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A bill to be entitled An act relating to health care services rulemaking; amending s. 390.012, F.S.; revising rulemaking authority relating to the operation of certain abortion clinics; amending s. 400.021, F.S.; revising the definition of the term "nursing home bed" to remove rulemaking authority for determining minimum space requirements for nursing home beds; amending s. 400.0712, F.S.; removing rulemaking authority relating to inactive nursing home facility licenses; amending s. 400.23, F.S.; revising general rulemaking authority relating to nursing homes and certain health care providers; amending s. 400.487, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to home health agency personnel; amending s. 400.497, F.S.; revising rulemaking authority relating to the Home Health Services Act; amending s. 400.506, F.S.; removing rulemaking authority relating to the licensure of nurse registries and the establishment of certain emergency management plans; amending s. 400.509, F.S.; removing rulemaking authority relating to registration of certain companion services and homemaker services; amending s. 400.6095, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to a hospice care team; amending s. 400.914,

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F.S.; revising rulemaking authority relating to standards for prescribed pediatric extended care (PPEC) centers; removing rulemaking authority relating to certain limitations on PPEC centers; creating s. 400.9141, F.S.; providing limitations on PPEC centers; amending s. 400.934, F.S.; revising rulemaking authority relating to the preparation of emergency managements plans by home medical equipment providers; amending s. 400.935, F.S.; revising rulemaking authority relating to minimum standards for home medical equipment providers; amending s. 400.962, F.S.; removing rulemaking authority relating to certain standards for active treatment by intermediate care facilities for the developmentally disabled; amending s. 400.967, F.S.; revising rulemaking authority relating to the construction of, the preparation of emergency management plans by, and the classification of deficiencies of intermediate care facilities for the developmentally disabled; amending s. 400.980, F.S.; removing rulemaking authority relating to the registration of health care services pools; amending s. 409.912, F.S.; removing rulemaking authority relating to Medicaid provider lock-in programs; amending s. 429.255, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to assisted living facility

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staff and the use of automated external defibrillators; amending s. 429.73, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to adult family-care home providers; amending s. 440.102, F.S.; removing rulemaking authority relating to certain guidelines for drug-free workplace laboratories; amending s. 483.245, F.S.; revising rulemaking authority relating to the imposition of certain administrative penalties against clinical laboratories; amending s. 765.541, F.S.; revising rulemaking authority relating to standards and guidelines for certain organ donation programs; amending s. 765.544, F.S., removing rulemaking authority relating to administrative penalties for violations with respect to organ and tissue donations; providing an effective date.

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WHEREAS, rulemaking is not a matter of agency discretion; rulemaking authority is delegated by the Legislature for agencies to adopt statements of general applicability that interpret or implement law; the valid adoption of a rule requires both a grant of express rulemaking authority and a specific law to be implemented or interpreted, and

WHEREAS, the repeal or deletion of a redundant or unnecessary provision authorizing agency rulemaking does not repeal rulemaking authority otherwise provided that clearly

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applies to the same subject, and

WHEREAS, statutory provisions mandating rules, when the substantive law otherwise would be implemented either without need for administrative rules or by rulemaking under a broader grant of authority, may be repealed without altering the substantive law or rulemaking authority on which existing rules rely, NOW THEREFORE

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

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Section 1. Paragraph (d) of subsection (3) of section 390.012, Florida Statutes, is amended to read:

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390.012 Powers of agency; rules; disposal of fetal remains.—

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(3) For clinics that perform or claim to perform abortions after the first trimester of pregnancy, the agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter, including the following:

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(d) Rules relating to the medical screening and evaluation of each abortion clinic patient. At a minimum, these rules shall require:

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1. A medical history, including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history.

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2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.

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3. The appropriate laboratory tests, including:

- a. Urine or blood tests for pregnancy performed before the abortion procedure.
  - b. A test for anemia.

- c. Rh typing, unless reliable written documentation of blood type is available.
  - d. Other tests as indicated from the physical examination.
- 4. An ultrasound evaluation for all patients. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed in rule. The rules shall require clinics to be in compliance with s. 390.0111.
- 5. That the physician is responsible for estimating the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule and shall write the estimate in the patient's medical history. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.
- Section 2. Subsection (11) of section 400.021, Florida Statutes, is amended to read:
- 400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:
- (11) "Nursing home bed" means an accommodation that which is ready for immediate occupancy, or is capable of being made

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ready for occupancy within 48 hours, excluding provision of staffing; and that which conforms to minimum space requirements, including the availability of appropriate equipment and furnishings within the 48 hours, as specified by rule of the agency, for the provision of services specified in this part to a single resident.

Section 3. Subsection (3) of section 400.0712, Florida Statutes, is amended to read:

400.0712 Application for inactive license.-

- (3) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.
- Section 4. Subsection (2), paragraph (a) of subsection (3), subsections (4) and (5), paragraph (e) of subsection (7), and subsection (8) of section 400.23, Florida Statutes, are amended to read:
- 400.23 Rules; evaluation and deficiencies; licensure status.—
- (2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, may shall adopt and enforce rules to implement this part and part II of chapter 408. The rules, which shall include, but need not be limited to, reasonable and fair criteria in relation to:
- (a) The location of the facility and housing conditions that will ensure the health, safety, and comfort of residents, including an adequate call system. In making such rules, the

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agency shall be guided by criteria recommended by nationally recognized reputable professional groups and associations with knowledge of such subject matters. The agency shall update or revise such criteria as the need arises. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. In performing any inspections of facilities authorized by this part or part II of chapter 408, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to nursing homes. Residents or their representatives shall be able to request a change in the placement of the bed in their room, provided that at admission they are presented with a room that meets requirements of the Florida Building Code. The location of a bed may be changed if the requested placement does not infringe on the resident's roommate or interfere with the resident's care or safety as determined by the care planning team in accordance with facility policies and procedures. In addition, the bed placement may not be used as a restraint. Each facility shall maintain a log of resident rooms with beds that are not in strict compliance with the Florida Building Code in order for such log to be used by surveyors and nurse monitors during inspections and visits. A resident or resident representative who requests that a bed be moved shall sign a statement indicating that he or she understands the room will not be in compliance with the Florida Building Code, but they

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would prefer to exercise their right to self-determination. The statement must be retained as part of the resident's care plan. Any facility that offers this option must submit a letter signed by the nursing home administrator of record to the agency notifying it of this practice with a copy of the policies and procedures of the facility. The agency is directed to provide assistance to the Florida Building Commission in updating the construction standards of the code relative to nursing homes.

- (b) The number and qualifications of all personnel, including management, medical, nursing, and other professional personnel, and nursing assistants, orderlies, and support personnel, having responsibility for any part of the care given residents.
- (c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene which will ensure the health and comfort of residents.
- (d) The equipment essential to the health and welfare of the residents.
  - (e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof, based on rules developed under this chapter and the Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203) (December 22, 1987), Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended.

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| (g) The preparation and annual update of a comprehensive                               |  |  |
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| emergency management plan. The agency shall $\underline{establish}\ \underline{adopt}$ |  |  |
| rules establishing minimum criteria for the plan after                                 |  |  |
| consultation with the Division of Emergency Management. At a                           |  |  |
| minimum, the rules must provide for plan components shall                              |  |  |
| <pre>provide for that address emergency evacuation transportation;</pre>               |  |  |
| adequate sheltering arrangements; postdisaster activities,                             |  |  |
| including emergency power, food, and water; postdisaster                               |  |  |
| transportation; supplies; staffing; emergency equipment;                               |  |  |
| individual identification of residents and transfer of records;                        |  |  |
| and responding to family inquiries. The comprehensive emergency                        |  |  |
| management plan is subject to review and approval by the local                         |  |  |
| emergency management agency. During its review, the local                              |  |  |
| emergency management agency shall ensure that the following                            |  |  |
| agencies, at a minimum, are given the opportunity to review the                        |  |  |
| plan: the Department of Elderly Affairs, the Department of                             |  |  |
| Health, the Agency for Health Care Administration, and the                             |  |  |
| Division of Emergency Management. Also, appropriate volunteer                          |  |  |
| organizations must be given the opportunity to review the plan.                        |  |  |
| The local emergency management agency shall complete its review                        |  |  |
| within 60 days and either approve the plan or advise the                               |  |  |
| facility of necessary revisions.   |  |  |
| (1) [7]  |  |  |

- The availability, distribution, and posting of reports and records pursuant to s. 400.191 and the Gold Seal Program pursuant to s. 400.235.
  - The agency shall enforce adopt rules providing

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minimum staffing requirements for nursing home facilities <a href="these-requirements">that</a>.

These requirements must include, for each facility:

- a. A minimum weekly average of certified nursing assistant and licensed nursing staffing combined of 3.6 hours of direct care per resident per day. As used in this sub-subparagraph, a week is defined as Sunday through Saturday.
- b. A minimum certified nursing assistant staffing of 2.5 hours of direct care per resident per day. A facility may not staff below one certified nursing assistant per 20 residents.
- c. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day. A facility may not staff below one licensed nurse per 40 residents.
- 2. Nursing assistants employed under s. 400.211(2) may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.
- 3. Each nursing home facility must document compliance with staffing standards as required under this paragraph and post daily the names of staff on duty for the benefit of facility residents and the public.
- 4. The agency shall recognize the use of licensed nurses for compliance with minimum staffing requirements for certified nursing assistants if the nursing home facility otherwise meets the minimum staffing requirements for licensed nurses and the licensed nurses are performing the duties of a certified nursing assistant. Unless otherwise approved by the agency, licensed

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nurses counted toward the minimum staffing requirements for certified nursing assistants must exclusively perform the duties of a certified nursing assistant for the entire shift and not also be counted toward the minimum staffing requirements for licensed nurses. If the agency approved a facility's request to use a licensed nurse to perform both licensed nursing and certified nursing assistant duties, the facility must allocate the amount of staff time specifically spent on certified nursing assistant duties for the purpose of documenting compliance with minimum staffing requirements for certified and licensed nursing staff. The hours of a licensed nurse with dual job responsibilities may not be counted twice.

- (4) Rules developed pursuant to This section does shall not restrict the use of shared staffing and shared programming in facilities that which are part of retirement communities that provide multiple levels of care and otherwise meet the requirement of law or rule.
- (5) (a) The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, may establish must adopt rules for:
- (a) minimum standards of care for persons under 21 years of age who reside in nursing home facilities. A facility may be exempted from these standards and the requirements of paragraph (b) for specific persons between 18 and 21 years of age, if the person's physician agrees that minimum standards of care based on age are not necessary.

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(b) The following 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

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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.
- (7) The agency shall, at least every 15 months, evaluate all nursing home facilities and make a determination as to the degree of compliance by each licensee with the established rules adopted under this part as a basis for assigning a licensure status to that facility. The agency shall base its evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. In addition to license categories authorized under part II of chapter 408, the agency shall assign a licensure status of standard or conditional to each nursing home.
  - (e) The agency shall adopt rules that:
- 1. Establish uniform procedures for the evaluation of facilities.
  - 2. Provide criteria in the areas referenced in paragraph (c).
- 3. Address other areas necessary for carrying out the intent of this section.
- (8) The agency shall ensure that adopt rules pursuant to this part and part II of chapter 408 to provide that, when the criteria established under subsection (2) are not met, such deficiencies shall be classified according to the nature and the

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scope of the deficiency. The scope shall be cited as isolated, patterned, or widespread. An isolated deficiency is a deficiency affecting one or a very limited number of residents, or involving one or a very limited number of staff, or a situation that occurred only occasionally or in a very limited number of locations. A patterned deficiency is a deficiency where more than a very limited number of residents are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same resident or residents have been affected by repeated occurrences of the same deficient practice but the effect of the deficient practice is not found to be pervasive throughout the facility. A widespread deficiency is a deficiency in which the problems causing the deficiency are pervasive in the facility or represent systemic failure that has affected or has the potential to affect a large portion of the facility's residents. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. The condition or practice constituting a class I violation shall be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class

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I deficiency is subject to a civil penalty of \$10,000 for an isolated deficiency, \$12,500 for a patterned deficiency, and \$15,000 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A fine must be levied notwithstanding the correction of the deficiency.

- determines has compromised the resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class II deficiency is subject to a civil penalty of \$2,500 for an isolated deficiency, \$5,000 for a patterned deficiency, and \$7,500 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A fine shall be levied notwithstanding the correction of the deficiency.
- (c) A class III deficiency is a deficiency that the agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to the resident or has the potential to compromise the resident's ability to maintain or reach his or

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her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class III deficiency is subject to a civil penalty of \$1,000 for an isolated deficiency, \$2,000 for a patterned deficiency, and \$3,000 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A citation for a class III deficiency must specify the time within which the deficiency is required to be corrected. If a class III deficiency is corrected within the time specified, a civil penalty may not be imposed.

- (d) A class IV deficiency is a deficiency that the agency determines has the potential for causing no more than a minor negative impact on the resident. If the class IV deficiency is isolated, no plan of correction is required.
- Section 5. Subsection (7) of section 400.487, Florida Statutes, is amended to read:
- 400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—
  - (7) Home health agency personnel may withhold or withdraw

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cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and rules adopted by the agency.

Section 6. Section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency may shall adopt, publish, and enforce rules to implement part II of chapter 408 and this part, including, as applicable, ss. 400.506 and 400.509, which must provide reasonable and fair minimum standards relating to:

- (1) The home health aide competency test and home health aide training. The agency shall create the home health aide competency test and establish the curriculum and instructor qualifications for home health aide training. Licensed home health agencies may provide this training and shall furnish documentation of such training to other licensed home health agencies upon request. Successful passage of the competency test by home health aides may be substituted for the training required under this section and any rule adopted pursuant thereto.
  - (2) Shared staffing. The agency shall allow Shared Page 17 of 40

staffing <u>is permitted</u> if the home health agency is part of a retirement community that provides multiple levels of care, is located on one campus, is licensed under this chapter or chapter 429, and otherwise meets the requirements of law and rule.

- (3) The criteria for the frequency of onsite licensure surveys.
  - (4) Licensure application and renewal.

- (5) Oversight by the director of nursing, including. The agency shall develop rules related to:
- (a) Standards that address oversight responsibilities by the director of nursing of skilled nursing and personal care services provided by the home health agency's staff;
- (b) Requirements for a director of nursing to provide to the agency, upon request, a certified daily report of the home health services provided by a specified direct employee or contracted staff member on behalf of the home health agency. The agency may request a certified daily report only for a period not to exceed 2 years <u>before</u> prior to the date of the request; and
- (c) A quality assurance program for home health services provided by the home health agency.
- (6) Conditions for using a recent unannounced licensure inspection for the inspection required in s. 408.806 related to a licensure application associated with a change in ownership of a licensed home health agency.
  - (7) The requirements for onsite and electronic

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accessibility of supervisory personnel of home health agencies.

- (8) Information to be included in patients' records.
- (9) Geographic service areas.

- (10) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.
- (a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan and plan updates, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.
- (a) (b) An emergency plan The rules must address the requirements in s. 400.492. In addition, the rules shall provide for the maintenance of patient-specific medication lists that can accompany patients who are transported from their homes.
- (b)(c) The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan complies is in accordance with the requirements of law criteria in the Agency for Health Care Administration rules within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health department, the county health department shall notify the Agency

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for Health Care Administration. The agency shall notify the home health agency that its failure constitutes a deficiency, subject to a fine of \$5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

- (c) (d) For any home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders when necessary. The department shall complete its review within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. The department shall make every effort to avoid imposing differing requirements on a home health agency that operates in more than one county as a result of differing or conflicting comprehensive plan requirements of the counties in which the home health agency operates.
- $\underline{\text{(d)}}$  (e) The requirements in this subsection do not apply to:
- 1. A facility that is certified under chapter 651 and has a licensed home health agency used exclusively by residents of the facility; or
- 2. A retirement community that consists of residential units for independent living and either a licensed nursing home or an assisted living facility, and has a licensed home health agency used exclusively by the residents of the retirement community, provided the comprehensive emergency management plan

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for the facility or retirement community provides for continuous care of all residents with special needs during an emergency.

Section 7. Paragraph (f) of subsection (12) and subsection (17) of section 400.506, Florida Statutes, are amended to read: 400.506 Licensure of nurse registries; requirements;

526 penalties.-

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(12) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include the means by which the nurse registry will continue to provide the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients prior to evacuation. The plan shall specify how the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residences. Nurse registries may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for a provider to reach its clients. Nurse registries shall demonstrate a good faith effort to comply with the requirements of this subsection by documenting attempts of staff to follow procedures outlined in the nurse registry's comprehensive emergency management plan which support a finding that the

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provision of continuing care has been attempted for patients identified as needing care by the nurse registry and registered under s. 252.355 in the event of an emergency under this subsection.

- (f) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the comprehensive emergency management plan and plan updates required by this subsection, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.
- (17) The Agency for Health Care Administration shall adopt rules to implement this section and part II of chapter 408.
- Section 8. Subsection (7) 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.—
- (7) The Agency for Health Care Administration shall adopt rules to administer this section and part II of chapter 408.
- Section 9. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:
- 400.6095 Patient admission; assessment; plan of care; discharge; death.—
- (8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The department shall adopt rules providing for the implementation of such orders.

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Hospice staff shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules. The absence of an order 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 10. Section 400.914, Florida Statutes, is amended to read:

400.914 Rulemaking; Rules establishing standards.-

- (1) Pursuant to the intention of the Legislature to provide safe and sanitary facilities and healthful programs, the agency in conjunction with the Division of Children's Medical Services of the Department of Health may shall adopt and publish rules to implement the provisions of this part and part II of chapter 408, which shall include reasonable and fair standards. Any conflict between these rules standards and those standards that may be set forth in local, county, or city ordinances shall be resolved in favor of those having statewide effect. The rules shall include, but need not be limited to, reasonable and fair standards relating Such standards shall relate to:
- $\underline{\text{(1)}}_{\text{(a)}}$  The assurance that PPEC services are family centered and provide individualized medical, developmental, and family training services.
  - (2) (b) The maintenance of PPEC centers, not in conflict

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with the provisions of chapter 553 and based upon the size of the structure and number of children, relating to plumbing, heating, lighting, ventilation, and other building conditions, including adequate space, which will ensure the health, safety, comfort, and protection from fire of the children served.

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- (c) The appropriate provisions of the most recent edition of the "Life Safety Code" (NFPA-101) shall be applied.
- (d) The number and qualifications of all personnel who have responsibility for the care of the children served.
- (e) All sanitary conditions within the PPEC center and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, and maintenance thereof, which will ensure the health and comfort of children served.
- (f) Programs and basic services promoting and maintaining the health and development of the children served and meeting the training needs of the children's legal guardians.
- (g) Supportive, contracted, other operational, and transportation services.
- (h) Maintenance of appropriate medical records, data, and information relative to the children and programs. Such records shall be maintained in the facility for inspection by the agency.
  - (2) The agency shall adopt rules to ensure that:
- 622 (a) No child attends a PPEC center for more than 12 hours
  623 within a 24-hour period.
  - (b) No PPEC center provides services other than those

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625 provided to medically or technologically dependent children. 626 Section 11. Section 400.9141, Florida Statutes, is created 627 to read: 628 400.9141 Limitations.— 629 A child may not attend a PPEC center for more than 12 630 hours within a 24-hour period. (2) A PPEC center may only provide those services that are 631 provided to medically or technologically dependent children. 632 633 Section 12. Paragraph (a) of subsection (20) of section 400.934, Florida Statutes, is amended to read: 634 635 400.934 Minimum standards.—As a requirement of licensure, home medical equipment providers shall: 636 637 (20)(a)Prepare and maintain a comprehensive emergency 638 management plan that meets minimum criteria established by 639 agency rule, including the maintenance of patient equipment and 640 supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation 641 642 with the Department of Health and the Division of Emergency 643 Management under s. 400.935. The plan shall be updated annually 644 and shall provide for continuing home medical equipment services 645 for life-supporting or life-sustaining equipment, as defined in 646 s. 400.925, during an emergency that interrupts home medical 647 equipment services in a patient's home. The plan shall include: 648 The means by which the home medical equipment provider 649 will continue to provide equipment to perform the same type and

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quantity of services to its patients who evacuate to special

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needs shelters which were being provided to those patients prior to evacuation.

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- 2. The means by which the home medical equipment provider establishes and maintains an effective response to emergencies and disasters, including plans for:
- a. Notification of staff when emergency response measures are initiated.
- b. Communication between staff members, county health departments, and local emergency management agencies, which includes provisions for a backup communications system.
- c. Identification of resources necessary to continue essential care or services or referrals to other organizations subject to written agreement.
- d. Contacting and prioritizing patients in need of continued medical equipment services and supplies.
- Section 13. Section 400.935, Florida Statutes, is amended to read:
- A00.935 Rulemaking authority Rules establishing minimum standards.—The agency shall adopt, publish, and enforce rules necessary to implement this part and part II of chapter 408.7 which must provide reasonable and fair minimum standards relating to:
- (1) The qualifications and minimum training requirements of all home medical equipment provider personnel.
  - (2) Financial ability to operate.
- 676 (3) The administration of the home medical equipment

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677 provider. 678 (4) Procedures for maintaining patient records. 679 (5) Ensuring that the home medical equipment and services 680 provided by a home medical equipment provider are in accordance with the plan of treatment established for each patient, when 681 682 provided as a part of a plan of treatment. 683 Contractual arrangements for the provision of home 684 medical equipment and services by providers not employed by the 685 home medical equipment provider providing for the consumer's 686 needs. (7) Physical location and zoning requirements. 687 688 (8) Home medical equipment requiring home medical 689 equipment services. 690 (9) Preparation of the comprehensive emergency management 691 plan under s. 400.934 and the establishment of minimum criteria 692 for the plan, including the maintenance of patient equipment and 693 supply lists that can accompany patients who are transported 694 from their homes. Such rules shall be formulated in consultation 695 with the Department of Health and the Division of Emergency 696 Management. 697 Section 14. Subsection (5) of section 400.962, Florida 698 Statutes, is amended to read: 699 400.962 License required; license application.-700 The applicant must agree to provide or arrange for 701 active treatment services by an interdisciplinary team to

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maximize individual independence or prevent regression or loss

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of functional status. Standards for active treatment shall be adopted by the Agency for Health Care Administration by rule pursuant to ss. 120.536(1) and 120.54. Active treatment services shall be provided in accordance with the individual support plan and shall be reimbursed as part of the per diem rate as paid under the Medicaid program.

Section 15. Subsections (2) and (3) of section 400.967, Florida Statutes, are amended to read:

400.967 Rules and classification of deficiencies.-

- (2) Pursuant to the intention of the Legislature, The agency, in consultation with the Agency for Persons with Disabilities and the Department of Elderly Affairs, may shall adopt and enforce rules necessary to administer this part and part II of chapter 408, which may shall include reasonable and fair criteria governing:
- (a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The agency shall update or revise the criteria as the need arises.

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

- (b) The number and qualifications of all personnel, including management, medical nursing, and other personnel, having responsibility for any part of the care given to residents.
- (c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which will ensure the health and comfort of residents.
- (d) The equipment essential to the health and welfare of the residents.
  - (e) A uniform accounting system.

- (f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof.
- (g) The preparation and annual update of a comprehensive emergency management plan. After consultation with the Division of Emergency Management, the agency may establish shall adopt

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rules establishing minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(h) The use of restraint and seclusion. Such rules must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff during an incident of restraint or seclusion; establish

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procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

- (3) The agency shall adopt rules to provide that, When the criteria established under this part and part II of chapter 408 are not met, such deficiencies shall be classified according to the nature of the deficiency. The agency shall indicate the classification on the face of the notice of deficiencies as follows:
- determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical harm would result therefrom. The condition or practice constituting a class I violation must be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class I deficiency is subject to a civil penalty in an amount not less than \$5,000 and not exceeding \$10,000 for each deficiency. A fine may be levied notwithstanding the correction of the

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807 deficiency.

- (b) Class II deficiencies are those which the agency determines have a direct or immediate relationship to the health, safety, or security of the facility residents, other than class I deficiencies. A class II deficiency is subject to a civil penalty in an amount not less than \$1,000 and not exceeding \$5,000 for each deficiency. A citation for a class II deficiency shall specify the time within which the deficiency must be corrected. If a class II deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.
- determines to have an indirect or potential relationship to the health, safety, or security of the facility residents, other than class I or class II deficiencies. A class III deficiency is subject to a civil penalty of not less than \$500 and not exceeding \$1,000 for each deficiency. A citation for a class III deficiency shall specify the time within which the deficiency must be corrected. If a class III deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.
- Section 16. Subsection (2) of section 400.980, Florida Statutes, is amended to read:
  - 400.980 Health care services pools.
- 831 (2) The requirements of part II of chapter 408 apply to 832 the provision of services that require licensure or registration

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pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall adopt rules and provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within 14 days prior to the change.

Section 17. Subsection (43) 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

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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

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the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid singlesource-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers 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

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necessary to administer these policies.

- shall mandate a recipient's participation in a provider lock-in program, when appropriate, if a recipient is found by the agency to have used Medicaid goods or services at a frequency or amount not medically necessary, limiting the receipt of goods or services to medically necessary providers after the 21-day appeal process has ended, for a period of not less than 1 year. The lock-in programs shall include, but are not limited to, pharmacies, medical doctors, and infusion clinics. The limitation does not apply to emergency services and care provided to the recipient in a hospital emergency department. The agency shall seek any federal waivers necessary to implement this subsection. The agency shall adopt any rules necessary to comply with or administer this subsection. This subsection expires October 1, 2014.
- Section 18. Subsections (4) and (5) of section 429.255, Florida Statutes, are amended to read:
  - 429.255 Use of personnel; emergency care.—
- (4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45. The department shall adopt rules providing for the implementation of such orders. Facility staff and facilities shall not be subject to criminal prosecution or civil liability, nor be considered to have

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engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator pursuant to such an order and rules adopted by the department. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator as otherwise permitted by law.

- (5) The Department of Elderly Affairs may adopt rules to implement the provisions of this section relating to use of an automated external defibrillator.
- Section 19. Subsection (3) of section 429.73, Florida Statutes, is amended to read:
- 429.73 Rules and standards relating to adult family-care homes.—
- implementation of orders not to resuscitate. The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The provider shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules.
- Section 20. Subsection (10) of section 440.102, Florida Statutes, is amended to read:

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

- (10) RULES.—The Agency for Health Care Administration shall adopt rules Pursuant to s. 112.0455, part II of chapter 408, and using criteria established by the United States Department of Health and Human Services, the agency shall adopt rules as necessary to establish as general guidelines for modeling drug-free workplace laboratories, concerning, but not limited to:
- (a) Standards for licensing drug-testing laboratories and suspension and revocation of such licenses.
- (b) Urine, hair, blood, and other body specimens and minimum specimen amounts that are appropriate for drug testing.
- (c) Methods of analysis and procedures to ensure reliable drug-testing results, including standards for initial tests and confirmation tests.
- (d) Minimum cutoff detection levels for each drug or metabolites of such drug for the purposes of determining a positive test result.
- (e) Chain-of-custody procedures to ensure proper identification, labeling, and handling of specimens tested.
- (f) Retention, storage, and transportation procedures to ensure reliable results on confirmation tests and retests.
  - Section 21. Subsection (2) of section 483.245, Florida

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Statutes, is amended to read:

483.245 Rebates prohibited; penalties.-

- (2) The agency <u>may establish and shall adopt rules that</u> assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the agency, such penalties may include any disciplinary action available to the agency under the appropriate licensing laws. In the case of an entity not licensed by the agency, such penalties may include:
  - (a) A fine not to exceed \$1,000;
- (b) If applicable, a recommendation by the agency to the appropriate licensing board that disciplinary action be taken.
- Section 22. Subsection (2) of section 765.541, Florida Statutes, is amended to read:
- 765.541 Certification of procurement organizations; agency responsibilities.—The agency shall:
- (2) Adopt rules <u>necessary to implement</u> that set forth appropriate standards and guidelines for the program in accordance with ss. 765.541-765.546 and part II of chapter 408.
- <u>(a)</u> These Standards and guidelines for the program adopted by the agency must be substantially based on the existing laws of the Federal Government and this state and the existing standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the

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| 1015 | Eye Bank Association of America (EBAA), existing as of January                            |
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| 1016 | <u>1, 2014</u> .  |
| 1017 | (b) In addition, the agency shall, Before adopting these                                  |
| 1018 | standards and guidelines $\underline{	ext{for the program, the agency shall}_{	au}}$ seek |
| 1019 | input from all procurement organizations based in this state.                             |
| 1020 | Section 23. Subsection (2) of section 765.544, Florida                                    |
| 1021 | Statutes, is amended to read:   |
| 1022 | 765.544 Fees; organ and tissue donor education and  |
| 1023 | procurement   |
| 1024 | (2) The agency shall specify by rule the administrative                                   |
| 1025 | penalties for the purpose of ensuring adherence to the standards                          |
| 1026 | of quality and practice required by this chapter, part II of                              |
| 1027 | chapter 408, and applicable rules of the agency for continued                             |
| 1028 | certification.  |
| 1029 | Section 24. This act shall take effect July 1, 2014.                                      |

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