed under chapter 465 who is nominated by the Florida Pharmacy Association; one member licensed under chapter 465 who is nominated by the Florida Society of Health System Pharmacists, Inc.; one member licensed under chapter 465 who is nominated by the Florida Retail Federation; one member licensed under chapter 465 who works in a retail setting for an independent, nonchain pharmacy; one member licensed under chapter 458 or chapter 459 who is nominated by the Florida Academy of Physician Assistants; and one consumer representative who represents a patient advocacy group.

(b) Each member of the committee, except the consumer representative, must practice in this state and participate in the Florida Medicaid Fee for Service Pharmacy Program.

(c) The Governor shall appoint the members for 2-year terms. Members may be appointed to more than one term. The agency shall serve as staff for the committee and assist the

members with administrative duties. ~~Four members shall be physicians, licensed under chapter 458; one member licensed under chapter 459; five members shall be pharmacists licensed under chapter 465; and one member shall be a consumer representative. The members shall be appointed to serve for terms of 2 years from the date of their appointment. Members may be appointed to more than one term. The agency shall serve as staff for the committee and assist them with all ministerial duties. The Governor shall ensure that at least some of the members of the committee represent Medicaid participating physicians and pharmacies serving all segments and diversity of the Medicaid population, and have experience in either developing or practicing under a preferred drug list. At least one of the members shall represent the interests of pharmaceutical manufacturers.~~

(7) The committee shall ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate as outlined in this chapter, have an opportunity to present public testimony to the committee with information or evidence supporting inclusion of a product on the preferred drug list. Such public testimony shall occur prior to any recommendations made by the committee for inclusion or exclusion from the preferred drug list, allow for members of the committee to ask questions of the presenters of the public testimony, and allow for 3 minutes of testimony for each drug reviewed. The agency may not limit the number of interested parties that provide public testimony. Upon timely notice, the agency shall ensure that any drug that has been approved or had any of its particular uses approved by the United States Food

and Drug Administration under a priority review classification will be reviewed by the committee at the next regularly scheduled meeting following 3 months of distribution of the drug to the general public.

(8) The committee shall develop its preferred drug list recommendations by considering the clinical efficacy, safety, and cost-effectiveness of a product. If the agency does not follow a recommendation of the committee, the committee members must be informed in writing of the agency's action at the next meeting of the committee following the reversal of its recommendation.

Section 49. Effective upon this act becoming a law, paragraph (e) is added to subsection (1) of section 409.975, Florida Statutes, to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(b). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(e) Before the selection of managed care plans as specified in s. 409.966, each essential provider and each hospital that are necessary in order for a managed care plan to demonstrate an adequate network, as determined by the agency, are a part of that managed care plan's network for purposes of the provider's

or hospital's application for enrollment or expansion in the Medicaid program. A managed care plan's payment under this section to an essential provider must be made in accordance with this section.

Section 50. Subsection (6) of section 429.11, Florida Statutes, is repealed.

Section 51. Subsection (1) of section 429.294, Florida Statutes is amended to read:

429.294 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility within 10 days, in accordance with the provisions of s. 400.141(3)~~400.145~~, shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 52. Subsections (1) and (5) of section 429.71, Florida Statutes, 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 53. 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 54. Subsection (3) of section 430.80, Florida Statutes, is 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:

(a) Provide a comprehensive program of integrated senior services that include institutional services and community-based services;

(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;

(c) Have been in business in this state for a minimum of 10 consecutive years;

(d) Demonstrate an active program in multidisciplinary education and research that relates to gerontology;

(e) Have a formalized contractual relationship with at least one accredited health profession education program located in this state;

(f) Have senior staff members who hold formal faculty appointments at universities, which must include at least one accredited health profession education program; and

(g) Maintain insurance coverage pursuant to s.

400.141(1)(q) ~~s. 400.141(1)(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 55. Paragraph (h) of subsection (2) of section 430.81, Florida Statutes, is amended to read:

430.81 Implementation of a teaching agency for home and community-based care.—

(2) The Department of Elderly Affairs may designate a home health agency as a teaching agency for home and community-based care if the home health agency:

(h) Maintains insurance coverage pursuant to s. 400.141(1)(q) ~~s. 400.141(1)(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 authorized to do business in this state. This letter of credit shall be used to satisfy the obligation of the agency to the claimant upon presentation 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 agency.

Section 56. Paragraph (d) of subsection (9) of section 440.102, Florida Statutes, is repealed.

Section 57. 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, or chapter 466, or as an advanced registered nurse practitioner licensed under part I in chapter 464, 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 58. 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 59. Section 483.245, Florida Statutes, is amended to read:

483.245 Rebates prohibited; penalties; private action.—

(1) It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any dialysis facility, physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a clinical laboratory licensed under this part. A clinical laboratory licensed under this part is prohibited from placing, directly or indirectly, through an independent staffing company or lease arrangement, or otherwise, a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the

same entity.

(2) The agency shall adopt rules that assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the agency, such penalties may include any disciplinary action available to the agency under the appropriate licensing laws. In the case of an entity not licensed by the agency, such penalties may include:

(a) A fine not to exceed $1,000;

(b) If applicable, a recommendation by the agency to the appropriate licensing board that disciplinary action be taken.

(3) Any person aggrieved by a violation of this section may bring a civil action for appropriate relief, including an action for a declaratory judgment, injunctive relief, and actual damages.

Section 60. 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 61. 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 62. Effective May 1, 2012, paragraph (h) is added to subsection (1) of section 627.602, Florida Statutes, to read:

627.602 Scope, format of policy.—

(1) Each health insurance policy delivered or issued for delivery to any person in this state must comply with all applicable provisions of this code and all of the following requirements:

(h) Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances. This paragraph does not apply to a health insurance policy that is subject to the Subscriber Assistance Program in s. 408.7056.

Section 63. Effective May 1, 2012, section 627.6513, Florida Statutes, is created to read:

627.6513 Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances, apply to all group health insurance policies issued under this part. This section does not apply to a group health insurance policy that is subject to the Subscriber Assistance Program in s. 408.7056.

Section 64. Effective May 1, 2012, section 641.312, Florida Statutes, is created to read:

641.312 The Office of Insurance Regulation within the Department of Financial Services shall adopt rules to administer the provisions of the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act, dated April 2010. This section does not apply to a health maintenance contract that is subject to the Subscriber Assistance Program in s. 408.7056.

Section 65. 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)1.d ~~s. 400.141(1)(o)1.d~~.

Section 66. In the interim between this act becoming law and the 2013 Regular Session of the Legislature, the Division of Statutory Revision shall provide the relevant substantive committees of the Senate and the House of Representatives with assistance, upon request, to enable such committees to prepare draft legislation to correct the names of accrediting organizations in the related Florida Statutes.

Section 67. Except as otherwise expressly provided in this act, and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2012.