CHAPTER 2012-160

Committee Substitute for Committee Substitute for House Bill No. 787

An act relating to health care facilities; amending s. 395.002, F.S.; revising a definition of the term "urgent care" as it relates to the regulation of hospitals and other licensed facilities; amending s. 395.107, F.S.; requiring that a urgent care center publish a post a schedule of charges; providing requirements for the schedule; amending s. 400.9935, F.S.; adding additional responsibilities of medical and clinic directors with respect to the posting of a schedule of charges for services; amending s. 400.021, F.S.; revising definitions of the terms "geriatric outpatient clinic" and "resident care plan" and defining the term "therapeutic spa services"; amending s. 400.1183, F.S.; revising requirements relating to nursing home facility grievance reports; amending s. 400.141, F.S.; revising provisions relating to other needed services provided by licensed nursing home facilities, including respite care, adult day, and therapeutic spa services; revising provisions relating to facilities eligible to share programming and staff; deleting requirements for the submission of certain reports to the Agency for Health Care Administration; amending s. 400.142, F.S.; deleting the agency's authority to adopt rules relating to orders not to resuscitate; amending s. 400.147, F.S.; revising provisions relating to adverse incident reports; deleting certain reporting requirements; creating s. 400.172, F.S.; providing requirements for a nursing home facility operated by a licensee that provides respite care services; providing for rights of persons receiving respite care in nursing home facilities; requiring a prospective respite care recipient to provide certain information to the nursing home facility; 400.23, F.S.; specifying the content of rules relating to nursing home facility staffing requirements for residents under 21 years of age; amending s. 400.275, F.S.; revising agency duties with regard to training nursing home surveyor teams; revising requirements for team members; reenacting s. 400.506(6)(a), F.S., relating to licensure of nurse registries, respectively, to incorporate the amendment made to s. 400.509, F.S., in references 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 or homemaker 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.; revising the definition of "hospice"; 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. 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.; providing an exception from certain requirement for exemption from certificate-of-need review for hospitals providing percutaneous coronary intervention for certain patients; amending s. 408.0361, F.S.; revising the criteria for qualifying for an exemption from certificateof-need review for hospitals providing cardiovascular services; amending s. 408.10, F.S.; removing agency authority to investigate certain consumer complaints; 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. 408.810, 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. 429.195, F.S.; revising provisions prohibiting certain rebates relating to assisted living facilities; amending s. 429.905, F.S.; defining the term "day" for purposes of day care services provided to adults who are not residents; amending s. 456.44, F.S.; revising the definition of the term "addiction medicine specialist" to include board-certified psychiatrists; defining the term "board eligible"; excluding a board-certified physiatrist as an addiction medicine specialist; including the American Board of Medical Specialties as a recognized certification entity; revising the definition of the term "chronic nonmalignant pain" to exclude reference to rheumatoid arthritis; exempting specified board-eligible health care providers from application of certain provisions; adding the American Board of Pain Medicine as a recognized board-certification entity for purposes of exemption from application of certain provisions; amending s. 458.3265, F.S.; defining the term "board eligible"; revising the definition of the term "chronic nonmalignant pain" to exclude reference to rheumatoid arthritis; permitting specified board-eligible physicians to own a pain-

management clinic without registering the clinic; permitting a rheumatologist to own a pain-management clinic without registering the clinic; including a physician multispecialty practice to permitted ownership forms of pain-management clinics; requiring at least one specialist in multispecialty practice to be board-eligible; recognizing the American Board of Pain Medicine, the American Association of Physician Specialists, and the American Osteopathic Association as board-certification organizations for purposes of determining a board-certified pain medicine specialist as an owner of a pain-management clinic; amending s. 459.0137, F.S.; defining the term "board eligible"; revising the definition of the term "chronic nonmalignant pain" to exclude reference to rheumatoid arthritis; permitting a board-eligible rheumatologist to own a pain-management clinic; including a physician multispecialty practice to permitted ownership forms of pain-management clinics; permitting specified board-eligible physicians to own a pain-management clinic without registering the clinic; permitting a rheumatologist to own a pain-management clinic without registering the clinic; adding multispecialty practice to permitted ownership forms of pain-management clinics; requiring at least one specialist in multispecialty practice to be board eligible; recognizing the American Board of Pain Medicine and the American Association of Physician Specialists as board-certification organizations for purposes of determining a board-certified pain medicine specialist as owner of a pain-management clinic; amending s. 483.23, F.S.; requiring the agency to refer criminal acts regarding the operation of a clinical laboratory to a local law enforcement agency; authorizing the agency to issue and deliver notice to cease and desist and impose an administrative penalty for each act; amending s. 483.245, F.S.; providing that a clinical laboratory is prohibited from providing personnel to perform functions or duties in a physician's office unless the laboratory and the physician's office are owned and operated by the same entity; prohibiting a clinical laboratory from leasing space in a physician's office; requiring the agency to investigate complaints, impose fines, and deny an application for a license or license renewal under certain circumstances; amending s. 651.118, F.S.; providing a funding limitation on sheltered nursing home beds used to provide assisted living, rather than extended congregate care services; authorizing certain sharing of areas, services, and staff between such sheltered beds and nursing home beds in those facilities; amending s. 817.505, F.S.; conforming provisions to changes made by the act; providing that the licensure requirements of part X of ch. 400, F.S., do not apply to certain specified entities; providing that the Agency for Health Care Administration may deny or revoke the exemption from the licensure requirements under certain circumstances; amending s. 409.912, F.S.; revising provisions requiring the agency to post certain information relating to drugs subject to prior authorization on its Internet website; providing a definition of the term "step edit"; 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. 400.462, F.S.; revising the definition of

3

"remuneration" to exclude items having a value of \$15 or less; 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. 468.1695, F.S.; providing that a health services administration or an equivalent major satisfies the education requirements for nursing home administrator applicants; providing an effective date.

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

Section 1. Subsection (30) of section 395.002, Florida Statutes, is amended to read:

395.002 Definitions.—As used in this chapter:

(30) "Urgent care center" means a facility or clinic that provides immediate but not emergent ambulatory medical care to patients with or without an appointment. The term includes an offsite It does not include the emergency department of a hospital <u>that is presented to the general public in</u> any manner as a department where immediate and not only emergent medical care is provided. The term also includes:

(a) An offsite facility of a facility licensed under chapter 395, or a joint venture between a facility licensed under chapter 395 and a provider licensed under chapter 458 or chapter 459, that does not require a patient to make an appointment and is presented to the general public in any manner as a facility where immediate but not emergent medical care is provided.

(b) A clinic organization that is licensed under part X of chapter 400, maintains three or more locations using the same or a similar name, does not require a patient to make an appointment, and holds itself out to the general public in any manner as a facility or clinic where immediate but not emergent medical care is provided.

Section 2. Section 395.107, Florida Statutes, is amended to read:

395.107 Urgent care centers; publishing and posting schedule of charges; penalties.—

(1) An urgent care center must publish <u>and post</u> a schedule of charges for the medical services offered to patients.

(2) The schedule of charges must describe the medical services in language comprehensible to a layperson. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area of the urgent care center and must include, but is not limited to, the 50 services most frequently provided by the urgent care center. The schedule may group services by three price levels, listing services in each price level. The posting may be a sign, which must be at least 15 square feet in size, or may be through an electronic messaging

4

board. If an urgent care center is affiliated with a facility licensed under this chapter, the schedule must include text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital. The text notifying the patient of the schedule of charges shall be in a font size equal to or greater than the font size used for prices and must be in a contrasting color. The text that notifies the insured patients whether the charges for medical services received at the center will be the same as, or more than, charges for medical services received at the affiliated hospital shall be included in all media and Internet advertisements for the center and in language comprehensible to a layperson.

(3) The posted text describing the medical services must fill at least 12 square feet of the posting. A center may use an electronic device or messaging board to post the schedule of charges. Such a device must be at least 3 square feet and patients must be able to access the schedule during all hours of operation of the urgent care center.

(4) An urgent care center that is operated and used exclusively for employees and the dependents of employees of the business that owns or contracts for the urgent care center is exempt from this section.

(5) The failure of an urgent care center to publish and post a schedule of charges as required by this section shall result in a fine of not more than \$1,000, per day, until the schedule is published and posted.

Section 3. Paragraph (i) of subsection (1) of section 400.9935, Florida Statutes, is amended to read:

400.9935 Clinic responsibilities.—

(1) Each clinic shall appoint a medical director or clinic director who shall agree in writing to accept legal responsibility for the following activities on behalf of the clinic. The medical director or the clinic director shall:

(i) Ensure that the clinic publishes a schedule of charges for the medical services offered to patients. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area of the urgent care center and must include, but is not limited to, the 50 services most frequently provided by the clinic. The schedule may group services by three price levels, listing services in each price level. The posting may be a sign that must be at least 15 square feet in size or through an electronic messaging board that is at least 3 square feet in size. The failure of a clinic to publish and post a schedule of charges as required by this section shall result in a fine of not more than \$1,000, per day, until the schedule is published and posted.

Section 4. Subsections (8) and (16) of section 400.021, Florida Statutes, are amended, and subsection (19) is added to that section, to read:

 $\mathbf{5}$

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, <u>or a licensed practical nurse under the direct</u> <u>supervision of a registered nurse, advanced registered nurse practitioner,</u> <u>physician assistant, or physician</u>.

(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.

(19) "Therapeutic spa services" means bathing, nail, and hair care services and other similar services related to personal hygiene.

Section 5. Subsection (2) of section 400.1183, Florida Statutes, is amended to read:

400.1183 Resident grievance procedures.—

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

Section 6. Paragraphs (p), (q), (s), (t), (u), (v), (w) of subsection (1) of section 400.141, Florida Statutes, are redesignated as paragraphs (o), (p), (q), (r), (s), (t), and (u), respectively, and present paragraphs (f), (g), (j), (n), (o), (p), (q), (r), and (s) of that subsection are amended, to read:

400.141 Administration and management of nursing home facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(f) Be allowed and encouraged by the agency to provide other needed services under certain conditions. If the facility has a standard licensure

6

status, and has had no class I or class II deficiencies during the past 2 years or has been awarded a Gold Scal under the program established in s. 400.235, it may be encouraged by the agency to provide services, including, but not limited to, respite, therapeutic spa, and adult day services to nonresidents, which enable individuals to move in and out of the facility. A facility is not subject to any additional licensure requirements for providing these services. Respite care may be offered to persons in need of short-term or temporary nursing home services. Respite care must be provided in accordance with this part and rules adopted by the agency. However, the agency shall, by rule, adopt modified requirements for resident assessment, resident care plans, resident contracts, physician orders, and other provisions, as appropriate, for short-term or temporary nursing home services. Providers of adult day services must comply with the requirements of s. 429.905(2). The agency shall allow for shared programming and staff in a facility which meets minimum standards and offers services pursuant to this paragraph, but, if the facility is cited for deficiencies in patient care, may require additional staff and programs appropriate to the needs of service recipients. A person who receives respite care may not be counted as a resident of the facility for purposes of the facility's licensed capacity unless that person receives 24-hour respite care. A person receiving either respite care for 24 hours or longer or adult day services must be included when calculating minimum staffing for the facility. Any costs and revenues generated by a nursing home facility from nonresidential programs or services shall be excluded from the calculations of Medicaid per diems for nursing home institutional care reimbursement.

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

7

nursing assistants or licensed nurses. The agency may adopt rules for the documentation necessary to determine compliance with this provision.

(j) Keep full records of resident admissions and discharges; medical and general health status, including medical records, personal and social history, and identity and address of next of kin or other persons who may have responsibility for the affairs of the <u>resident residents</u>; and individual resident care plans, including, but not limited to, prescribed services, service frequency and duration, and service goals. The records <u>must shall</u> be open to <u>agency</u> inspection by the <u>agency</u>. <u>The licensee shall maintain clinical records on each resident in accordance with accepted professional standards and practices, which must be complete, accurately documented, readily accessible, and systematically organized.</u>

(n) Submit to the agency the information specified in s. 400.071(1)(b) for a management company within 30 days after the effective date of the management agreement.

(o)1. Submit semiannually to the agency, or more frequently if requested by the agency, information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. For purposes of this reporting:

a. Staff-to-resident ratios must be reported in the categories specified in s. 400.23(3)(a) and applicable rules. The ratio must be reported as an average for the most recent calendar quarter.

b. Staff turnover must be reported for the most recent 12-month period ending on the last workday of the most recent calendar quarter prior to the date the information is submitted. The turnover rate must be computed quarterly, with the annual rate being the cumulative sum of the quarterly rates. The turnover rate is the total number of terminations or separations experienced during the quarter, excluding any employee terminated during a probationary period of 3 months or less, divided by the total number of staff employed at the end of the period for which the rate is computed, and expressed as a percentage.

c. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.

(n) Comply with state minimum-staffing requirements:

<u>1.d.</u> A nursing facility that has failed to comply with state minimumstaffing requirements for 2 consecutive days is prohibited from accepting new admissions until the facility has achieved the minimum-staffing requirements for <u>a period of</u> 6 consecutive days. For the purposes of this <u>subparagraph</u> sub-subparagraph, any person who was a resident of the

8

facility and was absent from the facility for the purpose of receiving medical care at a separate location or was on a leave of absence is not considered a new admission. Failure <u>by the facility</u> to impose such an admissions moratorium is subject to a \$1,000 fine constitutes a class II deficiency.

<u>2.e.</u> A nursing facility <u>that which</u> does not have a conditional license may be cited for failure to comply with the standards in s. 400.23(3)(a)1.b. and c. only if it has failed to meet those standards on 2 consecutive days or if it has failed to meet at least 97 percent of those standards on any one day.

<u>3.f.</u> A facility that which has a conditional license must be in compliance with the standards in s. 400.23(3)(a) at all times.

2. This paragraph does not limit the agency's ability to impose a deficiency or take other actions if a facility does not have enough staff to meet the residents' needs.

(\underline{o})(\underline{p}) Notify a licensed physician when a resident exhibits signs of dementia or cognitive impairment or has a change of condition in order to rule out the presence of an underlying physiological condition that may be contributing to such dementia or impairment. The notification must occur within 30 days after the acknowledgment of such signs by facility staff. If an underlying condition is determined to exist, the facility shall arrange, with the appropriate health care provider, arrange for the necessary care and services to treat the condition.

 $(\underline{p})(\underline{q})$ If the facility implements a dining and hospitality attendant program, ensure that the program is developed and implemented under the supervision of the facility director of nursing. A licensed nurse, licensed speech or occupational therapist, or a registered dietitian must conduct training of dining and hospitality attendants. A person employed by a facility as a dining and hospitality attendant must perform tasks under the direct supervision of a licensed nurse.

(r) Report to the agency any filing for bankruptcy protection by the facility or its parent corporation, divestiture or spin-off of its assets, or corporate reorganization within 30 days after the completion of such activity.

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

Section 7. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate.—

(3) Facility staff may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s.

9

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

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

400.147 Internal risk management and quality assurance program.—

The nursing home facility shall initiate an investigation and shall (7)notify the agency within 1 business day after the risk manager or his or her designee has received a report pursuant to paragraph (1)(d). The facility must complete the investigation and submit a report to the agency within 15 calendar days after the adverse incident occurred. The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery. The agency shall develop a form for the report which notification must include the name of the risk manager, information regarding the identity of the affected resident, the type of adverse incident, the initiation of an investigation by the facility, and whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The report notification is confidential as provided by law and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The agency may investigate, as it deems appropriate, any such incident and prescribe measures that must or may be taken in response to the incident. The agency shall review each report incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

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

(b) The information reported to the agency pursuant to paragraph (a) which relates to persons licensed under chapter 458, chapter 459, chapter 461, or chapter 466 shall be reviewed by the agency. The agency shall determine whether any of the incidents potentially involved conduct by a health care professional who is subject to disciplinary action, in which case the provisions of s. 456.073 shall apply.

10

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

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

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

Section 9. Section 400.172, Florida Statutes, is created to read:

400.172 Respite care provided in nursing home facilities.—

(1) For each person admitted for respite care as authorized under s. 400.141(1)(f), a nursing home facility operated by a licensee must:

(a) Have a written abbreviated plan of care that, at a minimum, includes nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. The nursing or physician assessments may take the place of all other assessments required for full-time residents.

(b) Have a contract that, at a minimum, specifies the services to be provided to a resident receiving respite care, including charges for services, activities, equipment, emergency medical services, and the administration of medications. If multiple admissions for a single person for respite care are anticipated, the original contract is valid for 1 year after the date the contract is executed.

(c) Ensure that each resident is released to his or her caregiver or an individual designated in writing by the caregiver.

(2) A person admitted under the respite care program shall:

(a) Be exempt from department rules relating to the discharge planning process.

(b) Be covered by the residents' rights specified in s. 400.022(1)(a)-(o) and (r)-(t). Funds or property of the resident are not be considered trust funds

11

subject to the requirements of s. 400.022(1)(h) until the resident has been in the facility for more than 14 consecutive days.

(c) Be allowed to use his or her personal medications during the respite stay if permitted by facility policy. The facility must obtain a physician's order for the medications. The caregiver may provide information regarding the medications as part of the nursing assessment and that information must agree with the physician's order. Medications shall be released with the resident upon discharge in accordance with current physician's orders.

(d) Be entitled to reside in the facility for a total of 60 days within a contract year or for a total of 60 days within a calendar year if the contract is for less than 12 months. However, each single stay may not exceed 14 days. If a stay exceeds 14 consecutive days, the facility must comply with all assessment and care planning requirements applicable to nursing home residents.

(e) Reside in a licensed nursing home bed.

(3) A prospective respite care resident must provide medical information from a physician, physician assistant, or nurse practitioner and any other information provided by the primary caregiver required by the facility before or when the person is admitted to receive respite care. The medical information must include a physician's order for respite care and proof of a physical examination by a licensed physician, physician assistant, or nurse practitioner. The physician's order and physical examination may be used to provide intermittent respite care for up to 12 months after the date the order is written.

(4) The facility shall assume the duties of the primary caregiver. To ensure continuity of care and services, the resident may retain his or her personal physician and shall have access to medically necessary services such as physical therapy, occupational therapy, or speech therapy, as needed. The facility shall arrange for transportation of the resident to these services, if necessary.

Section 10. Subsection (5) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(5) The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, must, no later than December 31, 1993, adopt rules for<u>:</u>

(a) Minimum standards of care for persons under 21 years of age who reside in nursing home facilities. The rules must include a methodology for reviewing a nursing home facility under ss. 408.031-408.045 which serves only persons under 21 years of age. A facility may be exempted exempt from these standards for specific persons between 18 and 21 years of age, if the

12

person's physician agrees that minimum standards of care based on age are not necessary.

(b) Minimum staffing requirements for persons under 21 years of age who reside in nursing home facilities, which apply in lieu of the requirements contained in subsection (3).

1. For persons under 21 years of age who require skilled care:

a. A minimum combined average of 3.9 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day must be provided.

c. No more than 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

2. For persons under 21 years of age who are medically fragile:

a. A minimum combined average of 5.0 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.7 hours of direct care per resident per day must be provided.

c. No more than 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

Section 11. 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 eitation 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

13

visit at a nursing home facility in which the surveyor was an employee within the preceding $\underline{2} \ \underline{5}$ years.

Section 12. 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, Florida Statutes, is reenacted, and subsection (18) 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 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.

(18) 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 13. 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. <u>An organization under contract with the Agency for Persons with Disabilities</u> which provides companion services only for persons with a developmental disability, as defined in s. 393.063, is exempt from registration.

Section 14. Subsection (3) of section 400.601, Florida Statutes, is amended to read:

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

14

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

Section 15. 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 <u>that has with six or fewer beds is shall not be</u> required to comply with institutional standards such as, but not limited to, standards requiring sprinkler systems, emergency electrical systems, or special lavatory devices.

Section 16. 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 17. Section 400.931, Florida Statutes, is amended to read:

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

15

(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

16

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

17

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 20. Paragraph (n) of subsection (3) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

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

(n) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart-surgery program. In addition to any other documentation required by the agency, a request for an exemption submitted under this paragraph must comply with the following:

1. The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements shall be adopted by rule pursuant to ss. 120.536(1) and 120.54 and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum, the rules <u>must shall</u> require the following:

a. Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.

b. The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.

c. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.

d. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on previous experience in dedicated interventional laboratories or surgical centers.

e. Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.

f. Formalized written transfer agreements must be developed with a hospital with an adult open-heart-surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be reviewed and

18

tested, with appropriate documentation maintained at least every 3 months. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols that ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

g. Hospitals implementing the service must first undertake a training program of 3 to 6 months' duration, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.

2. The applicant must certify that it will use at all times the patientselection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the following:

a. Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.

b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.

3. The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.

4. The exemption provided by this paragraph does not apply unless the agency determines that the hospital has taken all necessary steps to be in compliance with all requirements of this paragraph, including the training program required under sub-subparagraph 1.g.

5. Failure of the hospital to continuously comply with the requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. and 3. will result in the immediate expiration of this exemption.

6. Failure of the hospital to meet the volume requirements of subsubparagraphs 1.a. and b. within 18 months after the program begins offering the service will result in the immediate expiration of the exemption.

If the exemption for this service expires under subparagraph 5. or subparagraph 6., the agency may not grant another exemption for this service to the same hospital for 2 years and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused

19

expiration of the exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted pursuant to this paragraph.

Section 21. Paragraph (b) of subsection (3) of section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.-

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

For a hospital seeking a Level I program, demonstration that, for the (b) most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

Section 22. 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 23. <u>Subsection (11) of section 408.802</u>, Florida Statutes, is repealed.

Section 24. Subsection (3) is added to section 408.804, Florida Statutes, to read:

20

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 25. 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)

The agency shall notify the licensee by mail or electronically at least (d) 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 handcanceled 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 26. 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 <u>projected pro forma</u> financial statements, including a balance sheet, income and expense statement, and a statement of cash flows for the

21

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 27. 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 28. 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.

22

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

Section 29. Section 429.195, Florida Statutes, is amended to read:

429.195 Rebates prohibited; penalties.—

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

(2) This section does not apply to:

(a) An individual employed by the assisted living facility, or with whom the facility contracts to provide marketing services for the facility, if the individual clearly indicates that he or she works with or for the facility.

(b) Payments by an assisted living facility to a referral service that provides information, consultation, or referrals to consumers to assist them in finding appropriate care or housing options for seniors or disabled adults if the referred consumers are not Medicaid recipients.

(c) A resident of an assisted living facility who refers a friend, family members, or other individuals with whom the resident has a personal relationship to the assisted living facility, in which case the assisted living facility may provide a monetary reward to the resident for making such referral.

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

Section 30. Subsection (2) of section 429.905, Florida Statutes, is amended to read:

429.905 Exemptions; monitoring of adult day care center programs colocated with assisted living facilities or licensed nursing home facilities.

(2) A licensed assisted living facility, a licensed hospital, or a licensed nursing home facility may provide services during the day which include, but are not limited to, social, health, therapeutic, recreational, nutritional, and respite services, to adults who are not residents. Such a facility need not be licensed as an adult day care center; however, the agency must monitor the

23

facility during the regular inspection and at least biennially to ensure adequate space and sufficient staff. If an assisted living facility, a hospital, or a nursing home holds itself out to the public as an adult day care center, it must be licensed as such and meet all standards prescribed by statute and rule. For the purpose of this subsection, the term "day" means any portion of a 24-hour day.

Section 31. Present paragraphs (a), (c), and (d) of subsection (1), paragraph (a) of subsection (2), and paragraph (e) of subsection (3) of section 456.44, Florida Statutes, are amended, and a new paragraph (d) is added to subsection (1) of that section, to read:

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.—

(a) "Addiction medicine specialist" means a board-certified <u>psychiatrist</u> physiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(c) "Board-certified pain management physician" means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management <u>or</u> <u>pain medicine</u> by a specialty board recognized by the American Association of Physician Specialists <u>or the American Board of Medical Specialties</u> or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e)(d) "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(2) REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, <u>listed in Schedule II, Schedule III, or Schedule IV</u> as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.

24

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an <u>addiction medicine specialist or psychiatrist</u> addictionologist or physiatrist.

This subsection does not apply to a <u>board-eligible or</u> board-certified anesthesiologist, physiatrist, <u>rheumatologist</u>, or neurologist, or to a boardcertified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a <u>board-eligible or</u> board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is <u>board eligible or</u> board certified in pain medicine by <u>the American Board of Pain Medicine or</u> a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. <u>This subsection does not apply to a physician who prescribes</u> <u>medically necessary controlled substances for a patient during an inpatient</u> stay in a hospital licensed under chapter 395.

Section 32. Paragraph (a) of subsection (1) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

<u>b.a.</u> "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

<u>c.b.</u> "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

25

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:

a. That clinic is licensed as a facility pursuant to chapter 395;

b. The majority of the physicians who provide services in the clinic primarily provide surgical services;

c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;

d. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

e. The clinic does not prescribe controlled substances for the treatment of pain;

f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);

g. The clinic is wholly owned and operated by one or more <u>board-eligible</u> <u>or</u> board-certified anesthesiologists, physiatrists, <u>rheumatologists</u>, or neurologists; or

h. The clinic is wholly owned and operated by <u>a physician multispecialty</u> <u>practice where</u> one or more <u>board-eligible or</u> board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education, or who are also board-certified in pain medicine by <u>the American Board of Pain Medicine or</u> a board approved by the American Board of Medical Specialties, <u>the American Association of Physician Specialists</u>, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

Section 33. Paragraph (a) of subsection (1) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

<u>b.a.</u> "Chronic nonmalignant pain" means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

<u>c.b.</u> "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:

a. That clinic is licensed as a facility pursuant to chapter 395;

b. The majority of the physicians who provide services in the clinic primarily provide surgical services;

c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;

d. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

e. The clinic does not prescribe controlled substances for the treatment of pain;

f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);

g. The clinic is wholly owned and operated by one or more <u>board-eligible</u> <u>or</u> board-certified anesthesiologists, physiatrists, <u>rheumatologists</u>, or neurologists; or

h. The clinic is wholly owned and operated by <u>a physician multispecialty</u> <u>practice where</u> one or more <u>board-eligible or</u> board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who are also board-certified in pain

27

medicine by <u>the American Board of Pain Medicine or</u> a board approved by the American Board of Medical Specialties, <u>the American Association of Physician Specialists</u>, or the American Osteopathic Association and perform interventional pain procedures of the type routinely billed using surgical codes.

Section 34. Paragraph (b) of subsection (1) of section 483.23, Florida Statutes, is amended to read:

483.23 Offenses; criminal penalties.—

(1)

(b) The performance of any act specified in paragraph (a) <u>shall be referred</u> by the agency to the local law enforcement agency and constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. <u>Additionally, the agency may issue and deliver a notice to cease</u> and desist from such act and may impose by citation an administrative penalty not to exceed \$5,000 per act. Each day that unlicensed activity continues after issuance of a notice to cease and desist constitutes a separate act.

Section 35. Subsection (1) of section 483.245, Florida Statutes, is amended, and subsection (3) is added to that section, to read:

483.245 Rebates prohibited; penalties.—

(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. <u>A clinical laboratory is prohibited from</u>, directly or indirectly, providing through employees, contractors, an independent staffing company, lease agreement, or otherwise, personnel to perform any functions or duties in a physician's office, or any part of a physician's office, for any purpose whatsoever, including for the collection or handling of specimens, unless the laboratory and the physician's office are wholly owned and operated by the same entity. A clinical laboratory is prohibited from leasing space within any part of a physician's office for any purpose of establishing a collection station.

(3) The agency shall promptly investigate all complaints of noncompliance with subsection (1). The agency shall impose a fine of \$5,000 for each separate violation of subsection (1). In addition, the agency shall deny an application for a license or license renewal if the applicant, or any other entity with one or more common controlling interests in the applicant, demonstrates a pattern of violating subsection (1). A pattern may be demonstrated by a showing of at least two such violations.

Section 36. Subsection (8) of section 651.118, Florida Statutes, is amended to read:

28

651.118 Agency for Health Care Administration; certificates of need; sheltered beds; community beds.—

(8) A provider may petition the Agency for Health Care Administration to use a designated number of sheltered nursing home beds to provide <u>assisted</u> <u>living extended congregate care as defined in s. 429.02</u> if the beds are in a distinct area of the nursing home which can be adapted to meet the requirements for <u>an assisted living facility as defined in s. 429.02</u> extended congregate care. The provider may subsequently use such beds as sheltered beds after notifying the agency of the intended change. Any sheltered beds used to provide <u>assisted living</u> extended congregate care pursuant to this subsection may not qualify for funding under the Medicaid waiver. Any sheltered beds used to provide <u>assisted living</u> extended congregate care pursuant to this subsection may share common areas, services, and staff with beds designated for nursing home care, provided that all of the beds are under common ownership. For the purposes of this subsection, fire and life safety codes applicable to nursing home facilities shall apply.

Section 37. Paragraph (j) is added to subsection (3) of section 817.505, Florida Statutes, to read:

817.505 Patient brokering prohibited; exceptions; penalties.—

(3) This section shall not apply to:

(j) Any activity permitted under s. 429.195(2).

Section 38. Paragraphs (m) and (n) are added to subsection (4) of section 400.9905, Florida Statutes, 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 equipment provider. For purposes of this part, the term does not include and the licensure requirements of this part do not apply to:

(m) Entities that are owned by a corporation that has \$250 million or more in total annual sales of health care services provided by licensed health care practitioners where one or more of the owners is a health care practitioner who is licensed in this state and who 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 part.

(n) Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 where the billing for medical services is under a single tax identification number, the application for exemption under this subsection shall contain information that includes: the name, residence and business address and phone number of the entity that owns the practice; a complete list of the names and contact information of all

29

the officers and directors of the corporation; the name, residence address, business address and medical license number of each licensed Florida health care practitioner 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 personal injury protection insurance coverage for the preceding year. If the agency determines that an entity which is exempt under this subsection has received payments for medical services under personal injury protection insurance coverage the agency may deny or revoke the exemption from licensure under this subsection.

Section 39. 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

30

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

31

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-programmanagement 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 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

32

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.

The agency may establish a preferred drug list as described in this 7. 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.

33

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 qualitybased 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

34

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.

35

The agency <u>shall may</u> post prior authorization, <u>step-edit</u> criteria and protocol, and updates to the list of drugs that are subject to prior authorization on <u>the agency's</u> an Internet website <u>within 21 days after the</u> prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "stepedit" means an automatic electronic review of certain medications subject to prior authorization 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

36

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.

(b) The agency shall implement this subsection to the extent that funds are appropriated to administer the Medicaid prescribed-drug spendingcontrol program. The agency may contract all or any part of this program to private organizations.

(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.

Section 40. 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 41. Subsection (27) of section 400.462, Florida Statutes, is amended to read:

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

(27) "Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. <u>However, if the term is</u> <u>used in any provision of law relating to health care providers, the term does</u> <u>not apply to an item that has an individual value of up to \$15, including, but</u> <u>not limited to, a plaque, a certificate, a trophy, or a novelty item that is</u> <u>intended solely for presentation or is customarily given away solely for</u> <u>promotional, recognition, or advertising purposes.</u>

Section 42. Paragraph (c) of subsection (1) of section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

37

(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 <u>or the applicant's</u> parent corporation if audited financial statements of the applicant do not <u>exist</u>. 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 43. Subsection (2) of section 468.1695, Florida Statutes, is amended to read:

468.1695 Licensure by examination.—

(2) The department shall examine each applicant who the board certifies has completed the application form and remitted an examination fee set by the board not to exceed \$250 and who:

(a)1. Holds a baccalaureate degree from an accredited college or university and majored in health care administration, <u>health services</u> <u>administration</u>, or an equivalent major, or has credit for at least 60 semester hours in subjects, as prescribed by rule of the board, which prepare the applicant for total management of a nursing home; and

2. Has fulfilled the requirements of a college-affiliated or universityaffiliated internship in nursing home administration or of a 1,000-hour nursing home administrator-in-training program prescribed by the board; or

 $(b)\mathbf{1}.$ Holds a baccalaureate degree from an accredited college or university; and

2.a. Has fulfilled the requirements of a 2,000-hour nursing home administrator-in-training program prescribed by the board; or

b. Has 1 year of management experience allowing for the application of executive duties and skills, including the staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, hospital, hospice, assisted living facility with a minimum of 60 licensed beds, or geriatric residential treatment program and, if such experience is not in a skilled nursing facility, has fulfilled the requirements of a 1,000-hour nursing home administrator-in-training program prescribed by the board.

Section 44. This act shall take effect July 1, 2012.

Approved by the Governor April 27, 2012.

Filed in Office Secretary of State April 27, 2012.