An act relating to health care; amending s. 395.4001, F.S.; revising the definition of the terms "level II trauma center" and "trauma center"; amending s. 395.401, F.S.; making conforming changes; amending s. 395.4025, F.S.; establishing criteria for designating Level II trauma centers in areas with limited access to trauma center services; amending s. 400.9905, F.S.; revising a definition; amending s. 408.036, F.S.; providing for expedited review of certificate-of-need for licensed skilled nursing facilities in qualifying retirement communities; providing criteria for expedited review for licensed skilled nursing homes in qualifying retirement communities; limiting the number of beds per retirement community that can be added through expedited review; amending s. 395.003, F.S.; authorizing certain specialty-licensed children's hospitals to provide obstetrical services under certain circumstances; providing a short title; creating ss. 627.42391 and 641.313, F.S.; providing definitions; requiring that an individual or group insurance policy or contract or a health maintenance contract that provides coverage for cancer treatment medications provide coverage for orally administered cancer treatment medications; requiring that an individual or group insurance policy or contract or a health maintenance contract provide coverage for orally administered cancer treatment medications on a

basis no less favorable than that required by the policy or contract for intravenously administered or injected cancer treatment medications; excluding grandfathered health plans and other specified types of health care policies and supplemental limited-benefit plans from coverage and from coverage and cost-sharing requirements; prohibiting insurers, health maintenance organizations, and certain other entities from engaging in specified actions to avoid compliance with this act; providing limits on certain cost-sharing requirements; providing an appropriation to the Department of Health to fund the administration of the prescription drug monitoring program; providing effective dates.

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

Section 1. Paragraph (a) of subsection (7) and subsection (14) of section 395.4001, Florida Statutes, are amended to read:

395.4001 Definitions.—As used in this part, the term:

(7) "Level II trauma center" means a trauma center that:

(a) Is verified by the department to be in substantial compliance with Level II trauma center standards and has been approved by the department to operate as a Level II trauma center <u>or is designated pursuant to s. 395.4025(14)</u>.

(14) "Trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the

department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated by the department as a Level II trauma center pursuant to s. 395.4025(14).

Section 2. Paragraph (k) of subsection (1) of section 395.401, Florida Statutes, is amended to read:

395.401 Trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.—

(1)

(k) It is unlawful for any hospital or other facility to hold itself out as a trauma center unless it has been so verified or designated pursuant to s. 395.4025(14).

Section 3. Subsection (14) of section 395.4025, Florida Statutes, is amended to read:

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

(14) Notwithstanding the procedures established pursuant to subsections (1) through (13) in this section, hospitals located in areas with limited access to trauma center services shall be designated by the department as Level II trauma centers based on documentation of a valid certificate of trauma center verification from the American College of Surgeons. Areas with limited access to trauma center services are defined by the following criteria:

(a) The hospital is located in a trauma service area with a population greater than 600,000 persons but a population density of less than 225 persons per square mile; and

(b) The hospital is located in a county with no verified

trauma center; and

(c) The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center ~~any other provisions of this section and rules adopted pursuant to this section, until the department has conducted the review provided under s. 395.402, only hospitals located in trauma services areas where there is no existing trauma center may apply~~.

Section 4. Paragraphs (l) and (m) 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:

(l) Orthotic, ~~or~~ prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt under paragraph (a) or paragraph (k) and that are a publicly traded corporation or ~~that~~ are wholly owned, directly or indirectly, by a publicly traded corporation. As used in this paragraph, a publicly traded corporation is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

(m) Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services

provided by licensed health care practitioners where one or more of the persons responsible for the operations of the entity are ~~owners is~~ a health care practitioner who is licensed in this state and who is responsible for supervising the business activities of the entity and is ~~legally~~ responsible for the entity's compliance with state law for purposes of this part.

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).

Section 5. Subsection (2) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), projects subject to an expedited review shall include, but not be limited to:

(a) A transfer of a certificate of need, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet operational shall be acquired by the purchaser, without need for a transfer.

(b) Replacement of a nursing home within the same district, if the proposed project site is located within a geographic area that contains at least 65 percent of the facility's current residents and is within a 30-mile radius of the replaced nursing home.

(c) Relocation of a portion of a nursing home's licensed

beds to a facility within the same district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the district does not increase.

(d) The new construction of a community nursing home in a retirement community as further provided in this paragraph.

1. Expedited review under this paragraph is available if all of the following criteria are met:

a. The residential use area of the retirement community is deed-restricted as housing for older persons as defined in s. 760.29(4)(b).

b. The retirement community is located in a county in which 25 percent or more of its population is age 65 and older.

c. The retirement community is located in a county that has a rate of no more than 16.1 beds per 1,000 persons age 65 years or older. The rate shall be determined by using the current number of licensed and approved community nursing home beds in the county per the agency's most recent published inventory.

d. The retirement community has a population of at least 8,000 residents within the county, based on a population data source accepted by the agency.

e. The number of proposed community nursing home beds in an application does not exceed the projected bed need after applying the rate of 16.1 beds per 1,000 persons aged 65 years and older projected for the county 3 years into the future using the estimates adopted by the agency, after subtracting the inventory of licensed and approved community nursing home beds

in the county per the agency's most recent published inventory.

2. No more than 120 community nursing home beds shall be approved for a qualified retirement community under each request for application for expedited review. Subsequent requests for expedited review under this process shall not be made until 2 years after construction of the facility has commenced or 1 year after the beds approved through the initial request are licensed, whichever occurs first.

3. The total number of community nursing home beds which may be approved for any single deed-restricted community pursuant to this paragraph shall not exceed 240, regardless of whether the retirement community is located in more than one qualifying county.

4. Each nursing home facility approved under this paragraph shall be dually certified for participation in the Medicare and Medicaid programs.

5. Each nursing home facility approved under this paragraph shall be at least one mile from an existing approved and licensed community nursing home, measured over publicly owned roadways.

6. Section 408.0435 does not apply to this paragraph.

7. A retirement community requesting expedited review under this paragraph shall submit a written request to the agency for an expedited review. The request shall include the number of beds to be added and provide evidence of compliance with the criteria specified in subparagraph 1.

8. After verifying that the retirement community meets the criteria for expedited review specified in subparagraph 1., the

agency shall publicly notice in the Florida Administrative Register that a request for an expedited review has been submitted by a qualifying retirement community and that the qualifying retirement community intends to make land available for the construction and operation of a community nursing home. The agency's notice shall identify where potential applicants can obtain information describing the sales price of, or terms of the land lease for, the property on which the project will be located and the requirements established by the retirement community. The agency notice shall also specify the deadline for submission of any certificate-of-need application, which shall not be earlier than the 91st day and not be later than the 125th day after the date the notice appears in the Florida Administrative Register.

9. The qualified retirement community shall make land available to applicants it deems to have met its requirements for the construction and operation of a community nursing home but will sell or lease the land only to the applicant that is issued a certificate of need by the agency under the provisions of this paragraph.

a. A certificate of need application submitted pursuant to this paragraph shall identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site. The application shall also include written evidence that the retirement community has determined that the provider submitting the application and the project proposed by that provider satisfies its requirements for the project.

b. The retirement community's determination that more than one provider satisfies its requirements for the project does not preclude the retirement community from notifying the agency of the provider it prefers.

10. Each application submitted shall be reviewed by the agency. If multiple applications are submitted for the project as published pursuant to subparagraph 8. above, then the competing applications shall be reviewed by the agency.

The agency shall develop rules to implement the provisions for expedited review, including time schedule, application content which may be reduced from the full requirements of s. 408.037(1), and application processing.

Section 6. Subsection (6) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

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

treatment. This subsection does not apply to a specialty-licensed children's hospital that is already licensed to provide adult cardiovascular services.

(b) A specialty-licensed children's hospital that has licensed neonatal intensive care unit beds and is located in a county with a population of 1,750,000 or more may provide obstetrical services, in accordance with the pertinent guidelines promulgated by the American College of Obstetricians and Gynecologists and with verification of guidelines and compliance with internal safety standards by the Voluntary Review for Quality of Care Program of the American College of Obstetricians and Gynecologists and in compliance with the agency's rules pertaining to the obstetrical department in a hospital and offer healthy mothers all necessary critical care equipment, services, and the capability of providing up to 10 beds for labor and delivery care, which services are restricted to the diagnosis, care, and treatment of pregnant women of any age who have documentation by an examining physician that includes information regarding:

1. At least one fetal characteristic or condition diagnosed intra-utero that would characterize the pregnancy or delivery as high risk including structural abnormalities of the digestive, central nervous, and cardiovascular systems and disorders of genetic malformations and skeletal dysplasia, acute metabolic emergencies, and babies of mothers with rheumatologic disorders; or

2. Medical advice or a diagnosis indicating that the fetus may require at least one perinatal intervention.

This paragraph shall not preclude a specialty-licensed children's hospital from complying with s. 395.1041 or the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. 1395dd.

Section 7. Sections 8 and 9 of this act may be cited as the "Cancer Treatment Fairness Act."

Section 8. Effective July 1, 2014, and applicable to policies issued or renewed on or after that date, section 627.42391, Florida Statutes, is created to read:

627.42391 Insurance policies; cancer treatment parity; orally administered cancer treatment medications.—

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

(a) "Cancer treatment medication" means medication prescribed by a treating physician who determines that the medication is medically necessary to kill or slow the growth of cancerous cells in a manner consistent with nationally accepted standards of practice.

(b) "Cost sharing" includes copayments, coinsurance, dollar limits, and deductibles imposed on the covered person.

(c) "Grandfathered health plan" has the same meaning as provided in 42 U.S.C. s. 18011 and is subject to the conditions for maintaining status as a grandfathered health plan as specified in 45 C.F.R. s. 147.140.

(2) An individual or group insurance policy delivered, issued for delivery, renewed, amended, or continued in this state that provides medical, major medical, or similar comprehensive coverage and includes coverage for cancer

treatment medications must also cover prescribed, orally administered cancer treatment medications and may not apply cost-sharing requirements for orally administered cancer treatment medications that are less favorable to the covered person than cost-sharing requirements for intravenous or injected cancer treatment medications covered under the policy or contract.

(3) An insurer providing a policy or contract described in subsection (2) and any participating entity through which the insurer offers health services may not:

(a) Vary the terms of the policy in effect on July 1, 2014, to avoid compliance with this section.

(b) Provide any incentive, including, but not limited to, a monetary incentive, or impose treatment limitations to encourage a covered person to accept less than the minimum protections available under this section.

(c) Penalize a health care practitioner or reduce or limit the compensation of a health care practitioner for recommending or providing services or care to a covered person as required under this section.

(d) Provide any incentive, including, but not limited to, a monetary incentive, to induce a health care practitioner to provide care or services that do not comply with this section.

(e) Change the classification of any intravenous or injected cancer treatment medication or increase the amount of cost sharing applicable to any intravenous or injected cancer treatment medication in effect on the effective date of this section in order to achieve compliance with this section.

(4) This section does not apply to grandfathered health plans or to Medicare supplement, dental, vision, long-term care, disability, accident only, specified disease policies, or other supplemental limited-benefit plans.

Notwithstanding this section, if the cost-sharing requirements for intravenous or injected cancer treatment medications under the policy or contract are less than $50 per month, then the cost-sharing requirements for orally administered cancer treatment medications may be up to $50 per month.

Section 9. Effective July 1, 2014, and applicable to policies issued or renewed on or after that date, section 641.313, Florida Statutes, is created to read:

641.313 Health maintenance contracts; cancer treatment parity; orally administered cancer treatment medications.—

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

(a) "Cancer treatment medication" means medication prescribed by a treating physician who determines that the medication is medically necessary to kill or slow the growth of cancerous cells in a manner consistent with nationally accepted standards of practice.

(b) "Cost sharing" includes copayments, coinsurance, dollar limits, and deductibles imposed on the covered person.

(c) "Grandfathered health plan" has the same meaning as provided in 42 U.S.C. s. 18011 and is subject to the conditions for maintaining status as a grandfathered health plan as specified in 45 C.F.R. s. 147.140.

(2) A health maintenance contract delivered, issued for

delivery, renewed, amended, or continued in this state that provides medical, major medical, or similar comprehensive coverage and includes coverage for cancer treatment medications must also cover prescribed, orally administered cancer treatment medications and may not apply cost-sharing requirements for orally administered cancer treatment medications that are less favorable to the covered person than cost-sharing requirements for intravenous or injected cancer treatment medications covered under the contract.

(3) A health maintenance organization providing a contract described in subsection (2) and any participating entity through which the health maintenance organization offers health services may not:

(a) Vary the terms of the policy in effect on July 1, 2014, to avoid compliance with this section.

(b) Provide any incentive, including, but not limited to, a monetary incentive, or impose treatment limitations to encourage a covered person to accept less than the minimum protections available under this section.

(c) Penalize a health care practitioner or reduce or limit the compensation of a health care practitioner for recommending or providing services or care to a covered person as required under this section.

(d) Provide any incentive, including, but not limited to, a monetary incentive, to induce a health care practitioner to provide care or services that do not comply with this section.

(e) Change the classification of any intravenous or injected cancer treatment medication or increase the amount of

cost sharing applicable to any intravenous or injected cancer treatment medication in effect on the effective date of this section in order to achieve compliance with this section.

(4) This section does not apply to grandfathered health plans or to Medicare supplement, dental, vision, long-term care, disability, accident only, specified disease policies, or other supplemental limited-benefit plans.

Notwithstanding this section, if the cost-sharing requirements for intravenous or injected cancer treatment medications under the contract are less than $50 per month, then the cost-sharing requirements for orally administered cancer treatment medications may be up to $50 per month.

Section 10. Notwithstanding s. 893.055, Florida Statutes, for the 2013-2014 fiscal year, the sum of $500,000 in nonrecurring funds is appropriated from the General Revenue Fund to the Department of Health for the general administration of the prescription drug monitoring program.

Section 11. Except as otherwise provided in this act, this act shall take effect upon becoming a law.