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By the Committee on Appropriations; and Senators Grimsley and Bean

576-02719A-18 2018622c1

A bill to be entitled An act relating to health care facility regulation; creating s. 154.13, F.S.; providing that a designated facility owned or operated by a public health trust and located within the boundaries of a municipality is under the exclusive jurisdiction of the county creating the public health trust; amending ss. 381.0031, 381.004, 384.31, 395.009, 400.0625, and 409.905, F.S.; eliminating state licensure requirements for clinical laboratories; requiring clinical laboratories to be federally certified; amending s. 383.313, F.S.; requiring a birth center to be federally certified and meet specified requirements to perform certain laboratory tests; repealing s. 383.335, F.S., relating to partial exemptions from licensure requirements for certain facilities that provide obstetrical and gynecological surgical services; amending s. 395.002, F.S.; revising and deleting definitions to remove the term "mobile surgical facility"; conforming a cross-reference; creating s. 395.0091, F.S.; requiring the Agency for Health Care Administration, in consultation with the Board of Clinical Laboratory Personnel, to adopt rules establishing criteria for alternate-site laboratory testing; requiring specifications to be included in the criteria; defining the term "alternate-site testing"; amending ss. 395.0161 and 395.0163, F.S.; deleting licensure and inspection requirements for mobile surgical facilities to conform to changes made

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by the act; amending s. 395.0197, F.S.; requiring the manager of a hospital or ambulatory surgical center internal risk management program to demonstrate competence in specified administrative and health care service areas; conforming provisions to changes made by the act; repealing s. 395.1046, F.S., relating to hospital complaint investigation procedures; amending s. 395.1055, F.S.; requiring hospitals that provide specified services to meet agency licensure requirements; providing standards to be included in licensure requirements; conforming a provision to changes made by the act; requiring a level 2 background screening for personnel of distinct part nursing units; requiring the agency to adopt rules establishing standards for pediatric cardiac catheterization and pediatric cardiovascular surgery programs located in licensed hospitals; providing requirements for such programs; establishing minimum standards for rules for such pediatric cardiac programs; requiring hospitals with pediatric cardiac programs to participate in the clinical outcome reporting systems; revising duties and membership of the pediatric cardiac technical advisory panel; repealing ss. 395.10971 and 395.10972, F.S., relating to the purpose and the establishment of the Health Care Risk Manager Advisory Council, respectively; amending s. 395.10973, F.S.; removing requirements relating to agency standards for health care risk managers to conform provisions to changes made by the

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act; repealing s. 395.10974, F.S., relating to licensure of health care risk managers, qualifications, licensure, and fees; repealing s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license and an administrative fine; amending s. 395.602, F.S.; deleting definitions for the terms "emergency care hospital," "essential access community hospital," "inactive rural hospital bed," and "rural primary care hospital"; amending s. 395.603, F.S.; deleting provisions relating to deactivation of general hospital beds by certain rural and emergency care hospitals; repealing s. 395.604, F.S., relating to other rural hospital programs; repealing s. 395.605, F.S., relating to emergency care hospitals; amending s. 395.701, F.S.; revising the definition of the term "hospital" to exclude hospitals operated by a state agency; amending s. 400.191, F.S.; removing the 30-month reporting timeframe for the Nursing Home Guide; amending s. 400.464, F.S.; requiring that a license issued to a home health agency on or after a specified date specify the services the organization is authorized to perform and whether the services constitute skilled care; providing that the provision or advertising of certain services constitutes unlicensed activity under certain circumstances; authorizing certain persons, entities or organizations providing home health services to voluntarily apply for a certificate of exemption from licensure by

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providing certain information to the agency; providing that the certificate is valid for a specified time and is nontransferable; authorizing the agency to charge a fee for the certificate; amending s. 400.471, F.S.; revising home health agency licensure requirements; providing requirements for proof of accreditation for home health agencies applying for change of ownership or the addition of skilled care services; removing a provision prohibiting the agency from issuing a license to a home health agency that fails to satisfy the requirements of a Medicare certification survey from the agency; amending s. 400.474, F.S.; revising conditions for the imposition of a fine against a home health agency; amending s. 400.476, F.S.; requiring a home health agency providing skilled nursing care to have a director of nursing; amending s. 400.484, F.S.; imposing administrative fines on home health agencies for specified classes of violations; amending s. 400.497, F.S.; requiring the agency to adopt, publish, and enforce rules establishing standards for certificates of exemption; amending s. 400.506, F.S.; specifying a criminal penalty for any person who owns, operates, or maintains an unlicensed nurse registry that fails to cease operation immediately and apply for a license after notification from the agency; revising provisions authorizing the agency to impose a fine on a nurse registry that fails to cease operation after agency notification; revising circumstances under which the agency is authorized to deny, suspend,

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or revoke a license or impose a fine on a nurse registry; prohibiting a nurse registry from monitoring, supervising, managing, or training a certain caregiver who is an independent contractor; amending s. 400.606, F.S.; removing a requirement that an existing licensed health care provider's hospice licensure application be accompanied by a copy of the most recent profit-loss statement and licensure inspection report; amending s. 400.925, F.S.; revising the definition of the term "home medical equipment"; amending s. 400.931, F.S.; requiring a home medical equipment provider to notify the agency of certain personnel changes within a specified timeframe; amending s. 400.933, F.S.; requiring the agency to accept the submission of a valid medical oxygen retail establishment permit issued by the Department of Business and Professional Regulation in lieu of an agency inspection for licensure; amending s. 400.980, F.S.; revising the timeframe within which a health care services pool registrant must provide the agency with certain changes of information; amending s. 400.9935, F.S.; specifying that a voluntary certificate of exemption may be valid for up to 2 years; amending s. 408.036, F.S.; conforming provisions to changes made by the act; deleting obsolete provisions relating to certificate of need requirements for specified services; amending s. 408.0361, F.S.; providing an exception for a hospital to become a Level I Adult Cardiovascular provider if

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certain requirements are met; amending s. 408.05, F.S.; requiring the agency to contract with the Society of Thoracic Surgeons and the American College of Cardiology for the collection of certain data for publication on the agency's website for certain purposes; amending s. 408.061, F.S.; excluding hospitals operated by state agencies from certain financial reporting requirements; conforming a crossreference; amending s. 408.07, F.S.; deleting the definition for the term "clinical laboratory"; amending s. 408.20, F.S.; exempting hospitals operated by any state agency from assessments against the Health Care Trust Fund to fund certain agency activities; repealing s. 408.7056, F.S., relating to the Subscriber Assistance Program; amending s. 408.803, F.S.; defining the term "relative" for purposes of the Health Care Licensing Procedures Act; amending s. 408.806, F.S.; authorizing licensees who hold licenses for multiple providers to request that the agency align related license expiration dates; authorizing the agency to issue licenses for an abbreviated licensure period and to charge a prorated licensure fee; amending s. 408.809, F.S.; expanding the scope of persons subject to a level 2 background screening to include any employee of a licensee who is a controlling interest and certain part-time contractors; amending s. 408.810, F.S.; providing that an applicant for change of ownership licensure is exempt from furnishing proof of financial ability to

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operate if certain conditions are met; authorizing the agency to adopt rules governing circumstances under which a controlling interest may act in certain legal capacities on behalf of a patient or client; requiring a licensee to ensure that certain persons do not hold an ownership interest if the licensee is not organized as or owned by a publicly traded corporation; defining the term "publicly traded corporation"; amending s. 408.812, F.S.; providing that certain unlicensed activity by a provider constitutes abuse and neglect; clarifying that the agency may impose a fine or penalty, as prescribed in an authorizing statute, if an unlicensed provider who has received notification fails to cease operation; authorizing the agency to revoke all licenses and impose a fine or penalties upon a controlling interest or licensee who has an interest in more than one provider and who fails to license a provider rendering services that require licensure in certain circumstances; amending s. 408.820, F.S.; deleting certain exemptions from part II of ch. 408, F.S., for specified providers to conform provisions to changes made by the act; amending s. 409.907, F.S.; removing the agency's authority to consider certain factors in determining whether to enter into, and in maintaining, a Medicaid provider agreement; amending s. 429.02, F.S.; revising definitions of the terms "assisted living facility" and "personal services"; amending s. 429.04, F.S.; providing additional exemptions from licensure as an

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assisted living facility; requiring a person or entity asserting the exemption to provide documentation that substantiates the claim upon agency investigation of unlicensed activity; amending s. 429.08, F.S.; providing criminal penalties and fines for a person who rents or otherwise maintains a building or property used as an unlicensed assisted living facility; providing criminal penalties and fines for a person who owns, operates, or maintains an unlicensed assisted living facility after receiving notice from the agency; amending s. 429.176, F.S.; prohibiting an assisted living facility from operating for more than a specified time without an administrator who has completed certain educational requirements; amending s. 429.24, F.S.; providing that 30-day written notice of rate increase for residency in an assisted living facility is not required in certain situations; amending s. 429.28, F.S.; revising the assisted living facility resident bill of rights to include assistance with obtaining access to adequate and appropriate health care; defining the term "adequate and appropriate health care"; deleting a requirement that the agency conduct at least one monitoring visit under certain circumstances; deleting provisions authorizing the agency to conduct periodic followup inspections and complaint investigations under certain circumstances; amending s. 429.294, F.S.; deleting the specified timeframe within which an assisted living facility must provide complete copies of a resident's

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records in an investigation of resident's rights; amending s. 429.34, F.S.; authorizing the agency to inspect and investigate assisted living facilities as necessary to determine compliance with certain laws; removing a provision requiring the agency to inspect each licensed assisted living facility at least biennially; authorizing the agency to conduct monitoring visits of each facility cited for prior violations under certain circumstances; amending s. 429.52, F.S.; requiring an assisted living facility administrator to complete required training and education within a specified timeframe; amending s. 435.04, F.S.; providing that security background investigations must ensure that a person has not been arrested for, and is not awaiting final disposition of, certain offenses; requiring that security background investigations for purposes of participation in the Medicaid program screen for violations of federal or state law, rule, or regulation governing any state Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program; specifying offenses under federal law or any state law that the security background investigations must screen for; amending s. 456.054, F.S.; prohibiting any person or entity from paying or receiving a kickback for referring patients to a clinical laboratory; prohibiting a clinical laboratory from providing personnel to perform certain functions or duties in a

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health care practitioner's office or dialysis facility; providing an exception; prohibiting a clinical laboratory from leasing space in any part of a health care practitioner's office or dialysis facility; repealing part I of ch. 483, F.S., relating to clinical laboratories; amending s. 483.294, F.S.; removing a requirement that the agency inspect multiphasic health testing centers at least once annually; amending s. 483.801, F.S.; providing an exemption from regulation for certain persons employed by certain laboratories; amending s. 483.803, F.S.; revising definitions of the terms "clinical laboratory" and "clinical laboratory examination"; removing a cross-reference; amending s. 641.511, F.S.; revising health maintenance organization subscriber grievance reporting requirements; repealing s. 641.60, F.S., relating to the Statewide Managed Care Ombudsman Committee; repealing s. 641.65, F.S., relating to district managed care ombudsman committees; repealing s. 641.67, F.S., relating to a district managed care ombudsman committee, exemption from public records requirements, and exceptions; repealing s. 641.68, F.S., relating to a district managed care ombudsman committee and exemption from public meeting requirements; repealing s. 641.70, F.S., relating to agency duties relating to the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman committees; repealing s. 641.75, F.S., relating to immunity from liability and limitation on

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291 testimony; amending s. 945.36, F.S.; authorizing law 292 enforcement personnel to conduct drug tests on certain 293 inmates and releasees; amending ss. 20.43, 220.1845, 294 376.30781, 376.86, 381.0034, 381.0405, 383.14, 383.30, 295 383.301, 383.302, 383.305, 383.309, 383.33, 385.211, 296 394.4787, 395.001, 395.003, 395.7015, 400.9905, 297 408.033, 408.802, 409.9116, 409.975, 429.19, 456.001, 456.057, 456.076, 458.307, 458.345, 459.021, 483.813, 298 483.823, 491.003, 627.351, 627.602, 627.6406, 299 300 627.64194, 627.6513, 627.6574, 641.185, 641.31, 301 641.312, 641.3154, 641.51, 641.515, 641.55, 766.118, 302 766.202, 1009.65, and 1011.52, F.S.; conforming 303 provisions to changes made by the act; providing an 304 effective date.

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

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Section 1. Paragraph (g) of subsection (3) of section 20.43, Florida Statutes, is amended to read:

310 20.43 Department of Health.—There is created a Department 311 of Health.

- (3) The following divisions of the Department of Health are established:
- (g) Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:
 - 1. The Board of Acupuncture, created under chapter 457.
 - 2. The Board of Medicine, created under chapter 458.
 - 3. The Board of Osteopathic Medicine, created under chapter

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- 4. The Board of Chiropractic Medicine, created under chapter 460.
- 5. The Board of Podiatric Medicine, created under chapter 461.
 - 6. Naturopathy, as provided under chapter 462.
 - 7. The Board of Optometry, created under chapter 463.
- 8. The Board of Nursing, created under part I of chapter 464.
- 9. Nursing assistants, as provided under part II of chapter 330 464.
 - 10. The Board of Pharmacy, created under chapter 465.
 - 11. The Board of Dentistry, created under chapter 466.
- 333 12. Midwifery, as provided under chapter 467.
- 13. The Board of Speech-Language Pathology and Audiology, 335 created under part I of chapter 468.
- 336 14. The Board of Nursing Home Administrators, created under part II of chapter 468.
- 338 15. The Board of Occupational Therapy, created under part 339 III of chapter 468.
- 16. Respiratory therapy, as provided under part V of chapter 468.
- 342 17. Dietetics and nutrition practice, as provided under part X of chapter 468.
- 344 18. The Board of Athletic Training, created under part XIII of chapter 468.
- 19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.
 - 20. Electrolysis, as provided under chapter 478.

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349 21. The Board of Massage Therapy, created under chapter 350 480.

- 22. The Board of Clinical Laboratory Personnel, created under part II III of chapter 483.
- 353 23. Medical physicists, as provided under part IV of 354 chapter 483.
- 355 24. The Board of Opticianry, created under part I of 356 chapter 484.
 - 25. The Board of Hearing Aid Specialists, created under part II of chapter 484.
- 26. The Board of Physical Therapy Practice, created under chapter 486. 360
 - 27. The Board of Psychology, created under chapter 490.
 - 28. School psychologists, as provided under chapter 490.
 - 29. The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.
 - 30. Emergency medical technicians and paramedics, as provided under part III of chapter 401.
- 368 Section 2. Section 154.13, Florida Statutes, is created to 369 read:
 - 154.13 Designated facilities; jurisdiction.—Any designated facility owned or operated by a public health trust and located within the boundaries of a municipality is under the exclusive jurisdiction of the county creating the public health trust and is not within the jurisdiction of the municipality.
 - Section 3. Paragraph (k) of subsection (2) of section 220.1845, Florida Statutes, is amended to read:
 - 220.1845 Contaminated site rehabilitation tax credit.-

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(2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.-

(k) In order to encourage the construction and operation of a new health care facility as defined in s. 408.032 or s. 408.07, or a health care provider as defined in s. 408.07 or s. 408.7056, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed \$500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 4. Paragraph (f) of subsection (3) of section 376.30781, Florida Statutes, is amended to read:

376.30781 Tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.—

(3)

(f) In order to encourage the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or, s. 408.07, or s. 408.7056, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed \$500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the

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construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 5. Subsection (1) of section 376.86, Florida Statutes, is amended to read:

376.86 Brownfield Areas Loan Guarantee Program.-

(1) The Brownfield Areas Loan Guarantee Council is created to review and approve or deny, by a majority vote of its membership, the situations and circumstances for participation in partnerships by agreements with local governments, financial institutions, and others associated with the redevelopment of brownfield areas pursuant to the Brownfields Redevelopment Act for a limited state guaranty of up to 5 years of loan guarantees or loan loss reserves issued pursuant to law. The limited state loan guaranty applies only to 50 percent of the primary lenders loans for redevelopment projects in brownfield areas. If the redevelopment project is for affordable housing, as defined in s. 420.0004, in a brownfield area, the limited state loan guaranty applies to 75 percent of the primary lender's loan. If the redevelopment project includes the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or τ s. 408.07, or s. 408.7056_{r} on a brownfield site and the applicant has obtained documentation in accordance with s. 376.30781 indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been

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issued for the operation of the health care facility or health care provider, the limited state loan guaranty applies to 75 percent of the primary lender's loan. A limited state guaranty of private loans or a loan loss reserve is authorized for lenders licensed to operate in the state upon a determination by the council that such an arrangement would be in the public interest and the likelihood of the success of the loan is great.

Section 6. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of public health significance to department.—

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder which licensed under chapter 483 that diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 7. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.-

(3) The department shall require, as a condition of granting a license under chapter 467 or part <u>II</u> III of chapter 483, that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency

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syndrome. Upon submission of an affidavit showing good cause, an applicant who has not taken a course at the time of licensure shall be allowed 6 months to complete this requirement.

Section 8. Paragraph (c) of subsection (4) of section 381.004, Florida Statutes, is amended to read:

381.004 HIV testing.-

- (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS; REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM REGISTRATION.—No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:
- (c) The program shall have all laboratory procedures performed in a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder licensed under the provisions of chapter 483.

Section 9. Paragraph (f) of subsection (4) of section 381.0405, Florida Statutes, is amended to read:

381.0405 Office of Rural Health.-

- (4) COORDINATION.—The office shall:
- (f) Assume responsibility for state coordination of the Rural Hospital Transition Grant Program, the Essential Access Community Hospital Program, and other federal rural health care programs.
 - Section 10. Paragraph (a) of subsection (2) of section

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383.14, Florida Statutes, is amended to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(2) RULES.-

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- (a) After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall:
- 1. Before becoming 1 week of age, be subjected to a test for phenylketonuria;
- 2. Be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. After the council recommends that a condition be included, the department shall submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 18 months after the council renders such advice, if a test approved by the United States Food and Drug Administration or a test offered by an alternative vendor which is compatible with the clinical standards established under part I of chapter 483 is available. If such a test is not available within 18 months after the council makes its recommendation, the department shall implement such screening as soon as a test offered by the United States Food and Drug Administration or by an alternative vendor is available; and
- 3. At the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary from time to time.

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Section 11. Section 383.30, Florida Statutes, is amended to read:

383.30 Birth Center Licensure Act; short title.—Sections $\frac{383.30-383.332}{89.30-383.335}$ shall be known and may be cited as the "Birth Center Licensure Act."

Section 12. Section 383.301, Florida Statutes, is amended to read:

383.301 Licensure and regulation of birth centers; legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, maintenance, and operation of birth centers by providing for licensure of birth centers and for the development, establishment, and enforcement of minimum standards with respect to birth centers. The requirements of part II of chapter 408 shall apply to the provision of services that require licensure pursuant to ss. 383.30-383.332 383.30-383.335 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 383.30-383.332 383.30-383.335. A license issued by the agency is required in order to operate a birth center in this state.

Section 13. Section 383.302, Florida Statutes, is amended to read:

383.302 Definitions of terms used in ss. $\underline{383.30-383.332}$ $\underline{383.30-383.335}$.—As used in ss. $\underline{383.30-383.332}$ $\underline{383.30-383.335}$, the term:

- (1) "Agency" means the Agency for Health Care Administration.
 - (2) "Birth center" means any facility, institution, or

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place, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.

- (3) "Clinical staff" means individuals employed full time or part time by a birth center who are licensed or certified to provide care at childbirth.
- (4) "Consultant" means a physician licensed pursuant to chapter 458 or chapter 459 who agrees to provide advice and services to a birth center and who either:
- (a) Is certified or eligible for certification by the American Board of Obstetrics and Gynecology, or
 - (b) Has hospital obstetrical privileges.
- (5) "Governing body" means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center.
- (6) "Governmental unit" means the state or any county, municipality, or other political subdivision or any department, division, board, or other agency of any of the foregoing.
- (7) "Licensed facility" means a facility licensed in accordance with s. 383.305.
- (8) "Low-risk pregnancy" means a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.
- (9) "Person" means any individual, firm, partnership, corporation, company, association, institution, or joint stock association and means any legal successor of any of the foregoing.

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(10) "Premises" means those buildings, beds, and facilities located at the main address of the licensee and all other buildings, beds, and facilities for the provision of maternity care located in such reasonable proximity to the main address of the licensee as to appear to the public to be under the dominion and control of the licensee.

Section 14. Subsection (1) of section 383.305, Florida Statutes, is amended to read:

383.305 Licensure; fees.-

(1) In accordance with s. 408.805, an applicant or a licensee shall pay a fee for each license application submitted under ss. $\underline{383.30-383.332}$ $\underline{383.30-383.335}$ and part II of chapter 408. The amount of the fee shall be established by rule.

Section 15. Subsection (1) of section 383.309, Florida Statutes, is amended to read:

383.309 Minimum standards for birth centers; rules and enforcement.—

- (1) The agency shall adopt and enforce rules to administer ss. 383.30-383.332 383.30-383.335 and part II of chapter 408, which rules shall include, but are not limited to, reasonable and fair minimum standards for ensuring that:
- (a) Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.
- (b) Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures that will adequately protect patient care and provide safety are established and implemented.
 - (c) Licensed facilities are established, organized, and

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operated consistent with established programmatic standards.

Section 16. Subsection (1) of section 383.313, Florida Statutes, is amended to read:

383.313 Performance of laboratory and surgical services; use of anesthetic and chemical agents.—

(1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center must obtain and continuously maintain certification by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder in order to may perform simple laboratory tests specified, as defined by rule of the agency, and which are appropriate to meet the needs of the patient is exempt from the requirements of chapter 483, provided no more than five physicians are employed by the birth center and testing is conducted exclusively in connection with the diagnosis and treatment of clients of the birth center.

Section 17. Subsection (1) and paragraph (a) of subsection (2) of section 383.33, Florida Statutes, are amended to read:
383.33 Administrative penalties; moratorium on admissions.—

- (1) In addition to the requirements of part II of chapter 408, the agency may impose an administrative fine not to exceed \$500 per violation per day for the violation of any provision of ss. 383.30-383.332 383.30-383.335, part II of chapter 408, or applicable rules.
- (2) In determining the amount of the fine to be levied for a violation, as provided in this section, the following factors shall be considered:
 - (a) The severity of the violation, including the

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probability that death or serious harm to the health or safety of any person will result or has resulted; the severity of the actual or potential harm; and the extent to which the provisions of ss. 383.30-383.332 383.30-383.335, part II of chapter 408, or applicable rules were violated.

Section 18. <u>Section 383.335</u>, <u>Florida Statutes</u>, <u>is repealed</u>. Section 19. Section 384.31, Florida Statutes, is amended to read:

384.31 Testing of pregnant women; duty of the attendant.-Every person, including every physician licensed under chapter 458 or chapter 459 or midwife licensed under part I of chapter 464 or chapter 467, attending a pregnant woman for conditions relating to pregnancy during the period of gestation and delivery shall cause the woman to be tested for sexually transmissible diseases, including HIV, as specified by department rule. Testing shall be performed by a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder approved for such purposes under part I of chapter 483. The woman shall be informed of the tests that will be conducted and of her right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the woman, shall be placed in the woman's medical record and no testing shall occur.

Section 20. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

385.211 Refractory and intractable epilepsy treatment and research at recognized medical centers.—

(2) Notwithstanding chapter 893, medical centers recognized

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pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(27) s. 395.002(28) that contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 21. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

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

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to $\underline{s.\ 395.002(27)}\ \underline{s.\ 395.002(28)}$ and part II of chapter 408 as a specialty psychiatric hospital.

Section 22. Section 395.001, Florida Statutes, is amended to read:

395.001 Legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of hospitals and, ambulatory surgical centers, and mobile surgical facilities by providing for licensure of same and for the development, establishment, and enforcement of

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minimum standards with respect thereto.

Section 23. Present subsections (22) through (33) of section 395.002, Florida Statutes, are redesignated as subsections (21) through (32), respectively, and subsections (3) and (16) of that section and present subsections (21) and (23) of that section are amended, to read:

395.002 Definitions.—As used in this chapter:

- (3) "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry may shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.
- (16) "Licensed facility" means a hospital $\underline{\text{or}}_{\tau}$ ambulatory surgical center, or mobile surgical facility licensed in accordance with this chapter.
 - (21) "Mobile surgical facility" is a mobile facility in

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which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957 and in which inmate patients are admitted to and discharged from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.

(22) (23) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or, ambulatory surgical, or mobile surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07 s. 408.07(45), reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

Section 24. Paragraphs (a) and (b) of subsection (1) and paragraph (b) of subsection (2) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.-

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(1) (a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital \underline{or}_{7} ambulatory surgical center, or mobile surgical facility in this state.

- (b)1. It is unlawful for a person to use or advertise to the public, in any way or by any medium whatsoever, any facility as a "hospital— τ " or "ambulatory surgical center— τ " or "mobile surgical facility" unless such facility has first secured a license under the provisions of this part.
- 2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital τ " or "ambulatory surgical center τ " or "mobile surgical facility" as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

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

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the number of beds, services, or programs operated by the licensee.

Section 25. Subsection (1) of section 395.009, Florida Statutes, is amended to read:

395.009 Minimum standards for clinical laboratory test results and diagnostic X-ray results; prerequisite for issuance or renewal of license.—

(1) As a requirement for issuance or renewal of its license, each licensed facility shall require that all clinical laboratory tests performed by or for the licensed facility be performed by a clinical laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder licensed under the provisions of chapter 483.

Section 26. Section 395.0091, Florida Statutes, is created to read:

395.0091 Alternate-site testing.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. At a minimum, the criteria must address hospital internal needs assessment; a protocol for implementation, including the identification of tests to be performed and who will perform them; selection of the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training and initial and

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ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for the central laboratory to identify and track alternate-site testing; and recordkeeping requirements. Alternate-site testing locations must register when the hospital applies to renew its license. For purposes of this section, the term "alternate-site testing" includes any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

Section 27. Paragraph (f) of subsection (1) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.-

- (1) In addition to the requirement of s. 408.811, the agency shall make or cause to be made such inspections and investigations as it deems necessary, including:
- (f) Inspections of mobile surgical facilities at each time a facility establishes a new location, prior to the admission of patients. However, such inspections shall not be required when a mobile surgical facility is moved temporarily to a location where medical treatment will not be provided.

Section 28. Subsection (3) of section 395.0163, Florida Statutes, is amended to read:

395.0163 Construction inspections; plan submission and approval; fees.—

(3) In addition to the requirements of s. 408.811, the agency shall inspect a mobile surgical facility at initial licensure and at each time the facility establishes a new location, prior to admission of patients. However, such inspections shall not be required when a mobile surgical

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facility is moved temporarily to a location where medical treatment will not be provided. 843

Section 29. Subsection (2), paragraph (c) of subsection (6), and subsections (16) and (17) of section 395.0197, Florida Statutes, are amended to read:

395.0197 Internal risk management program.

- (2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager, licensed under s. 395.10974, who is responsible for implementation and oversight of the such facility's internal risk management program and who demonstrates competence, through education or experience, in all of the following areas:
 - (a) Applicable standards of health care risk management.
- (b) Applicable federal, state, and local health and safety laws and rules.
 - (c) General risk management administration.
 - (d) Patient care.
 - (e) Medical care.
- (f) Personal and social care.
 - (g) Accident prevention.
 - (h) Departmental organization and management.
 - (i) Community interrelationships.
- (j) Medical terminology as required by this section. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals.

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(c) The report submitted to the agency must shall also contain the name and license number of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

- (16) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager, licensed under s. 395.10974, for the implementation and oversight of the internal risk management program in a facility licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such internal risk management program if the risk manager acts without intentional fraud.
 - (17) A privilege against civil liability is hereby granted

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to any licensed risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the licensed risk manager or facility acted in bad faith or with malice in providing such information.

Section 30. <u>Section 395.1046</u>, <u>Florida Statutes</u>, is repealed.

Section 31. Present subsection (10) of section 395.1055, Florida Statutes, is redesignated as subsection (12), subsections (2), (3), and (9) of that section are amended, paragraph (i) is added to subsection (1) of that section, and a new subsection (10) and subsection (11) are added to that section, to read:

395.1055 Rules and enforcement.

- (1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:
- (i) All hospitals providing organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. Such licensure requirements must include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards.
- (2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, mobile surgical facilities, and statutory rural hospitals as defined in s. 395.602.
 - (3) The agency shall adopt rules with respect to the care

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and treatment of patients residing in distinct part nursing units of hospitals which are certified for participation in Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act skilled nursing facility program. Such rules shall take into account the types of patients treated in hospital skilled nursing units, including typical patient acuity levels and the average length of stay in such units, and shall be limited to the appropriate portions of 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. The agency shall require level 2 background screening as specified in s. 408.809(1)(e) pursuant to s. 408.809 and chapter 435 for personnel of distinct part nursing units.

- (9) The agency shall establish a technical advisory panel, pursuant to s. 20.052, to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular open-heart surgery programs.
- (a) Members of the panel must have technical expertise in pediatric cardiac medicine, shall serve without compensation, and may not be reimbursed for per diem and travel expenses. be composed
- (b) Voting members of the panel shall include: 3 at-large members, including 1 cardiologist who is board certified in caring for adults with congenital heart disease and 2 board-certified pediatric cardiologists, neither of whom may be employed by any of the hospitals specified in subparagraphs 1.-10. or their affiliates, each of whom is appointed by the Secretary of Health Care Administration, and 10 members, and an

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958 <u>alternate for each member</u>, each of whom is a pediatric 959 cardiologist or a pediatric cardiovascular surgeon, each 960 appointed by the chief executive officer of one of the following 961 hospitals:

- 1. Johns Hopkins All Children's Hospital in St. Petersburg.
- 2. Arnold Palmer Hospital for Children in Orlando.
- 3. Joe DiMaggio Children's Hospital in Hollywood.
- 4. Nicklaus Children's Hospital in Miami.
- 5. St. Joseph's Children's Hospital in Tampa.
- 6. University of Florida Health Shands Hospital in Gainesville.
 - 7. University of Miami Holtz Children's Hospital in Miami.
 - 8. Wolfson Children's Hospital in Jacksonville.
 - 9. Florida Hospital for Children in Orlando.
 - 10. Nemours Children's Hospital in Orlando.

Appointments made under subparagraphs 1.-10. are contingent upon the hospital's maintenance of pediatric certificates of need and

976 the hospital's compliance with this section and rules adopted

977 thereunder, as determined by the Secretary of Health Care

978 Administration. A member appointed under subparagraphs 1.-10.

whose hospital fails to maintain such certificates or comply

with standards may serve only as a nonvoting member until the

hospital restores such certificates or complies with such

982 standards.

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- (c) The Secretary of Health Care Administration may appoint nonvoting members to the panel. Nonvoting members may include:
 - 1. The Secretary of Health Care Administration.
 - 2. The Surgeon General.

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3. The Deputy Secretary of Children's Medical Services.

- $\underline{\text{4. Any current or past Division Director of Children's}}\\ \text{Medical Services.}$
 - 5. A parent of a child with congenital heart disease.
 - 6. An adult with congenital heart disease.
- 7. A representative from each of the following organizations: the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Cardiology, the Greater Southeast Affiliate of the American Heart Association, the Adult Congenital Heart Association, the March of Dimes, the Florida Association of Children's Hospitals, and the Florida Society of Thoracic and Cardiovascular Surgeons.
- (d) The panel shall meet biannually, or more frequently upon the call of the Secretary of Health Care Administration.

 Such meetings may be conducted telephonically, or by other electronic means.
- (e) The duties of the panel include recommending to the agency standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services.
- (f) Beginning on January 1, 2020, and annually thereafter, the panel shall submit a report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General. The report must summarize the panel's activities during the preceding fiscal year and include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.
 - (b) Based on the recommendations of the panel, the agency

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1016 shall develop and adopt rules for pediatric cardiac catheterization programs and pediatric open-heart surgery programs which include at least the following: 1018

- 1. A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state;
- 2. Outcome standards specifying expected levels of performance in pediatric cardiac programs. Such standards may include, but are not limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of postoperative bleeds, and returns to surgery; and
- 3. Specific steps to be taken by the agency and licensed facilities that do not meet the outcome standards within a specified time, including time required for detailed case reviews and development and implementation of corrective action plans.
 - (c) This subsection is repealed on July 1, 2022.
- (10) Based on the recommendations of the advisory panel in subsection (9), the agency shall adopt rules for pediatric cardiac programs which, at a minimum, include:
- (a) Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.
- (b) Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.
- (c) Specific steps to be taken by the agency and licensed facilities when the facilities do not me<u>et the outcome standards</u>

576-02719A-18 2018622c1 1045 within a specified time, including time required for detailed 1046 case reviews and the development and implementation of 1047 corrective action plans. 1048 (11) A pediatric cardiac program shall: 1049 (a) Be located in a hospital licensed under this chapter 1050 and include the following colocated components: a pediatric 1051 cardiology clinic, a pediatric cardiac catheterization 1052 laboratory, and a pediatric cardiovascular surgery program. 1053 (b) Have a risk adjustment surgical procedure protocol 1054 following the guidelines established by the Society of Thoracic 1055 Surgeons. 1056 (c) Have quality assurance and quality improvement 1057 processes in place to enhance clinical operation and patient 1058 satisfaction with services. 1059 (d) Participate in the clinical outcome reporting systems 1060 operated by the Society of Thoracic Surgeons and the American 1061 College of Cardiology. 1062 (12) (10) The agency may adopt rules to administer the 1063 requirements of part II of chapter 408. 1064 Section 32. Section 395.10971, Florida Statutes, is 1065 repealed. 1066 Section 33. Section 395.10972, Florida Statutes, is 1067 repealed. 1068 Section 34. Section 395.10973, Florida Statutes, is amended 1069 to read: 1070 395.10973 Powers and duties of the agency.—It is the 1071 function of the agency to: (1) Adopt rules pursuant to ss. 120.536(1) and 120.54 to 1072

implement the provisions of this part and part II of chapter 408

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1074 conferring duties upon it.

- (2) Develop, impose, and enforce specific standards within the scope of the general qualifications established by this part which must be met by individuals in order to receive licenses as health care risk managers. These standards shall be designed to ensure that health care risk managers are individuals of good character and otherwise suitable and, by training or experience in the field of health care risk management, qualified in accordance with the provisions of this part to serve as health care risk managers, within statutory requirements.
- (3) Develop a method for determining whether an individual meets the standards set forth in s. 395.10974.
- (4) Issue licenses to qualified individuals meeting the standards set forth in s. 395.10974.
- (5) Receive, investigate, and take appropriate action with respect to any charge or complaint filed with the agency to the effect that a certified health care risk manager has failed to comply with the requirements or standards adopted by rule by the agency or to comply with the provisions of this part.
- (6) Establish procedures for providing periodic reports on persons certified or disciplined by the agency under this part.
- $\underline{(2)}$ (7) Develop a model risk management program for health care facilities which will satisfy the requirements of s. 395.0197.
- (3) (8) Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate residential treatment facilities, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

2018622c1 576-02719A-18 1103 Section 35. Section 395.10974, Florida Statutes, is 1104 repealed. 1105 Section 36. Section 395.10975, Florida Statutes, is 1106 repealed. 1107 Section 37. Subsection (2) of section 395.602, Florida 1108 Statutes, is amended to read: 1109 395.602 Rural hospitals.-1110 (2) DEFINITIONS.—As used in this part, the term: (a) "Emergency care hospital" means a medical facility 1111 which provides: 1112 1113 1. Emergency medical treatment; and 1114 2. Inpatient care to ill or injured persons prior to their transportation to another hospital or provides inpatient medical 1115 care to persons needing care for a period of up to 96 hours. The 1116 1117 96-hour limitation on inpatient care does not apply to respite, 1118 skilled nursing, hospice, or other nonacute care patients. 1119 (b) "Essential access community hospital" means any 1120 facility which: 1121 1. Has at least 100 beds; 1122 2. Is located more than 35 miles from any other essential 1123 access community hospital, rural referral center, or urban 1124 hospital meeting criteria for classification as a regional 1125 referral center; 1126 3. Is part of a network that includes rural primary care 1127 hospitals; 1128 4. Provides emergency and medical backup services to rural 1129 primary care hospitals in its rural health network; 5. Extends staff privileges to rural primary care hospital 1130

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physicians in its network; and

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1132 6. Accepts patients transferred from rural primary care
1133 hospitals in its network.

- (c) "Inactive rural hospital bed" means a licensed acute care hospital bed, as defined in s. 395.002(13), that is inactive in that it cannot be occupied by acute care inpatients.
- (a) (d) "Rural area health education center" means an area health education center (AHEC), as authorized by Pub. L. No. 94-484, which provides services in a county with a population density of up to no greater than 100 persons per square mile.
- (b) (e) "Rural hospital" means an acute care hospital licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:
- 1. The sole provider within a county with a population density of up to 100 persons per square mile;
- 2. An acute care hospital, in a county with a population density of up to 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;
- 3. A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;
- 4. A hospital classified as a sole community hospital under 42 C.F.R. s. 412.92, regardless of the number of licensed beds;
- 5. A hospital with a service area that has a population of up to 100 persons per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from

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the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency; or

6. A hospital designated as a critical access hospital, as defined in s. 408.07.

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation, to the agency. A hospital that was licensed as a rural hospital during the 2010-2011 or 2011-2012 fiscal year shall continue to be a rural hospital from the date of designation through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room.

- (f) "Rural primary care hospital" means any facility meeting the criteria in paragraph (e) or s. 395.605 which provides:
 - 1. Twenty-four-hour emergency medical care;
- 2. Temporary inpatient care for periods of 72 hours or less to patients requiring stabilization before discharge or transfer to another hospital. The 72-hour limitation does not apply to respite, skilled nursing, hospice, or other nonacute care patients; and

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3. Has no more than six licensed acute care inpatient beds.

 $\underline{\text{(c)}}$ "Swing-bed" means a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

Section 38. Section 395.603, Florida Statutes, is amended to read:

395.603 Deactivation of general hospital beds; Rural hospital impact statement.—

(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with inactive beds shall provide 24-hour emergency medical care by staffing an emergency room. Providers with inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the

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agency for certificate-of-need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.

- (2) In formulating and implementing policies and rules that may have significant impact on the ability of rural hospitals to continue to provide health care services in rural communities, the agency, the department, or the respective regulatory board adopting policies or rules regarding the licensure or certification of health care professionals shall provide a rural hospital impact statement. The rural hospital impact statement shall assess the proposed action in light of the following questions:
- $\underline{(1)}$ (a) Do the health personnel affected by the proposed action currently practice in rural hospitals or are they likely to in the near future?
- (2) (b) What are the current numbers of the affected health personnel in this state, their geographic distribution, and the number practicing in rural hospitals?
- (3)(c) What are the functions presently performed by the affected health personnel, and are such functions presently performed in rural hospitals?
- $\underline{(4)}$ What impact will the proposed action have on the ability of rural hospitals to recruit the affected personnel to practice in their facilities?
- $\underline{\text{(5)}}$ (e) What impact will the proposed action have on the limited financial resources of rural hospitals through increased

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576-02719A-18 2018622c1 1248 salaries and benefits necessary to recruit or retain such health 1249 personnel? 1250 (6) (f) Is there a less stringent requirement which could 1251 apply to practice in rural hospitals? 1252 (7) (q) Will this action create staffing shortages, which 1253 could result in a loss to the public of health care services in 1254 rural hospitals or result in closure of any rural hospitals? 1255 Section 39. Section 395.604, Florida Statutes, is repealed. 1256 Section 40. Section 395.605, Florida Statutes, is repealed. 1257 Section 41. Paragraph (c) of subsection (1) of section 1258 395.701, Florida Statutes, is amended to read: 1259 395.701 Annual assessments on net operating revenues for 1260 inpatient and outpatient services to fund public medical 1261 assistance; administrative fines for failure to pay assessments 1262 when due; exemption.-1263 (1) For the purposes of this section, the term: 1264 (c) "Hospital" means a health care institution as defined 1265 in s. 395.002(12), but does not include any hospital operated by 1266 a state the agency or the Department of Corrections. 1267 Section 42. Paragraph (b) of subsection (2) of section 1268 395.7015, Florida Statutes, is amended to read: 1269 395.7015 Annual assessment on health care entities.-1270 (2) There is imposed an annual assessment against certain 1271 health care entities as described in this section: 1272 (b) For the purpose of this section, "health care entities" 1273 include the following: 1274 1. Ambulatory surgical centers and mobile surgical

facilities licensed under s. 395.003. This subsection shall only

apply to mobile surgical facilities operating under contracts

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1277 entered into on or after July 1, 1998.

2. Clinical laboratories licensed under s. 483.091, excluding any hospital laboratory defined under s. 483.041(6), any clinical laboratory operated by the state or a political subdivision of the state, any clinical laboratory which qualifies as an exempt organization under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and which receives 70 percent or more of its gross revenues from services to charity patients or Medicaid patients, and any blood, plasma, or tissue bank procuring, storing, or distributing blood, plasma, or tissue either for future manufacture or research or distributed on a nonprofit basis, and further excluding any clinical laboratory which is wholly owned and operated by 6 or fewer physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of the same group.

2.3. Diagnostic-imaging centers that are freestanding outpatient facilities that provide specialized services for the identification or determination of a disease through examination and also provide sophisticated radiological services, and in which services are rendered by a physician licensed by the Board of Medicine under s. 458.311, s. 458.313, or s. 458.317, or by an osteopathic physician licensed by the Board of Osteopathic Medicine under s. 459.0055 or s. 459.0075. For purposes of this paragraph, "sophisticated radiological services" means the following: magnetic resonance imaging; nuclear medicine; angiography; arteriography; computed tomography; positron emission tomography; digital vascular imaging; bronchography;

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lymphangiography; splenography; ultrasound, excluding ultrasound providers that are part of a private physician's office practice or when ultrasound is provided by two or more physicians licensed under chapter 458 or chapter 459 who are members of the same professional association and who practice in the same medical specialties; and such other sophisticated radiological services, excluding mammography, as adopted in rule by the board.

Section 43. Subsection (1) of section 400.0625, Florida Statutes, is amended to read:

400.0625 Minimum standards for clinical laboratory test results and diagnostic X-ray results.—

(1) Each nursing home, as a requirement for issuance or renewal of its license, shall require that all clinical laboratory tests performed for the nursing home be performed by a clinical laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder licensed under the provisions of chapter 483, except for such self-testing procedures as are approved by the agency by rule. Results of clinical laboratory tests performed prior to admission which meet the minimum standards provided in s. 483.181(3) shall be accepted in lieu of routine examinations required upon admission and clinical laboratory tests which may be ordered by a physician for residents of the nursing home.

Section 44. Paragraph (a) of subsection (2) of section 400.191, Florida Statutes, is amended to read:

400.191 Availability, distribution, and posting of reports and records.—

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(2) The agency shall publish the Nursing Home Guide quarterly in electronic form to assist consumers and their families in comparing and evaluating nursing home facilities.

- (a) The agency shall provide an Internet site which shall include at least the following information either directly or indirectly through a link to another established site or sites of the agency's choosing:
- 1. A section entitled "Have you considered programs that provide alternatives to nursing home care?" which shall be the first section of the Nursing Home Guide and which shall prominently display information about available alternatives to nursing homes and how to obtain additional information regarding these alternatives. The Nursing Home Guide shall explain that this state offers alternative programs that permit qualified elderly persons to stay in their homes instead of being placed in nursing homes and shall encourage interested persons to call the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program to inquire if they qualify. The Nursing Home Guide shall list available home and community-based programs which shall clearly state the services that are provided and indicate whether nursing home services are included if needed.
- 2. A list by name and address of all nursing home facilities in this state, including any prior name by which a facility was known during the previous 24-month period.
- 3. Whether such nursing home facilities are proprietary or nonproprietary.
- 4. The current owner of the facility's license and the year that that entity became the owner of the license.

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5. The name of the owner or owners of each facility and whether the facility is affiliated with a company or other organization owning or managing more than one nursing facility in this state.

- 6. The total number of beds in each facility and the most recently available occupancy levels.
- 7. The number of private and semiprivate rooms in each facility.
 - 8. The religious affiliation, if any, of each facility.
- 9. The languages spoken by the administrator and staff of each facility.
- 10. Whether or not each facility accepts Medicare or Medicaid recipients or insurance, health maintenance organization, Veterans Administration, CHAMPUS program, or workers' compensation coverage.
- 11. Recreational and other programs available at each facility.
- 12. Special care units or programs offered at each facility.
- 13. Whether the facility is a part of a retirement community that offers other services pursuant to part III of this chapter or part I or part III of chapter 429.
- 14. Survey and deficiency information, including all federal and state recertification, licensure, revisit, and complaint survey information, for each facility for the past 30 months. For noncertified nursing homes, state survey and deficiency information, including licensure, revisit, and complaint survey information for the past 30 months shall be provided.

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Section 45. Subsection (1) and paragraphs (b), (e), and (f) of subsection (4) of section 400.464, Florida Statutes, are amended, and subsection (6) is added to that section, to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and entities licensed or registered by or applying for such licensure or registration from the Agency for Health Care Administration pursuant to this part. A license issued by the agency is required in order to operate a home health agency in this state. A license issued on or after July 1, 2018, must specify the home health services the organization is authorized to perform and indicate whether such specified services are considered skilled care. The provision or advertising of services that require licensure pursuant to this part without such services being specified on the face of the license issued on or after July 1, 2018, constitutes unlicensed activity as prohibited under s. 408.812.

(4)

(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of this part is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of this part or part II of chapter 408, until

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compliance with this part or the rules adopted under this part has been demonstrated to the satisfaction of the agency.

- (e) Any person who owns, operates, or maintains an unlicensed home health agency and who, within 10 working days after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.
- (f) Any home health agency that fails to cease operation after agency notification may be fined in accordance with s. 408.812 \$500 for each day of noncompliance.
- (6) Any person, entity, or organization providing home health services which is exempt from licensure under subsection (5) may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that specifies its name or names and addresses, a statement of the reasons why it is exempt from licensure as a home health agency, and other information deemed necessary by the agency. A certificate of exemption is valid for a period of not more than 2 years and is not transferable. The agency may charge an applicant \$100 for a certificate of exemption or charge the actual cost of processing the certificate.

Section 46. Subsections (6) through (9) of section 400.471, Florida Statutes, are redesignated as subsections (5) through (8), respectively, and present subsections (2),(6), and (9) of that section are amended, to read:

- 400.471 Application for license; fee.-
- (2) In addition to the requirements of part II of chapter

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408, the initial applicant, the applicant for a change of ownership, and the applicant for the addition of skilled care services must file with the application satisfactory proof that the home health agency is in compliance with this part and applicable rules, including:

- (a) A listing of services to be provided, either directly by the applicant or through contractual arrangements with existing providers.
- (b) The number and discipline of professional staff to be employed.
- (c) Completion of questions concerning volume data on the renewal application as determined by rule.
- (c) (d) A business plan, signed by the applicant, which details the home health agency's methods to obtain patients and its plan to recruit and maintain staff.
- (d) (e) Evidence of contingency funding <u>as required under s.</u>
 408.8065 equal to 1 month's average operating expenses during the first year of operation.
- (e) (f) A balance sheet, income and expense statement, and statement of cash flows for the first 2 years of operation which provide evidence of having sufficient assets, credit, and projected revenues to cover liabilities and expenses. The applicant has demonstrated financial ability to operate if the applicant's assets, credit, and projected revenues meet or exceed projected liabilities and expenses. An applicant may not project an operating margin of 15 percent or greater for any month in the first year of operation. All documents required under this paragraph must be prepared in accordance with generally accepted accounting principles and compiled and signed

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by a certified public accountant.

 $\underline{\text{(f)}}$ All other ownership interests in health care entities for each controlling interest, as defined in part II of chapter 408.

(g) (h) In the case of an application for initial licensure, an application for a change of ownership, or an application for the addition of skilled care services, documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408. A home health agency that is not Medicare or Medicaid certified and does not provide skilled care is exempt from this paragraph. Notwithstanding s. 408.806, an initial applicant that has applied for accreditation must provide proof of accreditation that is not conditional or provisional and a survey demonstrating compliance with the requirements of this part, part II of chapter 408, and applicable rules from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408 within 120 days after the date of the agency's receipt of the application for licensure or the application shall be withdrawn from further consideration. Such accreditation must be continuously maintained by the home health agency to maintain licensure. The agency shall accept, in lieu of its own periodic licensure survey, the submission of the survey of an accrediting organization that is recognized by the agency if the accreditation of the licensed home health agency is not provisional and if the licensed home health agency authorizes

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releases of, and the agency receives the report of, the accrediting organization.

- (6) The agency may not issue a license designated as certified to a home health agency that fails to satisfy the requirements of a Medicare certification survey from the agency.
- (8) (9) The agency may not issue a renewal license for a home health agency in any county having at least one licensed home health agency and that has more than one home health agency per 5,000 persons, as indicated by the most recent population estimates published by the Legislature's Office of Economic and Demographic Research, if the applicant or any controlling interest has been administratively sanctioned by the agency during the 2 years prior to the submission of the licensure renewal application for one or more of the following acts:
- (a) An intentional or negligent act that materially affects the health or safety of a client of the provider;
- (b) Knowingly providing home health services in an unlicensed assisted living facility or unlicensed adult family-care home, unless the home health agency or employee reports the unlicensed facility or home to the agency within 72 hours after providing the services;
- (c) Preparing or maintaining fraudulent patient records, such as, but not limited to, charting ahead, recording vital signs or symptoms which were not personally obtained or observed by the home health agency's staff at the time indicated, borrowing patients or patient records from other home health agencies to pass a survey or inspection, or falsifying signatures;
 - (d) Failing to provide at least one service directly to a

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patient for a period of 60 days;

- (e) Demonstrating a pattern of falsifying documents relating to the training of home health aides or certified nursing assistants or demonstrating a pattern of falsifying health statements for staff who provide direct care to patients. A pattern may be demonstrated by a showing of at least three fraudulent entries or documents;
- (f) Demonstrating a pattern of billing any payor for services not provided. A pattern may be demonstrated by a showing of at least three billings for services not provided within a 12-month period;
- (g) Demonstrating a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the patient's legal representative, or the plan of care for that patient, except unless a reduction in service is mandated by Medicare, Medicaid, or a state program or as provided in s. 400.492(3). A pattern may be demonstrated by a showing of at least three incidents, regardless of the patient or service, in which the home health agency did not provide a service specified in a written agreement or plan of care during a 3-month period;
- (h) Giving remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from whom the home health agency receives referrals or gives remuneration as prohibited in s. 400.474(6)(a);
- (i) Giving cash, or its equivalent, to a Medicare or Medicaid beneficiary;

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

- (k) Providing services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration; or
- (1) Providing staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

Section 47. Subsection (5) of section 400.474, Florida Statutes, is amended to read:

400.474 Administrative penalties.-

(5) The agency shall impose a fine of \$5,000 against a home health agency that demonstrates a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the patient's legal representative, or the plan of care for that patient, except unless a reduction in service is mandated by Medicare, Medicaid, or a state program or as provided in s. 400.492(3). A pattern may be demonstrated by a showing of at least three incidences, regardless of the patient or service, where the home health agency did not provide a service specified in a written agreement or plan of care during a 3-month period. The agency shall impose the fine for each occurrence. The agency may also impose additional administrative fines under s. 400.484 for the direct or indirect harm to a patient, or deny, revoke, or suspend the license of

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the home health agency for a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the plan of care for that patient.

Section 48. Paragraph (c) of subsection (2) of section 400.476, Florida Statutes, is amended to read:

400.476 Staffing requirements; notifications; limitations on staffing services.—

- (2) DIRECTOR OF NURSING.-
- (c) A home health agency that provides skilled nursing care must is not Medicare or Medicaid certified and does not provide skilled care or provides only physical, occupational, or speech therapy is not required to have a director of nursing and is exempt from paragraph (b).

Section 49. Section 400.484, Florida Statutes, is amended to read:

400.484 Right of inspection; <u>violations</u> deficiencies; fines.—

- (1) In addition to the requirements of s. 408.811, the agency may make such inspections and investigations as are necessary in order to determine the state of compliance with this part, part II of chapter 408, and applicable rules.
- (2) The agency shall impose fines for various classes of violations deficiencies in accordance with the following schedule:
- (a) Class I violations are as provided in s. 408.813 A class I deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury. Upon finding a class I violation deficiency,

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the agency shall impose an administrative fine in the amount of \$15,000 for each occurrence and each day that the <u>violation</u> deficiency exists.

- (b) Class II violations are as provided in s. 408.813 A class II deficiency is any act, omission, or practice that has a direct adverse effect on the health, safety, or security of a patient. Upon finding a class II violation deficiency, the agency shall impose an administrative fine in the amount of \$5,000 for each occurrence and each day that the violation deficiency exists.
- (c) Class III violations are as provided in s. 408.813 A class III deficiency is any act, omission, or practice that has an indirect, adverse effect on the health, safety, or security of a patient. Upon finding an uncorrected or repeated class III violation deficiency, the agency shall impose an administrative fine not to exceed \$1,000 for each occurrence and each day that the uncorrected or repeated violation deficiency exists.
- (d) Class IV violations are as provided in s. 408.813 A class IV deficiency is any act, omission, or practice related to required reports, forms, or documents which does not have the potential of negatively affecting patients. These violations are of a type that the agency determines do not threaten the health, safety, or security of patients. Upon finding an uncorrected or repeated class IV violation deficiency, the agency shall impose an administrative fine not to exceed \$500 for each occurrence and each day that the uncorrected or repeated violation deficiency exists.
- (3) In addition to any other penalties imposed pursuant to this section or part, the agency may assess costs related to an

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investigation that results in a successful prosecution, excluding costs associated with an attorney's time.

Section 50. Subsection (4) of section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency 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:

(4) Licensure application and renewal <u>and certificates of</u> exemption.

Section 51. Subsection (5), paragraphs (d) and (e) of subsection (6), paragraph (a) of subsection (15), and subsection (19) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

- (5) (a) In addition to the requirements of s. 408.812, any person who owns, operates, or maintains an unlicensed nurse registry and who, within 10 working days after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.
- (b) If a nurse registry fails to cease operation after agency notification, the agency may impose a fine <u>pursuant to s.</u> 408.812 of \$500 for each day of noncompliance.

(6)

(d) A registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide

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referred for contract under this chapter by a nurse registry is deemed an independent contractor and not an employee of the nurse registry <u>under any chapter</u> regardless of the obligations imposed on a nurse registry under this chapter or chapter 408.

- (e) Upon referral of a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide for contract in a private residence or facility, the nurse registry shall advise the patient, the patient's family, or any other person acting on behalf of the patient, at the time of the contract for services, that the caregiver referred by the nurse registry is an independent contractor and that the it is not the obligation of a nurse registry may not to monitor, supervise, manage, or train a caregiver referred for contract under this chapter.
- (15)(a) The agency may deny, suspend, or revoke the license of a nurse registry and shall impose a fine of \$5,000 against a nurse registry that:
- 1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.
- 2. Provides staffing to an assisted living facility for which the nurse registry does not receive fair market value remuneration.
- 3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within the last 5 years.
- 4. Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility

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licensed under chapter 395 or this chapter and from whom the nurse registry receives referrals. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.

- 5. Gives remuneration to a physician, a member of the physician's office staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician's office staff. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.
- (19) It is not the obligation of A nurse registry may not to monitor, supervise, manage, or train a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide referred for contract under this chapter. In the event of a violation of this chapter or a violation of any other law of this state by a referred registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker, or home health aide, or a deficiency in credentials which comes to the attention of the nurse registry, the nurse registry shall advise the patient to terminate the referred person's contract, providing the reason for the suggested termination; cease referring the person to other patients or facilities; and, if practice violations are

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involved, notify the licensing board. This section does not affect or negate any other obligations imposed on a nurse registry under chapter 408.

Section 52. Subsection (1) of section 400.606, Florida Statutes, is 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:
- (a) The estimated average number of terminally ill persons to be served monthly.
- (b) The geographic area in which hospice services will be available.
- (c) A listing of services which are or will be provided, either directly by the applicant or through contractual arrangements with existing providers.
- (d) Provisions for the implementation of hospice home care within 3 months after licensure.
- (e) Provisions for the implementation of hospice homelike inpatient care within 12 months after licensure.
- (f) The number and disciplines of professional staff to be employed.
- (g) The name and qualifications of any existing or potential contractee.
 - (h) A plan for attracting and training volunteers.

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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.

Section 53. Subsection (6) of section 400.925, Florida Statutes, is amended to read:

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

- (6) "Home medical equipment" includes any product as defined by the Food and Drug Administration's Federal Food, Drug, and Cosmetic Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes:
- (a) Oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner;
 - (b) Motorized scooters;
 - (c) Personal transfer systems; and
- (d) Specialty beds, for use by a person with a medical need; and
 - (e) Manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner.

Section 54. Subsection (4) of section 400.931, Florida Statutes, is amended to read:

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400.931 Application for license; fee.-

(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 the timeframes established in part II of chapter 408 and applicable rules 45 days.

Section 55. Subsection (2) of section 400.933, Florida Statutes, is amended to read:

400.933 Licensure inspections and investigations.-

- (2) The agency shall accept, in lieu of its own periodic inspections for licensure, submission of the following:
- (a) The survey or inspection of an accrediting organization, provided the accreditation of the licensed home medical equipment provider is not provisional and provided the licensed home medical equipment provider authorizes release of, and the agency receives the report of, the accrediting organization; or
- (b) A copy of a valid medical oxygen retail establishment permit issued by the Department of <u>Business and Professional</u>

 <u>Regulation</u> <u>Health</u>, pursuant to chapter 499.

Section 56. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.-

(2) The requirements of part II of chapter 408 apply to the provision of services that require licensure or registration 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

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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 the timeframes established in this part, part II of chapter 408, and applicable rules 14 days prior to the change.

Section 57. Paragraphs (a) through (d) of subsection (4) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.-

- (4) "Clinic" means an entity where 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. As used in this part, the term does not include and the licensure requirements of this part do not apply to:
- (a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers

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certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

- (b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.
- (c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or

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chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 383.30-383.335, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, part I of chapter 483, chapter 484, or chapter 651; endstage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

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Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

1913 Section 58. Subsection (6) of section 400.9935, Florida 1914 Statutes, is amended to read:

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400.9935 Clinic responsibilities.-

(6) Any person or entity providing health care services which is not a clinic, as defined under s. 400.9905, may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that sets forth its name or names and addresses, a statement of the reasons why it cannot be defined as a clinic, and other information deemed necessary by the agency. An exemption may be valid for up to 2 years and is not transferable. The agency may charge an applicant for a certificate of exemption in an amount equal to \$100 or the actual cost of processing the certificate, whichever is less. An entity seeking a certificate of exemption must publish and maintain 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 entity and must include, but is not limited to, the 50 services most frequently provided by the entity. The schedule may group services by three price levels, listing services in each price level. The posting must be at least 15 square feet in size. As a condition precedent to receiving a certificate of exemption, an applicant must provide to the agency documentation of compliance with these requirements.

Section 59. 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

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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, birth 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 60. Present paragraphs (f) through (l) of subsection (3) of section 408.036, Florida Statutes, are redesignated as paragraphs (e) through (k), respectively, present paragraphs (o) through (t) of that subsection are redesignated as paragraphs (l) through (q), respectively, and present paragraphs (e), (m), (n), and (p) of that subsection are 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):
- (e) For mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957.

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(m)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:

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

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

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of its program until December 31, 2006.

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

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

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

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

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

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

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

g. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay

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patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.

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

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

(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 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 must require the following:

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

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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 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.

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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 patient-selection 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

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2118 exemption.

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

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

 $\underline{\text{(m)}}$ For replacement of a licensed nursing home on the same site, or within 5 miles of the same site if within the same subdistrict, if the number of licensed beds does not increase except as permitted under paragraph $\underline{\text{(e)}}$ $\underline{\text{(f)}}$.

Section 61. 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:
- (b) 1. For a hospital seeking a Level I program, demonstration that, for the 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

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transferred at least 300 patients 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.

- 2.a. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the diagnostic cardiac catheterization volume and ischemic heart disease diagnosis volume requirements in subparagraph 1., if the hospital demonstrates that it has, for the most recent 12-month period as reported to the agency, provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations or that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease.
- <u>b.</u> 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 requirement in subparagraph 1., 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.
- 3. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have

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2176 demonstrated experience in handling acutely ill patients requiring intervention, based on the staff member's previous experience in dedicated cardiac interventional laboratories or 2179 surgical centers. If a staff member's previous experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open-heart-surgery program, the staff member's previous experience qualifies only if, at the time the staff member acquired his or her experience, the dedicated cardiac interventional laboratory:

- a. Had an annual volume of 500 or more percutaneous cardiac intervention procedures;
- b. Achieved a demonstrated success rate of 95 percent or greater for percutaneous cardiac intervention procedures;
- c. Experienced a complication rate of less than 5 percent for percutaneous cardiac intervention procedures; and
- d. Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

Section 62. Paragraph (k) is added to subsection (3) of section 408.05, Florida Statutes, to read:

- 408.05 Florida Center for Health Information and Transparency.-
- (3) HEALTH INFORMATION TRANSPARENCY.-In order to disseminate and facilitate the availability of comparable and uniform health information, the agency shall perform the following functions:
- (k) Contract with the Society of Thoracic Surgeons and the American College of Cardiology to obtain data reported pursuant

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to s. 395.1055 for publication on the agency's website in a manner that will allow consumers to be informed of aggregate data and to compare pediatric cardiac programs.

Section 63. Subsection (4) of section 408.061, Florida Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(4) Within 120 days after the end of its fiscal year, each health care facility, excluding continuing care facilities, hospitals operated by state agencies, and nursing homes as those terms are defined in s. $408.07 \cdot \frac{408.07(14)}{14} \cdot \frac{140}{14} \cdot \frac{$ file with the agency, on forms adopted by the agency and based on the uniform system of financial reporting, its actual financial experience for that fiscal year, including expenditures, revenues, and statistical measures. Such data may be based on internal financial reports which are certified to be complete and accurate by the provider. However, hospitals' actual financial experience shall be their audited actual experience. Every nursing home shall submit to the agency, in a format designated by the agency, a statistical profile of the nursing home residents. The agency, in conjunction with the Department of Elderly Affairs and the Department of Health, shall review these statistical profiles and develop recommendations for the types of residents who might more appropriately be placed in their homes or other noninstitutional settings.

Section 64. Subsection (11) of section 408.07, Florida Statutes, is amended to read:

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408.07 Definitions.—As used in this chapter, with the exception of ss. 408.031-408.045, the term:

(11) "Clinical laboratory" means a facility licensed under s. 483.091, excluding: any hospital laboratory defined under s. 483.041(6); any clinical laboratory operated by the state or a political subdivision of the state; any blood or tissue bank where the majority of revenues are received from the sale of blood or tissue and where blood, plasma, or tissue is procured from volunteer donors and donated, processed, stored, or distributed on a nonprofit basis; and any clinical laboratory which is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that same group practice.

Section 65. Subsection (4) of section 408.20, Florida Statutes, is amended to read:

408.20 Assessments; Health Care Trust Fund.-

(4) Hospitals operated by <u>a state agency</u> the Department of Children and Families, the Department of Health, or the Department of Corrections are exempt from the assessments required under this section.

Section 66. <u>Section 408.7056</u>, Florida Statutes, is repealed.

Section 67. Subsections (10), (11), and (27) of section 408.802, Florida Statutes, are amended to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or

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2263 certified by the agency, as described in chapters 112, 383, 390, 2264 394, 395, 400, 429, 440, 483, and 765: 2265 (10) Mobile surgical facilities, as provided under part I 2266 of chapter 395. 2267 (11) Health care risk managers, as provided under part I of 2268 chapter 395. 2269 (27) Clinical laboratories, as provided under part I of 2270 chapter 483. 2271 Section 68. Subsections (12) and (13) of section 408.803, 2272 Florida Statutes, are redesignated as subsections (13) and (14), 2273 respectively, and a new subsection (12) is added to that 2274 section, to read: 2275 408.803 Definitions.—As used in this part, the term: 2276 (12) "Relative" means an individual who is the father, mother, stepfather, stepmother, son, daughter, brother, sister, 2277 2278 grandmother, grandfather, great-grandmother, great-grandfather, 2279 grandson, granddaughter, uncle, aunt, first cousin, nephew, 2280 niece, husband, wife, father-in-law, mother-in-law, son-in-law, 2281 daughter-in-law, brother-in-law, sister-in-law, stepson, 2282 stepdaughter, stepbrother, stepsister, half-brother, or half-2283 sister of a patient or client. 2284 Section 69. Paragraph (c) of subsection (7) of section 2285 408.806, Florida Statutes, is amended, and subsection (9) is 2286 added to that section, to read: 2287 408.806 License application process.-2288 (7) 2289 (c) If an inspection is required by the authorizing statute 2290 for a license application other than an initial application, the

inspection must be unannounced. This paragraph does not apply to

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inspections required pursuant to ss. 383.324, 395.0161(4) $\frac{\text{and}_{7}}{429.67(6)_{7}}$ and $\frac{483.061(2)}{429.67(6)_{7}}$.

(9) A licensee that holds a license for multiple providers licensed by the agency may request that all related license expiration dates be aligned. Upon such request, the agency may issue a license for an abbreviated licensure period with a prorated licensure fee.

Section 70. Paragraphs (d) and (e) of subsection (1) of section 408.809, Florida Statutes, are amended to read:

408.809 Background screening; prohibited offenses.-

- (1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who are considered employees for the purposes of conducting screening under chapter 435:
- (d) Any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the conviction at the time of license application.
- (e) Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients, or contracting with a licensee or provider to work 20

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hours a week or more who will have access to client funds, personal property, or living areas. Evidence of contractor screening may be retained by the contractor's employer or the licensee.

Section 71. Subsection (8) of section 408.810, Florida Statutes, is amended, and subsections (11), (12), and (13) are added to that section, 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.

(8) Upon application for initial licensure or change of ownership licensure, the applicant shall furnish satisfactory proof of the applicant's financial ability to operate in accordance with the requirements of this part, authorizing statutes, and applicable rules. The agency shall establish standards for this purpose, including information concerning the applicant's controlling interests. The agency shall also establish documentation requirements, to be completed by each applicant, that show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A current certificate of authority, pursuant to chapter 651, may be provided as proof of financial ability to operate. The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to, unpaid expenses necessary for the basic operations of the

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provider. An applicant applying for change of ownership
licensure is exempt from furnishing proof of financial ability
to operate if the provider has been licensed for at least 5
years, and:

- (a) The ownership change is a result of a corporate reorganization under which the controlling interest is unchanged and the applicant submits organizational charts that represent the current and proposed structure of the reorganized corporation; or
- (b) The ownership change is due solely to the death of a person holding a controlling interest, and the surviving controlling interests continue to hold at least 51 percent of ownership after the change of ownership.
- (11) The agency may adopt rules that govern the circumstances under which a controlling interest, an administrator, an employee, or a contractor, or a representative thereof, who is not a relative of the client may act as an agent of the client in authorizing consent for medical treatment, assignment of benefits, and release of information. Such rules may include requirements related to disclosure, bonding, restrictions, and client protections.
- (12) The licensee shall ensure that no person holds any ownership interest, either directly or indirectly, regardless of ownership structure, who:
 - (a) Has a disqualifying offense pursuant to s. 408.809; or
- (b) Holds or has held any ownership interest, either directly or indirectly, regardless of ownership structure, in a provider that had a license revoked or an application denied pursuant to s. 408.815.

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(13) If the licensee is a publicly traded corporation or is wholly owned, directly or indirectly, by a publicly traded corporation, subsection (12) does not apply to those persons whose sole relationship with the corporation is as a shareholder of publicly traded shares. As used in this subsection, a "publicly traded corporation" is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

Section 72. Section 408.812, Florida Statutes, is amended to read:

408.812 Unlicensed activity.-

- (1) A person or entity may not offer or advertise services that require licensure as defined by this part, authorizing statutes, or applicable rules to the public without obtaining a valid license from the agency. A licenseholder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.
- (2) The operation or maintenance of an unlicensed provider or the performance of any services that require licensure without proper licensure is a violation of this part and authorizing statutes. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients, and constitutes abuse and neglect, as defined in s. 415.102. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the unlicensed provider or the performance of any services in violation of this part and authorizing statutes,

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until compliance with this part, authorizing statutes, and agency rules has been demonstrated to the satisfaction of the agency.

- (3) It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. If after receiving notification from the agency, such person or entity fails to cease operation and apply for a license under this part and authorizing statutes, the person or entity is shall be subject to penalties as prescribed by authorizing statutes and applicable rules. Each day of continued operation is a separate offense.
- (4) Any person or entity that fails to cease operation after agency notification may be fined \$1,000 for each day of noncompliance.
- (5) When a controlling interest or licensee has an interest in more than one provider and fails to license a provider rendering services that require licensure, the agency may revoke all licenses, and impose actions under s. 408.814, and regardless of correction, impose a fine of \$1,000 per day, unless otherwise specified by authorizing statutes, against each licensee until such time as the appropriate license is obtained or the unlicensed activity ceases for the unlicensed operation.
- (6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part,

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authorizing statutes, and agency rules.

(7) Any person aware of the operation of an unlicensed provider must report that provider to the agency.

Section 73. Subsections (10), (11) and (26) of section 408.820, Florida Statutes, are amended, and subsections (12) through (25) and (27) and (28) are redesignated as subsections (10) through (23) and (24) and (25), respectively, to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

(11) Health care risk managers, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810(4)-(10), and 408.811.

(26) Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(10).

Section 74. Subsection (7) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency

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from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(7) INDEPENDENT LABORATORY SERVICES.—The agency shall pay for medically necessary diagnostic laboratory procedures ordered by a licensed physician or other licensed practitioner of the healing arts which are provided for a recipient in a laboratory that meets the requirements for Medicare participation and is appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder licensed under chapter 483, if required.

Section 75. Subsection (10) of section 409.907, Florida Statutes, is amended to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(10) The agency may consider whether the provider, or any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder having an ownership

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interest equal to 5 percent or greater in the provider if the provider is a corporation, partnership, or other business entity, has:

- (a) Made a false representation or omission of any material fact in making the application, including the submission of an application that conceals the controlling or ownership interest of any officer, director, agent, managing employee, affiliated person, or partner or shareholder who may not be eligible to participate;
- (b) Been or is currently excluded, suspended, terminated from, or has involuntarily withdrawn from participation in, Florida's Medicaid program or any other state's Medicaid program, or from participation in any other governmental or private health care or health insurance program;
- (c) Been convicted of a criminal offense relating to the delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program including the performance of management or administrative services relating to the delivery of goods or services under any such program;
- (d) Been convicted under federal or state law of a criminal offense related to the neglect or abuse of a patient in connection with the delivery of any health care goods or services;
- (e) Been convicted under federal or state law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;
- (f) Been convicted of any criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility,

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or other financial misconduct;

- (g) Been convicted under federal or state law of a crime punishable by imprisonment of a year or more which involves moral turpitude;
- (h) Been convicted in connection with the interference or obstruction of any investigation into any criminal offense listed in this subsection;
- (i) Been found to have violated federal or state laws, rules, or regulations governing Florida's Medicaid program or any other state's Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program, and been sanctioned accordingly;
- (c)(j) Been previously found by a licensing, certifying, or professional standards board or agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided; or
- (d) (k) Failed to pay any fine or overpayment properly assessed under the Medicaid program in which no appeal is pending or after resolution of the proceeding by stipulation or agreement, unless the agency has issued a specific letter of forgiveness or has approved a repayment schedule to which the provider agrees to adhere.
- Section 76. Subsection (6) of section 409.9116, Florida Statutes, is amended to read:
- 409.9116 Disproportionate share/financial assistance program for rural hospitals.—In addition to the payments made under s. 409.911, the Agency for Health Care Administration shall administer a federally matched disproportionate share program and a state-funded financial assistance program for

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statutory rural hospitals. The agency shall make disproportionate share payments to statutory rural hospitals that qualify for such payments and financial assistance payments to statutory rural hospitals that do not qualify for disproportionate share payments. The disproportionate share program payments shall be limited by and conform with federal requirements. Funds shall be distributed quarterly in each fiscal year for which an appropriation is made. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(6) This section applies only to hospitals that were defined as statutory rural hospitals, or their successor-ininterest hospital, prior to January 1, 2001. Any additional hospital that is defined as a statutory rural hospital, or its successor-in-interest hospital, on or after January 1, 2001, is not eligible for programs under this section unless additional funds are appropriated each fiscal year specifically to the rural hospital disproportionate share and financial assistance programs in an amount necessary to prevent any hospital, or its successor-in-interest hospital, eligible for the programs prior to January 1, 2001, from incurring a reduction in payments because of the eligibility of an additional hospital to participate in the programs. A hospital, or its successor-ininterest hospital, which received funds pursuant to this section before January 1, 2001, and which qualifies under s. 395.602(2) (b) s. 395.602(2) (c), shall be included in the programs under this section and is not required to seek

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additional appropriations under this subsection.

Section 77. Paragraphs (a) and (b) of subsection (1) of section 409.975, Florida Statutes, are amended to read:

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

- (1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.
- (a) Plans must include all providers in the region that are classified by the agency as essential Medicaid providers, unless the agency approves, in writing, an alternative arrangement for securing the types of services offered by the essential providers. Providers are essential for serving Medicaid enrollees if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of the Medicaid patients. The agency may not classify physicians and other practitioners as essential providers. The agency, at a minimum, shall determine which providers in the following categories are essential Medicaid providers:
 - 1. Federally qualified health centers.

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2611 2. Statutory teaching hospitals as defined in $\underline{s. 408.07(44)}$ 2612 $\underline{s. 408.07(45)}$.

- 3. Hospitals that are trauma centers as defined in s. 395.4001(14).
- 4. Hospitals located at least 25 miles from any other hospital with similar services.

Managed care plans that have not contracted with all essential providers in the region as of the first date of recipient enrollment, or with whom an essential provider has terminated its contract, must negotiate in good faith with such essential providers for 1 year or until an agreement is reached, whichever is first. Payments for services rendered by a nonparticipating essential provider shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. A rate schedule for all essential providers shall be attached to the contract between the agency and the plan. After 1 year, managed care plans that are unable to contract with essential providers shall notify the agency and propose an alternative arrangement for securing the essential services for Medicaid enrollees. The arrangement must rely on contracts with other participating providers, regardless of whether those providers are located within the same region as the nonparticipating essential service provider. If the alternative arrangement is approved by the agency, payments to nonparticipating essential providers after the date of the agency's approval shall equal 90 percent of the applicable Medicaid rate. Except for payment for emergency services, if the alternative arrangement is not approved by the agency, payment

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to nonparticipating essential providers shall equal 110 percent of the applicable Medicaid rate.

- (b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:
 - 1. Faculty plans of Florida medical schools.
- 2. Regional perinatal intensive care centers as defined in s. 383.16(2).
- 3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(27) s. 395.002(28).
- 4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider

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and any other Medicaid managed care plan.

Section 78. Subsections (5) and (17) of section 429.02, Florida Statutes, are amended to read:

429.02 Definitions.—When used in this part, the term:

- (5) "Assisted living facility" means any building or buildings, section or distinct part of a building, private home, boarding home, home for the aged, or other residential facility, regardless of whether operated for profit or not, which undertakes through its ownership or management provides to provide housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.
- (17) "Personal services" means direct physical assistance with or supervision of the activities of daily living, and the self-administration of medication, or and other similar services which the department may define by rule. The term may "Personal services" shall not be construed to mean the provision of medical, nursing, dental, or mental health services.

Section 79. Paragraphs (b) and (d) of subsection (2) of section 429.04, Florida Statutes, are amended, and subsection (3) is added that section, to read:

429.04 Facilities to be licensed; exemptions.-

- (2) The following are exempt from licensure under this part:
- (b) Any facility or part of a facility licensed by the Agency for Persons with Disabilities under chapter 393, a mental health facility licensed under or chapter 394, a hospital licensed under chapter 395, a nursing home licensed under part II of chapter 400, an inpatient hospice licensed under part IV

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of chapter 400, a home for special services licensed under part V of chapter 400, an intermediate care facility licensed under part VIII of chapter 400, or a transitional living facility licensed under part XI of chapter 400.

- (d) Any person who provides housing, meals, and one or more personal services on a 24-hour basis in the person's own home to not more than two adults who do not receive optional state supplementation. The person who provides the housing, meals, and personal services must own or rent the home and must have established the home as his or her permanent residence. For purposes of this paragraph, any person holding a homestead exemption at an address other than that at which the person asserts this exemption is presumed to not have established permanent residence reside therein. This exemption does not apply to a person or entity that previously held a license issued by the agency which was revoked or for which renewal was denied by final order of the agency, or when the person or entity voluntarily relinquished the license during agency enforcement proceedings.
- (3) Upon agency investigation of unlicensed activity, any person or entity that claims that it is exempt under this section must provide documentation substantiating entitlement to the exemption.

Section 80. Paragraphs (b) and (d) of subsection (1) of section 429.08, Florida Statutes, are amended to read:

429.08 Unlicensed facilities; referral of person for residency to unlicensed facility; penalties.—

(1)

(b) Except as provided under paragraph (d), Any person who

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owns, rents, or otherwise maintains a building or property used as operates, or maintains an unlicensed assisted living facility commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

(d) In addition to the requirements of s. 408.812, any person who owns, operates, or maintains an unlicensed assisted living facility after receiving notice from the agency due to a change in this part or a modification in rule within 6 months after the effective date of such change and who, within 10 working days after receiving notification from the agency, fails to cease operation or apply for a license under this part commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

Section 81. Section 429.176, Florida Statutes, is amended to read:

429.176 Notice of change of administrator.—If, during the period for which a license is issued, the owner changes administrators, the owner must notify the agency of the change within 10 days and provide documentation within 90 days that the new administrator has completed the applicable core educational requirements under s. 429.52. A facility may not be operated for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Section 82. Subsection(7) of section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

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

Section 83. Subsection (2) of section 429.24, Florida Statutes, is amended to read:

429.24 Contracts.

- (2) Each contract must contain express provisions specifically setting forth the services and accommodations to be provided by the facility; the rates or charges; provision for at least 30 days' written notice of a rate increase; the rights, duties, and obligations of the residents, other than those specified in s. 429.28; and other matters that the parties deem appropriate. A new service or accommodation added to, or implemented in, a resident's contract for which the resident was not previously charged does not require a 30-day written notice of a rate increase. Whenever money is deposited or advanced by a resident in a contract as security for performance of the contract agreement or as advance rent for other than the next immediate rental period:
- (a) Such funds shall be deposited in a banking institution in this state that is located, if possible, in the same community in which the facility is located; shall be kept separate from the funds and property of the facility; may not be represented as part of the assets of the facility on financial statements; and shall be used, or otherwise expended, only for

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2785 the account of the resident.

(b) The licensee shall, within 30 days of receipt of advance rent or a security deposit, notify the resident or residents in writing of the manner in which the licensee is holding the advance rent or security deposit and state the name and address of the depository where the moneys are being held. The licensee shall notify residents of the facility's policy on advance deposits.

Section 84. Paragraphs (e) and (j) of subsection (1) and paragraphs (c), (d), and (e) of subsection (3) of section 429.28, Florida Statutes, are amended to read:

429.28 Resident bill of rights.-

- (1) No resident of a facility shall be deprived of any civil or legal rights, benefits, or privileges guaranteed by law, the Constitution of the State of Florida, or the Constitution of the United States as a resident of a facility. Every resident of a facility shall have the right to:
- (e) Freedom to participate in and benefit from community services and activities and to <u>pursue</u> achieve the highest possible level of independence, autonomy, and interaction within the community.
- (j) Assistance with obtaining access to adequate and appropriate health care. For purposes of this paragraph, the term "adequate and appropriate health care" means the management of medications, assistance in making appointments for health care services, the provision of or arrangement of transportation to health care appointments, and the performance of health care services in accordance with s. 429.255 which are consistent with established and recognized standards within the community.

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- (c) During any calendar year in which no survey is conducted, the agency shall conduct at least one monitoring visit of each facility cited in the previous year for a class I or class II violation, or more than three uncorrected class III violations.
- (d) The agency may conduct periodic followup inspections as necessary to monitor the compliance of facilities with a history of any class II, or class III violations that threaten the health, safety, or security of residents.
- (e) The agency may conduct complaint investigations as warranted to investigate any allegations of noncompliance with requirements required under this part or rules adopted under this part.
- Section 85. Subsection (1) of section 429.294, Florida Statutes, is amended to read:
- 429.294 Availability of facility records for investigation of resident's rights violations and defenses; penalty .-
- (1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility within 10 days, in accordance with the provisions of s. 400.145, shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the good faith certificate and presuit notice requirements under this part by the requesting party.
- Section 86. Subsection (2) of section 429.34, Florida Statutes, is amended to read:
 - 429.34 Right of entry and inspection.

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(2) (a) In addition to the requirements of s. 408.811, the agency may inspect and investigate facilities as necessary to determine compliance with this part, part II of chapter 408, and rules adopted thereunder. The agency shall inspect each licensed assisted living facility at least once every 24 months to determine compliance with this chapter and related rules. If an assisted living facility is cited for a class I violation or three or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, the agency must conduct an additional licensure inspection within 6 months.

(b) During any calendar year in which a survey is not conducted, the agency may conduct monitoring visits of each facility cited in the previous year for a class I or class II violation or for more than three uncorrected class III violations.

Section 87. Subsection (4) of section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational programs; core educational requirement.—

(4) Effective January 1, 2004, a new facility administrator must complete the required training and education, including the competency test, within 90 days after date of employment a reasonable time after being employed as an administrator, as determined by the department. Failure to do so is a violation of this part and subjects the violator to an administrative fine as prescribed in s. 429.19. Administrators licensed in accordance with part II of chapter 468 are exempt from this requirement. Other licensed professionals may be exempted, as determined by

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2872 the department by rule.

Section 88. Subsection (3) of section 435.04, Florida Statutes, is amended, and subsection (4) is added to that section, to read:

435.04 Level 2 screening standards.-

- (3) The security background investigations under this section must ensure that no person subject to this section has been arrested for and is awaiting final disposition of, been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, any offense that constitutes domestic violence as defined in s. 741.28, whether such act was committed in this state or in another jurisdiction.
- (4) For the purpose of screening applicability to participate in the Medicaid program, the security background investigations under this section must ensure that a person subject to screening under this section has not been arrested for and is not awaiting final disposition of; has not been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to; and has not been adjudicated delinquent and the record sealed or expunged for, any of the following offenses:
- (a) Violation of a federal law or a law in any state which creates a criminal offense relating to:
- 1. The delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program, including the performance of management or administrative services relating to the delivery of goods or services under any such program;
 - 2. Neglect or abuse of a patient in connection with the

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456.001 Definitions.—As used in this chapter, the term:

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(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 90. Subsection (3) of section 456.054, Florida Statutes, is redesignated as subsection (4), and a new subsection (3) is added to that section, to read:

456.054 Kickbacks prohibited.-

- (3) (a) It is unlawful for any person or any entity to pay or receive, directly or indirectly, a commission, bonus, kickback, or rebate from, or to engage in any form of a split-fee arrangement with, a dialysis facility, health care practitioner, surgeon, person, or entity for referring patients to a clinical laboratory as defined in s. 483.803.
 - (b) It is unlawful for any clinical laboratory to:
- 1. Provide personnel to perform any functions or duties in a health care practitioner's office or dialysis facility for any purpose, including for the collection or handling of specimens, directly or indirectly through an employee, contractor, independent staffing company, lease agreement, or otherwise, unless the laboratory and the practitioner's office, or dialysis facility, are wholly owned and operated by the same entity.
- 2. Lease space within any part of a health care practitioner's office or dialysis facility for any purpose, including for the purpose of establishing a collection station where materials or specimens are collected or drawn from

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patients.

Section 91. Paragraphs (h) and (i) of subsection (2) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

- (2) As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:
- (h) Clinical laboratory personnel licensed under part $\overline{\text{II}}$ of chapter 483.
- (i) Medical physicists licensed under part $\overline{\text{III}}$ $\overline{\text{IV}}$ of chapter 483.

Section 92. Paragraph (j) of subsection (1) of section 456.076, Florida Statutes, is amended to read:

456.076 Impaired practitioner programs.

- (1) As used in this section, the term:
- (j) "Practitioner" means a person licensed, registered, certified, or regulated by the department under part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; or an

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applicant for a license, registration, or certification under the same laws.

Section 93. Subsection (2) of section 458.307, Florida Statutes, is amended to read:

458.307 Board of Medicine.-

(2) Twelve members of the board must be licensed physicians in good standing in this state who are residents of the state and who have been engaged in the active practice or teaching of medicine for at least 4 years immediately preceding their appointment. One of the physicians must be on the full-time faculty of a medical school in this state, and one of the physicians must be in private practice and on the full-time staff of a statutory teaching hospital in this state as defined in s. 408.07. At least one of the physicians must be a graduate of a foreign medical school. The remaining three members must be residents of the state who are not, and never have been, licensed health care practitioners. One member must be a health care risk manager licensed under s. 395.10974. At least one member of the board must be 60 years of age or older.

Section 94. Subsection (1) of section 458.345, Florida Statutes, is amended to read:

458.345 Registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.—

(1) Any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, assistant resident

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physician, house physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in <u>s.</u> <u>408.07 s. 408.07(45)</u> or s. 395.805(2), who does not hold a valid, active license issued under this chapter shall apply to the department to be registered and shall remit a fee not to exceed \$300 as set by the board. The department shall register any applicant the board certifies has met the following requirements:

- (a) Is at least 21 years of age.
- (b) Has not committed any act or offense within or without the state which would constitute the basis for refusal to certify an application for licensure pursuant to s. 458.331.
- (c) Is a graduate of a medical school or college as specified in s. 458.311(1)(f).

Section 95. Subsection (1) of s. 459.021, Florida Statutes, is amended to read:

- 459.021 Registration of resident physicians, interns, and fellows; list of hospital employees; penalty.—
- (1) Any person who holds a degree of Doctor of Osteopathic Medicine from a college of osteopathic medicine recognized and approved by the American Osteopathic Association who desires to practice as a resident physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07 s. 408.07(45) or s. 395.805(2), who does not hold an active license issued under this chapter shall apply to the department to be registered, on an application provided by the

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department, before commencing such a training program and shall remit a fee not to exceed \$300 as set by the board.

Section 96. Part I of chapter 483, Florida Statutes, consisting of sections 483.011, 483.021, 483.031, 483.035, 483.041, 483.051, 483.061, 483.091, 483.101, 483.111, 483.172, 483.181, 483.191, 483.201, 483.221, 483.23, 483.245, and 483.26, is repealed.

Section 97. Section 483.294, Florida Statutes, is amended to read:

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

Section 98. Subsections (3) and (5) of section 483.801, Florida Statutes, are amended, and subsection (6) is added to that section, to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

- (3) Persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466 who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that group practice regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).
 - (5) Advanced registered nurse practitioners licensed under

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part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in \underline{a} an exclusive-use laboratory setting pursuant to subsection (3).

(6) Persons performing laboratory testing within a physician office practice for patients referred by a health care provider who is a member of the same physician office practice, if the laboratory or entity operating the laboratory within a physician office practice is under common ownership, directly or indirectly, with an entity licensed pursuant to chapter 395.

Section 99. Subsections (2), (3), and (4) of section 483.803, Florida Statutes, are amended to read:

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

- (2) "Clinical laboratory" means the physical location in which one or more of the following services are performed to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition:
- (a) Clinical laboratory services, which entail the examination of fluids or other materials taken from the human body.
- (b) Anatomic laboratory services, which entail the examination of tissue taken from the human body.
- (c) Cytology laboratory services, which entail the examination of cells from individual tissues or fluid taken from the human body a clinical laboratory as defined in s. 483.041.
- (3) "Clinical laboratory examination" means a <u>procedure</u> performed to deliver the services identified in subsection (2), including the oversight or interpretation of such services elinical laboratory examination as defined in s. 483.041.

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(4) "Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities, or persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2).

Section 100. Section 483.813, Florida Statutes, is amended to read:

483.813 Clinical laboratory personnel license.—A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures. However, this provision does not apply to any practitioner of the healing arts authorized to practice in this state or to persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2). The department may grant a temporary license to any candidate it deems properly qualified, for a period not to exceed 1 year.

Section 101. Subsection (2) of section 483.823, Florida Statutes, is amended to read:

483.823 Qualifications of clinical laboratory personnel.-

(2) Personnel qualifications may require appropriate education, training, or experience or the passing of an examination in appropriate subjects or any combination of these,

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but \underline{a} no practitioner of the healing arts licensed to practice in this state is <u>not</u> required to obtain any license under this part or to pay any fee <u>under this part</u> hereunder except the fee required for clinical laboratory licensure.

Section 102. Paragraph (c) of subsection (7), and subsections (8) and (9) of section 491.003, Florida Statutes, are amended to read:

491.003 Definitions.—As used in this chapter:

(7) The "practice of clinical social work" is defined as the use of scientific and applied knowledge, theories, and methods for the purpose of describing, preventing, evaluating, and treating individual, couple, marital, family, or group behavior, based on the person-in-situation perspective of psychosocial development, normal and abnormal behavior, psychopathology, unconscious motivation, interpersonal relationships, environmental stress, differential assessment, differential planning, and data gathering. The purpose of such services is the prevention and treatment of undesired behavior and enhancement of mental health. The practice of clinical social work includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of clinical social work includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy. The practice of clinical social work also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients,

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when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of clinical social work may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

- (c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, may shall not be construed to permit the performance of any act which clinical social workers are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures pursuant to chapter 483, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition shall may not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.
- (8) The term "practice of marriage and family therapy" means is defined as the use of scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family

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systems, including the context of marital formation and dissolution, and is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic and marriage and family therapy theories and techniques. The practice of marriage and family therapy includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of marriage and family therapy includes, but is not limited to, marriage and family therapy, psychotherapy, including behavioral family therapy, hypnotherapy, and sex therapy. The practice of marriage and family therapy also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of marriage and family therapy may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(a) Marriage and family therapy may be rendered to individuals, including individuals affected by termination of marriage, to couples, whether married or unmarried, to families, or to groups.

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(b) The use of specific methods, techniques, or modalities within the practice of marriage and family therapy is restricted to marriage and family therapists appropriately trained in the use of such methods, techniques, or modalities.

- (c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, may shall not be construed to permit the performance of any act that which marriage and family therapists are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures pursuant to chapter 483, or radiological procedures, or the use of electroconvulsive therapy. In addition, this definition may shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.
- (d) The definition of "marriage and family therapy" contained in this subsection includes all services offered directly to the general public or through organizations, whether public or private, and applies whether payment is requested or received for services rendered.
- (9) The term "practice of mental health counseling" means is defined as the use of scientific and applied behavioral science theories, methods, and techniques for the purpose of describing, preventing, and treating undesired behavior and

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enhancing mental health and human development and is based on the person-in-situation perspectives derived from research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation. The practice of mental health counseling includes methods of a psychological nature used to evaluate, assess, diagnose, and treat emotional and mental dysfunctions or disorders, (whether cognitive, affective, or behavioral), behavioral disorders, interpersonal relationships, sexual dysfunction, alcoholism, and substance abuse. The practice of mental health counseling includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy. The practice of mental health counseling also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), behavioral disorders, sexual dysfunction, alcoholism, or substance abuse. The practice of mental health counseling may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(a) Mental health counseling may be rendered to individuals, including individuals affected by the termination of marriage, and to couples, families, groups, organizations, and communities.

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(b) The use of specific methods, techniques, or modalities within the practice of mental health counseling is restricted to mental health counselors appropriately trained in the use of such methods, techniques, or modalities.

- (c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, may shall not be construed to permit the performance of any act that which mental health counselors are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures pursuant to chapter 483, or radiological procedures, or the use of electroconvulsive therapy. In addition, this definition may shall not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.
- (d) The definition of "mental health counseling" contained in this subsection includes all services offered directly to the general public or through organizations, whether public or private, and applies whether payment is requested or received for services rendered.

Section 103. Paragraph (h) of subsection (4) of section 627.351, Florida Statutes, is amended to read:

- 627.351 Insurance risk apportionment plans.-
- (4) MEDICAL MALPRACTICE RISK APPORTIONMENT.-

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(h) As used in this subsection:

- 1. "Health care provider" means hospitals licensed under chapter 395; physicians licensed under chapter 458; osteopathic physicians licensed under chapter 459; podiatric physicians licensed under chapter 461; dentists licensed under chapter 466; chiropractic physicians licensed under chapter 460; naturopaths licensed under chapter 462; nurses licensed under part I of chapter 464; midwives licensed under chapter 467; clinical laboratories registered under chapter 483; physician assistants licensed under chapter 458 or chapter 459; physical therapists and physical therapist assistants licensed under chapter 486; health maintenance organizations certificated under part I of chapter 641; ambulatory surgical centers licensed under chapter 395; other medical facilities as defined in subparagraph 2.; blood banks, plasma centers, industrial clinics, and renal dialysis facilities; or professional associations, partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.
- 2. "Other medical facility" means a facility the primary purpose of which is to provide human medical diagnostic services or a facility providing nonsurgical human medical treatment, to which facility the patient is admitted and from which facility the patient is discharged within the same working day, and which facility is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy or an office maintained by a physician or dentist for the practice of medicine may shall not be construed to be an "other medical facility."
 - 3. "Health care facility" means any hospital licensed under

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chapter 395, health maintenance organization certificated under part I of chapter 641, ambulatory surgical center licensed under chapter 395, or other medical facility as defined in subparagraph 2.

Section 104. Paragraph (h) of subsection (1) of section 627.602, Florida Statutes, is amended to read:

627.602 Scope, format of policy.-

- (1) Each health insurance policy delivered or issued for delivery to any person in this state must comply with all applicable provisions of this code and all of the following requirements:
- (h) Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances. This paragraph does not apply to a health insurance policy that is subject to the Subscriber Assistance Program under s. 408.7056 or to the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 105. Subsection (1) of section 627.6406, Florida Statutes, is amended to read:

627.6406 Maternity care.

(1) Any policy of health insurance which that provides coverage for maternity care must also cover the services of certified nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed under ss. 383.30-383.332 383.30-383.335.

Section 106. Paragraphs (b) and (e) of subsection (1) of section 627.64194, Florida Statutes, are amended to read:

627.64194 Coverage requirements for services provided by

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nonparticipating providers; payment collection limitations.-

- (1) As used in this section, the term:
- (b) "Facility" means a licensed facility as defined in s. 395.002(16) and an urgent care center as defined in $\underline{s. 395.002}$ $\underline{s. 395.002(30)}$.
- (e) "Nonparticipating provider" means a provider who is not a preferred provider as defined in s. 627.6471 or a provider who is not an exclusive provider as defined in s. 627.6472. For purposes of covered emergency services under this section, a facility licensed under chapter 395 or an urgent care center defined in $\underline{s.\ 395.002}\ \underline{s.\ 395.002(30)}$ is a nonparticipating provider if the facility has not contracted with an insurer to provide emergency services to its insureds at a specified rate.

Section 107. Section 627.6513, Florida Statutes, is amended to read:

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

- (1) Coverage only for accident insurance, or disability income insurance, or any combination thereof.
 - (2) Coverage issued as a supplement to liability insurance.
- (3) Liability insurance, including general liability insurance and automobile liability insurance.
 - (4) Workers' compensation or similar insurance.
 - (5) Automobile medical payment insurance.

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- (6) Credit-only insurance.
- (7) Coverage for onsite medical clinics, including prepaid health clinics under part II of chapter 641.
- (8) Other similar insurance coverage, specified in rules adopted by the commission, under which benefits for medical care are secondary or incidental to other insurance benefits. To the extent possible, such rules must be consistent with regulations adopted by the United States Department of Health and Human Services.
- (9) Limited scope dental or vision benefits, if offered separately.
- (10) Benefits for long-term care, nursing home care, home health care, or community-based care, or any combination thereof, if offered separately.
- (11) Other similar, limited benefits, if offered separately, as specified in rules adopted by the commission.
- (12) Coverage only for a specified disease or illness, if offered as independent, noncoordinated benefits.
- (13) Hospital indemnity or other fixed indemnity insurance, if offered as independent, noncoordinated benefits.
- (14) Benefits provided through a Medicare supplemental health insurance policy, as defined under s. 1882(g)(1) of the Social Security Act, coverage supplemental to the coverage provided under 10 U.S.C. chapter 55, and similar supplemental coverage provided to coverage under a group health plan, which are offered as a separate insurance policy and as independent, noncoordinated benefits.
- Section 108. Subsection (1) of section 627.6574, Florida Statutes, is amended to read:

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627.6574 Maternity care.-

(1) Any group, blanket, or franchise policy of health insurance which that provides coverage for maternity care must also cover the services of certified nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed under ss. 383.30-383.332 383.30-383.335.

Section 109. Paragraph (j) of subsection (1) of section 641.185, Florida Statutes, is amended to read:

- 641.185 Health maintenance organization subscriber protections.—
- (1) With respect to the provisions of this part and part III, the principles expressed in the following statements shall serve as standards to be followed by the commission, the office, the department, and the Agency for Health Care Administration in exercising their powers and duties, in exercising administrative discretion, in administrative interpretations of the law, in enforcing its provisions, and in adopting rules:
- (j) A health maintenance organization should receive timely and, if necessary, urgent review by an independent state external review organization for unresolved grievances and appeals pursuant to s. 408.7056.

Section 110. Paragraph (a) of subsection (18) of section 641.31, Florida Statutes, is amended to read:

- 641.31 Health maintenance contracts.-
- (18) (a) Health maintenance contracts that provide coverage, benefits, or services for maternity care must provide, as an option to the subscriber, the services of nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed pursuant to ss. 383.30-383.332 383.30-

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383.335, if such services are available within the service area. Section 111. Section 641.312, Florida Statutes, is amended to read:

641.312 Scope.—The Office of Insurance Regulation may adopt rules to administer the provisions of the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act, issued by the National Association of Insurance Commissioners and dated April 2010. This section does not apply to a health maintenance contract that is subject to the Subscriber Assistance Program under s. 408.7056 or to the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 112. Subsection (4) of section 641.3154, Florida Statutes, is amended to read:

641.3154 Organization liability; provider billing prohibited.—

(4) A provider or any representative of a provider, regardless of whether the provider is under contract with the health maintenance organization, may not collect or attempt to collect money from, maintain any action at law against, or report to a credit agency a subscriber of an organization for payment of services for which the organization is liable, if the provider in good faith knows or should know that the organization is liable. This prohibition applies during the pendency of any claim for payment made by the provider to the organization for payment of the services and any legal proceedings or dispute resolution process to determine whether the organization is liable for the services if the provider is informed that such proceedings are taking place. It is presumed

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that a provider does not know and should not know that an organization is liable unless:

- (a) The provider is informed by the organization that it accepts liability;
- (b) A court of competent jurisdiction determines that the organization is liable; $\underline{\text{or}}$
- (c) The office or agency makes a final determination that the organization is required to pay for such services subsequent to a recommendation made by the Subscriber Assistance Panel pursuant to s. 408.7056; or
- $\underline{\text{(c)}}$ The agency issues a final order that the organization is required to pay for such services subsequent to a recommendation made by a resolution organization pursuant to s. 408.7057.
- Section 113. Paragraph (c) of subsection (5) of section 641.51, Florida Statutes, is amended to read:
- 641.51 Quality assurance program; second medical opinion requirement.—
- (5) (c) For second opinions provided by contract physicians the organization is prohibited from charging a fee to the subscriber in an amount in excess of the subscriber fees established by contract for referral contract physicians. The organization shall pay the amount of all charges, which are usual, reasonable, and customary in the community, for second opinion services performed by a physician not under contract with the organization, but may require the subscriber to be responsible for up to 40 percent of such amount. The organization may require that any tests deemed necessary by a noncontract physician shall be conducted by the organization.

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The organization may deny reimbursement rights granted under this section in the event the subscriber seeks in excess of three such referrals per year if such subsequent referral costs are deemed by the organization to be evidence that the subscriber has unreasonably overutilized the second opinion privilege. A subscriber thus denied reimbursement under this section has shall have recourse to grievance procedures as specified in ss. 408.7056_{7} 641.495 $_{7}$ and 641.511. The organization's physician's professional judgment concerning the treatment of a subscriber derived after review of a second opinion is shall be controlling as to the treatment obligations of the health maintenance organization. Treatment not authorized by the health maintenance organization is shall be at the subscriber's expense.

Section 114. Subsection (1), paragraph (e) of subsection (3), paragraph (d) of subsection (4), paragraphs (g) and (h) of subsection (6), and subsections (7) through (12) of section 641.511, Florida Statutes, are amended to read:

641.511 Subscriber grievance reporting and resolution requirements.—

(1) Every organization must have a grievance procedure available to its subscribers for the purpose of addressing complaints and grievances. Every organization must notify its subscribers that a subscriber must submit a grievance within 1 year after the date of occurrence of the action that initiated the grievance, and may submit the grievance for review to the Subscriber Assistance Program panel as provided in s. 408.7056 after receiving a final disposition of the grievance through the organization's grievance process. An organization shall maintain

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records of all grievances and shall report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievances, and the final disposition of the grievances.

- (3) Each organization's grievance procedure, as required under subsection (1), must include, at a minimum:
- (e) A notice that a subscriber may voluntarily pursue binding arbitration in accordance with the terms of the contract if offered by the organization, after completing the organization's grievance procedure and as an alternative to the Subscriber Assistance Program. Such notice shall include an explanation that the subscriber may incur some costs if the subscriber pursues binding arbitration, depending upon the terms of the subscriber's contract.

(4)

(d) In any case when the review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber, the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.

(6)

- (g) In any case when the expedited review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber, the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.
 - (g) (h) An organization shall not provide an expedited

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retrospective review of an adverse determination.

(7) Each organization shall send to the agency a copy of its quarterly grievance reports submitted to the office pursuant to s. 408.7056(12).

(7) (8) The agency shall investigate all reports of unresolved quality of care grievances received from:

(a) annual and quarterly grievance reports submitted by the organization to the office.

(b) Review requests of subscribers whose grievances remain unresolved after the subscriber has followed the full grievance procedure of the organization.

(9) (a) The agency shall advise subscribers with grievances to follow their organization's formal grievance process for resolution prior to review by the Subscriber Assistance Program. The subscriber may, however, submit a copy of the grievance to the agency at any time during the process.

(b) Requiring completion of the organization's grievance process before the Subscriber Assistance Program panel's review does not preclude the agency from investigating any complaint or grievance before the organization makes its final determination.

(10) Each organization must notify the subscriber in a final decision letter that the subscriber may request review of the organization's decision concerning the grievance by the Subscriber Assistance Program, as provided in s. 408.7056, if the grievance is not resolved to the satisfaction of the subscriber. The final decision letter must inform the subscriber that the request for review must be made within 365 days after receipt of the final decision letter, must explain how to initiate such a review, and must include the addresses and toll—

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free telephone numbers of the agency and the Subscriber Assistance Program.

- (8) (11) Each organization, as part of its contract with any provider, must require the provider to post a consumer assistance notice prominently displayed in the reception area of the provider and clearly noticeable by all patients. The consumer assistance notice must state the addresses and toll-free telephone numbers of the Agency for Health Care Administration, the Subscriber Assistance Program, and the Department of Financial Services. The consumer assistance notice must also clearly state that the address and toll-free telephone number of the organization's grievance department shall be provided upon request. The agency may adopt rules to implement this section.
- $\underline{(9)}$ (12) The agency may impose administrative sanction, in accordance with s. 641.52, against an organization for noncompliance with this section.

Section 115. Subsection (1) of section 641.515, Florida Statutes, is amended to read:

641.515 Investigation by the agency.-

(1) The agency shall investigate further any quality of care issue contained in recommendations and reports submitted pursuant to <u>s. ss. 408.7056 and</u> 641.511. The agency shall also investigate further any information that indicates that the organization does not meet accreditation standards or the standards of the review organization performing the external quality assurance assessment pursuant to reports submitted under s. 641.512. Every organization shall submit its books and records and take other appropriate action as may be necessary to

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facilitate an examination. The agency shall have access to the organization's medical records of individuals and records of employed and contracted physicians, with the consent of the subscriber or by court order, as necessary to administer carry out the provisions of this part.

Section 116. Subsection (2) of section 641.55, Florida Statutes, is amended to read:

641.55 Internal risk management program.-

(2) The risk management program shall be the responsibility of the governing authority or board of the organization. Every organization which has an annual premium volume of \$10 million or more and which directly provides health care in a building owned or leased by the organization shall hire a risk manager, certified under ss. 395.10971-395.10975, who is shall be responsible for implementation of the organization's risk management program required by this section. A part-time risk manager may shall not be responsible for risk management programs in more than four organizations or facilities. Every organization that which does not directly provide health care in a building owned or leased by the organization and every organization with an annual premium volume of less than \$10 million shall designate an officer or employee of the organization to serve as the risk manager.

The gross data compiled under this section or s. 395.0197 shall be furnished by the agency upon request to organizations to be utilized for risk management purposes. The agency shall adopt rules necessary to administer carry out the provisions of this section.

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Section 117. <u>Section 641.60</u>, <u>Florida Statutes</u>, is repealed. 3655 3656 Section 118. Section 641.65, Florida Statutes, is repealed. Section 119. Section 641.67, Florida Statutes, is repealed. 3657 3658 Section 120. Section 641.68, Florida Statutes, is repealed. 3659 Section 121. Section 641.70, Florida Statutes, is repealed. 3660 Section 122. Section 641.75, Florida Statutes, is repealed. 3661 Section 123. Paragraph (b) of subsection (6) of section 766.118, Florida Statutes, is amended to read: 3662

766.118 Determination of noneconomic damages.-

(6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF A PRACTITIONER PROVIDING SERVICES AND CARE TO A MEDICAID RECIPIENT.—Notwithstanding subsections (2), (3), and (5), with respect to a cause of action for personal injury or wrongful death arising from medical negligence of a practitioner committed in the course of providing medical services and medical care to a Medicaid recipient, regardless of the number of such practitioner defendants providing the services and care, noneconomic damages may not exceed \$300,000 per claimant, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. A practitioner providing medical services and medical care to a Medicaid recipient is not liable for more than \$200,000 in noneconomic damages, regardless of the number of claimants, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. The fact that a claimant proves that a practitioner acted in a wrongful manner does not preclude the application of the limitation on noneconomic damages prescribed elsewhere in this section. For purposes of this subsection:

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(b) The term "practitioner," in addition to the meaning prescribed in subsection (1), includes any hospital or, ambulatory surgical center, or mobile surgical facility as defined and licensed under chapter 395.

Section 124. Subsection (4) of section 766.202, Florida Statutes, is amended to read:

766.202 Definitions; ss. 766.201-766.212.—As used in ss. 766.201-766.212, the term:

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

Section 125. Section 945.36, Florida Statutes, is amended to read:

- 945.36 Exemption from health testing regulations for Law enforcement personnel <u>authorized to conduct</u> conducting drug tests on inmates and releasees.—
- (1) Any law enforcement officer, state or county probation officer, employee of the Department of Corrections, or employee of a contracted community correctional center who is certified by the Department of Corrections pursuant to subsection (2) may

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<u>administer</u>, is exempt from part I of chapter 483, for the limited purpose of administering a urine screen drug test to:

- (a) Persons during incarceration;
- (b) Persons released as a condition of probation for either a felony or misdemeanor;
 - (c) Persons released as a condition of community control;
 - (d) Persons released as a condition of conditional release;
 - (e) Persons released as a condition of parole;
 - (f) Persons released as a condition of provisional release;
 - (g) Persons released as a condition of pretrial release; or
 - (h) Persons released as a condition of control release.
- (2) The Department of Corrections shall develop a procedure for certification of any law enforcement officer, state or county probation officer, employee of the Department of Corrections, or employee of a contracted community correctional center to perform a urine screen drug test on the persons specified in subsection (1).

Section 126. Paragraph (b) of subsection (2) of section 1009.65, Florida Statutes, is amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

- (2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:
- (b) All payments <u>are</u> shall be contingent on continued proof of primary care practice in an area defined in <u>s. 395.602(2)(b)</u> s. 395.602(2)(e), or an underserved area designated by the Department of Health, provided the practitioner accepts Medicaid reimbursement if eligible for such reimbursement. Correctional

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facilities, state hospitals, and other state institutions that employ medical personnel shall be designated by the Department of Health as underserved locations. Locations with high incidences of infant mortality, high morbidity, or low Medicaid participation by health care professionals may be designated as underserved.

Section 127. Subsection (2) of section 1011.52, Florida Statutes, is amended to read:

1011.52 Appropriation to first accredited medical school.-

- (2) In order for a medical school to qualify under the provisions of this section and to be entitled to the benefits herein, such medical school:
- (a) Must be primarily operated and established to offer, afford, and render a medical education to residents of the state qualifying for admission to such institution;
- (b) Must be operated by a municipality or county of this state, or by a nonprofit organization heretofore or hereafter established exclusively for educational purposes;
- (c) Must, upon the formation and establishment of an accredited medical school, transmit and file with the Department of Education documentary proof evidencing the facts that such institution has been certified and approved by the council on medical education and hospitals of the American Medical Association and has adequately met the requirements of that council in regard to its administrative facilities, administrative plant, clinical facilities, curriculum, and all other such requirements as may be necessary to qualify with the council as a recognized, approved, and accredited medical school;

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(d) Must certify to the Department of Education the name, address, and educational history of each student approved and accepted for enrollment in such institution for the ensuing school year; and

- (e) Must have in place an operating agreement with a government-owned hospital that is located in the same county as the medical school and that is a statutory teaching hospital as defined in s. 408.07(44) s. 408.07(45). The operating agreement must shall provide for the medical school to maintain the same level of affiliation with the hospital, including the level of services to indigent and charity care patients served by the hospital, which was in place in the prior fiscal year. Each year, documentation demonstrating that an operating agreement is in effect shall be submitted jointly to the Department of Education by the hospital and the medical school prior to the payment of moneys from the annual appropriation.
 - Section 128. This act shall take effect July 1, 2018.