An act relating to direct health care agreements; amending s. 624.27, F.S.; expanding the scope of direct primary care agreements; providing definitions; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 624.27, Florida Statutes, is amended to read:

624.27 Direct health ~~primary~~ care agreements; exemption from code.—

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

(a) "Direct health ~~primary~~ care agreement" means a contract between a health ~~primary~~ care provider and a patient, a patient's legal representative, or a patient's employer, which meets the requirements of subsection (4) and does not indemnify for services provided by a third party.

(b) "Health ~~Primary~~ care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 464, or chapter 466, or a health ~~primary~~ care group practice, who provides health ~~primary~~ care services to patients.

(c) "Health ~~Primary~~ care services" means the screening, assessment, diagnosis, and treatment of a patient conducted

within the competency and training of the health ~~primary~~ care provider for the purpose of promoting health or detecting and managing disease or injury.

(2) A direct health ~~primary~~ care agreement does not constitute insurance and is not subject to the Florida Insurance Code. The act of entering into a direct health ~~primary~~ care agreement does not constitute the business of insurance and is not subject to the Florida Insurance Code.

(3) A health ~~primary~~ care provider or an agent of a health ~~primary~~ care provider is not required to obtain a certificate of authority or license under the Florida Insurance Code to market, sell, or offer to sell a direct health ~~primary~~ care agreement.

(4) For purposes of this section, a direct health ~~primary~~ care agreement must:

(a) Be in writing.

(b) Be signed by the health ~~primary~~ care provider or an agent of the health ~~primary~~ care provider and the patient, the patient's legal representative, or the patient's employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of health ~~primary~~ care services that are covered by the monthly fee.

(e) Specify the monthly fee and any fees for health ~~primary~~ care services not covered by the monthly fee.

(f) Specify the duration of the agreement and any automatic renewal provisions.

(g) Offer a refund to the patient, the patient's legal representative, or the patient's employer of monthly fees paid in advance if the health ~~primary~~ care provider ceases to offer health ~~primary~~ care services for any reason.

(h) Contain, in contrasting color and in at least 12-point type, the following statement on the signature page: "This agreement is not health insurance and the health ~~primary~~ care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any health ~~primary~~ care services covered by the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not workers' compensation insurance and does not replace an employer's obligations under chapter 440."

Section 2. This act shall take effect July 1, 2019.

An act relating to prescription drug importation programs; creating s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor, including the payment of a bond; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of this state; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating the program within a specified

timeframe after receiving federal approval; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to submit an annual report to the Governor and the Legislature by a specified date; providing requirements for such report; requiring the agency to notify the Legislature upon federal approval of the program and to submit a proposal to the Legislature for program implementation and funding before a certain date; requiring the agency to adopt necessary rules; creating s. 465.0157, F.S.; establishing an international export pharmacy permit for participation in the International Prescription Drug Importation Program; providing requirements for permit application and renewal; requiring the Department of Health to adopt certain rules governing the financial responsibility of the pharmacy permittee; amending s. 465.017, F.S.; authorizing the department to inspect international export pharmacy permittees; amending s. 499.005, F.S.; providing that the importation of a prescription drug under the International Prescription Drug Importation Program is not a prohibited act under

that chapter; amending s. 499.0051, F.S.; providing an exemption from prosecution as a criminal offense for the importation of a prescription drug for wholesale distribution under the International Prescription Drug Importation Program; amending s. 499.01, F.S.; requiring an international prescription drug wholesale distributor to be permitted before operating; requiring nonresident prescription drug manufacturers to register with the Department of Business and Professional Regulation to participate in the program; providing an exception; establishing an international prescription drug wholesale distributor drug permit; providing permit requirements; requiring the Department of Business and Professional Regulation to adopt certain rules governing the financial responsibility of nonresident prescription drug manufacturer licensee or permittee and international prescription drug wholesale distributor permittees; amending s. 499.012, F.S.; providing application requirements for international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the program; amending s. 499.015, F.S.; establishing that prescription drugs imported under the International Prescription Drug Importation Program are not required

to be registered under a specified provision; amending s. 499.065, F.S.; requiring the department to inspect international prescription drug wholesale distributor establishments; authorizing the department to determine that an international prescription drug wholesale distributor establishment is an imminent danger to the public and require its immediate closure under certain conditions; creating s. 499.0285, F.S.; requiring the department to establish the International Prescription Drug Importation Program for a specified purpose; providing definitions; providing eligibility criteria for prescription drugs, exporters, and importers under the program; requiring participating importers to submit certain documentation to the department for prescription drugs imported under the program; requiring the department to immediately suspend the importation of specific prescription drug or the importation of prescription drugs by a specific importer if a violation has occurred under the program; authorizing the department to revoke such suspension under certain circumstances; requiring the department to adopt necessary rules; requiring the agency, in collaboration with the Department of Business and Professional Regulation and the Department of Health, to negotiate a federal

arrangement to operate a pilot program for importing prescription drugs into this state; providing that implementation of the act is contingent upon the federal authorization; requiring the department to notify the Legislature before implementation of the pilot program and to submit a proposal for pilot program implementation and funding; providing an effective date.

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

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The Agency for Health Care Administration shall establish the Canadian Prescription Drug Importation Program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Agency" means the Agency for Health Care Administration.

(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense

prescription drugs.

(c) "County health department" means a health care facility established under part I of chapter 154.

(d) "Department" means the Department of Health.

(e) "Drug" or "prescription drug" has the same meaning as "prescription drug" in s. 499.003, but is limited to drugs intended for human use.

(f) "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

(g)"Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(h) "Medicaid pharmacy" means a pharmacy licensed under chapter 465 that has a Medicaid provider agreement in effect with the agency and is in good standing with the agency.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(j) "Program" means the Canadian Prescription Drug Importation Program.

(k) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security

Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

(l) "Vendor" means the entity contracted by the agency to manage specified functions of the program.

(3) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program.

(b) By December 1, 2019, and each year thereafter, the vendor shall develop a Wholesale Prescription Drug Importation List identifying the prescription drugs that have the highest potential for cost savings to the state. In developing the list, the vendor shall consider, at a minimum, which prescription drugs will provide the greatest cost savings to state programs, including prescriptions drugs for which there are shortages, specialty prescription drugs, and high volume prescription drugs. The agency, in consultation with the department, shall review the Wholesale Prescription Drug Importation List every 3 months to ensure that it continues to meet the requirements of the programs and may direct the vendor to revise the list, as necessary.

(c) The vendor shall identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the federal act and who have agreed to export drugs identified on the list at prices that will provide cost savings to the state. The vendor must verify that such Canadian suppliers meet all of the requirements of the program,

while meeting or exceeding the federal and state track-and-trace laws and regulations.

(d) The vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

(e) The vendor shall maintain a list of all registered importers that participate in the program.

(f) The vendor shall ensure compliance with Title II of the federal Drug Quality and Security Act, Pub. L. No. 113-54, by all suppliers, importers and other distributors, and participants in the program.

(g) The vendor shall assist the agency in the preparation of the annual report required by subsection (12), including the timely provision of any information requested by the agency.

(h) The vendor shall provide an annual financial audit of its operations to the agency as required by the agency. The vendor shall also provide quarterly financial reports specific to the program and shall include information on the performance of its subcontractors and vendors. The agency shall determine the format and contents of the reports.

(4) BOND REQUIREMENT.—The agency shall require a bond from the vendor to mitigate the financial consequences of potential acts of malfeasance or misfeasance or fraudulent or dishonest acts committed by the vendor, any employees of the vendor, or its subcontractors.

(5) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers, as described in subsection (7), may import a drug from an eligible Canadian supplier, as described in subsection (6), if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate federal patent laws;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(6) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export prescription drugs into this state under the program if the supplier:

(a) Is in full compliance with relevant Canadian federal and provincial laws and regulations;

(b) Is identified by the vendor as eligible to participate

in the program; and

(c) Submits an attestation that the supplier has a registered agent in the United States, including the name and United States address of the registered agent.

(7) ELIGIBLE IMPORTERS.—The following entities may import prescription drugs from an eligible Canadian supplier under the program:

(a) A pharmacist or wholesaler employed by or under contract with the department's central pharmacy, for distribution to a county health department or free clinic for dispensing to clients treated in such department or clinic.

(b) A pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients.

(c) A pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections.

(d) A pharmacist or wholesaler employed by or under contract with a developmental disabilities center, as defined in s. 393.063, for dispensing to clients treated in such center.

(e) A pharmacist or wholesaler employed by or under contract with a treatment facility, as defined in s. 394.455, for dispensing to patients treated in such facility.

(8) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and eligible importers participating under the program:

(a) Must comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.

(b) May not distribute, dispense, or sell prescription drugs imported under the program outside of the state.

(9) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(l). The agency shall begin operating the program within 6 months after receiving such approval. The request must, at a minimum:

(a) Describe the agency's plan for operating the program.

(b) Demonstrate how the prescription drugs imported into this state under the program will meet the applicable federal and state standards for safety and effectiveness.

(c) Demonstrate how the drugs imported into this state under the program will comply with federal tracing procedures.

(d) Include a list of proposed prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(e) Estimate the total cost savings attributable to the program.

(f) Provide the costs of program implementation to the state.

(g) Include a list of potential Canadian suppliers from which the state would import drugs and demonstrate that the

suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

(10) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

1. For an initial imported shipment of a specific drug by an importer, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act.

2. For every subsequent imported shipment of that drug by that importer, ensure that a statistically valid sample of the shipment is tested for authenticity and degradation in a manner consistent with the federal act.

3. Certify that the drug:

a. Is approved for marketing in the United States and is not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

4. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

5. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable

federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the vendor:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following:

1. The original source of the drug, including:

a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug that is shipped.

4. The quantity of each lot of the drug originally received and the source of the lot.

5. The lot or control number and the batch number assigned to the drug by the manufacturer.

(f) The agency may require that the vendor collect any other information necessary to ensure the protection of the public health.

(11) IMMEDIATE SUSPENSION.—The agency shall immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The agency may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into this state.

(12) ANNUAL REPORT.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the prescription drugs that were imported

under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date attributable the program;

(e) A description of the methodology used to determine which drugs should be included on the Wholesale Prescription Drug Importation List; and

(f) Documentation as to how the program ensures the following:

1. That Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all federal laws and regulations and state laws and rules;

2. That prescription drugs imported under the program are not shipped, sold, or dispensed outside of this state once in the possession of the importer;

3. That prescription drugs imported under the program are pure, unadulterated, potent, and safe;

4. That the program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

5. That the program provides cost savings to the state on

imported prescription drugs.

(13) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of federal approval of the program, the agency shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. After approval is received and before the start of the next regular session of the Legislature in which the proposal could be funded, the agency shall submit to all parties a proposal for program implementation and program funding.

(14) RULEMAKING.—The agency shall adopt rules necessary to implement this section.

Section 2. Section 465.0157, Florida Statutes, is created to read:

465.0157 International export pharmacy permit.—

(1) To participate as an exporter of prescription drugs into this state under the International Prescription Drug Importation Program established in s. 499.0285, a pharmacy located outside of the United States must hold an international export pharmacy permit.

(2) An international export pharmacy shall maintain at all times an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported. Such jurisdiction must be

in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(3) An application for an international export pharmacy permit must be submitted on a form developed and provided by the board. The board may require an applicant to provide any information it deems reasonably necessary to carry out the purposes of this section.

(4) An applicant shall submit the following to the board to obtain an initial permit, or to the department to renew a permit:

(a) Proof of an active and unencumbered license or permit to operate the pharmacy in compliance with the laws of the jurisdiction in which the dispensing facility is located and from which the prescription drugs will be exported.

(b) Documentation demonstrating that the country in which the pharmacy operates has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(c) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the

prescription department manager for prescription drugs exported into this state under the International Prescription Drug Importation Program.

(d) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager, that:

1. The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state.

2. A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy.

3. A prescription drug product shipped, mailed, or delivered into this state must not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.

(e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If the applicant is unable to

submit a current inspection report conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department must:

1. Conduct, or contract with an entity to conduct, an onsite inspection, with all related costs borne by the applicant;

2. Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or

3. Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

(5) The department shall adopt rules governing the financial responsibility of the pharmacy permittee. The rules must establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

Section 3. Subsection (2) of section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.—

(2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156, an international export pharmacy permittee under s. 465.0157, or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

Section 4. Subsection (20) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(20) The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

Section 5. Paragraph (e) of subsection (12) of section 499.0051, Florida Statutes, is amended to read:

499.0051 Criminal acts.—

(12) REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(e) The importation of a prescription drug for wholesale

distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act or s. 499.0285.

Section 6. Subsection (1) and paragraph (c) of subsection (2) of section 499.01, Florida Statutes, are amended, and paragraph (s) is added to subsection (2) of that section, to read:

499.01 Permits.—

(1) Before operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) A nonresident prescription drug manufacturer;

(d) A nonresident prescription drug repackager;

(e) A prescription drug wholesale distributor;

(f) An out-of-state prescription drug wholesale distributor;

(g) A retail pharmacy drug wholesale distributor;

(h) A restricted prescription drug distributor;

(i) A complimentary drug distributor;

(j) A freight forwarder;

(k) A veterinary prescription drug retail establishment;

(l) A veterinary prescription drug wholesale distributor;

(m) A limited prescription drug veterinary wholesale distributor;

(n) An over-the-counter drug manufacturer;

(o) A device manufacturer;

(p) A cosmetic manufacturer;

(q) A third party logistics provider; ~~or~~

(r) A health care clinic establishment; or

(s) An international prescription drug wholesale distributor.

(2) The following permits are established:

(c) *Nonresident prescription drug manufacturer permit.*—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a prescription drug manufacturer under this part. The department shall adopt rules for issuing a virtual nonresident prescription drug manufacturer permit to a person who engages in the manufacture of prescription drugs but does not make or take physical possession of any prescription drugs. The rules adopted by the department under this section may exempt virtual nonresident manufacturers from certain establishment, security, and storage requirements set forth in s. 499.0121.

1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-

state prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or third party logistics provider permit pursuant to this section to engage in the distribution of such prescription drugs when required by this part. This subparagraph does not apply to a manufacturer that distributes prescription drugs only for the manufacturer of the prescription drugs where both manufacturers are affiliates.

2. Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any prescription drug distributed into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

3.a. A nonresident prescription drug manufacturer that has registered to participate in the International Prescription Drug Importation Program pursuant to this section is not required to provide the list and approval required by subparagraph 2. for prescription drugs imported under that program.

b. To participate as an exporter of prescription drugs into this state under the International Prescription Drug

Importation Program established under s. 499.0285, a nonresident prescription drug manufacturer located outside of the United States must register with the Department of Business and Professional Regulation before engaging in any activities under that section. Such manufacturer must be licensed or permitted in a country with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

c. The department shall adopt rules governing the financial responsibility of a nonresident prescription drug manufacturer licensee or permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.

(s) *International prescription drug wholesale distributor.*—

1. A wholesale distributor located outside of the United States must obtain an international prescription drug wholesale distributor permit to engage in the wholesale exportation and

distribution of prescription drugs in the state under the International Prescription Drug Importation Program established in s. 499.0285. The wholesale distributor must be licensed or permitted to operate in a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products. The wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with the laws of the jurisdiction in which it operates. An international prescription drug wholesale distributor permit may not be issued to a wholesale distributor if the jurisdiction in which the wholesale distributor operates does not require a license to engage in the wholesale distribution of prescription drugs.

2. The department shall adopt rules governing the financial responsibility of an international prescription drug wholesale distributor permittee. The rules will establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee

or its contractors.

Section 7. Subsection (2), paragraph (a) of subsection (4), subsections (8), (10), (11), and (14), and paragraphs (a), (b), and (f) of subsection (15) of section 499.012, Florida Statutes, are amended to read:

499.012 Permit application requirements.—

(2) Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, an international prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(4)(a) Except for a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug

wholesale distributor, an application for a permit must include:

1. The name, full business address, and telephone number of the applicant;

2. All trade or business names used by the applicant;

3. The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4. The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5. The names of the owner and the operator of the establishment, including:

a. If an individual, the name of the individual;

b. If a partnership, the name of each partner and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f. Any other relevant information that the department requires.

(8) An application for a permit or to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a) The name, full business address, and telephone number of the applicant.

(b) All trade or business names used by the applicant.

(c) The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e) The names of the owner and the operator of the establishment, including:

1. If an individual, the name of the individual.

2. If a partnership, the name of each partner and the name of the partnership.

3. If a corporation:

a. The name, address, and title of each corporate officer and director.

b. The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the corporation's state of incorporation.

c. The name and address of each shareholder of the

corporation that owns 5 percent or more of the outstanding stock of the corporation.

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5. If a limited liability company:

a. The name and address of each member.

b. The name and address of each manager.

c. The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f) If applicable, the name and address of each affiliate of the applicant.

(g) The applicant's gross annual receipts attributable to prescription drug wholesale distribution activities for the previous tax year.

(h) The tax year of the applicant.

(i) A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j) A list of all licenses and permits issued to the applicant by any other state or jurisdiction which authorize the

applicant to purchase or possess prescription drugs.

(k) The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l) The name of each of the applicant's designated representatives as required by subsection (15), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m) Evidence of a surety bond in this state or any other state in the United States in the amount of $100,000. If the annual gross receipts of the applicant's previous tax year are $10 million or less, evidence of a surety bond in the amount of $25,000. The specific language of the surety bond must include the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. In lieu of the surety bond, the applicant may provide other equivalent security such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, which includes the State of Florida as a beneficiary, payable to the Professional Regulation Trust Fund. The purpose of the bond or other security is to secure payment of any administrative penalties imposed by the department and

any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

(n) For establishments used in wholesale distribution, proof of an inspection conducted by the department, the United States Food and Drug Administration, or another governmental entity charged with the regulation of good manufacturing practices related to wholesale distribution of prescription drugs, within timeframes set forth by the department in departmental rules, which demonstrates substantial compliance with current good manufacturing practices applicable to wholesale distribution of prescription drugs. The department may recognize another state's or jurisdiction's inspection of a wholesale distributor located in that state or jurisdiction if such state's or jurisdiction's laws are deemed to be substantially equivalent to the law of this state by the department. The department may accept an inspection by a third-party accreditation or inspection service which meets the criteria set forth in department rule.

(o) Any other relevant information that the department

requires.

(p) Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(q) For international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the International Prescription Drug Importation Program established under s. 499.0285, documentation demonstrating that the applicant is appropriately licensed or permitted by a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

(10) The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor if:

(a) The applicant has not met the requirements for the permit.

(b) The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c) The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed

permit hazardous to the public health.

(d) The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e) The applicant is lacking in experience in the distribution of prescription drugs.

(f) The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g) The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h) The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i) The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j) The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license

to manufacture or distribute drugs, devices, or cosmetics.

(k) That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l) The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n) The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company

or a mutual fund.

(o) The applicant for renewal of a permit under s. 499.01(2)(e) or (f) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p) Information obtained in response to s. 499.01(2)(e) or (f) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q) The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r) The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11) Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor permit to the applicant.

(14) The name of a permittee or establishment on a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(15)(a) Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor, an international prescription drug wholesale distributor, or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b) To be certified as a designated representative, a natural person must:

1. Submit an application on a form furnished by the department and pay the appropriate fees.

2. Be at least 18 years of age.

3. Have at least 2 years of verifiable full-time:

a. Work experience in a pharmacy licensed in this state or another state or jurisdiction, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs;

b. Managerial experience with a prescription drug wholesale distributor licensed in this state or in another state or jurisdiction; or

c. Managerial experience with the United States Armed Forces, where the person's responsibilities included, but were not limited to, recordkeeping, warehousing, distributing, or other logistics services pertaining to prescription drugs.

4. Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year.

5. Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(f) A wholesale distributor may not operate under a prescription drug wholesale distributor permit, an international prescription drug wholesale distributor permit, or an out-of-

state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

Section 8. Subsection (1) of section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for

prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

Section 9. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Inspections; imminent danger.—

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(3) The department may determine that a prescription drug wholesale distributor establishment, international prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public

health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

Section 10. Section 499.0285, Florida Statutes, is created to read:

499.0285 International Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The department shall establish a program for the importation of safe and effective prescription drugs from foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing their adherence to current good manufacturing practices for pharmaceutical products.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Exporter" means an international prescription drug wholesale distributor, a nonresident prescription drug manufacturer registered to participate in the program, or an international export pharmacy that exports prescription drugs into this state under the program.

(b) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

(c) "Foreign recipient" means an entity other than the original prescription drug manufacturer which receives the prescription drug before its importation into this state under the program.

(d) "Good manufacturing practice" refers to the good manufacturing practice regulations in 21 C.F.R. parts 210 and 211.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "International export pharmacy" means a pharmacy located outside of the United States which holds an active and unencumbered permit under chapter 465 to export prescription drugs into this state under the program.

(g) "International prescription drug wholesale distributor" means a prescription drug wholesale distributor located outside of the United States which holds an active and unencumbered permit under this part to export and distribute prescription drugs into this state under the program.

(h) "Nonresident prescription drug manufacturer" means an entity located outside of the United States which holds an active and unencumbered permit under this part to manufacture prescription drugs and has registered with the department to

export and distribute such prescription drugs into this state under the program.

(i) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy under chapter 465.

(j) "Pharmacy" means an entity that holds an active and unencumbered permit under chapter 465.

(k) "Prescription drug" has the same meaning as defined in this part, but is limited to drugs intended for human use.

(l) "Program" means the International Prescription Drug Importation Program established under this section.

(m) "Qualified laboratory" means a laboratory that has been approved by the department for the purposes of this section.

(3) ELIGIBLE PRESCRIPTION DRUGS.—An eligible importer may import a prescription drug from an eligible exporter if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States; and

(c) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(4) EXPORTERS.—

(a) The following entities may export prescription drugs into this state under the program:

1. An international prescription drug wholesale distributor.

2. A nonresident prescription drug manufacturer.

3. An international export pharmacy.

(b) An eligible exporter must register with the department before exporting prescription drugs into this state under the program.

(c) An exporter may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

(5) IMPORTERS.—

(a) The following entities may import prescription drugs under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must register with the department before importing prescription drugs into this state under the

program.

(c) An importer may not distribute, sell, or dispense prescription drugs imported under the program to any person residing outside of the state.

(6) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—

(a) A participating importer must submit the following information and documentation to the department:

1. The name and quantity of the active ingredient of the prescription drug.

2. A description of the dosage form of the prescription drug.

3. The date on which the prescription drug is shipped.

4. The quantity of the prescription drug that is shipped.

5. The point of origin and destination of the prescription drug.

6. The price paid by the importer for the prescription drug.

7. Documentation from the exporter specifying:

a. The original source of the prescription drug; and

b. The quantity of each lot of the prescription drug originally received by the seller from that source.

8. The lot or control number assigned to the prescription drug by the manufacturer.

9. The name, address, telephone number, and professional license or permit number of the importer.

10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:

a. Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

b. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into this state is not more than the quantity that was received by the first foreign recipient.

c. For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

11. In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into this state was statistically sampled and tested for authenticity and degradation.

12. For an initial imported shipment of a specific drug by an importer, the department shall ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the federal act. The agency may contract with a vendor for these

functions.

13. For every subsequent imported shipment of that drug by that importer, the department shall ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the federal act.

14. Certify that the drug:

a. Is approved for marketing in the United States and is not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

15. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

16. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the federal act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation submitted under this section for a period of at

least 7 years.

(d) A participating importer must submit the all of following information to the department:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating International Importation Drug supplier must submit the following information and documentation to the agency or the agency's designated vendor specifying all of the following:

1. The original source of the drug, including:

a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug that is shipped.

4. The quantity of each lot of the drug originally received and from which source.

5. The lot or control number and the batch number assigned to the drug by the manufacturer.

6. The name, address, and telephone number, and professional license or permit number of the importer.

(f) The department may require any other information necessary to ensure the protection of the public health.

(7) IMMEDIATE SUSPENSION.—The department shall immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity is in violation of this section. The department may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into this state.

(8) RULEMAKING AUTHORITY.—The department shall adopt rules necessary to implement this section.

Section 11. Notwithstanding the Federal Food, Drug, and Cosmetic Act, the Department of Business and Professional Regulation, in collaboration with the Department of Health, shall negotiate a federal arrangement to operate a pilot program for importing prescription drugs into this state. The proposal to operate such a pilot program shall demonstrate that the program sets safety standards consistent with the current federal requirements for the manufacturing and distribution of prescription drugs; limits the importation of prescription drugs under the program to entities licensed or permitted by the state to manufacture, distribute, or dispense prescription drugs; and

includes inspection and enforcement authority. Implementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval. The department shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives before implementation of the pilot program. The department shall submit to all parties a proposal for program implementation and program funding.

Section 12. This act shall take effect July 1, 2019.

An act relating to hospital licensure; amending s. 395.0191, F.S.; deleting provisions relating to certificate of need applications; amending s. 395.1055, F.S.; revising the Agency for Health Care Administration's rulemaking authority with respect to minimum standards for hospitals; requiring hospitals that provide certain services to meet specified licensure requirements; conforming provisions to changes made by the act; amending s. 395.1065, F.S.; conforming a cross-reference; repealing s. 395.6025, F.S., relating to rural hospital replacement facilities; amending s. 408.032, F.S.; revising and deleting definitions; amending s. 408.033, F.S.; conforming provisions to changes made by the act; amending s. 408.034, F.S.; authorizing the agency to issue a license to a general hospital that has not been issued a certificate of need under certain circumstances; revising duties and responsibilities of the agency relating to issuance of licenses to health care facilities and health service providers; conforming provisions to changes made by the act; amending s. 408.035, F.S.; deleting provisions related to the agency's consideration and review of applications for certificates of need for general

hospitals and health services; amending s. 408.036, F.S.; providing an exception to certificate of need review requirements for the construction or establishment of a general hospital and the conversion of a specialty hospital to a general hospital; revising health-care-related projects that are subject to agency review for a certificate of need and exemptions therefrom; deleting provisions requiring health care facilities and providers to provide certain notice to the agency upon termination of a health care service or the addition or delicensure of beds; conforming a provision to changes made by the act; repealing s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure; amending ss. 408.037 and 408.039, F.S.; deleting provisions relating to certificate of need applications for general hospitals; amending s. 408.043, F.S.; deleting provisions relating to certificates of need for osteopathic acute care hospitals; amending s. 408.0455, F.S.; establishing that specified rules remain in effect for a specified purpose and until the agency has adopted certain rules; amending s. 408.808, F.S.; authorizing the agency to issue an inactive license to a certain hospital under certain circumstances; requiring the

Office of Program Policy Analysis and Government Accountability to review specified requirements, statutes, and rules, and make recommendations to the Legislature by a specified date; providing effective dates.

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

Section 1. Subsection (10) of section 395.0191, Florida Statutes, is amended to read:

395.0191 Staff membership and clinical privileges.—

~~(10) Nothing herein shall be construed by the agency as requiring an applicant for a certificate of need to establish proof of discrimination in the granting of or denial of hospital staff membership or clinical privileges as a precondition to obtaining such certificate of need under the provisions of s. 408.043.~~

Section 2. Present subsection (12) of section 395.1055, Florida Statutes, is redesignated as subsection (15), a new subsection (12) and subsections (13) and (14) are added to that section, and paragraph (b) of subsection (9) of that section is amended, to read:

395.1055 Rules and enforcement.—

(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 surgery programs.

(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 alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following 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~~ the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care Administration. A member appointed under subparagraphs 1.-10. whose hospital fails to ~~maintain such certificates or~~ comply with such standards may serve only as a nonvoting member until the hospital ~~restores such certificates or~~ complies with such standards.

(12) Each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the agency which establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules must ensure that such programs:

(a) Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

(b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(d) Maintain appropriate times of operation and protocols

to ensure availability and appropriate referrals in the event of emergencies.

(e) Demonstrate a plan to provide services to Medicaid and charity care patients.

(13) Each provider of adult cardiovascular services or operator of a burn unit shall comply with rules adopted by the agency which establish licensure standards that govern the provision of adult cardiovascular services or the operation of a burn unit, as applicable. At a minimum, such rules must address staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure periods and fees, and enforcement of minimum standards.

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

(a) The establishment of two hospital program licensure levels, a Level I program that authorizes the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program that authorizes the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b)1. For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, the hospital has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac

catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 patients 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 is not required 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.

b. 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 demonstrated experience in handling acutely ill patients requiring intervention, based on the staff member's previous experience in dedicated cardiac interventional laboratories or 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.

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.

(c) For a hospital seeking a Level II program,

demonstration that, for the most recent 12-month period as reported to the agency, the hospital has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and the American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria, to ensure patient quality and safety.

(e) The establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) The demonstration of a plan to provide services to Medicaid and charity care patients.

Section 3. Effective July 1, 2021, paragraph (f) of subsection (1) of section 395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.—

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

~~(f) All hospitals submit such data as necessary to conduct certificate-of-need reviews required under part I of chapter 408. Such data shall include, but shall not be limited to, patient origin data, hospital utilization data, type of service reporting, and facility staffing data. The agency may not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals.~~

Section 4. Effective July 1, 2021, subsection (5) of section 395.1065, Florida Statutes, is amended to read:

395.1065 Criminal and administrative penalties; moratorium.—

(5) The agency shall impose a fine of $500 for each instance of the facility's failure to provide the information required by rules adopted pursuant to s. 395.1055(1)(g) ~~s. 395.1055(1)(h)~~.

Section 5. Section 395.6025, Florida Statutes, is repealed.

Section 6. Subsections (3), (8), and (13) through (17) of section 408.032, Florida Statutes, are amended to read:

408.032 Definitions relating to Health Facility and Services Development Act.—As used in ss. 408.031-408.045, the term:

(3) "Certificate of need" means a written statement issued

by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility~~, health service,~~ or hospice.

(8) "Health care facility" means a hospital, ~~long-term care hospital,~~ skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled. A facility relying solely on spiritual means through prayer for healing is not included as a health care facility.

~~(13) "Long-term care hospital" means a hospital licensed under chapter 395 which meets the requirements of 42 C.F.R. s. 412.23(e) and seeks exclusion from the acute care Medicare prospective payment system for inpatient hospital services.~~

~~(14) "Mental health services" means inpatient services provided in a hospital licensed under chapter 395 and listed on the hospital license as psychiatric beds for adults; psychiatric beds for children and adolescents; intensive residential treatment beds for children and adolescents; substance abuse beds for adults; or substance abuse beds for children and adolescents.~~

(13)~~(15)~~ "Nursing home geographically underserved area" means:

(a) A county in which there is no existing or approved nursing home;

(b) An area with a radius of at least 20 miles in which there is no existing or approved nursing home; or

(c) An area with a radius of at least 20 miles in which all existing nursing homes have maintained at least a 95 percent occupancy rate for the most recent 6 months or a 90 percent occupancy rate for the most recent 12 months.

(14) ~~(16)~~ "Skilled nursing facility" means an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

~~(17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.~~

Section 7. Effective July 1, 2021, subsection (8), and subsections (9) through (11), as amended by this act, of section 408.032, Florida Statutes, are amended to read:

408.032 Definitions relating to Health Facility and Services Development Act.—As used in ss. 408.031-408.045, the term:

(8) "Health care facility" means a ~~hospital,~~ skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled. A facility relying solely on spiritual means through prayer for healing is not included as a health care facility.

~~(9) "Health services" means inpatient diagnostic, curative, or comprehensive medical rehabilitative services and includes mental health services. Obstetric services are not health services for purposes of ss. 408.031-408.045.~~

(9)~~(10)~~ "Hospice" or "hospice program" means a hospice as defined in part IV of chapter 400.

~~(11) "Hospital" means a health care facility licensed under chapter 395.~~

(10)~~(12)~~ "Intermediate care facility for the developmentally disabled" means a residential facility licensed under part VIII of chapter 400.

(11)~~(13)~~ "Nursing home geographically underserved area" means:

(a) A county in which there is no existing or approved

nursing home;

(b) An area with a radius of at least 20 miles in which there is no existing or approved nursing home; or

(c) An area with a radius of at least 20 miles in which all existing nursing homes have maintained at least a 95 percent occupancy rate for the most recent 6 months or a 90 percent occupancy rate for the most recent 12 months.

(12) ~~(14)~~ "Skilled nursing facility" means an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Section 8. Effective July 1, 2021, paragraph (b) of subsection (1) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(1) LOCAL HEALTH COUNCILS.—

(b) Each local health council may:

1. Develop a district area health plan that permits each local health council to develop strategies and set priorities for implementation based on its unique local health needs.

2. Advise the agency on health care issues and resource allocations.

3. Promote public awareness of community health needs,

emphasizing health promotion and cost-effective health service selection.

4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of medically indigent persons, and assist the agency and other state agencies in carrying out data collection activities that relate to the functions in this subsection.

5. Monitor the onsite construction progress, if any, of certificate-of-need approved projects and report council findings to the agency on forms provided by the agency.

6. Advise and assist any regional planning councils within each district that have elected to address health issues in their strategic regional policy plans with the development of the health element of the plans to address the health goals and policies in the State Comprehensive Plan.

7. Advise and assist local governments within each district on the development of an optional health plan element of the comprehensive plan provided in chapter 163, to assure compatibility with the health goals and policies in the State Comprehensive Plan and district health plan. To facilitate the implementation of this section, the local health council shall annually provide the local governments in its service area, upon request, with:

a. A copy and appropriate updates of the district health plan;

b. A report of ~~hospital and~~ nursing home utilization statistics for facilities within the local government jurisdiction; and

c. Applicable agency rules and calculated need methodologies for health facilities and services regulated under s. 408.034 for the district served by the local health council.

8. Monitor and evaluate the adequacy, appropriateness, and effectiveness, within the district, of local, state, federal, and private funds distributed to meet the needs of the medically indigent and other underserved population groups.

9. In conjunction with the Department of Health, plan for services at the local level for persons infected with the human immunodeficiency virus.

10. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.

11. Provide the agency with data required by rule for the review of certificate-of-need applications and the projection of need for health ~~services and~~ facilities in the district.

Section 9. Subsection (2) of section 408.034, Florida Statutes, is amended to read:

408.034 Duties and responsibilities of agency; rules.—

(2) In the exercise of its authority to issue licenses to health care facilities ~~and health service providers~~, as provided

under chapters 393 and 395 and parts II, IV, and VIII of chapter 400, the agency may not issue a license to any health care facility ~~or health service provider~~ that fails to receive a certificate of need or an exemption for the licensed facility, except that the agency may issue a license to a general hospital that has not been issued a certificate of need ~~or service~~.

Section 10. Effective July 1, 2021, subsection (2), as amended by this act, and subsection (3) of section 408.034, Florida Statutes, are amended to read:

408.034 Duties and responsibilities of agency; rules.—

(2) In the exercise of its authority to issue licenses to health care facilities, as provided under chapter ~~chapters~~ 393 ~~and 395~~ and parts II, IV, and VIII of chapter 400, the agency may not issue a license to any health care facility that fails to receive a certificate of need or an exemption for the licensed facility~~, except that the agency may issue a license to a general hospital that has not been issued a certificate of need~~.

(3) The agency shall establish, by rule, uniform need methodologies for ~~health services and~~ health facilities. In developing uniform need methodologies, the agency shall, at a minimum, consider the demographic characteristics of the population, the health status of the population, service use patterns, standards and trends, geographic accessibility, and market economics.

Section 11. Section 408.035, Florida Statutes, is amended to read:

408.035 Review criteria.—

~~(1)~~ The agency shall determine the reviewability of applications and shall review applications for certificate-of-need determinations for health care facilities ~~and health services~~ in context with the following criteria~~, except for general hospitals as defined in s. 395.002~~:

(1)~~(a)~~ The need for the health care facilities ~~and health services~~ being proposed.

(2)~~(b)~~ The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant.

(3)~~(c)~~ The ability of the applicant to provide quality of care and the applicant's record of providing quality of care.

(4)~~(d)~~ The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation.

(5)~~(e)~~ The extent to which the proposed services will enhance access to health care for residents of the service district.

(6)~~(f)~~ The immediate and long-term financial feasibility of the proposal.

(7)~~(g)~~ The extent to which the proposal will foster

competition that promotes quality and cost-effectiveness.

(8) ~~(h)~~ The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction.

(9) ~~(i)~~ The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

(10) ~~(j)~~ The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, when the applicant is requesting additional nursing home beds at that facility.

~~(2) For a general hospital, the agency shall consider only the criteria specified in paragraph (1)(a), paragraph (1)(b), except for quality of care in paragraph (1)(b), and paragraphs (1)(e), (g), and (i).~~

Section 12. Effective July 1, 2021, subsection (2) of section 408.035, Florida Statutes, as amended by this act, is amended to read:

408.035 Review criteria.—The agency shall determine the reviewability of applications and shall review applications for certificate-of-need determinations for health care facilities in context with the following criteria:

(2) The availability, quality of care, accessibility, and extent of utilization of existing health care facilities ~~and health services~~ in the service district of the applicant.

Section 13. Subsection (1) and paragraphs (i) through (q) of subsection (3) of section 408.036, Florida Statutes, are amended to read:

408.036 Projects subject to review; exemptions.—

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

(a) The addition of beds in community nursing homes or intermediate care facilities for the developmentally disabled by new construction or alteration.

(b) The new construction or establishment of additional health care facilities, except for the construction of or establishment of a general hospital or ~~including~~ a replacement health care facility when the proposed project site is ~~not~~ located on the same site as or within 1 mile of the existing health care facility~~,~~ if the number of beds in each licensed bed category will not increase.

(c) The conversion from one type of health care facility to another, including the conversion from a general hospital or~~,~~ a specialty hospital, except that the conversion of a specialty hospital to a general hospital is not subject to review ~~or a~~

~~long-term care hospital~~.

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

~~(e) An increase in the number of beds for comprehensive rehabilitation.~~

~~(f) The establishment of tertiary health services, including inpatient comprehensive rehabilitation services.~~

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

~~(i) For the addition of hospital beds licensed under chapter 395 for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.~~

~~1. In addition to any other documentation otherwise required by the agency, a request for exemption submitted under this paragraph must:~~

~~a. Certify that the prior 12-month average occupancy rate for the licensed beds being expanded meets or exceeds 80 percent.~~

~~b. Certify that the beds have been licensed and operational for at least 12 months.~~

~~2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.~~

~~3. The agency shall count beds authorized under this~~

~~paragraph as approved beds in the published inventory of hospital beds until the beds are licensed.~~

(i) ~~(j)~~ For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.

1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must certify that:

a. The facility has not had any class I or class II deficiencies within the 30 months preceding the request.

b. The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent.

c. Any beds authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.

2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.

3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

~~(k) For the establishment of:~~

~~1. A Level II neonatal intensive care unit with at least 10 beds, upon documentation to the agency that the applicant hospital had a minimum of 1,500 births during the previous 12 months;~~

~~2. A Level III neonatal intensive care unit with at least 15 beds, upon documentation to the agency that the applicant hospital has a Level II neonatal intensive care unit of at least 10 beds and had a minimum of 3,500 births during the previous 12 months; or~~

~~3. A Level III neonatal intensive care unit with at least 5 beds, upon documentation to the agency that the applicant hospital is a verified trauma center pursuant to s. 395.4001(15), and has a Level II neonatal intensive care unit,~~

~~if the applicant demonstrates that it meets the requirements for quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting found in agency certificate-of-need rules for Level II and Level III neonatal intensive care units and if the applicant commits to the provision of services to Medicaid and charity patients at a level equal to or greater than the district average. Such a~~

~~commitment is subject to s. 408.040.~~

~~(l) For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.~~

(j) ~~(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 (e).

(k) ~~(n)~~ For consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning district, by nursing homes with any shared controlled interest within that planning district, if there is no increase in the planning district total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location.

(l) ~~(o)~~ For beds in state mental health treatment facilities defined in s. 394.455 and state mental health forensic facilities operated under chapter 916.

(m) ~~(p)~~ For beds in state developmental disabilities centers as defined in s. 393.063.

(n) ~~(q)~~ For the establishment of a health care facility or project that meets all of the following criteria:

1. The applicant was previously licensed within the past 21 days as a health care facility or provider that is subject to

subsection (1).

2. The applicant failed to submit a renewal application and the license expired on or after January 1, 2015.

3. The applicant does not have a license denial or revocation action pending with the agency at the time of the request.

4. The applicant's request is for the same service type, district, service area, and site for which the applicant was previously licensed.

5. The applicant's request, if applicable, includes the same number and type of beds as were previously licensed.

6. The applicant agrees to the same conditions that were previously imposed on the certificate of need or on an exemption related to the applicant's previously licensed health care facility or project.

7. The applicant applies for initial licensure as required under s. 408.806 within 21 days after the agency approves the exemption request. If the applicant fails to apply in a timely manner, the exemption expires on the 22nd day following the agency's approval of the exemption.

~~Notwithstanding subparagraph 1., an applicant whose license expired between January 1, 2015, and the effective date of this act may apply for an exemption within 30 days of this act becoming law.~~

Section 14. Effective July 1, 2021, paragraphs (b), (c), (l), (m), and (n) of subsection (1), as amended by this act, and subsections (2) and (5) of section 408.036, Florida Statutes, are amended to read:

408.036 Projects subject to review; exemptions.—

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

(b) The new construction or establishment of additional health care facilities, except for ~~the construction of or establishment of a general hospital or~~ a replacement health care facility when the proposed project site is located on the same site as or within 1 mile of the existing health care facility if the number of beds in each licensed bed category will not increase.

(c) The conversion from one type of health care facility to another~~, including the conversion from a general hospital or a specialty hospital, except that the conversion of a specialty hospital to a general hospital is not subject to review~~.

~~(l) For beds in state mental health treatment facilities defined in s. 394.455 and state mental health forensic facilities operated under chapter 916.~~

(l) ~~(m)~~ For beds in state developmental disabilities centers as defined in s. 393.063.

(m) ~~(n)~~ For the establishment of a health care facility or project that meets all of the following criteria:

1. The applicant was previously licensed within the past 21 days as a health care facility or provider that is subject to subsection (1).

2. The applicant failed to submit a renewal application and the license expired on or after January 1, 2015.

3. The applicant does not have a license denial or revocation action pending with the agency at the time of the request.

4. The applicant's request is for the same service type, district, service area, and site for which the applicant was previously licensed.

5. The applicant's request, if applicable, includes the same number and type of beds as were previously licensed.

6. The applicant agrees to the same conditions that were previously imposed on the certificate of need or on an exemption related to the applicant's previously licensed health care facility or project.

7. The applicant applies for initial licensure as required under s. 408.806 within 21 days after the agency approves the exemption request. If the applicant fails to apply in a timely manner, the exemption expires on the 22nd day following the

agency's approval of the exemption.

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), the following projects are subject to expedited review:

(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~~.

(5) NOTIFICATION.—Health care facilities and providers must provide to the agency notification of~~:~~

~~(a)~~ replacement of a health care facility when the proposed project site is located in the same district and on the existing site or within a 1-mile radius of the replaced health care facility, if the number and type of beds do not increase.

~~(b) The termination of a health care service, upon 30 days' written notice to the agency.~~

~~(c) The addition or delicensure of beds.~~ Notification ~~under this subsection~~ may be made by electronic, facsimile, or written means at any time before the described action has been taken.

Section 15. Section 408.0361, Florida Statutes, is repealed.

Section 16. Section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

(1) ~~Except as provided in subsection (2) for a general hospital,~~ An application for a certificate of need must contain:

(a) A detailed description of the proposed project and statement of its purpose and need in relation to the district health plan.

(b) A statement of the financial resources needed by and available to the applicant to accomplish the proposed project. This statement must include:

1. A complete listing of all capital projects, including new health facility development projects and health facility acquisitions applied for, pending, approved, or underway in any state at the time of application, regardless of whether or not that state has a certificate-of-need program or a capital expenditure review program pursuant to s. 1122 of the Social Security Act. The agency may, by rule, require less-detailed information from major health care providers. This listing must include the applicant's actual or proposed financial commitment to those projects and an assessment of their impact on the applicant's ability to provide the proposed project.

2. A detailed listing of the needed capital expenditures, including sources of funds.

3. A detailed financial projection, including a statement of the projected revenue and expenses for the first 2 years of operation after completion of the proposed project. This statement must include a detailed evaluation of the impact of

the proposed project on the cost of other services provided by the applicant.

(c) An audited financial statement of the applicant or the applicant's parent corporation if audited financial statements of the applicant do not exist. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

~~(2) An application for a certificate of need for a general hospital must contain a detailed description of the proposed general hospital project and a statement of its purpose and the needs it will meet. The proposed project's location, as well as its primary and secondary service areas, must be identified by zip code. Primary service area is defined as the zip codes from which the applicant projects that it will draw 75 percent of its discharges. Secondary service area is defined as the zip codes from which the applicant projects that it will draw its remaining discharges. If, subsequent to issuance of a final order approving the certificate of need, the proposed location of the general hospital changes or the primary service area materially changes, the agency shall revoke the certificate of need. However, if the agency determines that such changes are deemed to enhance access to hospital services in the service district, the agency may permit such changes to occur. A party~~

~~participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital has standing to participate in any subsequent proceeding regarding the revocation of the certificate of need for a hospital for which the location has changed or for which the primary service area has materially changed. In addition, the application for the certificate of need for a general hospital must include a statement of intent that, if approved by final order of the agency, the applicant shall within 120 days after issuance of the final order or, if there is an appeal of the final order, within 120 days after the issuance of the court's mandate on appeal, furnish satisfactory proof of the applicant's financial ability to operate. The agency shall establish documentation requirements, to be completed by each applicant, which 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 party participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital may provide written comments concerning the adequacy of the financial information provided, but such party does not have standing to participate in an administrative proceeding regarding proof of the applicant's 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 provider.~~

(2)~~(3)~~ The applicant must certify that it will license and operate the health care facility. For an existing health care facility, the applicant must be the licenseholder of the facility.

Section 17. Paragraphs (c) and (d) of subsection (3), paragraphs (b) and (c) of subsection (5), and paragraph (d) of subsection (6) of section 408.039, Florida Statutes, are amended to read:

408.039 Review process.—The review process for certificates of need shall be as follows:

(3) APPLICATION PROCESSING.—

~~(c) Except for competing applicants, in order to be eligible to challenge the agency decision on a general hospital application under review pursuant to paragraph (5)(c), existing hospitals must submit a detailed written statement of opposition to the agency and to the applicant. The detailed written statement must be received by the agency and the applicant within 21 days after the general hospital application is deemed complete and made available to the public.~~

~~(d) In those cases where a written statement of opposition has been timely filed regarding a certificate of need application for a general hospital, the applicant for the general hospital may submit a written response to the agency.~~

~~Such response must be received by the agency within 10 days of the written statement due date.~~

(5) ADMINISTRATIVE HEARINGS.—

(b) Hearings shall be held in Tallahassee unless the administrative law judge determines that changing the location will facilitate the proceedings. The agency shall assign proceedings requiring hearings to the Division of Administrative Hearings of the Department of Management Services within 10 days after the time has expired for requesting a hearing. Except upon unanimous consent of the parties or upon the granting by the administrative law judge of a motion of continuance, hearings shall commence within 60 days after the administrative law judge has been assigned. ~~For an application for a general hospital, administrative hearings shall commence within 6 months after the administrative law judge has been assigned, and a continuance may not be granted absent a finding of extraordinary circumstances by the administrative law judge.~~ All parties, except the agency, shall bear their own expense of preparing a transcript. In any application for a certificate of need which is referred to the Division of Administrative Hearings for hearing, the administrative law judge shall complete and submit to the parties a recommended order as provided in ss. 120.569 and 120.57. The recommended order shall be issued within 30 days after the receipt of the proposed recommended orders or the deadline for submission of such proposed recommended orders,

whichever is earlier. The division shall adopt procedures for administrative hearings which shall maximize the use of stipulated facts and shall provide for the admission of prepared testimony.

(c) In administrative proceedings challenging the issuance or denial of a certificate of need, only applicants considered by the agency in the same batching cycle are entitled to a comparative hearing on their applications. Existing health care facilities may initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need, whether reviewed under s. 408.036(1) or (2), to a competing proposed facility or program within the same district. ~~With respect to an application for a general hospital, competing applicants and only those existing hospitals that submitted a detailed written statement of opposition to an application as provided in this paragraph may initiate or intervene in an administrative hearing. Such challenges to a general hospital application shall be limited in scope to the issues raised in the detailed written statement of opposition that was provided to the agency. The administrative law judge may, upon a motion showing good cause, expand the scope of the issues to be heard at the hearing. Such motion shall include substantial and detailed facts and reasons for failure to include such issues in the original written statement of opposition.~~

(6) JUDICIAL REVIEW.—

~~(d) The party appealing a final order that grants a general hospital certificate of need shall pay the appellee's attorney's fees and costs, in an amount up to $1 million, from the beginning of the original administrative action if the appealing party loses the appeal, subject to the following limitations and requirements:~~

~~1. The party appealing a final order must post a bond in the amount of $1 million in order to maintain the appeal.~~

~~2. Except as provided under s. 120.595(5), in no event shall the agency be held liable for any other party's attorney's fees or costs.~~

Section 18. Subsection (1) of section 408.043, Florida Statutes, is amended to read:

408.043 Special provisions.—

~~(1) OSTEOPATHIC ACUTE CARE HOSPITALS.—When an application is made for a certificate of need to construct or to expand an osteopathic acute care hospital, the need for such hospital shall be determined on the basis of the need for and availability of osteopathic services and osteopathic acute care hospitals in the district. When a prior certificate of need to establish an osteopathic acute care hospital has been issued in a district, and the facility is no longer used for that purpose, the agency may continue to count such facility and beds as an existing osteopathic facility in any subsequent application for~~

~~construction of an osteopathic acute care hospital.~~

Section 19. Section 408.0455, Florida Statutes, is amended to read:

408.0455 Rules; pending proceedings.—The rules of the agency in effect on June 30, 2004, shall remain in effect and shall be enforceable by the agency with respect to ss. 408.031-408.045 until such rules are repealed or amended by the agency. Rules 59C-1.039 through 59C-1.044, F.A.C., remain in effect for the sole purpose of maintaining licensure requirements for the applicable services until the agency has adopted rules for the corresponding services pursuant to s. 395.1055(1)(i), Florida Statutes 2018.

Section 20. Subsection (3) of section 408.808, Florida Statutes, is amended to read:

408.808 License categories.—

(3) INACTIVE LICENSE.—An inactive license may be issued to a hospital or a health care provider subject to the certificate-of-need provisions in part I of this chapter when the provider is currently licensed, does not have a provisional license, and will be temporarily unable to provide services but is reasonably expected to resume services within 12 months. Such designation may be made for a period not to exceed 12 months but may be renewed by the agency for up to 12 additional months upon demonstration by the licensee of the provider's progress toward reopening. However, if after 20 months in an inactive license

status, a statutory rural hospital, as defined in s. 395.602, has demonstrated progress toward reopening, but may not be able to reopen prior to the inactive license expiration date, the inactive designation may be renewed again by the agency for up to 12 additional months. For purposes of such a second renewal, if construction or renovation is required, the licensee must have had plans approved by the agency and construction must have already commenced pursuant to s. 408.032(4); however, if construction or renovation is not required, the licensee must provide proof of having made an enforceable capital expenditure greater than 25 percent of the total costs associated with the hiring of staff and the purchase of equipment and supplies needed to operate the facility upon opening. A request by a licensee for an inactive license or to extend the previously approved inactive period must be submitted to the agency and must include a written justification for the inactive license with the beginning and ending dates of inactivity specified, a plan for the transfer of any clients to other providers, and the appropriate licensure fees. The agency may not accept a request that is submitted after initiating closure, after any suspension of service, or after notifying clients of closure or suspension of service, unless the action is a result of a disaster at the licensed premises. For the purposes of this section, the term "disaster" means a sudden emergency occurrence beyond the control of the licensee, whether natural, technological, or

manmade, which renders the provider inoperable at the premises. Upon agency approval, the provider shall notify clients of any necessary discharge or transfer as required by authorizing statutes or applicable rules. The beginning of the inactive license period is the date the provider ceases operations. The end of the inactive license period shall become the license expiration date. All licensure fees must be current, must be paid in full, and may be prorated. Reactivation of an inactive license requires the approval of a renewal application, including payment of licensure fees and agency inspections indicating compliance with all requirements of this part, authorizing statutes, and applicable rules.

Section 21. The Office of Program Policy Analysis and Government Accountability shall review federal requirements and other states' licensure statutes and rules governing the provision of tertiary health services as defined in s. 408.032, Florida Statutes 2018, and shall make recommendations to the President of the Senate and the Speaker of the House of Representatives on best practices, including recommendations on minimum volume requirements, as applicable, regarding the establishment of licensure standards for such programs by November 1, 2019.

Section 22. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2019.

An act relating to telehealth; creating s. 456.47, F.S.; defining terms; establishing standards of practice for telehealth providers; authorizing telehealth providers to use telehealth to perform patient evaluations; authorizing certain telehealth providers to use telehealth to prescribe certain controlled substances under specified circumstances; providing that a nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice is not deemed to be practicing medicine without a license; providing recordkeeping requirements for telehealth providers; providing registration requirements for out-of-state telehealth providers; requiring the Department of Health to publish certain information on its website; authorizing a board, or the department if there is no board, to take disciplinary action against a telehealth provider under certain circumstances; providing venue; providing exemptions from telehealth registration requirements; authorizing the applicable board, or the department if there is no board, to adopt rules; creating s. 627.42396, F.S.; providing requirements for a contract between a certain health insurer and a telehealth provider; amending s. 641.31,

F.S.; providing requirements for a contract between a certain health maintenance organization and a telehealth provider; requiring the department to annually review the amount of certain collected fees and make a determination relating to the sufficiency of funding to implement specified telehealth provisions; upon making a certain determination, requiring the department to indicate insufficient funding and recommend fee adjustments in its annual legislative budget request; providing an appropriation; authorizing positions; providing effective dates.

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

Section 1. Section 456.47, Florida Statutes, is created to read:

456.47 Use of telehealth to provide services.—

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

(a) "Telehealth" means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services;

and health administration. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

(b) "Telehealth provider" means any individual who provides health care and related services using telehealth and who is licensed or certified under s. 393.17; part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; who is licensed under a multi-state health care licensure compact of which Florida is a member state; or who is registered under and complies with subsection (4).

(2) PRACTICE STANDARDS.—

(a) A telehealth provider has the duty to practice in a manner consistent with his or her scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state.

(b) A telehealth provider may use telehealth to perform a patient evaluation. If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research a patient's medical history or conduct a physical examination of the patient before using telehealth to provide health care services to the

patient.

(c) A telehealth provider may not use telehealth to prescribe a controlled substance unless the controlled substance is prescribed for the following:

1. The treatment of a psychiatric disorder;

2. Inpatient treatment at a hospital licensed under chapter 395;

3. The treatment of a patient receiving hospice services as defined in s. 400.601; or

4. The treatment of a resident of a nursing home facility as defined in s. 400.021.

(d) A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to a patient.

(e) A nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice, as established by Florida law or rule, is not in violation of s. 458.327(1)(a) or s. 459.013(1)(a).

(3) RECORDS.—A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standard as used for in-person services. Medical records, including video, audio, electronic, or other records generated as a result of providing such services, are confidential pursuant to ss. 395.3025(4) and 456.057.

(4) REGISTRATION OF OUT-OF-STATE TELEHEALTH PROVIDERS.—

(a) A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule.

(b) The board, or the department if there is no board, shall register a health care professional not licensed in this state as a telehealth provider if the health care professional:

1. Completes an application in the format prescribed by the department;

2. Is licensed with an active, unencumbered license that is issued by another state, the District of Columbia, or a possession or territory of the United States and that is substantially similar to a license issued to a Florida-licensed provider specified in paragraph (1)(b);

3. Has not been the subject of disciplinary action relating to his or her license during the 5-year period immediately prior to the submission of the application;

4. Designates a duly appointed registered agent for service of process in this state on a form prescribed by the department; and

5. Demonstrates to the board, or the department if there is no board, that he or she is in compliance with paragraph (e).

The department shall use the National Practitioner Data Bank to verify the information submitted under this paragraph, as applicable.

(c) The website of a telehealth provider registered under paragraph (b) must prominently display a hyperlink to the department's website containing information required under paragraph (h).

(d) A health care professional may not register under this subsection if his or her license to provide health care services is subject to a pending disciplinary investigation or action, or has been revoked in any state or jurisdiction. A health care professional registered under this subsection must notify the appropriate board, or the department if there is no board, of restrictions placed on his or her license to practice, or any disciplinary action taken or pending against him or her, in any state or jurisdiction. The notification must be provided within 5 business days after the restriction is placed or disciplinary action is initiated or taken.

(e) A provider registered under this subsection shall maintain professional liability coverage or financial responsibility, that includes coverage or financial responsibility for telehealth services provided to patients not located in the provider's home state, in an amount equal to or greater than the requirements for a licensed practitioner under

s. 456.048, s. 458.320, or s. 459.0085, as applicable.

(f) A health care professional registered under this subsection may not open an office in this state and may not provide in-person health care services to patients located in this state.

(g) A pharmacist registered under this subsection may only use a pharmacy permitted under chapter 465, a nonresident pharmacy registered under s. 465.0156, or a nonresident pharmacy or outsourcing facility holding an active permit pursuant to s. 465.0158 to dispense medicinal drugs to patients located in this state.

(h) The department shall publish on its website a list of all registrants and include, to the extent applicable, each registrant's:

1. Name.

2. Health care occupation.

3. Completed health care training and education, including completion dates and any certificates or degrees obtained.

4. Out-of-state health care license with the license number.

5. Florida telehealth provider registration number.

6. Specialty.

7. Board certification.

8. Five-year disciplinary history, including sanctions and board actions.

9. Medical malpractice insurance provider and policy limits, including whether the policy covers claims that arise in this state.

10. The name and address of the registered agent designated for service of process in this state.

(i) The board, or the department if there is no board, may take disciplinary action against an out-of-state telehealth provider registered under this subsection if the registrant:

1. Fails to notify the applicable board, or the department if there is no board, of any adverse actions taken against his or her license as required under paragraph (d).

2. Has restrictions placed on or disciplinary action taken against his or her license in any state or jurisdiction.

3. Violates any of the requirements of this section.

4. Commits any act that constitutes grounds for disciplinary action under s. 456.072(1) or the applicable practice act for Florida-licensed providers.

Disciplinary action taken by a board, or the department if there is no board, under this paragraph may include suspension or revocation of the provider's registration or the issuance of a reprimand or letter of concern. A suspension may be accompanied by a corrective action plan as determined by the board, or the department if there is no board, the completion of which may lead to the suspended registration being reinstated according to

rules adopted by the board, or the department if there is no board.

(5) VENUE.—For the purposes of this section, any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the department, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.

(6) EXEMPTIONS.—A health care professional who is not licensed to provide health care services in this state but who holds an active license to provide health care services in another state or jurisdiction, and who provides health care services using telehealth to a patient located in this state, is not subject to the registration requirement under this section if the services are provided:

(a) In response to an emergency medical condition as defined in s. 395.002; or

(b) In consultation with a health care professional licensed in this state who has ultimate authority over the diagnosis and care of the patient.

(7) RULEMAKING.—The applicable board, or the department if there is no board, may adopt rules to administer this section.

Section 2. Effective January 1, 2020, section 627.42396, Florida Statutes, is created to read:

627.42396 Reimbursement for telehealth services.—A contract between a health insurer issuing major medical comprehensive coverage through an individual or group policy and a telehealth provider, as defined in s. 456.47, must be voluntary between the insurer and the provider and must establish mutually acceptable payment rates or payment methodologies for services provided through telehealth. Any contract provision that distinguishes between payment rates or payment methodologies for services provided through telehealth and the same services provided without the use of telehealth must be initialed by the telehealth provider.

Section 3. Effective January 1, 2020, subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45) A contract between a health maintenance organization issuing major medical individual or group coverage and a telehealth provider, as defined in s. 456.47, must be voluntary between the health maintenance organization and the provider must establish mutually acceptable payment rates or payment methodologies for services provided through telehealth. Any contract provision that distinguishes between payment rates or payment methodologies for services provided through telehealth and the same services provided without the use of telehealth

must be initialed by the telehealth provider.

Section 4. Effective July 1, 2020, the Department of Health shall annually review the amount of any fees collected under section 456.47, Florida Statutes, in the prior fiscal year and shall determine whether such fees are sufficient to enable the department and the boards, as defined in section 456.001, Florida Statutes, to fully implement section 456.47, Florida Statutes. If the department determines that the fees collected are insufficient, the department shall so indicate to the Legislature in its annual legislative budget request and shall recommend appropriate adjustments to the applicable fees.

Section 5. For fiscal year 2019-2020, the sums of $261,389 in recurring funds and $15,020 in nonrecurring funds from the Medical Quality Assurance Trust Fund are appropriated to the Department of Health, and four full-time equivalent positions with associated salary rate of 145,870 are authorized for the purpose of implementing s. 456.47, Florida Statutes, as created by this act.

Section 6. Except as otherwise provided, this act shall take effect July 1, 2019.

An act relating to the medical use of marijuana; amending s. 381.986, F.S.; redefining the term "marijuana delivery device" to provide an exception to the requirement that such devices must be purchased from a medical marijuana treatment center for devices that are intended for the medical use of marijuana by smoking; redefining the term "medical use" to include the possession, use, or administration of marijuana in a form for smoking; conforming provisions to changes made by the act; restricting the smoking of marijuana in enclosed indoor workplaces; requiring a patient's informed consent form to include the negative health risks associated with smoking marijuana; conforming a provision to changes made by the act; requiring a qualified physician to submit specified documentation to the Board of Medicine and the Board of Osteopathic Medicine upon determining that smoking is an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition; prohibiting a physician from certifying a patient under 18 years of age to smoke marijuana for medical use unless the patient is diagnosed with a terminal condition and the physician makes a certain determination in concurrence with a second physician who is a pediatrician; requiring a qualified physician to obtain the written informed consent of such patient's parent or legal guardian before certifying the patient to smoke marijuana for

medical use; requiring the qualified physician to use a certain informed consent form adopted in rule by the boards; requiring the boards to review specified documentation and adopt certain practice standards by rule by a specified date; establishing a supply limit for a physician certification for marijuana in a form for smoking; authorizing a qualified physician to request an exception to the supply limit and possession limit for marijuana in a form for smoking; authorizing more than one caregiver to assist with a qualified patient's medical use of marijuana if the patient is participating in a certain research program in a teaching nursing home; authorizing a caregiver to be listed in the medical marijuana use registry as a designated caregiver for qualified patients who are participating in a certain research program in a teaching nursing home; prohibiting a medical marijuana treatment center that produces prerolled marijuana cigarettes from using wrapping paper made with tobacco or hemp; requiring that marijuana in a form for smoking meet certain packaging and labeling requirements; requiring the Department of Health to adopt rules regulating the types, appearance, and labeling of marijuana delivery devices; prohibiting a medical marijuana treatment center from dispensing more than a specified supply limit of marijuana in a form for smoking; revising a provision prohibiting a medical marijuana treatment center from dispensing or selling specified products; establishing possession

limits on marijuana in a form for smoking for a qualified patient; allowing marijuana delivery devices to be purchased from a vendor other than a medical marijuana treatment center; providing applicability; amending s. 1004.4351, F.S.; renaming the Coalition for Medical Marijuana Research and Education as the Consortium for Medical Marijuana Clinical Outcomes Research; establishing the consortium for a specified purpose; renaming the Medical Marijuana Research and Education Board as the Medical Marijuana Research Board; requiring the board to direct the operations of the consortium; providing membership of the board; providing for the appointment of a consortium director; providing duties of the consortium director; requiring the board to annually adopt a plan for medical marijuana research; requiring the plan to include specified information; providing research requirements for the plan; requiring the board to award funds to members of the consortium; requiring the board to collaborate with and authorizing the board to award funds to teaching nursing homes for certain research; requiring the board to issue an annual report to the Governor and Legislature by a specified date; requiring the department to submit certain data sets to the board; amending s. 381.987, F.S.; conforming provisions to changes made by the act; providing appropriations; providing an effective date.

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

Section 1. Paragraphs (g) and (j) of subsection (1), subsection (4), paragraphs (c) and (d) of subsection (6), paragraph (e) of subsection (8), subsection (14), and subsection (15) of section 381.986, Florida Statutes, are amended to read:

381.986 Medical use of marijuana.—

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

(g) "Marijuana delivery device" means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing marijuana into the human body, and which is dispensed from a medical marijuana treatment center for medical use by a qualified patient, except that delivery devices intended for the medical use of marijuana by smoking need not be dispensed from a medical marijuana treatment center in order to qualify as marijuana delivery devices.

(j) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:

1. Possession, use, or administration of marijuana that was not purchased or acquired from a medical marijuana treatment center.

2. Possession, use, or administration of marijuana ~~in a form for smoking,~~ in the form of commercially produced food items other than edibles~~,~~ or of marijuana seeds ~~or flower, except for flower in a sealed, tamper-proof receptacle for vaping~~.

3. Use or administration of any form or amount of marijuana

in a manner that is inconsistent with the qualified physician's directions or physician certification.

4. Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient's caregiver on behalf of the qualified patient.

5. Use or administration of marijuana in the following locations:

a. On any form of public transportation, except for low-THC cannabis not in a form for smoking.

b. In any public place, except for low-THC cannabis not in a form for smoking.

c. In a qualified patient's place of employment, except when permitted by his or her employer.

d. In a state correctional institution, as defined in s. 944.02, or a correctional institution, as defined in s. 944.241.

e. On the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062.

f. In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis not in a form for smoking.

6. The smoking of marijuana in an enclosed indoor workplace as defined in s. 386.203(5).

(4) PHYSICIAN CERTIFICATION.—

(a) A qualified physician may issue a physician certification only if the qualified physician:

1. Conducted a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.

2. Diagnosed the patient with at least one qualifying medical condition.

3. Determined that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.

4. Determined whether the patient is pregnant and documented such determination in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.

5. Reviewed the patient's controlled drug prescription history in the prescription drug monitoring program database established pursuant to s. 893.055.

6. Reviews the medical marijuana use registry and confirmed that the patient does not have an active physician certification from another qualified physician.

7. Registers as the issuer of the physician certification for the named qualified patient on the medical marijuana use registry in an electronic manner determined by the department, and:

a. Enters into the registry the contents of the physician certification, including the patient's qualifying condition and the dosage not to exceed the daily dose amount determined by the department, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient for the medical use of marijuana.

b. Updates the registry within 7 days after any change is made to the original physician certification to reflect such change.

c. Deactivates the registration of the qualified patient and the patient's caregiver when the physician no longer recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of the patient for medical use of marijuana each time the qualified physician issues a physician certification for the patient, which shall be maintained in the patient's medical record. The patient, or the patient's parent or legal guardian if the patient is a minor, must sign the informed consent acknowledging that the qualified physician has sufficiently explained its content. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, which must include, at a minimum, information related to:

a. The Federal Government's classification of marijuana as a Schedule I controlled substance.

b. The approval and oversight status of marijuana by the Food and Drug Administration.

c. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section.

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

f. The potential side effects of marijuana use, including the negative health risks associated with smoking marijuana.

g. The risks, benefits, and drug interactions of marijuana.

h. That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

(b) If a qualified physician issues a physician certification for a qualified patient diagnosed with a qualifying medical condition pursuant to paragraph (2)(k), the physician must submit the following to the applicable board within 14 days after issuing the physician certification:

1. Documentation supporting the qualified physician's opinion that the medical condition is of the same kind or class as the conditions in paragraphs (2)(a)-(j).

2. Documentation that establishes the efficacy of marijuana as treatment for the condition.

3. Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient.

4. Any other documentation as required by board rule.

The department must submit such documentation to the Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research ~~and Education~~ established pursuant to s. 1004.4351.

(c) If a qualified physician determines that smoking is an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition, the qualified physician must submit the following documentation to the applicable board:

1. A list of other routes of administration, if any, certified by a qualified physician that the patient has tried,

the length of time the patient used such routes of administration, and an assessment of the effectiveness of those routes of administration in treating the qualified patient's qualifying condition.

2. Research documenting the effectiveness of smoking as a route of administration to treat similarly situated patients with the same qualifying condition as the qualified patient.

3. A statement signed by the qualified physician documenting the qualified physician's opinion that the benefits of smoking marijuana for medical use outweigh the risks for the qualified patient.

(d) A qualified physician may not issue a physician certification for marijuana in a form for smoking to a patient under 18 years of age unless the patient is diagnosed with a terminal condition, the qualified physician determines that smoking is the most effective route of administration for the patient, and a second physician who is a board-certified pediatrician concurs with such determination. Such determination and concurrence must be documented in the patient's medical record and in the medical marijuana use registry. The certifying physician must obtain the written informed consent of such patient's parent or legal guardian before issuing a physician certification to the patient for marijuana in a form for smoking. The qualified physician must use a standardized informed consent form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine which must include information concerning the negative health effects of smoking marijuana on persons under 18 years of age and an acknowledgement that the qualified physician has sufficiently

explained the contents of the form.

(e) The Board of Medicine and the Board of Osteopathic Medicine shall review the documentation submitted pursuant to paragraph (c) and shall each, by July 1, 2021, adopt by rule practice standards for the certification of smoking as a route of administration.

(f) ~~(e)~~ A qualified physician may not issue a physician certification for more than three 70-day supply limits of marijuana or more than six 35-day supply limits of marijuana in a form for smoking. The department shall quantify by rule a daily dose amount with equivalent dose amounts for each allowable form of marijuana dispensed by a medical marijuana treatment center. The department shall use the daily dose amount to calculate a 70-day supply.

1. A qualified physician may request an exception to the daily dose amount limit, the 35-day supply limit of marijuana in a form for smoking, and the 4-ounce possession limit of marijuana in a form for smoking established in paragraph (14)(a). The request shall be made electronically on a form adopted by the department in rule and must include, at a minimum:

a. The qualified patient's qualifying medical condition.

b. The dosage and route of administration that was insufficient to provide relief to the qualified patient.

c. A description of how the patient will benefit from an increased amount.

d. The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition.

2. A qualified physician must provide the qualified patient's records upon the request of the department.

3. The department shall approve or disapprove the request within 14 days after receipt of the complete documentation required by this paragraph. The request shall be deemed approved if the department fails to act within this time period.

(g) ~~(d)~~ A qualified physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification. A physician must:

1. Determine if the patient still meets the requirements to be issued a physician certification under paragraph (a).

2. Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription or nonprescription medication; or

b. A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research ~~and Education~~ established pursuant to s. 1004.4351.

(h) ~~(e)~~ An active order for low-THC cannabis or medical cannabis issued pursuant to former s. 381.986, Florida Statutes 2016, and registered with the compassionate use registry before June 23, 2017, is deemed a physician certification, and all patients possessing such orders are deemed qualified patients until the department begins issuing medical marijuana use

registry identification cards.

(i) ~~(f)~~ The department shall monitor physician registration in the medical marijuana use registry and the issuance of physician certifications for practices that could facilitate unlawful diversion or misuse of marijuana or a marijuana delivery device and shall take disciplinary action as appropriate.

(j) ~~(g)~~ The Board of Medicine and the Board of Osteopathic Medicine shall jointly create a physician certification pattern review panel that shall review all physician certifications submitted to the medical marijuana use registry. The panel shall track and report the number of physician certifications and the qualifying medical conditions, dosage, supply amount, and form of marijuana certified. The panel shall report the data both by individual qualified physician and in the aggregate, by county, and statewide. The physician certification pattern review panel shall, beginning January 1, 2018, submit an annual report of its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(k) ~~(h)~~ The department, the Board of Medicine, and the Board of Osteopathic Medicine may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this subsection.

(6) CAREGIVERS.—

(c) A qualified patient may designate no more than one caregiver to assist with the qualified patient’s medical use of marijuana, unless:

1. The qualified patient is a minor and the designated caregivers are parents or legal guardians of the qualified patient;

2. The qualified patient is an adult who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are the parents or legal guardians of the qualified patient; ~~or~~

3. The qualified patient is admitted to a hospice program; or

4. The qualified patient is participating in a research program in a teaching nursing home pursuant to s. 1004.4351.

(d) A caregiver may be registered in the medical marijuana use registry as a designated caregiver for no more than one qualified patient, unless:

1. The caregiver is a parent or legal guardian of more than one minor who is a qualified patient;

2. The caregiver is a parent or legal guardian of more than one adult who is a qualified patient and who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision; ~~or~~

3. All qualified patients the caregiver has agreed to assist are admitted to a hospice program and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice; and the caregiver provides personal care or other services directly to clients of the hospice in the scope of that employment; or

4. All qualified patients the caregiver has agreed to assist are participating in a research program in a teaching nursing home pursuant to s. 1004.4351.

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and dispensing of marijuana and marijuana delivery devices. A licensed medical marijuana treatment center must, at all times, maintain compliance with the criteria demonstrated and representations made in the initial application and the criteria established in this subsection. Upon request, the department may grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application. A variance may not be granted from the requirements in subparagraph 2. and subparagraphs (b)1. and 2.

1. A licensed medical marijuana treatment center may transfer ownership to an individual or entity who meets the

requirements of this section. A publicly traded corporation or publicly traded company that meets the requirements of this section is not precluded from ownership of a medical marijuana treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall notify the department in writing at least 60 days before the anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

c. Upon receipt of an application for a license, the department shall examine the application and, within 30 days after receipt, notify the applicant in writing of any apparent errors or omissions and request any additional information required.

d. Requested information omitted from an application for licensure must be filed with the department within 21 days after the department's request for omitted information or the application shall be deemed incomplete and shall be withdrawn from further consideration and the fees shall be forfeited.

Within 30 days after the receipt of a complete application, the department shall approve or deny the application.

2. A medical marijuana treatment center, and any individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or other form

of ownership of any other medical marijuana treatment center.

3. A medical marijuana treatment center may not enter into any form of profit-sharing arrangement with the property owner or lessor of any of its facilities where cultivation, processing, storing, or dispensing of marijuana and marijuana delivery devices occurs.

4. All employees of a medical marijuana treatment center must be 21 years of age or older and have passed a background screening pursuant to subsection (9).

5. Each medical marijuana treatment center must adopt and enforce policies and procedures to ensure employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

6. When growing marijuana, a medical marijuana treatment center:

a. May use pesticides determined by the department, after consultation with the Department of Agriculture and Consumer Services, to be safely applied to plants intended for human consumption, but may not use pesticides designated as restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and in a room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

7. Each medical marijuana treatment center must produce and make available for purchase at least one low-THC cannabis product.

8. A medical marijuana treatment center that produces edibles must hold a permit to operate as a food establishment pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles may have a potency variance of no greater than 15 percent. Edibles may not be attractive to children; be manufactured in the shape of humans, cartoons, or animals; be manufactured in a form that bears any reasonable resemblance to products available for consumption as commercially available candy; or contain any color additives. To discourage consumption of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

9. Within 12 months after licensure, a medical marijuana treatment center must demonstrate to the department that all of its processing facilities have passed a Food Safety Good Manufacturing Practices, such as Global Food Safety Initiative or equivalent, inspection by a nationally accredited certifying

body. A medical marijuana treatment center must immediately stop processing at any facility which fails to pass this inspection until it demonstrates to the department that such facility has met this requirement.

10. A medical marijuana treatment center that produces prerolled marijuana cigarettes may not use wrapping paper made with tobacco or hemp.

11.~~10.~~ When processing marijuana, a medical marijuana treatment center must:

a. Process the marijuana within an enclosed structure and in a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

d. Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees. Before dispensing, the medical marijuana treatment center must determine that the test results indicate that low-

THC cannabis meets the definition of low-THC cannabis, the concentration of tetrahydrocannabinol meets the potency requirements of this section, the labeling of the concentration of tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from contaminants that are unsafe for human consumption. The department shall determine by rule which contaminants must be tested for and the maximum levels of each contaminant which are safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the testing requirements for contaminants that are unsafe for human consumption in edibles. The department shall also determine by rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or department rule. The department may select a random sample from edibles available for purchase in a dispensing facility which shall be tested by the department to determine that the edible meets the potency requirements of this section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate. A medical marijuana treatment center may not require payment from the department for the sample. A medical marijuana treatment center must recall edibles, including all edibles made from the same batch of marijuana, which fail to meet the potency requirements of this section, which are unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol concentration is inaccurate. The medical marijuana treatment center must retain records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical

marijuana treatment center must contract with a marijuana testing laboratory to perform audits on the medical marijuana treatment center's standard operating procedures, testing records, and samples and provide the results to the department to confirm that the marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for human consumption. A medical marijuana treatment center shall reserve two processed samples from each batch and retain such samples for at least 9 months for the purpose of such audits. A medical marijuana treatment center may use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory holds the required certification, but in no event later than July 1, 2018.

e. Package the marijuana in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.

f. Package the marijuana in a receptacle that has a firmly affixed and legible label stating the following information:

(I) The marijuana or low-THC cannabis meets the requirements of sub-subparagraph d.

(II) The name of the medical marijuana treatment center from which the marijuana originates.

(III) The batch number and harvest number from which the marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form,

including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

(VII) The recommended dose.

(VIII) A warning that it is illegal to transfer medical marijuana to another person.

(IX) A marijuana universal symbol developed by the department.

12.~~11.~~ The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product dispensed related to:

a. Clinical pharmacology.

b. Indications and use.

c. Dosage and administration.

d. Dosage forms and strengths.

e. Contraindications.

f. Warnings and precautions.

g. Adverse reactions.

13. In addition to the packaging and labeling requirements specified in subparagraphs 11. and 12., marijuana in a form for smoking must be packaged in a sealed receptacle with a legible and prominent warning to keep away from children and a warning that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a form for smoking must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol.

14. The department shall adopt rules to regulate the types,

appearance, and labeling of marijuana delivery devices dispensed from a medical marijuana treatment center. The rules must require marijuana delivery devices to have an appearance consistent with medical use.

15.~~12.~~ Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 11. and 12. ~~10. and 11.~~, edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list all of the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

16.~~13.~~ When dispensing marijuana or a marijuana delivery device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC cannabis, medical cannabis and cannabis delivery devices issued pursuant to former s. 381.986, Florida Statutes 2016, which was entered into the medical marijuana use registry before July 1, 2017.

b. May not dispense more than a 70-day supply of marijuana within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking

may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

c. Must have the medical marijuana treatment center's employee who dispenses the marijuana or a marijuana delivery device enter into the medical marijuana use registry his or her name or unique employee identifier.

d. Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes~~,~~ ~~bongs,~~ or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

(14) EXCEPTIONS TO OTHER LAWS.—

(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a qualified patient and the qualified patient's caregiver may purchase from a medical marijuana treatment center for the patient's medical use a marijuana delivery device and up to the amount of marijuana authorized in the physician certification, but may not possess more than a 70-day supply of marijuana, or the greater of 4 ounces of marijuana in a form for smoking or an amount of marijuana in a form for smoking approved by the department pursuant to paragraph (4)(f), at any given time and all marijuana purchased must remain in its original packaging.

(b) Notwithstanding paragraph (a), s. 893.13, s. 893.135, s. 893.147, or any other provision of law, a qualified patient and the qualified patient's caregiver may purchase and possess a marijuana delivery device intended for the medical use of marijuana by smoking from a vendor other than a medical marijuana treatment center.

(c) ~~(b)~~ Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved medical marijuana treatment center and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of marijuana or a marijuana delivery device as provided in this section, s. 381.988, and by department rule. For the

purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(d) ~~(c)~~ Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a certified marijuana testing laboratory, including an employee of a certified marijuana testing laboratory acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of marijuana as provided in this section, in s. 381.988, and by department rule.

(e) ~~(d)~~ A licensed medical marijuana treatment center and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of marijuana or a marijuana delivery device, as provided in this section, in s. 381.988, and by department rule.

(f) ~~(e)~~ This subsection does not exempt a person from prosecution for a criminal offense related to impairment or intoxication resulting from the medical use of marijuana or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

(g) ~~(f)~~ Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section and pursuant to policies and procedures established pursuant to s. 1006.62(8), school personnel may possess marijuana that is obtained for medical use pursuant to

this section by a student who is a qualified patient.

(h) ~~(g)~~ Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, a research institute established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute, Inc., established under s. 1004.43, or a state university that has achieved the preeminent state research university designation under s. 1001.7065 may possess, test, transport, and lawfully dispose of marijuana for research purposes as provided by this section.

(15) APPLICABILITY.—

(a) This section does not limit the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy.

(b) This section does not require an employer to accommodate the medical use of marijuana in any workplace or any employee working while under the influence of marijuana.

(c) This section does not create a cause of action against an employer for wrongful discharge or discrimination.

(d) This section does not impair the ability of any party to restrict or limit smoking or vaping marijuana on his or her private property.

(e) This section does not prohibit the medical use of marijuana or a caregiver assisting with the medical use of marijuana in a nursing home facility licensed under part II of chapter 400, a hospice facility licensed under part IV of chapter 400, or an assisted living facility licensed under part I of chapter 429, if the medical use of marijuana is not prohibited in the facility's policies.

(f) Marijuana, as defined in this section, is not reimbursable under chapter 440.

Section 2. Section 1004.4351, Florida Statutes, is amended to read:

1004.4351 Medical marijuana research ~~and education~~.—

(1) SHORT TITLE.—This section shall be known and may be cited as the "Medical Marijuana Research ~~and Education~~ Act."

(2) LEGISLATIVE FINDINGS.—The Legislature finds that:

(a) The present state of knowledge concerning the use of marijuana to alleviate pain and treat illnesses is limited because permission to perform clinical studies on marijuana is difficult to obtain, with access to research-grade marijuana so restricted that little or no unbiased studies have been performed.

(b) Under the State Constitution, marijuana is available for the treatment of certain debilitating medical conditions.

(c) Additional clinical studies are needed to ensure that the residents of this state obtain the correct dosing, formulation, route, modality, frequency, quantity, and quality of marijuana for specific illnesses.

(d) An effective medical marijuana research ~~and education~~ program would mobilize the scientific~~, educational,~~ and medical resources that presently exist in this state to determine the appropriate and best use of marijuana to treat illness.

(3) DEFINITIONS.—As used in this section, the term:

(a) "Board" means the Medical Marijuana Research ~~and Education~~ Board.

(b) "Consortium" ~~"Coalition"~~ means the Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research ~~and Education~~.

(c) "Marijuana" has the same meaning as provided in s. 29, Art. X of the State Constitution.

(4) CONSORTIUM ~~COALITION~~ FOR MEDICAL MARIJUANA CLINICAL OUTCOMES RESEARCH ~~AND EDUCATION~~.—

(a) There is established within a state university designated by the Board of Governors ~~the H. Lee Moffitt Cancer Center and Research Institute, Inc.,~~ the Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research which shall consist of public and private universities ~~and Education~~. The purpose of the consortium ~~coalition~~ is to conduct rigorous scientific research and~~, provide education,~~ disseminate such research~~, and guide policy for the adoption of a statewide policy on ordering and dosing practices for the medical use of marijuana. The coalition shall be physically located at the H. Lee Moffitt Cancer Center and Research Institute, Inc~~.

(b) The Medical Marijuana Research ~~and Education~~ Board is established to direct the operations of the consortium ~~coalition~~. The board shall be composed of ~~seven~~ members representing each participating university appointed by the president of each participating university ~~the chief executive officer of the H. Lee Moffitt Cancer Center and Research Institute, Inc~~. Board members must have experience in a variety of scientific and medical fields, including, but not limited to, oncology, neurology, psychology, pediatrics, nutrition, and addiction. Members shall be appointed to 4-year terms and may be reappointed to serve additional terms. The chair shall be elected by the board from among its members to serve a 2-year term. The board shall meet at least semiannually at the call of the chair or, in his or her absence or incapacity, the vice

chair. Four members constitute a quorum. A majority vote of the members present is required for all actions of the board. The board may prescribe, amend, and repeal a charter governing the manner in which it conducts its business. A board member shall serve without compensation but is entitled to be reimbursed for travel expenses by the consortium ~~coalition~~ or the organization he or she represents in accordance with s. 112.061.

(c) The consortium ~~coalition~~ shall be administered by a ~~coalition~~ director, who shall be appointed by and serve at the pleasure of the board. The ~~coalition~~ director shall, subject to the approval of the board:

1. Propose a budget for the consortium ~~coalition~~.

2. Foster the collaboration of scientists, researchers, and other appropriate personnel in accordance with the consortium's ~~coalition's~~ charter.

3. Engage individuals in public and private university programs relevant to the consortium's work to participate in the consortium.

4.~~3.~~ Identify and prioritize the research to be conducted by the consortium ~~coalition~~.

5.~~4.~~ Prepare a plan for medical marijuana research ~~the Medical Marijuana Research and Education Plan~~ for submission to the board.

6.~~5.~~ Apply for grants to obtain funding for research conducted by the consortium ~~coalition~~.

7.~~6.~~ Perform other duties as determined by the board.

~~(d) The board shall advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medical marijuana research and education in this~~

~~state. The board shall explore methods of implementing and enforcing medical marijuana laws in relation to cancer control, research, treatment, and education.~~

(d) ~~(c)~~ The board shall annually adopt a plan for medical marijuana research. The plan must organize a program of research that contributes to the body of scientific knowledge on the effects of the medical use of marijuana and informs both policy and medical practice related to the treatment of debilitating medical conditions with marijuana. Research must include tracking clinical outcomes, certification standards, dosing standards, routes of administration, efficacy, and side effects. Research must also include the study of the effects of smoking marijuana to treat debilitating medical conditions. The board must award funds to members of the consortium and to perform research consistent with the plan. The board shall collaborate with and may award funds to teaching nursing homes, as defined in s. 430.08, for research on medical use of marijuana to alleviate conditions related to chronic disease and aging~~, known as the "Medical Marijuana Research and Education Plan," which must be in accordance with state law and coordinate with existing programs in this state. The plan must include recommendations for the coordination and integration of medical, pharmacological, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions; research related to the treatment of such medical conditions; and education~~.

(e) ~~(f)~~ By February 15 of each year, the board shall issue a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects,

research findings, community outreach initiatives, and future plans for the consortium ~~coalition~~.

(f) ~~(g)~~ Beginning August 1, 2019 ~~January 15, 2018~~, and quarterly thereafter, the Department of Health shall submit to the board a data set that includes, for each patient registered in the medical marijuana use registry, the patient's qualifying medical condition and the daily dose amount, routes of administration, and forms of marijuana certified for the patient. The department shall also provide the board with such data for all patients registered in the medical marijuana use registry before August 1, 2019.

~~(5) RESPONSIBILITIES OF THE H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.—The H. Lee Moffitt Cancer Center and Research Institute, Inc., shall allocate staff and provide information and assistance, as the coalition's budget permits, to assist the board in fulfilling its responsibilities.~~

Section 3. Paragraph (h) of subsection (2) and paragraph (b) of subsection (3) of section 381.987, Florida Statutes, are amended to read:

381.987 Public records exemption for personal identifying information relating to medical marijuana held by the department.—

(2) The department shall allow access to the confidential and exempt information in the medical marijuana use registry to:

(h) The Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research ~~and Education~~ established in s. 1004.4351(4).

(3) The department shall allow access to the confidential and exempt information pertaining to the physician certification for marijuana and the dispensing thereof, whether in the

registry or otherwise held by the department, to:

(b) The Consortium ~~Coalition~~ for Medical Marijuana Clinical Outcomes Research ~~and Education~~ pursuant to s. 381.986 for the purpose of conducting research regarding the medical use of marijuana.

Section 4. (1) For the 2019-2020 fiscal year, the sum of $1.5 million in recurring funds is appropriated from the General Revenue Fund to the Board of Governors for the Consortium for Medical Marijuana Clinical Outcomes Research established under s. 1004.4351, Florida Statutes.

(2) For the 2018-2019 fiscal year, the sum of $391,333 in nonrecurring funds is appropriated from the Grants and Donations Trust Fund to the Department of Health for the purpose of implementing the requirements of this act.

(3) For the 2019-2020 fiscal year, the sum of $705,331 in recurring funds is appropriated from the Grants and Donations Trust Fund to the Department of Health for the purpose of implementing the requirements of this act.

Section 5. This act shall take effect upon becoming a law.

An act relating to immunization registry; amending s. 381.003, F.S.; revising provisions relating to the communicable disease prevention and control program under the Department of Health; providing that certain students who obtain vaccinations from a college or university student health center or clinic in the state may refuse to be included in the immunization registry; requiring a specified consent to treatment form to contain a certain notice; requiring that an opt-out form be provided to certain health care practitioners and entities upon administration of a vaccination; requiring that such form be submitted to the department; authorizing certain persons to submit such form directly to the department; requiring that any records or identifying information pertaining to a child or college or university student be removed from the registry under certain circumstances; providing requirements for electronic availability of, rather than transfer of, immunization records; requiring certain health care practitioners to report data to the immunization registry; authorizing the department to adopt rules; amending s. 1003.22, F.S.; revising school-entry health requirements to require students to have a certificate of immunization on file with the

department's immunization registry; requiring each district school board and the governing authority of each private school to establish and enforce a policy requiring the age-appropriate screening of students for scoliosis; providing an effective date.

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

Section 1. Section 381.003, Florida Statutes, is amended to read:

381.003 Communicable disease and AIDS prevention and control.—

(1) The department shall conduct a communicable disease prevention and control program as part of fulfilling its public health mission. A communicable disease is any disease caused by transmission of a specific infectious agent, or its toxic products, from an infected person, an infected animal, or the environment to a susceptible host, either directly or indirectly. The communicable disease program must include, but need not be limited to:

(a) Programs for the prevention and control of tuberculosis in accordance with chapter 392.

(b) Programs for the prevention and control of human immunodeficiency virus infection and acquired immune deficiency syndrome in accordance with chapter 384 and this chapter.

(c) Programs for the prevention and control of sexually transmissible diseases in accordance with chapter 384.

(d) Programs for the prevention, control, and reporting of communicable diseases of public health significance as provided for in this chapter.

(e) Programs for the prevention and control of vaccine-preventable diseases, including programs to immunize school children as required by s. 1003.22(3)-(11) and the development of an automated, electronic, and centralized database and ~~or~~ registry of immunizations. The department shall ensure that all children in this state are immunized against vaccine-preventable diseases. The immunization registry must ~~shall~~ allow the department to enhance current immunization activities for the purpose of improving the immunization of all children in this state.

1. Except as provided in subparagraph 2., the department shall include all children born in this state in the immunization registry by using the birth records from the Office of Vital Statistics. The department shall add other children to the registry as immunization services are provided.

2. The parent or guardian of a child may refuse to have the child included in the immunization registry by signing a form obtained from the department, or from the health care practitioner or entity that provides the immunization, which indicates that the parent or guardian does not wish to have the

child included in the immunization registry. Each consent to treatment form provided by a health care practitioner or by an entity that administers vaccinations or causes vaccinations to be administered to children from birth through 17 years of age must contain a notice stating that the parent or guardian of a child may refuse to have his or her child included in the immunization registry. The parent or guardian must provide such opt-out form to the health care practitioner or entity upon administration of the vaccination. Such health care practitioner or entity shall submit the form to the department. A parent or guardian may submit the opt-out form directly to the department. Any records or identifying information pertaining to the child shall be removed from ~~The decision to not participate in the immunization registry must be noted in~~ the registry, if the parent or guardian has refused to have his or her child included in the immunization registry.

3. A college or university student, from 18 years of age to 23 years of age, who obtains a vaccination from a college or university student health center or clinic in the state may refuse to be included in the immunization registry by signing a form obtained from the department, health center, or clinic which indicates that the student does not wish to be included in the immunization registry. The student must provide such opt-out form to the health center or clinic upon administration of the vaccination. Such health center or clinic shall submit the form

to the department. A student may submit the opt-out form directly to the department. Any records or identifying information pertaining to the student shall be removed from the registry if the student has refused to be included in the immunization registry.

4.~~3.~~ The immunization registry shall allow for immunization records to be electronically available ~~transferred~~ to entities that are required by law to have such records, including, but not limited to, schools and~~,~~ licensed child care facilities~~, and any other entity that is required by law to obtain proof of a child's immunizations~~.

5.~~4.~~ A ~~Any~~ health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to children from birth through 17 years of age is required to report vaccination data to the immunization registry, unless a parent or guardian of a child has refused to have the child included in the immunization registry by meeting the requirements of subparagraph 2. A health care practitioner licensed under chapter 458, chapter 459, or chapter 464 in this state who administers vaccinations or causes vaccinations to be administered to college or university students from 18 years of age to 23 years of age at a college or university student health center or clinic is required to report vaccination data to the immunization registry, unless the student has refused to be

included in the immunization registry by meeting the requirements of subparagraph 3. Vaccination data for students in other age ranges may be submitted to the immunization registry only if the student consents to inclusion in the immunization registry. The upload of data from existing automated systems is an acceptable method for updating immunization information in the immunization registry ~~complies with rules adopted by the department to access the immunization registry may, through the immunization registry, directly access immunization records and update a child's immunization history or exchange immunization information with another authorized practitioner, entity, or agency involved in a child's care~~. The information ~~included~~ in the immunization registry must include the child's name, date of birth, address, and any other unique identifier necessary to correctly identify the child; the immunization record, including the date, type of administered vaccine, and vaccine lot number; and the presence or absence of any adverse reaction or contraindication related to the immunization. Information received by the department for the immunization registry retains its status as confidential medical information and the department must maintain the confidentiality of that information as otherwise required by law. A health care practitioner or other agency that obtains information from the immunization registry must maintain the confidentiality of any medical records in accordance with s. 456.057 or as otherwise required

by law.

(2) The department may adopt rules pursuant to ss. 120.536(1) and 120.54 to implement this section~~, repeal, and amend rules related to the prevention and control of communicable diseases and the administration of the immunization registry. Such rules may include procedures for investigating disease, timeframes for reporting disease, definitions, procedures for managing specific diseases, requirements for followup reports of known or suspected exposure to disease, and procedures for providing access to confidential information necessary for disease investigations. For purposes of the immunization registry, the rules may include procedures for a health care practitioner to obtain authorization to use the immunization registry, methods for a parent or guardian to elect not to participate in the immunization registry, and procedures for a health care practitioner licensed under chapter 458, chapter 459, or chapter 464 to access and share electronic immunization records with other entities allowed by law to have access to the records~~.

Section 2. Subsection (4) of section 1003.22, Florida Statutes, is amended to read:

1003.22 School-entry health examinations; immunization against communicable diseases; exemptions; duties of Department of Health.—

(4) Each district school board and the governing authority

of each private school shall establish and enforce policies ~~as policy~~ that:~~,~~

(a) Prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, require each child to ~~present or~~ have on file with the immunization registry ~~school~~ a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health. Any child who is excluded from participation in the immunization registry pursuant to s. 381.003(1)(e)2. must present or have on file with the school such certification of immunization ~~and further shall provide for appropriate screening of its students for scoliosis at the proper age~~. ~~Such~~ Certification of immunization shall be made on forms approved and provided by the Department of Health or be on file with the immunization registry and shall become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

(b) Require the screening of students for scoliosis at the appropriate age.

Section 3. This act shall take effect January 1, 2021.

An act relating to health plans; amending s. 624.438, F.S.; revising eligibility requirements for multiple-employer welfare arrangements; creating s. 627.443, F.S.; defining the terms "EHB-benchmark plan" and "PPACA"; authorizing health insurers and health maintenance organizations to create new health insurance policies and health maintenance contracts meeting certain criteria for essential health benefits under the federal Patient Protection and Affordable Care Act (PPACA); providing that such criteria may be met by certain means; providing construction; providing that such policies and contracts created by health insurers and health maintenance organizations may be submitted to the Office of Insurance Regulation for certain purposes; amending s. 627.6045, F.S.; revising applicability; revising font size for disclosure; creating ss. 627.6046 and 627.65612, F.S.; defining the terms "operative date" and "preexisting medical condition" with respect to individual and group health insurance policies, respectively; requiring insurers, contingent upon the occurrence of either of two specified events, to make at least one comprehensive major medical health insurance policy available to certain individuals within a specified timeframe; prohibiting such insurers from excluding, limiting, denying, or delaying coverage under such policy due to preexisting medical conditions; requiring such policy to have been actively marketed

on a specified date and during a certain timeframe before that date; providing applicability; creating ss. 627.6426 and 627.6525, F.S.; defining the term "short-term health insurance"; providing disclosure requirements for short-term health insurance policies; amending s. 627.654, F.S.; revising requirements for association and small employer policies; providing construction; amending s. 641.31, F.S.; defining the terms "operative date" and "preexisting medical condition" with respect to health maintenance contracts; requiring health maintenance organizations, contingent upon the occurrence of either of two specified events, to make at least one comprehensive major medical health maintenance contract available to certain individuals within a specified timeframe; prohibiting such health maintenance organizations from excluding, limiting, denying, or delaying coverage under such contract due to preexisting medical conditions; requiring such contract to have been actively marketed on a specified date and during a certain timeframe before that date; defining the terms "EHB-benchmark plan" and "office"; requiring the office to conduct a study evaluating this state's current benchmark plan for essential health benefits under PPACA and options for changing the benchmark plan for future plan years; requiring the office, in conducting the study, to consider plans and certain benefits used by other states and to compare costs with those of this state; requiring the office to

solicit and consider proposed health plans from health insurers and health maintenance organizations in developing recommendations; requiring the office, by a certain date, to provide a report with certain recommendations and a certain analysis to the Governor and the Legislature; providing for severability; providing an effective date.

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

Section 1. Paragraph (b) of subsection (1) of section 624.438, Florida Statutes, is amended to read:

624.438 General eligibility.—

(1) To meet the requirements for issuance of a certificate of authority and to maintain a multiple-employer welfare arrangement, an arrangement:

(b)~~1.~~ Must be established by a trade association, industry association, ~~or~~ professional association of employers or professionals, or a bona fide group as defined in 29 C.F.R. part 2510.3-5 which has a constitution or bylaws specifically stating its purpose and which has been organized ~~and maintained in good faith for a continuous period of 1 year~~ for purposes in addition to ~~other than that of~~ obtaining or providing insurance.

~~2. Must not combine member employers from disparate trades, industries, or professions as defined by the appropriate licensing agencies, and must not combine member employers from more than one of the employer categories defined in sub-subparagraphs a.-c.~~

1.~~a.~~ A trade association consists of member employers who

are in the same trade as recognized by the appropriate licensing agency.

2.~~b.~~ An industry association consists of member employers who are in the same major group code, as defined by the Standard Industrial Classification Manual issued by the federal Office of Management and Budget, unless restricted by subparagraph 1. ~~sub-subparagraph a.~~ or subparagraph 3 ~~sub-subparagraph c~~.

3.~~c.~~ A professional association consists of member employers who are of the same profession as recognized by the appropriate licensing agency.

The requirements of this paragraph ~~subparagraph~~ do not apply to an arrangement licensed before ~~prior to~~ April 1, 1995, regardless of the nature of its business. However, an arrangement exempt from the requirements of this paragraph ~~subparagraph~~ may not expand the nature of its business beyond that set forth in the articles of incorporation of its sponsoring association as of April 1, 1995, except as authorized in this paragraph ~~subparagraph~~.

Section 2. Section 627.443, Florida Statutes, is created to read:

627.443 Essential health benefits.—

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

(a) "EHB-benchmark plan" has the same meaning as provided in 45 C.F.R. s. 156.20.

(b) "PPACA" has the same meaning as in s. 627.402.

(2) A health insurer or health maintenance organization issuing or delivering an individual or a group health insurance policy or health maintenance contract in this state may create a

new health insurance policy or health maintenance contract that:

(a) Must include at least one service or coverage under each of the 10 essential health benefits categories under 42 U.S.C. s. 18022(b) which are required under PPACA;

(b) May fulfill the requirement in paragraph (a) by selecting one or more services or coverages for each of the required categories from the list of essential health benefits required by any single state or multiple states; and

(c) May comply with paragraphs (a) and (b) by selecting one or more services or coverages from any one or more of the required categories of essential health benefits from one state or multiple states.

(3) This section specifically authorizes an insurer or health maintenance organization to include any combination of services or coverages required by any one or a combination of states to provide the 10 categories of essential health benefits required under PPACA in a policy or contract issued in this state.

(4) Health insurance policies and health maintenance contracts created by health insurers and health maintenance organizations under this section:

(a) May be submitted to the office for consideration as part of the office’s study of this state’s essential health benefits benchmark plan; and

(b) May also be submitted to the office for evaluation as equivalent to the current state EHB-benchmark plan or to any EHB-benchmark plan created in the future.

Section 3. Subsection (3) of section 627.6045, Florida Statutes, is amended to read:

627.6045 Preexisting condition.—A health insurance policy must comply with the following:

(3) This section does not apply to short-term~~, nonrenewable~~ health insurance ~~policies of no more than a 6-month policy term~~, provided that it is clearly disclosed to the applicant in the advertising and application, in 14-point ~~10-point~~ contrasting type, that "This policy does not meet the definition of qualifying previous coverage or qualifying existing coverage as defined in s. 627.6699. As a result, if purchased in lieu of a conversion policy or other group coverage, you may have to meet a preexisting condition requirement when renewing or purchasing other coverage."

Section 4. Section 627.6046, Florida Statutes, is created to read:

627.6046 Limit on preexisting conditions.—

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

(a) "Operative date" means the date on which either of the following occurs with respect to the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (PPACA):

1. A federal law is enacted which expressly repeals PPACA; or

2. PPACA is invalidated by the United States Supreme Court.

(b) "Preexisting medical condition" means a condition that was present before the effective date of coverage under a policy, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before the effective date of coverage. The term includes a condition identified as a

result of a preenrollment questionnaire or physical examination given to the individual, or review of medical records relating to the preenrollment period.

(2)(a) Not later than 30 days after the operative date, and notwithstanding s. 627.6045 or any other law to the contrary, every insurer issuing, delivering, or issuing for delivery comprehensive major medical individual health insurance policies in this state shall make at least one comprehensive major medical health insurance policy available to residents in the insurer's approved service areas of this state, and such insurer may not exclude, limit, deny, or delay coverage under such policy due to one or more preexisting medical conditions.

(b) An insurer may not limit or exclude benefits under such policy, including a denial of coverage applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage, or if coverage is denied, the date of the denial.

(3) The comprehensive major medical health insurance policy that the insurer is required to offer under this section must be a policy that had been actively marketed in this state by the insurer as of the operative date and that was also actively marketed in this state during the year immediately preceding the operative date.

Section 5. Section 627.6426, Florida Statutes, is created to read:

627.6426 Short-term health insurance.—

(1) For purposes of this part, the term "short-term health insurance" means health insurance coverage provided by an issuer

with an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account renewals or extensions, has a duration not to exceed 36 months in total.

(2) All contracts for short-term health insurance entered into by an issuer and an individual seeking coverage shall include the following disclosure:

"This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Patient Protection and Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage."

Section 6. Section 627.6525, Florida Statutes, is created to read:

627.6525 Short-term health insurance.—

(1) For purposes of this part, the term "short-term health insurance" means a group, blanket, or franchise policy of health insurance coverage provided by an issuer with an expiration date specified in the contract that is less than 12 months after the original effective date of the contract and, taking into account

renewals or extensions, has a duration not to exceed 36 months in total.

(2) All contracts for short-term health insurance entered into by an issuer and a party seeking coverage shall include the following disclosure:

"This coverage is not required to comply with certain federal market requirements for health insurance, principally those contained in the Patient Protection and Affordable Care Act. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage."

Section 7. Subsection (1) of section 627.654, Florida Statutes, is amended to read:

627.654 Labor union, association, and small employer health alliance groups.—

(1)(a) A bona fide group or association of employers, as defined in 29 C.F.R. part 2510.3-5, or a group of individuals may be insured under a policy issued to an association, including a labor union, which association has a constitution and bylaws ~~and not less than 25 individual members~~ and which has been organized ~~and has been maintained in good faith for a~~

~~period of 1 year~~ for purposes in addition to ~~other than~~ that of obtaining insurance, or to the trustees of a fund established by such an association, which association or trustees shall be deemed the policyholder, insuring at least 15 individual members of the association for the benefit of persons other than the officers of the association, the association, or trustees.

(b) A small employer, as defined in s. 627.6699 and including the employer's eligible employees and the spouses and dependents of such employees, may be insured under a policy issued to a small employer health alliance by a carrier as defined in s. 627.6699. ~~A small employer health alliance must be organized as a not-for-profit corporation under chapter 617. Notwithstanding any other law, if a small employer member of an alliance loses eligibility to purchase health care through the alliance solely because the business of the small employer member expands to more than 50 and fewer than 75 eligible employees, the small employer member may, at its next renewal date, purchase coverage through the alliance for not more than 1 additional year. A small employer health alliance shall establish conditions of participation in the alliance by a small employer, including, but not limited to:~~

~~1. Assurance that the small employer is not formed for the purpose of securing health benefit coverage.~~

~~2. Assurance that the employees of a small employer have not been added for the purpose of securing health benefit coverage.~~

Section 8. Section 627.65612, Florida Statutes, is created to read:

627.65612 Limit on preexisting conditions.—

(1) As used in this section, the terms "operative date" and "preexisting medical condition" have the same meanings as provided in s. 627.6046.

(2)(a) Not later than 30 days after the operative date, and notwithstanding s. 627.6561 or any other law to the contrary, every insurer issuing, delivering, or issuing for delivery comprehensive major medical group health insurance policies in this state shall make at least one comprehensive major medical health insurance policy available to residents in the insurer's approved service areas of this state, and such insurer may not exclude, limit, deny, or delay coverage under such policy due to one or more preexisting medical conditions.

(b) An insurer may not limit or exclude benefits under such policy, including a denial of coverage applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage, or if coverage is denied, the date of the denial.

(3) The comprehensive major medical health insurance policy that the insurer is required to offer under this section must be a policy that had been actively marketed in this state by the insurer as of the operative date and that was also actively marketed in this state during the year immediately preceding the operative date.

Section 9. Subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45)(a) As used in this subsection, the terms "operative date" and "preexisting medical condition" have the same meanings

as provided in s. 627.6046.

(b) Not later than 30 days after the operative date, and notwithstanding s. 641.31071 or any other law to the contrary, every health maintenance organization issuing, delivering, or issuing for delivery comprehensive major medical individual or group contracts in this state shall make at least one comprehensive major medical health maintenance contract available to residents in the health maintenance organization's approved service areas of this state, and such health maintenance organization may not exclude, limit, deny, or delay coverage under such contract due to one or more preexisting medical conditions. A health maintenance organization may not limit or exclude benefits under such contract, including a denial of coverage applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage, or if coverage is denied, the date of the denial.

(c) The comprehensive major medical health maintenance contract the health maintenance organization is required to offer under this section must be a contract that had been actively marketed in this state by the health maintenance organization as of the operative date and that was also actively marketed in this state during the year immediately preceding the operative date.

Section 10. Study of state essential health benefits benchmark plan; report.—

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

(a) "EHB-benchmark plan" has the same meaning as provided in 45 C.F.R. s. 156.20.

(b) "Office" means the Office of Insurance Regulation.

(2) The office shall conduct a study to evaluate this state's current EHB-benchmark plan for nongrandfathered individual and group health plans and options for changing the EHB-benchmark plan pursuant to 45 C.F.R. s. 156.111 for future plan years. In conducting the study, the office shall:

(a) Consider EHB-benchmark plans and benefits under the 10 essential health benefits categories established under 45 C.F.R. s. 156.110(a) which are used by the other 49 states;

(b) Compare the costs of benefits within such categories and overall costs of EHB-benchmark plans used by other states with the costs of benefits within the categories and overall costs of the current EHB-benchmark plan of this state; and

(c) Solicit and consider proposed individual and group health plans from health insurers and health maintenance organizations in developing recommendations for changes to the current EHB-benchmark plan.

(3) By October 30, 2019, the office shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include recommendations for changing the current EHB-benchmark plan to provide comprehensive care at a lower cost than this state's current EHB-benchmark plan. In its report, the office shall provide an analysis as to whether proposed health plans it receives under paragraph (2)(c) meet the requirements for an EHB-benchmark plan under 45 C.F.R. s. 156.111(b).

Section 11. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act

which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

Section 12. This act shall take effect upon becoming a law.

An act relating to substance abuse services; amending s. 394.4572, F.S.; authorizing the Department of Children and Families and the Agency for Health Care Administration to grant exemptions from disqualification for certain service provider personnel; amending s. 397.311, F.S.; providing and revising definitions; amending s. 397.321, F.S.; providing for review by the department of certain decisions made by a department-recognized credentialing entity; authorizing certain persons to request an administrative hearing within a specified timeframe under certain conditions; amending s. 397.4073, F.S.; requiring individuals screened on or after a specified date to undergo specified background screening; requiring the department to grant or deny a request for an exemption from qualification within a certain timeframe; authorizing certain applicants for an exemption to work under the supervision of certain persons for a specified period of time while his or her application is pending; authorizing certain persons to be exempt from disqualification from employment; authorizing the department to grant exemptions from disqualification for service provider personnel to work solely in certain treatment

programs, facilities, or recovery residences; amending s. 397.4075, F.S.; increasing the criminal penalty for certain unlawful activities relating to personnel; providing a criminal penalty for inaccurately disclosing certain facts in an application for licensure; creating s. 397.417, F.S.; authorizing an individual to seek certification as a peer specialist if he or she meets certain requirements; requiring the department to approve one or more third-party credentialing entities for specified purposes; requiring the credentialing entity to demonstrate compliance with certain standards in order to be approved by the department; requiring an individual providing department-funded recovery support services as a peer specialist to be certified; authorizing an individual who is not certified to provide recovery support services as a peer specialist under certain circumstances; amending s. 397.487, F.S.; revising legislative findings relating to voluntary certification of recovery residences; revising background screening requirements for owners, directors, and chief financial officers of recovery residences; providing for review by the department of certain decisions made by a department-recognized credentialing entity; authorizing certain recovery

residences to request an administrative hearing within a specified timeframe under certain conditions; authorizing certain recovery residences to immediately discharge or transfer residents under certain circumstances; amending s. 397.4873, F.S.; expanding the exceptions to limitations on referrals by recovery residences to licensed service providers; amending s. 397.55, F.S.; revising the requirements for a service provider, operator of a recovery residence, or certain third parties to enter into certain contracts with marketing providers; amending s. 435.07, F.S.; authorizing the exemption of certain persons from disqualification from employment; amending s. 817.505, F.S.; revising provisions relating to payment practices exempt from prohibitions on patient brokering; amending ss. 212.055, 397.416, and 440.102, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Subsection (2) of section 394.4572, Florida Statutes, is amended to read:

394.4572 Screening of mental health personnel.—

(2)(a) The department or the Agency for Health Care

Administration may grant exemptions from disqualification as provided in chapter 435.

(b) The department or the Agency for Health Care Administration, as applicable, may grant exemptions from disqualification for service provider personnel to work solely in mental health treatment programs or facilities, or in programs or facilities that treat co-occurring substance use and mental health disorders.

Section 2. Subsections (30) through (49) of section 397.311, Florida Statutes, are renumbered as subsections (31) through (50), respectively, subsection (8) and present subsection (37) of that section are amended, and subsection (30) is added to that section, to read:

397.311 Definitions.—As used in this chapter, except part VIII, the term:

(8) "Clinical supervisor" means a person who meets the requirements of a qualified professional whose functions include managing ~~manages~~ personnel who provide direct clinical services or maintaining lead responsibility for the overall coordination and provision of clinical services ~~treatment~~.

(30) "Peer specialist" means a person who has been in recovery from a substance use disorder or mental illness for at least 2 years who uses his or her personal experience to provide services in behavioral health settings to support others in their recovery, or a person who has at least 2 years of

experience as a family member or caregiver of an individual who has a substance use disorder or mental illness. The term does not include a qualified professional or a person otherwise certified under chapter 394 or this chapter.

(38)~~(37)~~ "Recovery residence" means a residential dwelling unit, the community housing component of a licensed day or night treatment facility with community housing, or other form of group housing, which ~~that~~ is offered or advertised through any means, including oral, written, electronic, or printed means, by any person or entity as a residence that provides a peer-supported, alcohol-free, and drug-free living environment.

Section 3. Subsection (15) of section 397.321, Florida Statutes, is amended to read:

397.321 Duties of the department.—The department shall:

(15) Recognize a statewide certification process for addiction professionals and identify and endorse one or more entities ~~agencies~~ responsible for such certification of service provider personnel. Any decision by a department-recognized credentialing entity to deny, revoke, or suspend a certification, or otherwise impose sanctions on an individual who is certified, is reviewable by the department. Upon receiving an adverse determination, the person aggrieved may request an administrative hearing pursuant to ss. 120.569 and 120.57(1) within 30 days after completing any appeals process offered by the credentialing entity or the department, as

applicable.

Section 4. Paragraphs (a), (f), and (g) of subsection (1) and subsection (4) of section 397.4073, Florida Statutes, are amended to read:

397.4073 Background checks of service provider personnel.—

(1) PERSONNEL BACKGROUND CHECKS; REQUIREMENTS AND EXCEPTIONS.—

(a) For all individuals screened on or after July 1, 2019, background checks shall apply as follows:

1. All owners, directors, chief financial officers, and clinical supervisors of service providers are subject to level 2 background screening as provided under s. 408.809 and chapter 435. Inmate substance abuse programs operated directly or under contract with the Department of Corrections are exempt from this requirement.

2. All service provider personnel who have direct contact with children receiving services or with adults who are developmentally disabled receiving services are subject to level 2 background screening as provided under s. 408.809 and chapter 435.

3. All peer specialists who have direct contact with individuals receiving services are subject to level 2 background screening as provided under s. 408.809 and chapter 435.

(f) Service provider personnel who request an exemption from disqualification must submit the request within 30 days

after being notified of the disqualification. The department shall grant or deny the request within 60 days after receipt of a complete application.

(g) If 5 years or more, or 3 years or more in the case of a certified peer specialist or an individual seeking certification as a peer specialist pursuant to s. 397.417, have elapsed since an applicant for an exemption from disqualification has completed or has been lawfully released from confinement, supervision, or a nonmonetary condition imposed by a court for the applicant's most recent disqualifying offense, the applicant may work with adults with substance use disorders or co-occurring disorders under the supervision of persons who meet all personnel requirements of this chapter for up to 90 days after being notified of his or her disqualification or until the department makes a final determination regarding his or her request for an exemption from disqualification, whichever is earlier ~~the most recent disqualifying offense, service provider personnel may work with adults with substance use disorders under the supervision of a qualified professional licensed under chapter 490 or chapter 491 or a master's-level-certified addictions professional until the agency makes a final determination regarding the request for an exemption from disqualification~~.

(h) ~~(g)~~ The department may not issue a regular license to any service provider that fails to provide proof that background

screening information has been submitted in accordance with chapter 435.

(4) EXEMPTIONS FROM DISQUALIFICATION.—

(a) The department may grant to any service provider personnel an exemption from disqualification as provided in s. 435.07.

(b) Since rehabilitated substance abuse impaired persons are effective in the successful treatment and rehabilitation of individuals with substance use disorders, for service providers which treat adolescents 13 years of age and older, service provider personnel whose background checks indicate crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, and any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this paragraph.

(c) The department may grant exemptions from disqualification for service provider personnel to work solely in substance use disorder treatment programs, facilities, or recovery residences or in programs or facilities that treat co-occurring substance use and mental health disorders. The department may further limit such ~~grant~~ exemptions from disqualification ~~which would limit service provider personnel~~ to working with adults in substance abuse treatment facilities.

Section 5. Section 397.4075, Florida Statutes, is amended

to read:

397.4075 Unlawful activities relating to personnel; penalties.—It is a felony of the third ~~misdemeanor of the first~~ degree, punishable as provided in s. 775.082 or s. 775.083, for any person willfully, knowingly, or intentionally to:

(1) Inaccurately disclose by false statement, misrepresentation, impersonation, or other fraudulent means, or fail to disclose, in any application for licensure or voluntary or paid employment, any fact which is material in making a determination as to the person's qualifications to be an owner, a director, a volunteer, or other personnel of a service provider;

(2) Operate or attempt to operate as a service provider with personnel who are in noncompliance with the minimum standards contained in this chapter; or

(3) Use or release any criminal or juvenile information obtained under this chapter for any purpose other than background checks of personnel for employment.

Section 6. Section 397.417, Florida Statutes, is created to read:

397.417 Peer specialists.—

(1) An individual may seek certification as a peer specialist if he or she has been in recovery from a substance use disorder or mental illness for at least 2 years, or if he or she has at least 2 years of experience as a family member or

caregiver of a person with a substance use disorder or mental illness.

(2) The department shall approve one or more third-party credentialing entities for the purposes of certifying peer specialists, approving training programs for individuals seeking certification as peer specialists, approving continuing education programs, and establishing the minimum requirements and standards that applicants must achieve to maintain certification. To obtain approval, the third-party credentialing entity must demonstrate compliance with nationally recognized standards for developing and administering professional certification programs to certify peer specialists.

(3) An individual providing department-funded recovery support services as a peer specialist shall be certified pursuant to subsection (2). An individual who is not certified may provide recovery support services as a peer specialist for up to 1 year if he or she is working toward certification and is supervised by a qualified professional or by a certified peer specialist who has at least 3 years of full-time experience as a peer specialist at a licensed behavioral health organization.

Section 7. Subsections (1) and (6) of section 397.487, Florida Statutes, are amended, paragraph (e) is added to subsection (8), and subsection (11) is added to that section, to read:

397.487 Voluntary certification of recovery residences.—

(1) The Legislature finds that a person suffering from addiction has a higher success rate of achieving long-lasting sobriety when given the opportunity to build a stronger foundation by living in a recovery residence while receiving treatment or after completing treatment. The Legislature further finds that this state and its subdivisions have a legitimate state interest in protecting these persons, who represent a vulnerable consumer population in need of adequate housing. It is the intent of the Legislature to protect persons who reside in a recovery residence.

(6) All owners, directors, and chief financial officers of an applicant recovery residence are subject to level 2 background screening as provided under s. 408.809 and chapter 435. A recovery residence is ineligible for certification, and a credentialing entity shall deny a recovery residence's application, if any owner, director, or chief financial officer has been found guilty of, or has entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in s. 408.809(4) or s. 435.04(2) unless the department has issued an exemption under s. 397.4073 or s. 397.4872. In accordance with s. 435.04, the department shall notify the credentialing agency of an owner's, director's, or chief financial officer's eligibility based on the results of his or her background screening.

(8) Onsite followup monitoring of a certified recovery

residence may be conducted by the credentialing entity to determine continuing compliance with certification requirements. The credentialing entity shall inspect each certified recovery residence at least annually to ensure compliance.

(e) Any decision by a department-recognized credentialing entity to deny, revoke, or suspend a certification, or otherwise impose sanctions on a recovery residence, is reviewable by the department. Upon receiving an adverse determination, the recovery residence may request an administrative hearing pursuant to ss. 120.569 and 120.57(1) within 30 days after completing any appeals process offered by the credentialing entity or the department, as applicable.

(11) Notwithstanding any landlord and tenant rights and obligations under chapter 83, a recovery residence that is certified under this section and has a discharge policy approved by a department-recognized credentialing entity may immediately discharge or transfer a resident in accordance with that policy under any of the following circumstances:

(a) The discharge or transfer is necessary for the resident's welfare.

(b) The resident's needs cannot be met at the recovery residence.

(c) The health and safety of other residents or recovery residence employees is at risk or would be at risk if the resident continues to live at the recovery residence.

Section 8. Paragraph (d) is added to subsection (2) of section 397.4873, Florida Statutes, and subsection (1) of that section is republished, to read:

397.4873 Referrals to or from recovery residences; prohibitions; penalties.—

(1) A service provider licensed under this part may not make a referral of a prospective, current, or discharged patient to, or accept a referral of such a patient from, a recovery residence unless the recovery residence holds a valid certificate of compliance as provided in s. 397.487 and is actively managed by a certified recovery residence administrator as provided in s. 397.4871.

(2) Subsection (1) does not apply to:

(d) The referral of a patient to, or acceptance of a referral of such a patient from, a recovery residence that has no direct or indirect financial or other referral relationship with the licensed service provider and that is democratically operated by its residents pursuant to a charter from an entity recognized or sanctioned by Congress, and where the residence or any resident of the residence does not receive a benefit, directly or indirectly, for the referral.

Section 9. Paragraph (d) of subsection (1) of section 397.55, Florida Statutes, is amended to read:

397.55 Prohibition of deceptive marketing practices.—

(1) The Legislature recognizes that consumers of substance

abuse treatment have disabling conditions and that such consumers and their families are vulnerable and at risk of being easily victimized by fraudulent marketing practices that adversely impact the delivery of health care. To protect the health, safety, and welfare of this vulnerable population, a service provider, an operator of a recovery residence, or a third party who provides any form of advertising or marketing services to a service provider or an operator of a recovery residence may not engage in any of the following marketing practices:

(d) Entering into a contract with a marketing provider who agrees to generate referrals or leads for the placement of patients with a service provider or in a recovery residence through a call center or a web-based presence, unless the contract requires such agreement and the marketing provider ~~service provider or the operator of the recovery residence~~ discloses the following to the prospective patient so that the patient can make an informed health care decision:

1. Information about the specific licensed service providers or recovery residences that are represented by the marketing provider and pay a fee to the marketing provider, including the identity of such service providers or recovery residences; and

2. Clear and concise instructions that allow the prospective patient to easily access lists of licensed service

providers and recovery residences on the department website.

Section 10. Subsection (2) of section 435.07, Florida Statutes, is amended to read:

435.07 Exemptions from disqualification.—Unless otherwise provided by law, the provisions of this section apply to exemptions from disqualification for disqualifying offenses revealed pursuant to background screenings required under this chapter, regardless of whether those disqualifying offenses are listed in this chapter or other laws.

(2) Persons employed, or applicants for employment, by treatment providers who treat adolescents 13 years of age and older who are disqualified from employment solely because of crimes under s. 796.07(2)(e), s. 810.02(4), s. 812.014(2)(c), s. 817.563, s. 831.01, s. 831.02, s. 893.13, or s. 893.147, or any related criminal attempt, solicitation, or conspiracy under s. 777.04, may be exempted from disqualification from employment pursuant to this chapter without application of the waiting period in subparagraph (1)(a)1.

Section 11. Subsection (3) of section 817.505, Florida Statutes, is amended to read:

817.505 Patient brokering prohibited; exceptions; penalties.—

(3) This section shall not apply to the following payment practices:

(a) Any discount, payment, waiver of payment, or payment

practice expressly authorized ~~not prohibited~~ by 42 U.S.C. s. 1320a-7b(b)(3) ~~42 U.S.C. s. 1320a-7b(b)~~ or regulations adopted ~~promulgated~~ thereunder.

(b) Any payment, compensation, or financial arrangement within a group practice as defined in s. 456.053, provided such payment, compensation, or arrangement is not to or from persons who are not members of the group practice.

(c) Payments to a health care provider or health care facility for professional consultation services.

(d) Commissions, fees, or other remuneration lawfully paid to insurance agents as provided under the insurance code.

(e) Payments by a health insurer who reimburses, provides, offers to provide, or administers health, mental health, or substance abuse goods or services under a health benefit plan.

(f) Payments to or by a health care provider or health care facility, or a health care provider network entity, that has contracted with a health insurer, a health care purchasing group, or the Medicare or Medicaid program to provide health, mental health, or substance abuse goods or services under a health benefit plan when such payments are for goods or services under the plan. However, nothing in this section affects whether a health care provider network entity is an insurer required to be licensed under the Florida Insurance Code.

(g) Insurance advertising gifts lawfully permitted under s. 626.9541(1)(m).

(h) Commissions or fees paid to a nurse registry licensed under s. 400.506 for referring persons providing health care services to clients of the nurse registry.

(i) Payments by a health care provider or health care facility to a health, mental health, or substance abuse information service that provides information upon request and without charge to consumers about providers of health care goods or services to enable consumers to select appropriate providers or facilities, provided that such information service:

1. Does not attempt through its standard questions for solicitation of consumer criteria or through any other means to steer or lead a consumer to select or consider selection of a particular health care provider or health care facility;

2. Does not provide or represent itself as providing diagnostic or counseling services or assessments of illness or injury and does not make any promises of cure or guarantees of treatment;

3. Does not provide or arrange for transportation of a consumer to or from the location of a health care provider or health care facility; and

4. Charges and collects fees from a health care provider or health care facility participating in its services that are set in advance, are consistent with the fair market value for those information services, and are not based on the potential value of a patient or patients to a health care provider or

health care facility or of the goods or services provided by the health care provider or health care facility.

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

Section 12. Paragraph (e) of subsection (5) of section 212.055, Florida Statutes, is amended to read:

212.055 Discretionary sales surtaxes; legislative intent; authorization and use of proceeds.—It is the legislative intent that any authorization for imposition of a discretionary sales surtax shall be published in the Florida Statutes as a subsection of this section, irrespective of the duration of the levy. Each enactment shall specify the types of counties authorized to levy; the rate or rates which may be imposed; the maximum length of time the surtax may be imposed, if any; the procedure which must be followed to secure voter approval, if required; the purpose for which the proceeds may be expended; and such other requirements as the Legislature may provide. Taxable transactions and administrative procedures shall be as provided in s. 212.054.

(5) COUNTY PUBLIC HOSPITAL SURTAX.—Any county as defined in s. 125.011(1) may levy the surtax authorized in this subsection pursuant to an ordinance either approved by extraordinary vote of the county commission or conditioned to take effect only upon approval by a majority vote of the electors of the county voting in a referendum. In a county as defined in s. 125.011(1), for the purposes of this subsection,

"county public general hospital" means a general hospital as defined in s. 395.002 which is owned, operated, maintained, or governed by the county or its agency, authority, or public health trust.

(e) A governing board, agency, or authority shall be chartered by the county commission upon this act becoming law. The governing board, agency, or authority shall adopt and implement a health care plan for indigent health care services. The governing board, agency, or authority shall consist of no more than seven and no fewer than five members appointed by the county commission. The members of the governing board, agency, or authority shall be at least 18 years of age and residents of the county. No member may be employed by or affiliated with a health care provider or the public health trust, agency, or authority responsible for the county public general hospital. The following community organizations shall each appoint a representative to a nominating committee: the South Florida Hospital and Healthcare Association, the Miami-Dade County Public Health Trust, the Dade County Medical Association, the Miami-Dade County Homeless Trust, and the Mayor of Miami-Dade County. This committee shall nominate between 10 and 14 county citizens for the governing board, agency, or authority. The slate shall be presented to the county commission and the county commission shall confirm the top five to seven nominees, depending on the size of the governing board. Until such time as

the governing board, agency, or authority is created, the funds provided for in subparagraph (d)2. shall be placed in a restricted account set aside from other county funds and not disbursed by the county for any other purpose.

1. The plan shall divide the county into a minimum of four and maximum of six service areas, with no more than one participant hospital per service area. The county public general hospital shall be designated as the provider for one of the service areas. Services shall be provided through participants' primary acute care facilities.

2. The plan and subsequent amendments to it shall fund a defined range of health care services for both indigent persons and the medically poor, including primary care, preventive care, hospital emergency room care, and hospital care necessary to stabilize the patient. For the purposes of this section, "stabilization" means stabilization as defined in s. 397.311 ~~s. 397.311(45)~~. Where consistent with these objectives, the plan may include services rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital per service area. The plan shall provide that agreements negotiated between the governing board, agency, or authority and providers shall recognize hospitals that render a disproportionate share of indigent care, provide other incentives to promote the delivery of charity care to draw down federal funds where appropriate, and require cost

containment, including, but not limited to, case management. From the funds specified in subparagraphs (d)1. and 2. for indigent health care services, service providers shall receive reimbursement at a Medicaid rate to be determined by the governing board, agency, or authority created pursuant to this paragraph for the initial emergency room visit, and a per-member per-month fee or capitation for those members enrolled in their service area, as compensation for the services rendered following the initial emergency visit. Except for provisions of emergency services, upon determination of eligibility, enrollment shall be deemed to have occurred at the time services were rendered. The provisions for specific reimbursement of emergency services shall be repealed on July 1, 2001, unless otherwise reenacted by the Legislature. The capitation amount or rate shall be determined before program implementation by an independent actuarial consultant. In no event shall such reimbursement rates exceed the Medicaid rate. The plan must also provide that any hospitals owned and operated by government entities on or after the effective date of this act must, as a condition of receiving funds under this subsection, afford public access equal to that provided under s. 286.011 as to any meeting of the governing board, agency, or authority the subject of which is budgeting resources for the retention of charity care, as that term is defined in the rules of the Agency for Health Care Administration. The plan shall also include

innovative health care programs that provide cost-effective alternatives to traditional methods of service and delivery funding.

3. The plan's benefits shall be made available to all county residents currently eligible to receive health care services as indigents or medically poor as defined in paragraph (4)(d).

4. Eligible residents who participate in the health care plan shall receive coverage for a period of 12 months or the period extending from the time of enrollment to the end of the current fiscal year, per enrollment period, whichever is less.

5. At the end of each fiscal year, the governing board, agency, or authority shall prepare an audit that reviews the budget of the plan, delivery of services, and quality of services, and makes recommendations to increase the plan's efficiency. The audit shall take into account participant hospital satisfaction with the plan and assess the amount of poststabilization patient transfers requested, and accepted or denied, by the county public general hospital.

Section 13. Section 397.416, Florida Statutes, is amended to read:

397.416 Substance abuse treatment services; qualified professional.—Notwithstanding any other provision of law, a person who was certified through a certification process recognized by the former Department of Health and Rehabilitative

Services before January 1, 1995, may perform the duties of a qualified professional with respect to substance abuse treatment services as defined in this chapter, and need not meet the certification requirements contained in s. 397.311(35) ~~s. 397.311(34)~~.

Section 14. Paragraphs (d) and (g) of subsection (1) of section 440.102, Florida Statutes, are amended to read:

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

(1) DEFINITIONS.—Except where the context otherwise requires, as used in this act:

(d) "Drug rehabilitation program" means a service provider as defined in s. 397.311 which~~, established pursuant to s. 397.311(43), that~~ provides confidential, timely, and expert identification, assessment, and resolution of employee drug abuse.

(g) "Employee assistance program" means an established program capable of providing expert assessment of employee personal concerns; confidential and timely identification services with regard to employee drug abuse; referrals of employees for appropriate diagnosis, treatment, and assistance; and followup services for employees who participate in the program or require monitoring after returning to work. If, in

addition to the above activities, an employee assistance program provides diagnostic and treatment services, these services shall in all cases be provided by service providers as defined in s. 397.311 ~~pursuant to s. 397.311(43)~~.

Section 15. This act shall take effect July 1, 2019.

A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; defining the term "electronic health recordkeeping system"; authorizing the Department of Health to enter into reciprocal agreements to share prescription drug monitoring information with the United States Department of Veterans Affairs, the United States Department of Defense, or the Indian Health Service; providing requirements for such agreements; providing an exemption from the requirement to check a patient's dispensing history before the prescribing of or dispensing of a controlled substance for prescribing for or dispensing to patients admitted to hospice for the alleviation of pain related to a terminal condition or to patients receiving palliative care for terminal illnesses; providing an effective date.

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

Section 1. Paragraphs (f) through (k) of subsection (1) of section 893.055, Florida Statutes, are redesignated as paragraphs (g) through (l), respectively, subsections (6) and (8), are amended, and a new paragraph (f) is added to subsection (1) of that section, to read:

893.055 Prescription drug monitoring program.—

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

(f) "Electronic health recordkeeping system" means an electronic or computer-based information system used by health care practitioners or providers to create, collect, store, manipulate, exchange, or make available personal health information for the delivery of patient care.

(6) The department may enter into one or more reciprocal agreements or contracts to share prescription drug monitoring information with other states, districts, ~~or~~ territories, the United States Department of Veterans Affairs, the United States Department of Defense, or the Indian Health Service if the prescription drug monitoring programs of such other states, districts, ~~or~~ territories, the United States Department of Veterans Affairs, the United States Department of Defense, or the Indian Health Service are compatible with the Florida program.

(a) In determining compatibility, the department shall consider:

1. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.

2. The persons authorized to view the data collected by the program. Comparable entities and licensed health care practitioners in other states, districts, or territories of the United States; law enforcement agencies; the Attorney General's

Medicaid Fraud Control Unit; medical regulatory boards; the United States Department of Veterans Affairs; the United States Department of Defense; the Indian Health Service; and, as needed, management staff who have similar duties as management staff who work with the prescription drug monitoring program as authorized in s. 893.0551 are authorized access upon approval by the department.

3. The schedules of the controlled substances that are monitored by the program.

4. The data reported to or included in the program's system.

5. Any implementing criteria deemed essential for a thorough comparison.

6. The costs and benefits to the state of sharing prescription information.

(b) The department shall assess the prescription drug monitoring program's continued compatibility every 4 years with programs from other states ~~states'~~, districts ~~districts'~~, territories, the United States Department of Veterans Affairs, the United States Department of Defense, or the Indian Health Service ~~or territories' programs every 4 years~~.

(c) Any agreements or contracts for sharing of prescription drug monitoring information between the department and other states, districts, ~~or~~ territories, the United States Department of Veterans Affairs, the United States Department of

Defense, or the Indian Health Service shall contain the same restrictions and requirements as this section or s. 893.0551, and the information must be provided according to the department's determination of compatibility.

(8) A prescriber or dispenser or a designee of a prescriber or dispenser must consult the system to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient age 16 or older. This requirement does not apply when prescribing or dispensing a nonopioid controlled substance listed in Schedule V of s. 893.03 or 21 U.S.C. 812 or prescribing or dispensing a controlled substance to a patient who has been admitted to hospice pursuant to s. 400.6095. For purposes of this subsection, a "nonopioid controlled substance" is a controlled substance that does not contain any amount of a substance listed as an opioid in s. 893.03 or 21 U.S.C. 812.

(a) The duty to consult the system does not apply when the system:

1. Is determined by the department to be nonoperational; or

2. Cannot be accessed by the prescriber or dispenser or a designee of the prescriber or dispenser because of a temporary technological or electrical failure.

(b) A prescriber or dispenser or designee of a prescriber or dispenser who does not consult the system under this

subsection shall document the reason he or she did not consult the system in the patient's medical record or prescription record and shall not prescribe or dispense greater than a 3-day supply of a controlled substance to the patient.

(c) The department shall issue a nondisciplinary citation to any prescriber or dispenser who fails to consult the system as required by this subsection for an initial offense. Each subsequent offense is subject to disciplinary action pursuant to s. 456.073.

Section 2. This act shall take effect July 1, 2019.

An act relating to nonemergency medical transportation services; amending s. 316.87, F.S.; authorizing certain transportation network companies to provide nonemergency medical transportation services to a Medicaid recipient under certain circumstances; requiring the Agency for Health Care Administration to update its regulations, policies, or other guidance by a specified date to reflect such authorization; providing limitations on requirements for transportation network companies and transportation network company drivers; providing construction; providing an effective date.

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

Section 1. Section 316.87, Florida Statutes, is amended to read:

316.87 Nonemergency medical transportation services.—

(1) To ensure the availability of nonemergency medical transportation services throughout the state, a provider licensed by the county or operating under a permit issued by the county may not be required to use a vehicle that is larger than needed to transport the number of persons being transported or that is inconsistent with the medical condition of the

individuals receiving the nonemergency medical transportation services. This subsection ~~section~~ does not apply to the procurement, contracting, or provision of paratransit transportation services, directly or indirectly, by a county or an authority, pursuant to the Americans with Disabilities Act of 1990, as amended.

(2) Subject to compliance with state and federal Medicaid requirements, a transportation network company that:

(a) Is under contract with a Medicaid managed care plan;

(b) Is under contract with a transportation broker under contract with a Medicaid managed care plan;

(c) Is under contract with a transportation broker under contract with the Agency for Health Care Administration; or

(d) Receives referrals from a transportation broker under contract with a Medicaid managed care plan or the Agency for Health Care Administration,

may provide nonemergency medical transportation services under ss. 409.905 and 409.973 to a Medicaid recipient if all drivers and prospective drivers are screened pursuant to the procedures set forth in s. 435.03 or functionally equivalent procedures, as determined by the Agency for Health Care Administration. By October 1, 2019, the Agency for Health Care Administration shall update its regulations, policies, or other guidance, including its Medicaid Non-Emergency Transportation Services Coverage

Policy, as necessary, to reflect this authorization. Requirements for transportation network companies and transportation network company drivers may not exceed those imposed under s. 627.748, except as necessary to conform to other applicable state and federal Medicaid transportation requirements administered by the Agency for Health Care Administration.

(3) Subsection (2) may not be construed to:

(a) Expand or limit the transportation benefits provided to Medicaid recipients or to require a Medicaid managed care plan to contract with a transportation network company or transportation broker.

(b) Exempt any person, firm, corporation, association, or governmental entity that engages in the business or service of providing advanced life support or basic life support transportation services from the licensure requirements provided in s. 401.25.

Section 2. This act shall take effect July 1, 2019.

An act relating to Alzheimer's disease; amending s. 430.501, F.S.; increasing membership of the Alzheimer's Disease Advisory Committee; revising representative requirements of the committee; requiring the committee to submit an annual report to specified parties that includes certain information and recommendations; requiring the Department of Elderly Affairs to review and update the Alzheimer's disease state plan every 3 years in collaboration with certain parties; providing requirements for the plan; amending s. 430.502, F.S.; establishing a specified memory disorder clinic; providing that certain clinics shall not receive decreased funding for a specified reason; providing an effective date.

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

Section 1. Subsections (2) and (3) of section 430.501, Florida Statutes, are amended to read:

430.501 Alzheimer's Disease Advisory Committee; research grants.—

(2) There is created an Alzheimer's Disease Advisory Committee, composed of 15 ~~10~~ members ~~to be selected by the Governor~~, which shall advise the Department of Elderly Affairs

in the performance of its duties under this act. All members must be residents of the state. The committee shall advise the department regarding legislative, programmatic, and administrative matters that relate to persons living with Alzheimer's disease ~~victims~~ and their caretakers.

(3)(a) The committee membership shall include the following ~~be representative as follows~~:

1. Eleven members appointed by the Governor.

a. At least 4 of the 11 ~~10~~ members must be licensed pursuant to chapter 458 or chapter 459 or hold a Ph.D. degree and be currently involved in the research of Alzheimer's disease.

b.~~2.~~ ~~The 10 members must include~~ At least 4 of the 11 members must be persons who have been caregivers of persons living with ~~victims of~~ Alzheimer's disease.

c.~~3.~~ Whenever possible, the ~~10~~ members appointed by the Governor shall include 1 each of the following professionals: a gerontologist, a geriatric psychiatrist, a geriatrician, a neurologist, a social worker, ~~and~~ a registered nurse, and a first responder.

2. Two members appointed by the President of the Senate, one of whom must be a sitting member of the Senate, and two members appointed by the Speaker of the House of Representatives, one of whom must be a sitting member of the House of Representatives.

(b)1. The Governor shall appoint members from a broad cross-section of public, private, and volunteer sectors. All nominations shall be forwarded to the Governor by the Secretary of Elderly Affairs in accordance with this subsection.

2. Members shall be appointed to 4-year staggered terms in accordance with s. 20.052, except for the sitting members of the Senate and House of Representatives, who shall be appointed to a term corresponding to their term of office.

3. The Secretary of Elderly Affairs shall serve as an ex officio member of the committee.

4. The committee shall elect one of its members to serve as chair for a term of 1 year.

5. The committee may establish subcommittees as necessary to carry out the functions of the committee.

6. The committee shall meet quarterly, or as frequently as needed.

7. The committee shall submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Secretary of Elderly Affairs on or before September 1 of each year. The annual report shall include information and recommendations on Alzheimer's disease policy; all state-funded efforts in Alzheimer's disease research, clinical care, institutional, home-based and community-based programs and the outcomes of such efforts; and any proposed updates to the Alzheimer's disease state plan submitted under

subparagraph 8.

8. Beginning in 2020, and every third year thereafter, on or before November 1, the Department of Elderly Affairs shall review the Alzheimer's disease state plan and submit an updated state plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The Department of Elderly Affairs shall utilize the annual reports submitted by the committee and collaborate with state Alzheimer's disease organizations and professionals when considering such updates to the Alzheimer's disease state plan. The state plan shall:

a. Assess the current and future impact of Alzheimer's disease and related forms of dementia on the state.

b. Examine the existing industries, services, and resources addressing the needs of persons having Alzheimer's disease or a related form of dementia and their family caregivers.

c. Examine the needs of persons of all cultural backgrounds having Alzheimer's disease or a related form of dementia and how their lives are affected by the disease from younger-onset, through mid-stage, to late-stage.

d. Develop a strategy to mobilize a state response to this public health crisis.

e. Provide information regarding:

(I) State trends with respect to persons having Alzheimer's disease or a related form of dementia and their needs, including, but not limited to:

(A) The role of the state in providing community-based care, long-term care, and family caregiver support, including respite, education, and assistance to persons who are in the early stages of Alzheimer's disease, who have younger-onset Alzheimer's disease, or who have a related form of dementia.

(B) The development of state policy with respect to persons having Alzheimer's disease or a related form of dementia.

(C) Surveillance of persons having Alzheimer's disease or a related form of dementia for the purpose of accurately estimating the number of such persons in the state at present and projected population levels.

(II) Existing services, resources, and capacity, including, but not limited to:

(A) The type, cost, and availability of dementia-specific services throughout the state.

(B) Policy requirements and effectiveness for dementia-specific training for professionals providing care.

(C) Quality care measures employed by providers of care, including providers of respite, adult day care, assisted living facility, skilled nursing facility, and hospice services.

(D) The capability of public safety workers and law enforcement officers to respond to persons having Alzheimer's disease or a related form of dementia, including, but not limited to, responding to their disappearance, search and rescue, abuse, elopement, exploitation, or suicide.

(E) The availability of home and community-based services and respite care for persons having Alzheimer's disease or a related form of dementia and education and support services to assist their families and caregivers.

(F) An inventory of long-term care facilities and community-based services serving persons having Alzheimer's disease or a related form of dementia.

(G) The adequacy and appropriateness of geriatric-psychiatric units for persons having behavior disorders associated with Alzheimer's disease or a related form of dementia.

(H) Residential assisted living options for persons having Alzheimer's disease or a related form of dementia.

(I) The level of preparedness of service providers before, during, and after a catastrophic emergency involving a person having Alzheimer's disease or a related form of dementia and their caregivers and families.

(III) Needed state policies or responses, including, but not limited to, directions for the provision of clear and coordinated care, services, and support to persons having

Alzheimer's disease or a related form of dementia and their caregivers and families and strategies to address any identified gaps in the provision of services.

9.~~7.~~ The Department of Elderly Affairs shall provide staff support to assist the committee in the performance of its duties.

10.~~8.~~ Members of the committee and subcommittees shall receive no salary, but are entitled to reimbursement for travel and per diem expenses, as provided in s. 112.061, while performing their duties under this section.

Section 2. Subsection (1) of section 430.502, Florida Statutes, is amended to read:

430.502 Alzheimer's disease; memory disorder clinics and day care and respite care programs.—

(1) There is established:

(a) A memory disorder clinic at each of the three medical schools in this state;

(b) A memory disorder clinic at a major private nonprofit research-oriented teaching hospital, and may fund a memory disorder clinic at any of the other affiliated teaching hospitals;

(c) A memory disorder clinic at the Mayo Clinic in Jacksonville;

(d) A memory disorder clinic at the West Florida Regional Medical Center;

(e) A memory disorder clinic operated by Health First in Brevard County;

(f) A memory disorder clinic at the Orlando Regional Healthcare System, Inc.;

(g) A memory disorder center located in a public hospital that is operated by an independent special hospital taxing district that governs multiple hospitals and is located in a county with a population greater than 800,000 persons;

(h) A memory disorder clinic at St. Mary's Medical Center in Palm Beach County;

(i) A memory disorder clinic at Tallahassee Memorial Healthcare;

(j) A memory disorder clinic at Lee Memorial Hospital created by chapter 63-1552, Laws of Florida, as amended;

(k) A memory disorder clinic at Sarasota Memorial Hospital in Sarasota County;

(l) A memory disorder clinic at Morton Plant Hospital, Clearwater, in Pinellas County;

(m) A memory disorder clinic at Florida Atlantic University, Boca Raton, in Palm Beach County; ~~and~~

(n) A memory disorder clinic at Florida Hospital in Orange County; and

(o) A memory disorder clinic at Miami Jewish Health System in Miami-Dade County,

for the purpose of conducting research and training in a diagnostic and therapeutic setting for persons suffering from Alzheimer's disease and related memory disorders. However, memory disorder clinics ~~funded as of June 30, 1995,~~ shall not receive decreased funding due solely to subsequent additions of memory disorder clinics in this subsection.

Section 3. This act shall take effect July 1, 2019.

An act relating to nonopioid alternatives; amending s. 456.44, F.S.; providing legislative intent; requiring the Department of Health to develop and publish on its website an educational pamphlet regarding the use of nonopioid alternatives for the treatment of pain; requiring the pamphlet to include specified information, including the advantages and disadvantages of the use of such alternatives; providing requirements for health care practitioners; providing an effective date.

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

Section 1. Subsection (7) is added to section 456.44, Florida Statutes, to read:

456.44 Controlled substance prescribing.—

(7) NONOPIOID ALTERNATIVES.—

(a) The Legislature finds that every competent adult has the fundamental right of self-determination regarding decisions pertaining to his or her own health, including the right to refuse an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

(b) The department shall develop and publish on its website an educational pamphlet regarding the use of nonopioid

alternatives for the treatment of pain. The pamphlet shall, at a minimum, include:

1. Information on available nonopioid alternatives for the treatment of pain, including nonopioid medicinal drugs or drug products and nonpharmacological therapies.

2. The advantages and disadvantages of the use of nonopioid alternatives.

(c) Except in the provision of emergency services and care, as defined in s. 395.002, before providing anesthesia or prescribing, ordering, dispensing, or administering an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812 for the treatment of pain, a health care practitioner, excluding those licensed under chapter 465, must:

1. Inform the patient of available nonopioid alternatives for the treatment of pain, which may include nonopioid medicinal drugs or drug products, interventional procedures or treatments, acupuncture, chiropractic treatments, massage therapy, physical therapy, occupational therapy, or any other appropriate therapy as determined by the health care practitioner.

2. Discuss the advantages and disadvantages of the use of nonopioid alternatives, including whether the patient is at a high risk of, or has a history of, controlled substance abuse or misuse and the patient's personal preferences.

3. Provide the patient with the educational pamphlet described in paragraph (b).

4. Document the nonopioid alternatives considered in the patient's record.

Section 2. This act shall take effect July 1, 2019.

An act relating to carrying of firearms by tactical medical professionals; amending s. 790.25, F.S.; exempting certain licensed medical professionals from specified provisions concerning the carrying of firearms; requiring certain policies and procedures for law enforcement agencies; providing such professionals have no duty to retreat in certain circumstances; providing immunities and privileges for such professionals; providing construction; requiring the appointing law enforcement agency to issue to tactical medical professionals any firearm or ammunition; providing a definition; providing an effective date.

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

Section 1. Paragraph (q) is added to subsection (3) of section 790.25, Florida Statutes, to read:

790.25 Lawful ownership, possession, and use of firearms and other weapons.—

(3) LAWFUL USES.—The provisions of ss. 790.053 and 790.06 do not apply in the following instances, and, despite such sections, it is lawful for the following persons to own, possess, and lawfully use firearms and other weapons,

ammunition, and supplies for lawful purposes:

(q)1. A tactical medical professional who is actively operating in direct support of a tactical operation by a law enforcement agency provided that:

a. The tactical medical professional is lawfully able to possess firearms and has an active concealed weapons permit issued pursuant to s. 790.06.

b. The tactical medical professional is appointed to a law enforcement tactical team of a law enforcement agency by the head of the law enforcement agency.

c. The law enforcement agency has an established policy providing for the appointment, training, and deployment of the tactical medical professional.

d. The tactical medical professional successfully completes a firearms safety training and tactical training as established or designated by the appointing law enforcement agency.

e. The law enforcement agency provides and the tactical medical professional participates in annual firearm training and tactical training.

2. While actively operating in direct support of a tactical operation by a law enforcement agency, a tactical medical professional:

a. May carry a firearm in the same manner as a law enforcement officer, as defined in s. 943.10 and,

notwithstanding any other law, at any place a tactical law enforcement operation occurs.

b. Has no duty to retreat and is justified in the use of any force which he or she reasonably believes is necessary to defend himself or herself or another from bodily harm.

c. Has the same immunities and privileges as a law enforcement officer, as defined in s. 943.10, in a civil or criminal action arising out of a tactical law enforcement operation when acting within the scope of his or her official duties.

3. This paragraph may not be construed to authorize a tactical medical professional to carry, transport, or store any firearm or ammunition on any fire apparatus or EMS vehicle

4. The appointing law enforcement agency shall issue any firearm or ammunition that the tactical medical professional carries in accordance with this paragraph.

5. For the purposes of this paragraph, the term "tactical medical professional" means a paramedic, as defined in s. 401.23, a physician, as defined in s. 458.305, or an osteopathic physician, as defined in s. 459.003, who is appointed to provide direct support to a tactical law enforcement unit by providing medical services at high-risk incidents, including, but not limited to, hostages incidents, narcotics raids, hazardous surveillance, sniper incidents, armed suicidal persons, barricaded suspects, high risk felony warrant service, fugitives

refusing to surrender, and active shooter incidents.

Section 2. This act shall take effect July 1, 2019.

An act relating to alternative treatment options for veterans; creating s. 295.156, F.S.; providing definitions; authorizing the Department of Veterans' Affairs to contract with a state university or Florida College System institution to furnish specified alternative treatment options for certain veterans; providing university or institution responsibilities; providing requirements for provision of alternative treatment options and related assessment data; providing alternative treatment eligibility requirements; requiring direction and supervision by certain licensed providers; requiring an annual report to the Governor and Legislature; authorizing the department to adopt rules; providing an effective date.

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

Section 1. Section 295.156, Florida Statutes, is created to read:

295.156 Alternative treatment options for veterans.—

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

(a) "Posttraumatic stress disorder" means a mental health disorder that is developed after having experienced or witnessed

a life-threatening event, including, but not limited to, military sexual trauma.

(b) "Traumatic brain injury" means an acquired injury to the brain. The term does not include brain dysfunction caused by congenital or degenerative disorders or birth trauma.

(2) The Department of Veterans' Affairs may contract with a state university or Florida College System institution to furnish alternative treatment options for veterans who have been certified by the United States Department of Veterans Affairs or any branch of the United States Armed Forces as having a traumatic brain injury or posttraumatic stress disorder. The university or institution shall manage, monitor, and ensure the compliance of contracted providers who provide any of the following alternative treatment options:

(a) Accelerated resolution therapy.

(b) Equine therapy.

(c) Hyperbaric oxygen therapy, which must be provided at a registered hyperbaric oxygen facility.

(d) Music therapy.

(e) Service animal training therapy.

(3) A veteran qualifies to receive alternative treatment under this section if he or she:

(a) Has been diagnosed by a health care practitioner with service-connected posttraumatic stress disorder or a service-connected traumatic brain injury;

(b) Voluntarily agrees to such alternative treatment; and

(c) Can demonstrate that he or she has previously sought services for posttraumatic stress disorder or a traumatic brain injury through the federal Veterans Affairs service delivery system or through private health insurance, if such coverage is available to him or her.

(4)(a) The provision of alternative treatment must be under the direction and supervision of an individual licensed under chapter 458, chapter 459, chapter 460, chapter 464, chapter 490, or chapter 491.

(b) The supervising licensed provider must agree to cooperate with the Department of Veterans' Affairs to provide data sufficient to assess the efficacy of alternative treatment modalities.

(5) By January 1 of each year beginning in 2020, the Department of Veterans' Affairs shall prepare a report detailing each alternative treatment provided pursuant to this section, the provider type, the number of veterans served, and the treatment outcomes and shall submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

(6) The Department of Veterans' Affairs may adopt rules to implement this section.

Section 2. This act shall take effect July 1, 2019.

An act relating to Halifax Hospital Medical Center, Volusia County; amending chapter 2003-374, Laws of Florida; providing an exception to general law; authorizing the district to establish, own, construct, operate, manage, and maintain hospitals, facilities, and services within and beyond the boundaries of the district under certain conditions; providing legislative intent; providing that ad valorem taxes and non-ad valorem special assessments be expended only within the boundaries of the district; prohibiting the district from expending such funds outside the boundaries of the district; authorizing the district to contract with certain persons or entities to carry out the provisions of this act; authorizing the district to own and operate certain facilities and provide certain services throughout the state; providing an effective date.

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

Section 1. Section 5 of section 3 of chapter 2003-374, Laws of Florida, is amended to read:

Section 5. District authority.—

(1) The district may establish, own, construct, equip,

operate, manage, and maintain such hospitals, medical facilities, and other health care facilities and services as are necessary for the residents of the district. The hospitals, medical facilities, and other health care facilities and services shall be established, owned, constructed, equipped, operated, managed and maintained by the district for the preservation of the public health, for the public good, and for the use of the public of the district. Maintenance of such hospitals, medical facilities, and other health care facilities and services in the district is hereby found and declared to be a public purpose and necessary for the general welfare of the residents of the district.

(2) Notwithstanding any other provision of this act to the contrary, the district is authorized and empowered to establish, own, construct, equip, operate, manage, and maintain hospitals, all other types of health care facilities, and all other types of health care services that promote the public health within Brevard, Flagler, Lake, and Volusia Counties, subject to the provisions of sections 408.031-408.0455, Florida Statutes. The district is further expressly authorized to continue to construct, own, equip, operate, manage, and maintain all facilities and services in which the district was engaged as of January 1, 2019.

(3) It is the express intent of the Legislature that any ad valorem tax or non-ad valorem special assessment revenues

levied by the district be used solely toward health care facilities or health care services within the district. Accordingly, the district is expressly prohibited from using any ad valorem tax or non-ad valorem special assessment revenues levied by the district on property located within the district for any purpose outside the boundaries of the district.

(4) The district is authorized and empowered to contract with individuals, partnerships, corporations, municipalities, Brevard, Flagler, Lake, and Volusia Counties, the state, and any subdivision or agency thereof in the United States, to carry out the purposes and provisions of this act, including participation in the joint provision with other hospitals and health care providers of all manner of inpatient and outpatient facilities and health care services that provide benefits to those members of the public served by the district both within and beyond the boundaries of the district, but within Brevard, Flagler, Lake, or Volusia Counties, as limited in this act, and to the extent such participation is consistent with all restrictions contained in the Florida Constitution, the general laws of the state, or this act. The district is authorized to own and operate facilities and provide services authorized in part IV of chapter 400, Florida Statutes, both within and beyond the district boundaries throughout the State of Florida.

(5) The district shall have and exercise all of the powers necessary, incidental, or convenient to carry out and effectuate

the purposes for which the district is organized under the provisions of this act.

Section 2. This act shall take effect upon becoming a law.

An act relating to continuing education for dentists; amending s. 466.0135, F.S.; requiring a minimum of 2 hours of continuing education on the prescribing of controlled substances; providing an effective date.

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

Section 1. Subsection (1) of section 466.0135, Florida Statutes, is amended to read:

466.0135 Continuing education; dentists.—

(1) In addition to the other requirements for renewal set out in this chapter, each licensed dentist shall be required to complete biennially not less than 30 hours of continuing professional education in dental subjects, with a minimum of 2 hours of continuing education on the safe and effective prescribing of controlled substances. Programs of continuing education shall be programs of learning that contribute directly to the dental education of the dentist and may include, but shall not be limited to, attendance at lectures, study clubs, college postgraduate courses, or scientific sessions of conventions; and research, graduate study, teaching, or service as a clinician. Programs of continuing education shall be acceptable when adhering to the following general guidelines:

(a) The aim of continuing education for dentists is to

improve all phases of dental health care delivery to the public.

(b) Continuing education courses shall address one or more of the following areas of professional development, including, but not limited to:

1. Basic medical and scientific subjects, including, but not limited to, biology, physiology, pathology, biochemistry, and pharmacology;

2. Clinical and technological subjects, including, but not limited to, clinical techniques and procedures, materials, and equipment; and

3. Subjects pertinent to oral health and safety.

(c) The board may also authorize up to three hours of credit biennially for a practice management course that includes principles of ethical practice management, provides substance abuse, effective communication with patients, time management, and burnout prevention instruction.

(d) Continuing education credits shall be earned at the rate of one-half credit hour per 25-30 contact minutes of instruction and one credit hour per 50-60 contact minutes of instruction.

Section 2. This act shall take effect July 1, 2019.

An act relating to office surgery; amending s. 456.074, F.S.; requiring the Department of Health to issue an emergency order suspending or restricting the registration of certain facilities upon specified findings; amending s. 458.309, F.S.; deleting a provision relating to registration and inspection of an office in which a physician performs certain procedures or office surgeries; creating s. 458.328, F.S.; requiring an office in which a physician performs certain procedures or office surgeries to register with the department; requiring an office to designate a physician to be responsible for certain compliance requirements as part of registration by a specified date; requiring an office and physicians practicing at the office to meet certain financial responsibility requirements; authorizing the department to deny or revoke the registration of or impose certain penalties against a facility in which certain procedures or office surgeries are performed under certain circumstances; requiring the department to conduct certain inspections; providing exceptions; requiring the Board of Medicine to adopt rules governing the standards of practice for physicians practicing in such offices and to impose a specified fine on physicians who perform certain procedures or office surgeries in an unregistered office; authorizing the board to adopt rules to administer the registration, inspection, and safety of offices in

which certain procedures or office surgeries are performed; amending s. 458.331, F.S.; providing that a physician performing certain procedures or office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.005, F.S.; deleting a provision relating to registration and inspection of an office in which a physician performs certain procedures or office surgeries; creating s. 459.0138, F.S.; requiring an office in which a physician performs certain procedures or office surgeries to register with the department; requiring an office to designate a physician to be responsible for certain compliance requirements as part of registration by a specified date; requiring an office and physicians practicing at the office to meet certain financial responsibility requirements; authorizing the department to deny or revoke the registration of or impose certain penalties against a facility in which certain procedures or office surgeries are performed under certain circumstances; requiring the department to conduct certain inspections; providing exceptions; requiring the Board of Osteopathic Medicine to adopt rules governing the standards of practice for physicians practicing in such offices and to impose a specified fine on physicians who perform certain procedures or office surgeries in an unregistered office; authorizing the board to adopt rules to administer the registration, inspection, and safety of

offices in which certain procedures or office surgeries are performed; amending s. 459.015, F.S.; providing that the performance of certain procedures or office surgeries by a physician in an unregistered office constitutes grounds for denial of a license or disciplinary action; providing an effective date.

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

Section 1. Subsection (6) is added to section 456.074, Florida Statutes, to read:

456.074 Certain health care practitioners; immediate suspension of license.—

(6) The department must issue an emergency order suspending or restricting the registration of an office registered under s. 458.328 or s. 459.0139 upon a finding of probable cause that the office or a physician practicing in the office is not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.328 or s. 459.0138, as applicable, or is in violation of s. 458.331(1)(v) or s. 459.015(1)(z), and that such noncompliance or violation constitutes an immediate danger to the public.

Section 2. Subsection (3) of section 458.309, Florida Statutes, is amended to read:

458.309 Rulemaking authority.—

~~(3) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register~~

~~the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 3. Section 458.328, Florida Statutes, is created to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

(a) An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery must register with the department unless the office is licensed as a facility under chapter 390 or chapter 395.

(b) By January 1, 2020, each office registered under this section or s. 459.0138 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend the

registration of an office if the office fails to comply with the requirements of this paragraph.

(c) As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. Each physician practicing at an office registered under this section or s. 459.0138 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

(d) Each physician practicing at an office registered under this section or s. 459.0138 shall advise the board, in writing, within 10 calendar days after beginning or ending his or her practice at a registered office.

(e) The department shall inspect a registered office at least annually, including a review of patient records, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of a clinic specified in s. 458.3265(1)(a)3.h., and those wholly owned and operated physician offices described in s. 458.3265(1)(a)3.g. which perform procedures referenced in s. 458.3265(1)(a)3.h., which must be announced.

(f) The department may suspend or revoke the registration of an office in which a procedure or surgery identified in paragraph (a) is performed for failure of any of its physicians, owners, or operators to comply with this section and rules

adopted hereunder or s. 459.0138 and rules adopted thereunder. If an office's registration is revoked for any reason, the department may deny any person named in the registration documents of the office, including the persons who own or operate the office, individually or as part of a group, from registering an office to perform procedures or office surgeries pursuant to this section or s. 459.0138 for 5 years after the revocation date.

(g) The department may impose any penalty set forth in s. 456.072(2) against the designated physician for failure of the office to operate in compliance with the office health and safety requirements of this section and rules adopted hereunder or s. 459.0138 and rules adopted thereunder.

(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.

(i) The actual costs of registration and inspection or accreditation shall be paid by the person seeking to register and operate the office in which a procedure or surgery identified in paragraph (a) will be performed.

(2) RULEMAKING.—

(a) The board shall adopt by rule standards of practice for physicians who perform procedures or office surgeries pursuant to this section.

(b) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs procedures or office surgeries pursuant to

this section.

Section 4. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.328 or s. 459.0138.

Section 5. Subsection (2) of section 459.005, Florida Statutes, is amended to read:

459.005 Rulemaking authority.—

~~(2) A physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, level 2 procedures lasting more than 5 minutes, and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.~~

Section 6. Section 459.0138, Florida Statutes, is created

to read:

459.0138 Office surgeries.—

(1) REGISTRATION.—

(a) An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery must register with the department unless the office is licensed as a facility under chapter 390 or chapter 395.

(b) By January 1, 2020, each office registered under this section or s. 458.328 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend a registration for an office if the office fails to comply with the requirements of this paragraph.

(c) As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. Each physician practicing at an office registered under this section or s. 458.328 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as

applicable.

(d) Each physician practicing at an office registered under this section or s. 458.328 shall advise the board, in writing, within 10 calendar days after beginning or ending his or her practice at the registered office.

(e) The department shall inspect a registered office at least annually, including a review of patient records, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of clinic specified in s. 459.0137(1)(a)3.h., and those wholly owned and operated physician offices described in s. 459.0137(1)(a)3.g. which perform procedures referenced in s. 459.0137(1)(a)3.h., which must be announced.

(f) The department may suspend or revoke the registration of an office in which a procedure or surgery identified in paragraph (a) is performed for failure of any of its physicians, owners, or operators to comply with this section and rules adopted hereunder or s. 458.328 and rules adopted thereunder. If an office’s registration is revoked for any reason, the department may deny any person named in the registration documents of the office, including the persons who own or operate the office, individually or as part of a group, from registering an office to perform procedures or office surgeries pursuant to this section or s. 458.328 for 5 years after the revocation date.

(g) The department may impose any penalty set forth in s.

456.072(2) against the designated physician for failure of the office to operate in compliance with the office health and safety requirements of this section and rules adopted hereunder or s. 458.328 and rules adopted thereunder.

(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.

(i) The actual costs of registration and inspection or accreditation shall be paid by the person seeking to register and operate the office in which a procedure or surgery identified in paragraph (a) will be performed.

(2) RULEMAKING.—

(a) The board shall adopt by rule standards of practice for physicians who perform procedures or office surgeries pursuant to this section.

(b) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs procedures or office surgeries pursuant to this section.

Section 7. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level

II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.328 or s. 459.0138.

Section 8. This act shall take effect January 1, 2020.

An act relating to electronic prescribing; amending s. 456.42, F.S.; requiring certain health care practitioners to electronically generate and transmit prescriptions for medicinal drugs upon license renewal or by a specified date; providing exceptions; authorizing the Department of Health, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, the Board of Dentistry, the Board of Nursing, and the Board of Optometry, to adopt rules; amending s. 456.43, F.S.; revising the definitions of the terms "prescribing decision" and "point of care"; revising the authority for electronic prescribing software to display information regarding a payor's formulary under certain circumstances; amending ss. 409.912, 456.0392, 458.3265, 458.331, 459.0137, and 459.015, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—

(1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must contain the date and an electronic signature, as defined in s. 668.003(4), ~~be dated and signed~~ by the prescribing practitioner only on the day issued~~, which signature may be in an electronic format as defined in s. 668.003(4)~~.

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s.

408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

(3) A health care practitioner licensed by law to prescribe a medicinal drug who maintains a system of electronic health records as defined in s. 408.051(2)(a), or who prescribes medicinal drugs as an owner, an employee, or a contractor of a licensed health care facility or practice that maintains such a system and who is prescribing in his or her capacity as such an owner, an employee, or a contractor, may only electronically transmit prescriptions for such drugs. This requirement applies to such a health care practitioner upon renewal of the health care practitioner's license or by July 1, 2021, whichever is earlier, but does not apply if:

(a) The practitioner and the dispenser are the same entity;

(b) The prescription cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(c) The practitioner has been issued a waiver by the department, not to exceed 1 year in duration, from the requirement to use electronic prescribing due to demonstrated

economic hardship, technological limitations that are not reasonably within the control of the practitioner, or another exceptional circumstance demonstrated by the practitioner;

(d) The practitioner reasonably determines that it would be impractical for the patient in question to obtain a medicinal drug prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition;

(e) The practitioner is prescribing a drug under a research protocol;

(f) The prescription is for a drug for which the federal Food and Drug Administration requires the prescription to contain elements that may not be included in electronic prescribing; or

(g) The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility.

(h) The practitioner determines that it is in the best interest of the patient, or the patient determines that it is in his or her own best interest, to compare prescription drug prices among area pharmacies. The practitioner must document such determination in the patient's medical record.

The department, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, the Board of Dentistry, the Board of Nursing, and the Board of

Optometry, may adopt rules to implement this subsection.

Section 2. Section 456.43, Florida Statutes, is amended to read:

456.43 Electronic prescribing for medicinal drugs.—

(1) Electronic prescribing may ~~shall~~ not interfere with a patient's freedom to choose a pharmacy.

(2) Electronic prescribing software may ~~shall~~ not use any means or permit any other person to use any means to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner or his or her agent at the point of care, including, but not limited to, means such as advertising, instant messaging, ~~and~~ pop-up ads, and similar means ~~to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be~~ triggered by or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain medicinal drug ~~pharmaceutical~~ or directing a patient to a certain pharmacy. For purposes of this subsection, the term:

(a) ~~The term~~ "Prescribing decision" means a prescribing practitioner's or his or her agent's decision to prescribe any medicinal drug ~~a certain pharmaceutical~~.

(b) ~~The term~~ "Point of care" means the time at which ~~that~~

a prescribing practitioner or his or her agent prescribes any medicinal drug ~~is in the act of prescribing a certain pharmaceutical~~.

(3) Electronic prescribing software may display ~~show~~ information regarding a payor's formulary if ~~as long as~~ nothing is designed to preclude or make more difficult the selection of ~~the act of a prescribing practitioner or patient selecting~~ any particular pharmacy by a patient or the selection of a certain medicinal drug by a prescribing practitioner or his or her agent ~~pharmaceutical~~.

Section 3. Paragraph (a) of subsection (5) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other

alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as

Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(5)(a) The agency shall implement a Medicaid prescribed-

drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior consultation by telephone or other telecommunication device within 24 hours after receipt of a request for prior consultation; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The

agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that requires Medicaid practitioners who issue written prescriptions for medicinal ~~prescribe~~ drugs to use a counterfeit-proof

prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by ~~Medicaid-participating prescribers or~~ prescribers who issue written ~~write~~ prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or

generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8. The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid

pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.

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

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

b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators

that are based on national standards; and determine deviations from best practice guidelines.

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

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

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

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

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

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

(II) Implement processes for providing feedback to and

educating prescribers using best practice educational materials and peer-to-peer consultation.

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

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

12. The agency may contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

13. The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

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

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

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

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

15. The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

16. The agency shall implement a step-therapy prior

authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best

alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

17. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be reused.

Section 4. Section 456.0392, Florida Statutes, is amended to read:

456.0392 Prescription labeling.—

(1) A prescription issued ~~written~~ by a practitioner who is authorized under the laws of this state to prescribe ~~write prescriptions for~~ drugs that are not listed as controlled substances in chapter 893 but who is not eligible for a federal

Drug Enforcement Administration number shall include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is issued ~~written~~ by an advanced practice registered nurse licensed under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3) A prescription for a drug that is not listed as a controlled substance in chapter 893 which is issued ~~written~~ by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

Section 5. Paragraph (d) of subsection (3) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a

pain-management clinic that is required to be registered in subsection (1).

(d) A physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks or electronic prescribing software ~~and any other method~~ used for prescribing controlled substance pain medication. A ~~The~~ physician who issues written prescriptions shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. A ~~The~~ physician shall notify, in writing, the department within 24 hours after ~~following~~ any theft or loss of a prescription blank or breach of his or her electronic prescribing software used ~~any other method~~ for prescribing pain medication.

Section 6. Paragraph (qq) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(qq) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of a physician's electronic prescribing software ~~other methods for prescribing~~ within 24 hours as required by s. 458.3265(3).

Section 7. Paragraph (d) of subsection (3) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(3) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(d) An osteopathic physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks or electronic prescribing software ~~and any other method~~ used for prescribing controlled substance pain medication. An ~~The~~ osteopathic physician who issues written prescriptions shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. An ~~The~~ osteopathic physician shall notify, in writing, the department within 24 hours after ~~following~~ any theft or loss of a prescription blank or breach of his or her electronic prescribing software used ~~any other method~~ for prescribing pain medication.

Section 8. Paragraph (ss) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a

license or disciplinary action, as specified in s. 456.072(2):

(ss) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of an osteopathic physician's electronic prescribing software ~~other methods for prescribing~~ within 24 hours as required by s. 459.0137(3).

Section 9. This act shall take effect January 1, 2020.

An act relating to health care; providing legislative intent; creating s. 381.4019, F.S.; establishing the Dental Student Loan Repayment Program to support dentists who practice in public health programs located in certain underserved areas; providing definitions; requiring the Department of Health to establish a dental student loan repayment program for specified purposes; providing for the award of funds; providing the maximum number of years for which funds may be awarded; providing eligibility requirements; requiring the department to adopt rules; specifying that implementation of the program is subject to legislative appropriation; creating s. 381.40195, F.S.; providing a short title; providing definitions; requiring the Department of Health to establish the Donated Dental Services Program to provide comprehensive dental care to certain eligible individuals; requiring the department to contract with a nonprofit organization to implement and administer the program; specifying minimum contractual responsibilities; requiring the department to adopt rules; specifying that implementation of the program is subject to legislative appropriation; amending s. 395.1012, F.S.; requiring a licensed hospital to

provide specified information and data relating to patient safety and quality measures to a patient under certain circumstances or to any person upon request; creating s. 395.1052, F.S.; requiring a hospital to notify a patient's primary care provider within a specified timeframe after the patient's admission; requiring a hospital to inform a patient, upon admission, of the option to request consultation between the hospital's treating physician and the patient's primary care provider or specialist provider; requiring a hospital to notify a patient's primary care provider of the patient's discharge within a specified timeframe after discharge; requiring a hospital to provide specified information and records to the primary care provider within a specified timeframe after completion of the patient's discharge summary; amending s. 395.002, F.S.; revising the definition of the term "ambulatory surgical center"; amending s. 395.1055, F.S.; requiring the Agency for Health Care Administration to adopt rules that establish standards related to the delivery of surgical care to children in ambulatory surgical center; specifying that ambulatory surgical centers may provide certain procedures only if authorized by agency rule; authorizing the reimbursement of per diem

and travel expenses to members of the pediatric cardiac technical advisory panel, established within the Agency for Health Care Administration; revising panel membership to include certain alternate at-large members; providing term limits for voting members; providing that members of the panel under certain circumstances are agents of the state for a specified purpose; requiring the Secretary of Health Care Administration to consult the panel for advisory recommendations on certain certificate of need applications; authorizing the secretary to request announced or unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate of need process; providing a process for the appointment of physician experts to a site visit team; requiring each member of a site visit team to submit a report to the panel; requiring the panel to discuss such reports and present an advisory opinion to the secretary; providing requirements for an on-site inspection; requiring the Surgeon General of the Department of Health to provide specified reports to the secretary; amending. s. 395.301, F.S.; requiring a licensed facility, upon placing a patient on observation status, to immediately notify the

patient of such status using a specified form; requiring that such notification be documented in the patient's medical records and discharge papers; amending s. 400.9905, F.S.; revising the definition of the term "clinic" to exclude certain entities; creating s. 542.336, F.S.; specifying that certain restrictive covenants entered into with certain physicians are not supported by legitimate business interests; providing legislative findings; providing that such restrictive covenants are void and remain void and unenforceable for a specified period; amending s. 624.27, F.S.; expanding the scope of direct primary care agreements, which are renamed "direct health care agreements"; conforming provisions to changes made by the act; creating s. 627.42393, F.S.; prohibiting certain health insurers from employing step-therapy protocols under certain circumstances; defining the term "health coverage plan"; clarifying that a health insurer is not required to take specific actions regarding prescription drugs; amending s. 641.31, F.S.; prohibiting certain health maintenance organizations from employing step-therapy protocols under certain circumstances; defining the term "health coverage plan"; clarifying that a health maintenance

organization is not required to take specific actions regarding prescription drugs; requiring the Office of Program Policy Analysis and Government Accountability to submit by a specified date a report and recommendations to the Governor and the Legislature which addresses this state's prospective entrance into the Interstate Medical Licensure Compact as a member state; providing parameters for the report; providing effective dates.

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

Section 1. It is the intent of the Legislature to promote programs and initiatives that help make available preventive and educational dental services for the residents of the state, as well as provide quality dental treatment services. The geographic characteristics among the residents of the state are distinctive and vary from region to region, with such residents having unique needs regarding access to dental care. The Legislature recognizes that maintaining good oral health is integral to the overall health status of individuals and that the good health of the residents of this state is an important contributing factor in economic development. Better health, including better oral health, increases workplace productivity, reduces the burden of health care costs, and improves the

cognitive development of children, resulting in a reduction of missed school days.

Section 2. Section 381.4019, Florida Statutes, is created to read:

381.4019 Dental Student Loan Repayment Program.—The Dental Student Loan Repayment Program is established to promote access to dental care by supporting qualified dentists who treat medically underserved populations in dental health professional shortage areas or medically underserved areas.

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

(a) "Dental health professional shortage area" means a geographic area designated as such by the Health Resources and Services Administration of the United States Department of Health and Human Services.

(b) "Department" means the Department of Health.

(c) "Loan program" means the Dental Student Loan Repayment Program.

(d) "Medically underserved area" means a geographic area, an area having a special population, or a facility which is designated by department rule as a health professional shortage area as defined by federal regulation and which has a shortage of dental health professionals who serve Medicaid recipients and other low-income patients.

(e) "Public health program" means a county health department, the Children's Medical Services program, a federally

funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the department.

(2) The department shall establish a dental student loan repayment program to benefit Florida-licensed dentists who demonstrate, as required by department rule, active employment in a public health program that serves Medicaid recipients and other low-income patients and is located in a dental health professional shortage area or a medically underserved area.

(3) The department shall award funds from the loan program to repay the student loans of a dentist who meets the requirements of subsection (2).

(a) An award may not exceed $50,000 per year per eligible dentist.

(b) Only loans to pay the costs of tuition, books, dental equipment and supplies, uniforms, and living expenses may be covered.

(c) All repayments are contingent upon continued proof of eligibility and must be made directly to the holder of the loan. The state bears no responsibility for the collection of any interest charges or other remaining balances.

(d) A dentist may receive funds under the loan program for at least 1 year, up to a maximum of 5 years.

(e) The department shall limit the number of new dentists participating in the loan program to not more than 10 per fiscal

year.

(4) A dentist is no longer eligible to receive funds under the loan program if the dentist:

(a) Is no longer employed by a public health program that meets the requirements of subsection (2).

(b) Ceases to participate in the Florida Medicaid program.

(c) Has disciplinary action taken against his or her license by the Board of Dentistry for a violation of s. 466.028.

(5) The department shall adopt rules to administer the loan program.

(6) Implementation of the loan program is subject to legislative appropriation.

Section 3. Section 381.40195, Florida Statutes, is created to read:

381.40195 Donated Dental Services Program.—

(1) This act may be cited as the "Donated Dental Services Act."

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

(a) "Department" means the Department of Health.

(b) "Program" means the Donated Dental Services Program as established pursuant to subsection (3).

(3) The department shall establish the Donated Dental Services Program for the purpose of providing comprehensive dental care through a network of volunteer dentists and other dental providers to needy, disabled, elderly, and medically

compromised individuals who cannot afford necessary treatment but are ineligible for public assistance. An eligible individual may receive treatment in a volunteer dentist's or participating dental provider's private office or at any other suitable location. An eligible individual is not required to pay any fee or cost associated with the treatment he or she receives.

(4) The department shall establish the program. The department shall contract with a nonprofit organization that has experience in providing similar services or administering similar programs. The contract must specify the responsibilities of the nonprofit organization, which may include, but are not limited to:

(a) Maintaining a network of volunteer dentists and other dental providers, including, but not limited to, dental specialists and dental laboratories, to provide comprehensive dental services to eligible individuals.

(b) Maintaining a system to refer eligible individuals to the appropriate volunteer dentist or participating dental provider.

(c) Developing a public awareness and marketing campaign to promote the program and educate eligible individuals about its availability and services.

(d) Providing the necessary administrative and technical support to administer the program.

(e) Submitting an annual report to the department which

must include, at a minimum:

1. Financial data relating to administering the program.

2. Demographic data and other information relating to the eligible individuals who are referred to and receive treatment through the program.

3. Demographic data and other information relating to the volunteer dentists and participating dental providers who provide dental services through the program.

4. Any other data or information that the department may require.

(f) Performing any other program-related duties and responsibilities as required by the department.

(5) The department shall adopt rules to administer the program.

(6) Implementation of the program is subject to legislative appropriation.

Section 4. Subsection (3) is added to section 395.1012, Florida Statutes, to read:

395.1012 Patient safety.—

(3)(a) Each hospital shall provide to any patient or patient's representative identified pursuant to s. 765.401(1) upon scheduling of nonemergency care, or to any other stabilized patient or patient's representative identified pursuant to s. 765.401(1) within 24 hours of the patient being stabilized or at the time of discharge, whichever comes first, written

information on a form created by the agency which contains the following information available for the hospital for the most recent year and the statewide average for all hospitals related to the following quality measures:

1. The rate of hospital-acquired infections;

2. The overall rating of the Hospital Consumer Assessment of Healthcare Providers and Systems survey; and

3. The 15-day readmission rate.

(b) A hospital shall also provide to any person, upon request, the written information specified in paragraph (a).

(c) The information required by this subsection must be presented in a manner that is easily understandable and accessible to the patient and must also include an explanation of the quality measures and the relationship between patient safety and the hospital's data for the quality measures.

Section 5. Section 395.1052, Florida Statutes, is created to read:

395.1052 Patient access to primary care and specialty providers; notification.—A hospital shall:

(1) Notify each patient's primary care provider, if any, within 24 hours after the patient's admission to the hospital.

(2) Inform the patient immediately upon admission that he or she may request to have the hospital's treating physician consult with the patient's primary care provider or specialist provider, if any, when developing the patient's plan of care.

Upon the patient's request, the hospital's treating physician shall make reasonable efforts to consult with the patient's primary care provider or specialist provider when developing the patient's plan of care.

(3) Notify the patient's primary care provider, if any, of the patient's discharge from the hospital within 24 hours after the discharge.

(4) Provide the discharge summary and any related information or records to the patient's primary care provider, if any, within 14 days after the patient's discharge summary has been completed.

Section 6. Subsection (3) of section 395.002, Florida Statutes, is amended to read:

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" 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 24 hours ~~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 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.

Section 7. Section 395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.—

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

(a) Sufficient numbers and qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care and safety.

(b) Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patient care and safety are established and implemented.

(c) A comprehensive emergency management plan is prepared and updated annually. Such standards must be included in the rules adopted by the agency after consulting with the Division of Emergency Management. At a minimum, the rules must provide for plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records, and responding to family inquiries. The

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

(d) Licensed facilities are established, organized, and operated consistent with established standards and rules.

(e) Licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by the department.

(f) All hospitals submit such data as necessary to conduct certificate-of-need reviews required under part I of chapter 408. Such data shall include, but shall not be limited to, patient origin data, hospital utilization data, type of service reporting, and facility staffing data. The agency may not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals.

(g) Each hospital has a quality improvement program designed according to standards established by their current accrediting organization. This program will enhance quality of care and emphasize quality patient outcomes, corrective action for problems, governing board review, and reporting to the agency of standardized data elements necessary to analyze quality of care outcomes. The agency shall use existing data, when available, and shall not duplicate the efforts of other state agencies in order to obtain such data.

(h) Licensed facilities make available on their Internet websites, no later than October 1, 2004, and in a hard copy format upon request, a description of and a link to the patient charge and performance outcome data collected from licensed facilities pursuant to s. 408.061.

(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, and statutory rural hospitals as defined in s. 395.602.

(3) The agency shall adopt rules that establish minimum standards for pediatric patient care in ambulatory surgical centers to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. Such standards must include quality of care, nurse staffing, physician staffing, and equipment standards. Ambulatory surgical centers may not provide operative procedures to children under 18 years of age which require a length of stay past midnight until such standards are established by rule.

(4) ~~(3)~~ The agency shall adopt rules with respect to the care 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.

(5) ~~(4)~~ The agency shall adopt rules with respect to the

care and treatment of clients in intensive residential treatment programs for children and adolescents and with respect to the safe and healthful development, operation, and maintenance of such programs.

(6) ~~(5)~~ The agency shall enforce the provisions of part I of chapter 394, and rules adopted thereunder, with respect to the rights, standards of care, and examination and placement procedures applicable to patients voluntarily or involuntarily admitted to hospitals providing psychiatric observation, evaluation, diagnosis, or treatment.

(7) ~~(6)~~ No rule shall be adopted under this part by the agency which would have the effect of denying a license to a facility required to be licensed under this part, solely by reason of the school or system of practice employed or permitted to be employed by physicians therein, provided that such school or system of practice is recognized by the laws of this state. However, nothing in this subsection shall be construed to limit the powers of the agency to provide and require minimum standards for the maintenance and operation of, and for the treatment of patients in, those licensed facilities which receive federal aid, in order to meet minimum standards related to such matters in such licensed facilities which may now or hereafter be required by appropriate federal officers or agencies in pursuance of federal law or promulgated in pursuance of federal law.

(8)~~(7)~~ Any licensed facility which is in operation at the time of promulgation of any applicable rules under this part shall be given a reasonable time, under the particular circumstances, but not to exceed 1 year from the date of such promulgation, within which to comply with such rules.

(9)~~(8)~~ The agency may not adopt any rule governing the design, construction, erection, alteration, modification, repair, or demolition of any public or private hospital, intermediate residential treatment facility, or ambulatory surgical center. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern hospitals, intermediate residential treatment facilities, and ambulatory surgical centers.

(10)~~(9)~~ The agency shall establish a pediatric cardiac technical advisory panel, pursuant to s. 20.052, to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular 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.

(b) Voting members of the panel shall include: 3 at-large members, and 3 alternate at-large members with different program affiliations, 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 alternate for each member, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, each appointed by the chief executive officer of the following 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 the hospital's compliance with this section and rules adopted thereunder, as determined by the Secretary of Health Care 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 standards. A voting member may serve a maximum of two 2-year terms and may be reappointed to the panel after being retired from the panel for a full 2-year term.

(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.

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

4. Any current or past Division Director of Children's 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.

(g) Panel members are agents of the state for purposes of s. 768.28 throughout the good faith performance of the duties assigned to them by the Secretary of Health Care Administration.

(11) The Secretary of Health Care Administration shall consult the pediatric cardiac technical advisory panel for an

advisory recommendation on any certificate of need applications to establish pediatric cardiac surgical centers.

(12) ~~(10)~~ Based on the recommendations of the pediatric cardiac technical 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 meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

(13) ~~(11)~~ A pediatric cardiac program shall:

(a) Have a pediatric cardiology clinic affiliated with a hospital licensed under this chapter.

(b) Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgical program located in the hospital.

(c) Have a risk adjustment surgical procedure protocol

following the guidelines established by the Society of Thoracic Surgeons.

(d) Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.

(e) Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

(14)(a) The Secretary of Health Care Administration may request announced or unannounced site visits to any existing pediatric cardiac surgical center or facility seeking licensure as a pediatric cardiac surgical center through the certificate of need process, to ensure compliance with this section and rules adopted hereunder.

(b) At the request of the Secretary of Health Care Administration, the pediatric cardiac technical advisory panel shall recommend in-state physician experts to conduct an on-site visit. The Secretary may also appoint up to two out-of-state physician experts.

(c) A site visit team shall conduct an on-site inspection of the designated hospital's pediatric medical and surgical programs, and each member shall submit a written report of his or her findings to the panel. The panel shall discuss the written reports and present an advisory opinion to the Secretary of Health Care Administration which includes recommendations and

any suggested actions for correction.

(d) Each on-site inspection must include all of the following:

1. An inspection of the program's physical facilities, clinics, and laboratories.

2. Interviews with support staff and hospital administrators.

3. A review of:

a. Randomly selected medical records and reports, including, but not limited to, advanced cardiac imaging, computed tomography, magnetic resonance imaging, cardiac ultrasound, cardiac catheterization, and surgical operative notes.

b. The program's clinical outcome data submitted to the Society of Thoracic Surgeons and the American College of Cardiology pursuant to s. 408.05(3)(k).

c. Mortality reports from cardiac-related deaths that occurred in the previous year.

d. Program volume data from the preceding year for interventional and electrophysiology catheterizations and surgical procedures.

(15) The Surgeon General shall provide quarterly reports to the Secretary of Health Care Administration consisting of data from the Children's Medical Services' critical congenital heart disease screening program for review by the advisory

panel.

(16) ~~(12)~~ The agency may adopt rules to administer the requirements of part II of chapter 408.

Section 8. Subsection (3) of section 395.301, Florida Statutes, is amended to read:

395.301 Price transparency; itemized patient statement or bill; patient admission status notification.—

(3) If a licensed facility places a patient on observation status rather than inpatient status, the licensed facility must immediately notify the patient of such status using the form adopted under 42 C.F.R. s. 489.20 for Medicare patients or a form adopted by agency rule for non-Medicare patients. Such notification must ~~observation services shall~~ be documented in the patient's medical records and discharge papers. The ~~patient or the~~ patient's survivor or legal guardian must ~~shall~~ be notified of observation services through discharge papers, which may also include brochures, signage, or other forms of communication for this purpose.

Section 9. Paragraphs (a), (b), (c), and (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, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 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; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; 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, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter

429, chapter 463, chapter 465, chapter 466, chapter 478, 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; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; 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, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 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; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; 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, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, 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; providers certified by the Centers for Medicare and Medicaid services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

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 10. Section 542.336, Florida Statutes, is created to read:

542.336 Invalid restrictive covenants.—A restrictive covenant entered into with a physician who is licensed under chapter 458 or chapter 459 and who practices a medical specialty in a county wherein one entity employs or contracts with, either directly or through related or affiliated entities, all physicians who practice such specialty in that county is not supported by a legitimate business interest. The Legislature finds that such covenants restrict patient access to physicians, increase costs, and are void and unenforceable under current law. Such restrictive covenants shall remain void and unenforceable for 3 years after the date on which a second entity that employs or contracts with, either directly or through related or affiliated entities, one or more physicians who practice such specialty begins offering such specialty services in that county.

Section 11. Section 624.27, Florida Statutes, is amended to read:

624.27 Direct health ~~primary~~ care agreements; exemption from code.—

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

(a) "Direct health ~~primary~~ care agreement" means a contract between a health ~~primary~~ care provider and a patient, a patient's legal representative, or a patient's employer, which

meets the requirements of subsection (4) and does not indemnify for services provided by a third party.

(b) "Health ~~Primary~~ care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, ~~or~~ chapter 464, or chapter 466, or a health ~~primary~~ care group practice, who provides health ~~primary~~ care services to patients.

(c) "Health ~~Primary~~ care services" means the screening, assessment, diagnosis, and treatment of a patient conducted within the competency and training of the health ~~primary~~ care provider for the purpose of promoting health or detecting and managing disease or injury.

(2) A direct health ~~primary~~ care agreement does not constitute insurance and is not subject to the Florida Insurance Code. The act of entering into a direct health ~~primary~~ care agreement does not constitute the business of insurance and is not subject to the Florida Insurance Code.

(3) A health ~~primary~~ care provider or an agent of a health ~~primary~~ care provider is not required to obtain a certificate of authority or license under the Florida Insurance Code to market, sell, or offer to sell a direct health ~~primary~~ care agreement.

(4) For purposes of this section, a direct health ~~primary~~ care agreement must:

(a) Be in writing.

(b) Be signed by the health ~~primary~~ care provider or an agent of the health ~~primary~~ care provider and the patient, the

patient's legal representative, or the patient's employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of health ~~primary~~ care services that are covered by the monthly fee.

(e) Specify the monthly fee and any fees for health ~~primary~~ care services not covered by the monthly fee.

(f) Specify the duration of the agreement and any automatic renewal provisions.

(g) Offer a refund to the patient, the patient's legal representative, or the patient's employer of monthly fees paid in advance if the health ~~primary~~ care provider ceases to offer health ~~primary~~ care services for any reason.

(h) Contain, in contrasting color and in at least 12-point type, the following statement on the signature page: "This agreement is not health insurance and the health ~~primary~~ care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any health ~~primary~~ care services covered by the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not

workers' compensation insurance and does not replace an employer's obligations under chapter 440."

Section 12. Effective January 1, 2020, section 627.42393, Florida Statutes, is created to read:

627.42393 Step-therapy protocol.—

(1) A health insurer issuing a major medical individual or group policy may not require a step-therapy protocol under the policy for a covered prescription drug requested by an insured if:

(a) The insured has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

(b) The insured provides documentation originating from the health coverage plan that approved the prescription drug as described in paragraph (a) indicating that the health coverage plan paid for the drug on the insured's behalf during the 90 days immediately before the request.

(2) As used in this section, the term "health coverage plan" means any of the following which is currently or was previously providing major medical or similar comprehensive coverage or benefits to the insured:

(a) A health insurer or health maintenance organization.

(b) A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406.

(c) A multiple-employer welfare arrangement as defined in s. 624.437.

(d) A governmental entity providing a plan of self-insurance.

(3) This section does not require a health insurer to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer does not otherwise cover.

Section 13. Effective January 1, 2020, subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45)(a) A health maintenance organization issuing major medical coverage through an individual or group contract may not require a step-therapy protocol under the contract for a covered prescription drug requested by a subscriber if:

1. The subscriber has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan; and

2. The subscriber provides documentation originating from the health coverage plan that approved the prescription drug as described in subparagraph 1. indicating that the health coverage plan paid for the drug on the subscriber's behalf during the 90 days immediately before the request.

(b) As used in this subsection, the term "health coverage plan" means any of the following which previously provided or is currently providing major medical or similar comprehensive

coverage or benefits to the subscriber:

1. A health insurer or health maintenance organization;

2. A plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406;

3. A multiple-employer welfare arrangement as defined in s. 624.437; or

4. A governmental entity providing a plan of self-insurance.

(c) This subsection does not require a health maintenance organization to add a drug to its prescription drug formulary or to cover a prescription drug that the health maintenance organization does not otherwise cover.

Section 14. The Office of Program Policy Analysis and Government Accountability shall research and analyze the Interstate Medical Licensure Compact and the relevant requirements and provisions of general law and the State Constitution and shall develop a report and recommendations addressing this state's prospective entrance into the compact as a member state while remaining consistent with those requirements and provisions. In conducting such research and analysis, the office may consult with the executive director, other executive staff, or the executive committee of the Interstate Medical Licensure Compact Commission. The office shall submit the report and recommendations to the Governor, the

President of the Senate, and the Speaker of the House of Representatives by not later than October 1, 2019.

Section 15. Except as otherwise expressly provided in this act, and except for this section and s. 542.336, Florida Statutes, as created by this act, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2019.

An act relating to health insurance; amending s. 110.123, F.S.; requiring health maintenance organization to be cost-effective and to offer high value; authorizing the Department of Management Services to limit the number of HMOs that it contracts with in each region; requiring the department to establish regions by rule; requiring the department to submit the rule to the Legislature for ratification; providing requirements; amending s. 110.12303, F.S.; removing an obsolete date; adding products and services offered by certain entities to a list of products and services that may be included in the package of health insurance and other benefits under the state group insurance program; requiring the department to offer, as a voluntary supplemental benefit option, certain international prescription services; amending s. 110.12315, F.S.; requiring the department to implement formulary management for prescription drugs and supplies beginning with a specified plan year; specifying requirements for such management practices; providing that certain prescription drugs and supplies may not be covered until specifically included in the formulary; requiring the department to report to the Governor and

the Legislature regarding formulary exclusions by a specified date and annually thereafter; requiring the state employees' prescription drug program to provide coverage for certain enteral formulas and amino-acid-based elemental formulas; defining the term "medically necessary"; providing a cap on such coverage; repealing s. 8 of chapter 99-255, Laws of Florida, relating to a provision that prohibits the department from implementing a prior authorization or a restricted formulary program that restricts certain non-HMO enrollees' access to specified prescription drugs within the state employees' prescription drug program; creating ss. 627.6387, 627.6648, and 641.31076, F.S.; providing a short title; defining terms; authorizing individual and group health insurers and health maintenance organizations to offer shared savings incentive programs to insureds and subscribers; providing that insureds and subscribers are not required to participate in such programs; specifying requirements for health insurers and health maintenance organizations offering such programs; requiring the Office of Insurance Regulation to review filed descriptions of programs and make a certain determination; providing notification and account credit or deposit requirements for insurers and health

maintenance organizations; specifying the minimum shared savings incentive and the basis for calculating savings; specifying requirements for annual reports submitted by health insurers and health maintenance organizations to the office; providing construction; providing that certain shared savings incentive amounts reduce a health insurer's direct written premium for purposes of the insurance premium tax and the retaliatory tax; authorizing the Financial Services Commission to adopt rules; amending s. 287.056, F.S.; requiring the department to enter into contracts with benefits consulting companies; requiring the department to conduct an analysis of the procurement timelines and terms of certain contracts with HMOs, preferred provider organizations, and prescription drug programs for a specified purpose; providing department analysis and recommendation requirements; requiring the department to submit the analysis and recommendations to the Governor and the Legislature by a specified date; providing effective dates.

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

Section 1. Paragraphs (c) and (h) of subsection (3) of

section 110.123, Florida Statutes, are amended to read:

110.123 State group insurance program.—

(3) STATE GROUP INSURANCE PROGRAM.—

(c) Notwithstanding any provision in this section to the contrary, it is the intent of the Legislature that the department shall be responsible for all aspects of the purchase of health care for state employees under the state group health insurance plan or plans, TRICARE supplemental insurance plans, and the health maintenance organization plans. Responsibilities shall include, but not be limited to, the development of requests for proposals or invitations to negotiate for state employee health benefits ~~services~~, the determination of health care benefits to be provided, and the negotiation of contracts for health care and health care administrative services. Prior to the negotiation of contracts for health care services, the Legislature intends that the department shall develop, with respect to state collective bargaining issues, the health benefits and terms to be included in the state group health insurance program. The department shall adopt rules necessary to perform its responsibilities pursuant to this section. ~~It is the intent of the Legislature that~~ The department is ~~shall be~~ responsible for the contract management and day-to-day management of the state employee health insurance program, including, but not limited to, employee enrollment, premium collection, payment to health care providers, and other

administrative functions related to the program.

(h)1. A person eligible to participate in the state group insurance program may be authorized by rules adopted by the department, in lieu of participating in the state group health insurance plan, to exercise an option to elect membership in a health maintenance organization plan which is under contract with the state in accordance with criteria established by this section and by said rules. The offer of optional membership in a health maintenance organization plan permitted by this paragraph may be limited or conditioned by rule as may be necessary to meet the requirements of state and federal laws.

2. The department shall contract with health maintenance organizations seeking to participate in the state group insurance program through a request for proposal or other procurement process, as developed by the Department of Management Services and determined to be appropriate.

a. The department shall establish a schedule of minimum benefits for health maintenance organization coverage, and that schedule shall include: physician services; inpatient and outpatient hospital services; emergency medical services, including out-of-area emergency coverage; diagnostic laboratory and diagnostic and therapeutic radiologic services; mental health, alcohol, and chemical dependency treatment services meeting the minimum requirements of state and federal law; skilled nursing facilities and services; prescription drugs;

age-based and gender-based wellness benefits; and other benefits as may be required by the department. Additional services may be provided subject to the contract between the department and the HMO. As used in this paragraph, the term "age-based and gender-based wellness benefits" includes aerobic exercise, education in alcohol and substance abuse prevention, blood cholesterol screening, health risk appraisals, blood pressure screening and education, nutrition education, program planning, safety belt education, smoking cessation, stress management, weight management, and women's health education.

b. The department may establish uniform deductibles, copayments, coverage tiers, or coinsurance schedules for all participating HMO plans.

c. The department may require detailed information from each health maintenance organization participating in the procurement process, including information pertaining to organizational status, experience in providing prepaid health benefits, accessibility of services, financial stability of the plan, quality of management services, accreditation status, quality of medical services, network access and adequacy, performance measurement, ability to meet the department's reporting requirements, and the actuarial basis of the proposed rates and other data determined by the director to be necessary for the evaluation and selection of health maintenance organization plans and negotiation of appropriate rates for

these plans. Upon receipt of proposals by health maintenance organization plans and the evaluation of those proposals, the department may enter into negotiations with all of the plans or a subset of the plans, as the department determines appropriate. ~~Nothing shall preclude~~ The department may negotiate ~~from negotiating~~ regional or statewide contracts with health maintenance organization plans. Such plans must be ~~when this is~~ cost-effective and must offer ~~when the department determines that the plan offers~~ high value to enrollees.

d. The department may limit the number of HMOs that it contracts with in each region ~~service area~~ based on the nature of the bids the department receives, the number of state employees in the region ~~service area~~, or any unique ~~geographical~~ characteristics of the region ~~service area~~. The department shall establish the regions throughout the state by rule. The department must submit the rule to the President of the Senate and the Speaker of the House of Representatives for ratification no later than 30 days before the 2020 Regular Session of the Legislature. The rule may not take effect until it is ratified by the Legislature ~~by rule service areas throughout the state~~.

e. All persons participating in the state group insurance program may be required to contribute towards a total state group health premium that may vary depending upon the plan, coverage level, and coverage tier selected by the enrollee and the level of state contribution authorized by the Legislature.

3. The department is authorized to negotiate and to contract with specialty psychiatric hospitals for mental health benefits, on a regional basis, for alcohol, drug abuse, and mental and nervous disorders. The department may establish, subject to the approval of the Legislature pursuant to subsection (5), any such regional plan upon completion of an actuarial study to determine any impact on plan benefits and premiums.

4. In addition to contracting pursuant to subparagraph 2., the department may enter into contract with any HMO to participate in the state group insurance program which:

a. Serves greater than 5,000 recipients on a prepaid basis under the Medicaid program;

b. Does not currently meet the 25-percent non-Medicare/non-Medicaid enrollment composition requirement established by the Department of Health excluding participants enrolled in the state group insurance program;

c. Meets the minimum benefit package and copayments and deductibles contained in sub-subparagraphs 2.a. and b.;

d. Is willing to participate in the state group insurance program at a cost of premiums that is not greater than 95 percent of the cost of HMO premiums accepted by the department in each service area; and

e. Meets the minimum surplus requirements of s. 641.225.

The department is authorized to contract with HMOs that meet the requirements of sub-subparagraphs a.-d. prior to the open enrollment period for state employees. The department is not required to renew the contract with the HMOs as set forth in this paragraph more than twice. Thereafter, the HMOs shall be eligible to participate in the state group insurance program only through the request for proposal or invitation to negotiate process described in subparagraph 2.

5. All enrollees in a state group health insurance plan, a TRICARE supplemental insurance plan, or any health maintenance organization plan have the option of changing to any other health plan that is offered by the state within any open enrollment period designated by the department. Open enrollment shall be held at least once each calendar year.

6. When a contract between a treating provider and the state-contracted health maintenance organization is terminated for any reason other than for cause, each party shall allow any enrollee for whom treatment was active to continue coverage and care when medically necessary, through completion of treatment of a condition for which the enrollee was receiving care at the time of the termination, until the enrollee selects another treating provider, or until the next open enrollment period offered, whichever is longer, but no longer than 6 months after termination of the contract. Each party to the terminated contract shall allow an enrollee who has initiated a course of

prenatal care, regardless of the trimester in which care was initiated, to continue care and coverage until completion of postpartum care. This does not prevent a provider from refusing to continue to provide care to an enrollee who is abusive, noncompliant, or in arrears in payments for services provided. For care continued under this subparagraph, the program and the provider shall continue to be bound by the terms of the terminated contract. Changes made within 30 days before termination of a contract are effective only if agreed to by both parties.

7. Any HMO participating in the state group insurance program shall submit health care utilization and cost data to the department, in such form and in such manner as the department shall require, as a condition of participating in the program. The department shall enter into negotiations with its contracting HMOs to determine the nature and scope of the data submission and the final requirements, format, penalties associated with noncompliance, and timetables for submission. These determinations shall be adopted by rule.

8. The department may establish and direct, with respect to collective bargaining issues, a comprehensive package of insurance benefits that may include supplemental health and life coverage, dental care, long-term care, vision care, and other benefits it determines necessary to enable state employees to select from among benefit options that best suit their

individual and family needs. Beginning with the 2018 plan year, the package of benefits may also include products and services described in s. 110.12303.

a. Based upon a desired benefit package, the department shall issue a request for proposal or invitation to negotiate for providers interested in participating in the state group insurance program, and the department shall issue a request for proposal or invitation to negotiate for providers interested in participating in the non-health-related components of the state group insurance program. Upon receipt of all proposals, the department may enter into contract negotiations with providers submitting bids or negotiate a specially designed benefit package. Providers offering or providing supplemental coverage as of May 30, 1991, which qualify for pretax benefit treatment pursuant to s. 125 of the Internal Revenue Code of 1986, with 5,500 or more state employees currently enrolled may be included by the department in the supplemental insurance benefit plan established by the department without participating in a request for proposal, submitting bids, negotiating contracts, or negotiating a specially designed benefit package. These contracts shall provide state employees with the most cost-effective and comprehensive coverage available; however, except as provided in subparagraph (f)3., no state or agency funds shall be contributed toward the cost of any part of the premium of such supplemental benefit plans. With respect to dental

coverage, the division shall include in any solicitation or contract for any state group dental program made after July 1, 2001, a comprehensive indemnity dental plan option which offers enrollees a completely unrestricted choice of dentists. If a dental plan is endorsed, or in some manner recognized as the preferred product, such plan shall include a comprehensive indemnity dental plan option which provides enrollees with a completely unrestricted choice of dentists.

b. Pursuant to the applicable provisions of s. 110.161, and s. 125 of the Internal Revenue Code of 1986, the department shall enroll in the pretax benefit program those state employees who voluntarily elect coverage in any of the supplemental insurance benefit plans as provided by sub-subparagraph a.

c. Nothing herein contained shall be construed to prohibit insurance providers from continuing to provide or offer supplemental benefit coverage to state employees as provided under existing agency plans.

Section 2. Section 110.12303, Florida Statutes, is amended to read:

110.12303 State group insurance program; additional benefits; price transparency program; reporting. ~~Beginning with the 2018 plan year:~~

(1) In addition to the comprehensive package of health insurance and other benefits required or authorized to be included in the state group insurance program, the package of

benefits may also include products and services offered by:

(a) Prepaid limited health service organizations authorized pursuant to part I of chapter 636.

(b) Discount medical plan organizations authorized pursuant to part II of chapter 636.

(c) Prepaid health clinics licensed under part II of chapter 641.

(d) Licensed health care providers, including hospitals and other health care facilities, health care clinics, and health professionals, who sell service contracts and arrangements for a specified amount and type of health services.

(e) Provider organizations, including service networks, group practices, professional associations, and other incorporated organizations of providers, who sell service contracts and arrangements for a specified amount and type of health services.

(f) Entities that provide specific health services in accordance with applicable state law and sell service contracts and arrangements for a specified amount and type of health services.

(g) Entities that provide health services or treatments through a bidding process.

(h) Entities that provide health services or treatments through the bundling or aggregating of health services or treatments.

(i) Entities that provide international prescription services.

(j) Entities that provide optional participation in a Medicare Advantage Prescription Drug Plan.

(k) Entities that provide other innovative and cost-effective health service delivery methods.

(2)(a) The department shall contract with at least one entity that provides comprehensive pricing and inclusive services for surgery and other medical procedures which may be accessed at the option of the enrollee. The contract shall require the entity to:

1. Have procedures and evidence-based standards to ensure the inclusion of only high-quality health care providers.

2. Provide assistance to the enrollee in accessing and coordinating care.

3. Provide cost savings to the state group insurance program to be shared with both the state and the enrollee. Cost savings payable to an enrollee may be:

a. Credited to the enrollee's flexible spending account;

b. Credited to the enrollee's health savings account;

c. Credited to the enrollee's health reimbursement account; or

d. Paid as additional health plan reimbursements not exceeding the amount of the enrollee's out-of-pocket medical expenses.

4. Provide an educational campaign for enrollees to learn about the services offered by the entity.

(b) On or before January 15 of each year, the department shall report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level and cost-savings to both the enrollee and the state resulting from the contract or contracts described in this subsection.

(3) The department shall contract with an entity that provides enrollees with online information on the cost and quality of health care services and providers, allows an enrollee to shop for health care services and providers, and rewards the enrollee by sharing savings generated by the enrollee's choice of services or providers. The contract shall require the entity to:

(a) Establish an Internet-based, consumer-friendly platform that educates and informs enrollees about the price and quality of health care services and providers, including the average amount paid in each county for health care services and providers. The average amounts paid for such services and providers may be expressed for service bundles, which include all products and services associated with a particular treatment or episode of care, or for separate and distinct products and services.

(b) Allow enrollees to shop for health care services and

providers using the price and quality information provided on the Internet-based platform.

(c) Permit a certified bargaining agent of state employees to provide educational materials and counseling to enrollees regarding the Internet-based platform.

(d) Identify the savings realized to the enrollee and state if the enrollee chooses high-quality, lower-cost health care services or providers, and facilitate a shared savings payment to the enrollee. The amount of shared savings shall be determined by a methodology approved by the department and shall maximize value-based purchasing by enrollees. The amount payable to the enrollee may be:

1. Credited to the enrollee's flexible spending account;

2. Credited to the enrollee's health savings account;

3. Credited to the enrollee's health reimbursement account; or

4. Paid as additional health plan reimbursements not exceeding the amount of the enrollee's out-of-pocket medical expenses.

(e) On or before January 1 of 2019, 2020, and 2021, the department shall report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level, amount paid to enrollees, and cost-savings to both the enrollees and the state resulting from the implementation of this subsection.

(4) The department shall offer, as a voluntary supplemental benefit option, international prescription services that offer safe maintenance medications at a reduced cost to enrollees and that meet the standards of the United States Food and Drug Administration personal importation policy.

Section 3. Subsections (9) and (10) are added to section 110.12315, Florida Statutes, to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(9)(a) Beginning with the 2020 plan year, the department must implement formulary management for prescription drugs and supplies. Such management practices must require prescription drugs to be subject to formulary inclusion or exclusion but may not restrict access to the most clinically appropriate, clinically effective, and lowest net-cost prescription drugs and supplies. Drugs excluded from the formulary must be available for inclusion if a physician, advanced practice registered nurse, or physician assistant prescribing a pharmaceutical clearly states on the prescription that the excluded drug is medically necessary. Prescription drugs and supplies first made available in the marketplace after January 1, 2020, may not be

covered by the prescription drug program until specifically included in the list of covered prescription drugs and supplies.

(b) No later than October 1, 2019, and by each October 1 thereafter, the department must submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives the list of prescription drugs and supplies that will be excluded from program coverage for the next plan year. If the department proposes to exclude prescription drugs and supplies after the plan year has commenced, the department must provide notice to the Governor, the President of the Senate, and the Speaker of the House of Representatives of such exclusions at least 60 days before implementation of such exclusions.

(10) In addition to the comprehensive package of health insurance and other benefits required or authorized to be included in the state group insurance program, the program must provide coverage for medically necessary prescription and nonprescription enteral formulas and amino-acid-based elemental formulas for home use, regardless of the method of delivery or intake, which are ordered or prescribed by a physician. As used in this subsection, the term "medically necessary" means the formula to be covered represents the only medically appropriate source of nutrition for a patient. Such coverage may not exceed an amount of $20,000 annually for any insured individual.

Section 4. Effective December 31, 2019, section 8 of chapter 99-255, Laws of Florida, is repealed.

Section 5. Effective January 1, 2020, section 627.6387, Florida Statutes, is created to read:

627.6387 Shared savings incentive program.—

(1) This section and ss. 627.6648 and 641.31076 may be cited as the "Patient Savings Act."

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

(a) "Health care provider" means a hospital or facility licensed under chapter 395; an entity licensed under chapter 400; a health care practitioner as defined in s. 456.001; a blood bank, plasma center, industrial clinic, or renal dialysis facility; or a professional association, partnership, corporation, joint venture, or other association for professional activity by health care providers. The term includes entities and professionals outside of this state with an active, unencumbered license for an equivalent facility or practitioner type issued by another state, the District of Columbia, or a possession or territory of the United States.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603.

(c) "Shared savings incentive" means a voluntary and optional financial incentive that a health insurer may provide to an insured for choosing certain shoppable health care services under a shared savings incentive program and may include, but is not limited to, the incentives described in s. 626.9541(4)(a).

(d) "Shared savings incentive program" means a voluntary and optional incentive program established by a health insurer pursuant to this section.

(e) "Shoppable health care service" means a lower-cost, high-quality nonemergency health care service for which a shared savings incentive is available for insureds under a health insurer's shared savings incentive program. Shoppable health care services may be provided within or outside this state and include, but are not limited to:

1. Clinical laboratory services.

2. Infusion therapy.

3. Inpatient and outpatient surgical procedures.

4. Obstetrical and gynecological services.

5. Inpatient and outpatient nonsurgical diagnostic tests and procedures.

6. Physical and occupational therapy services.

7. Radiology and imaging services.

8. Prescription drugs.

9. Services provided through telehealth.

(3) A health insurer may offer a shared savings incentive program to provide incentives to an insured when the insured obtains a shoppable health care service from the health insurer's shared savings list. An insured may not be required to participate in a shared savings incentive program. A health insurer that offers a shared savings incentive program must:

(a) Establish the program as a component part of the policy or certificate of insurance provided by the health insurer and notify the insureds and the office at least 30 days before program termination.

(b) File a description of the program on a form prescribed by commission rule. The office must review the filing and determine whether the shared savings incentive program complies with this section.

(c) Notify an insured annually and at the time of renewal, and an applicant for insurance at the time of enrollment, of the availability of the shared savings incentive program and the procedure to participate in the program.

(d) Publish on a webpage easily accessible to insureds and to applicants for insurance a list of shoppable health care services and health care providers and the shared savings incentive amount applicable for each service. A shared savings incentive may not be less than 25 percent of the savings generated by the insured's participation in any shared savings incentive offered by the health insurer. The baseline for the savings calculation is the average in-network amount paid for that service in the most recent 12-month period or some other methodology established by the health insurer and approved by the office.

(e) At least quarterly, credit or deposit the shared savings incentive amount to the insured's account as a return or

reduction in premium, or credit the shared savings incentive amount to the insured's flexible spending account, health savings account, or health reimbursement account, such that the amount does not constitute income to the insured.

(f) Submit an annual report to the office within 90 business days after the close of each plan year. At a minimum, the report must include the following information:

1. The number of insureds who participated in the program during the plan year and the number of instances of participation.

2. The total cost of services provided as a part of the program.

3. The total value of the shared savings incentive payments made to insureds participating in the program and the values distributed as premium reductions, credits to flexible spending accounts, credits to health savings accounts, or credits to health reimbursement accounts.

4. An inventory of the shoppable health care services offered by the health insurer.

(4)(a) A shared savings incentive offered by a health insurer in accordance with this section:

1. Is not an administrative expense for rate development or rate filing purposes.

2. Does not constitute an unfair method of competition or an unfair or deceptive act or practice under s. 626.9541 and is

presumed to be appropriate unless credible data clearly demonstrates otherwise.

(b) A shared savings incentive amount provided as a return or reduction in premium reduces the health insurer's direct written premium by the shared savings incentive dollar amount for the purposes of the taxes in ss. 624.509 and 624.5091.

(5) The commission may adopt rules necessary to implement and enforce this section.

Section 6. Effective January 1, 2020, section 627.6648, Florida Statutes, is created to read:

627.6648 Shared savings incentive program.—

(1) This section and ss. 627.6387 and 641.31076 may be cited as the "Patient Savings Act."

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

(a) "Health care provider" means a hospital or facility licensed under chapter 395; an entity licensed under chapter 400; a health care practitioner as defined in s. 456.001; a blood bank, plasma center, industrial clinic, or renal dialysis facility; or a professional association, partnership, corporation, joint venture, or other association for professional activity by health care providers. The term includes entities and professionals outside this state with an active, unencumbered license for an equivalent facility or practitioner type issued by another state, the District of Columbia, or a possession or territory of the United States.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603. The term does not include the state group health insurance program provided under s. 110.123.

(c) "Shared savings incentive" means a voluntary and optional financial incentive that a health insurer may provide to an insured for choosing certain shoppable health care services under a shared savings incentive program and may include, but is not limited to, the incentives described in s. 626.9541(4)(a).

(d) "Shared savings incentive program" means a voluntary and optional incentive program established by a health insurer pursuant to this section.

(e) "Shoppable health care service" means a lower-cost, high-quality nonemergency health care service for which a shared savings incentive is available for insureds under a health insurer's shared savings incentive program. Shoppable health care services may be provided within or outside this state and include, but are not limited to:

1. Clinical laboratory services.

2. Infusion therapy.

3. Inpatient and outpatient surgical procedures.

4. Obstetrical and gynecological services.

5. Inpatient and outpatient nonsurgical diagnostic tests and procedures.

6. Physical and occupational therapy services.

7. Radiology and imaging services.

8. Prescription drugs.

9. Services provided through telehealth.

(3) A health insurer may offer a shared savings incentive program to provide incentives to an insured when the insured obtains a shoppable health care service from the health insurer's shared savings list. An insured may not be required to participate in a shared savings incentive program. A health insurer that offers a shared savings incentive program must:

(a) Establish the program as a component part of the policy or certificate of insurance provided by the health insurer and notify the insureds and the office at least 30 days before program termination.

(b) File a description of the program on a form prescribed by commission rule. The office must review the filing and determine whether the shared savings incentive program complies with this section.

(c) Notify an insured annually and at the time of renewal, and an applicant for insurance at the time of enrollment, of the availability of the shared savings incentive program and the procedure to participate in the program.

(d) Publish on a webpage easily accessible to insureds and to applicants for insurance a list of shoppable health care services and health care providers and the shared savings

incentive amount applicable for each service. A shared savings incentive may not be less than 25 percent of the savings generated by the insured's participation in any shared savings incentive offered by the health insurer. The baseline for the savings calculation is the average in-network amount paid for that service in the most recent 12-month period or some other methodology established by the health insurer and approved by the office.

(e) At least quarterly, credit or deposit the shared savings incentive amount to the insured's account as a return or reduction in premium, or credit the shared savings incentive amount to the insured's flexible spending account, health savings account, or health reimbursement account, such that the amount does not constitute income to the insured.

(f) Submit an annual report to the office within 90 business days after the close of each plan year. At a minimum, the report must include the following information:

1. The number of insureds who participated in the program during the plan year and the number of instances of participation.

2. The total cost of services provided as a part of the program.

3. The total value of the shared savings incentive payments made to insureds participating in the program and the values distributed as premium reductions, credits to flexible

spending accounts, credits to health savings accounts, or credits to health reimbursement accounts.

4. An inventory of the shoppable health care services offered by the health insurer.

(4)(a) A shared savings incentive offered by a health insurer in accordance with this section:

1. Is not an administrative expense for rate development or rate filing purposes.

2. Does not constitute an unfair method of competition or an unfair or deceptive act or practice under s. 626.9541 and is presumed to be appropriate unless credible data clearly demonstrates otherwise.

(b) A shared savings incentive amount provided as a return or reduction in premium reduces the health insurer's direct written premium by the shared savings incentive dollar amount for the purposes of the taxes in ss. 624.509 and 624.5091.

(5) The commission may adopt rules necessary to implement and enforce this section.

Section 7. Effective January 1, 2020, section 641.31076, Florida Statutes, is created to read:

641.31076 Shared savings incentive program.—

(1) This section and ss. 627.6387 and 627.6648 may be cited as the "Patient Savings Act."

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

(a) "Health care provider" means a hospital or facility

licensed under chapter 395; an entity licensed under chapter 400; a health care practitioner as defined in s. 456.001; a blood bank, plasma center, industrial clinic, or renal dialysis facility; or a professional association, partnership, corporation, joint venture, or other association for professional activity by health care providers. The term includes entities and professionals outside this state with an active, unencumbered license for an equivalent facility or practitioner type issued by another state, the District of Columbia, or a possession or territory of the United States.

(b) "Health maintenance organization" has the same meaning as provided in s. 641.19. The term does not include the state group health insurance program provided under s. 110.123.

(c) "Shared savings incentive" means a voluntary and optional financial incentive that a health maintenance organization may provide to a subscriber for choosing certain shoppable health care services under a shared savings incentive program and may include, but is not limited to, the incentives described in s. 641.3903(15).

(d) "Shared savings incentive program" means a voluntary and optional incentive program established by a health maintenance organization pursuant to this section.

(e) "Shoppable health care service" means a lower-cost, high-quality nonemergency health care service for which a shared savings incentive is available for subscribers under a health

maintenance organization's shared savings incentive program. Shoppable health care services may be provided within or outside this state and include, but are not limited to:

1. Clinical laboratory services.

2. Infusion therapy.

3. Inpatient and outpatient surgical procedures.

4. Obstetrical and gynecological services.

5. Inpatient and outpatient nonsurgical diagnostic tests and procedures.

6. Physical and occupational therapy services.

7. Radiology and imaging services.

8. Prescription drugs.

9. Services provided through telehealth.

(3) A health maintenance organization may offer a shared savings incentive program to provide incentives to a subscriber when the subscriber obtains a shoppable health care service from the health maintenance organization's shared savings list. A subscriber may not be required to participate in a shared savings incentive program. A health maintenance organization that offers a shared savings incentive program must:

(a) Establish the program as a component part of the contract of coverage provided by the health maintenance organization and notify the subscribers and the office at least 30 days before program termination.

(b) File a description of the program on a form prescribed

by commission rule. The office must review the filing and determine whether the shared savings incentive program complies with this section.

(c) Notify a subscriber annually and at the time of renewal, and an applicant for coverage at the time of enrollment, of the availability of the shared savings incentive program and the procedure to participate in the program.

(d) Publish on a webpage easily accessible to subscribers and to applicants for coverage a list of shoppable health care services and health care providers and the shared savings incentive amount applicable for each service. A shared savings incentive may not be less than 25 percent of the savings generated by the subscriber's participation in any shared savings incentive offered by the health maintenance organization. The baseline for the savings calculation is the average in-network amount paid for that service in the most recent 12-month period or some other methodology established by the health maintenance organization and approved by the office.

(e) At least quarterly, credit or deposit the shared savings incentive amount to the subscriber's account as a return or reduction in premium, or credit the shared savings incentive amount to the subscriber's flexible spending account, health savings account, or health reimbursement account, such that the amount does not constitute income to the subscriber.

(f) Submit an annual report to the office within 90

business days after the close of each plan year. At a minimum, the report must include the following information:

1. The number of subscribers who participated in the program during the plan year and the number of instances of participation.

2. The total cost of services provided as a part of the program.

3. The total value of the shared savings incentive payments made to subscribers participating in the program and the values distributed as premium reductions, credits to flexible spending accounts, credits to health savings accounts, or credits to health reimbursement accounts.

4. An inventory of the shoppable health care services offered by the health maintenance organization.

(4) A shared savings incentive offered by a health maintenance organization in accordance with this section:

(a) Is not an administrative expense for rate development or rate filing purposes.

(b) Does not constitute an unfair method of competition or an unfair or deceptive act or practice under s. 641.3903 and is presumed to be appropriate unless credible data clearly demonstrates otherwise.

(5) The commission may adopt rules necessary to implement and enforce this section.

Section 8. Subsection (3) is added to section 287.056,

Florida Statutes, to read:

287.056 Purchases from purchasing agreements and state term contracts.—

(3) The department must enter into and maintain one or more state term contracts with benefits consulting companies.

Section 9. The Department of Management Services shall conduct an analysis of the procurement timelines and terms of contracts for state employee health benefits with health maintenance organizations, preferred provider organizations, and prescription drug programs to develop an implementation plan for simultaneous procurement of such contracts for benefits offered beginning plan year 2023. The analysis and any recommendations from the department must identify any statutory changes and additional budgetary resources, if any, that will be necessary to implement the plan. The analysis and recommendations must be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than December 1, 2019.

Section 10. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2019.

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; defining the term "electronic health recordkeeping system"; requiring the Department of Health to develop a unique identifier for each patient in the system; prohibiting the unique identifier from identifying or providing a basis for identification by unauthorized individuals; authorizing the Attorney General to request information for an active investigation or pending civil or criminal litigation involving prescribed controlled substances; requiring such information to be released upon the granting of a petition or motion by a trial court; providing exceptions; requiring a trial court to grant a petition or motion under certain circumstances; limiting the patient information the department may provide; authorizing the Attorney General to introduce as evidence in certain actions specified information that is released to the Attorney General from the prescription drug monitoring program; authorizing certain persons to testify as to the authenticity of certain records; amending s. 893.0551, F.S.; authorizing the Attorney General to have access to records when ordered by a court under specified provisions; providing for future

repeal of amendments unless reviewed and saved from repeal through reenactment by the Legislature; providing for effect of amendments by other provisions; providing an effective date.

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

Section 1. Paragraphs (f) through (k) of subsection (1) of section 893.055, Florida Statutes, are redesignated as paragraphs (g) through (l), respectively, paragraph (b) of subsection (2) is redesignated as paragraph (c), paragraph (b) of subsection (5) and subsection (10) are amended, a new paragraph (f) is added to subsection (1), and a new paragraph (b) is added to subsection (2) of that section, to read:

893.055 Prescription drug monitoring program.—

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

(f) "Electronic health recordkeeping system" means an electronic or computer-based information system used by health care practitioners or providers to create, collect, store, manipulate, exchange, or make available personal health information for the delivery of patient care.

(2)

(b) To protect personally identifiable information, the department shall assign a unique identifier to each patient for whom a record exists in the system. Such identifier may not

identify or provide a reasonable basis to identify a patient by any person not authorized under this section to access personally identifiable information in the system.

(5) The following entities may not directly access information in the system, but may request information from the program manager or designated program and support staff:

(b) The Attorney General for:

1. Medicaid fraud cases involving prescribed controlled substances.

2. An active investigation or pending civil or criminal litigation involving prescribed controlled substances, other than Medicaid fraud cases, upon the granting of a petition or motion by a trial court which specifically identifies the active or pending matter. The Attorney General shall ensure that information obtained under this subparagraph is not used for any purpose other than the specific matter stated in the petition or motion. Notice to any party regarding such petition or motion is not required, except in cases of pending civil litigation. The trial court shall grant the petition or motion and authorize release of information when the information appears reasonably calculated to lead to the discovery of admissible evidence. The department may not release any patient information pursuant to this subparagraph other than the patient's unique identifier assigned pursuant to paragraph (2)(b), year of birth, and the county, city, and zip code where the patient resides, consistent

with the provisions of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. The Attorney General shall maintain a log of each person with whom the information is shared to document the chain of custody, execute a confidentiality agreement or an agreement bound by a protective order with each such person, ensure that the information is maintained in a secure manner, and require each such person to return all information or certify its destruction under penalty of perjury to the Attorney General upon the final resolution of the matter for which the information was requested.

(10) Information in the prescription drug monitoring program's system may be released only as provided in this section and s. 893.0551.

(a) Except as provided in paragraph (b), the content of the system is intended to be informational only. Information in the system is not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of information in the system. The program manager and authorized persons who participate in preparing, reviewing, issuing, or any other activity related to management of the system may not be permitted or required to testify in any such civil or administrative action as to any findings, recommendations, evaluations, opinions, or other

actions taken in connection with management of the system.

(b) The Attorney General may introduce information from the system released pursuant to subparagraph (5)(b)2. as evidence in a civil, criminal, or administrative action against a dispenser, manufacturer, or a pharmacy. The program manager and authorized persons who participate in preparing, reviewing, issuing, or any other activity related to the management of the system may testify for purposes of authenticating the records introduced into evidence pursuant to this paragraph.

Section 2. Paragraph (e) of subsection (3) and subsection (6) of section 893.0551, Florida Statutes, are amended to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

(3) The department shall disclose such information to the following persons or entities upon request and after using a verification process to ensure the legitimacy of the request as provided in s. 893.055:

(e) The Attorney General or his or her designee:

1. When working on Medicaid fraud cases involving prescribed controlled substances or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud or specific identifiers that warrant a Medicaid investigation regarding prescribed controlled substances. The Attorney General's Medicaid fraud investigators may not have direct access to the department's system. The Attorney General or his

or her designee may disclose to a criminal justice agency, as defined in s. 119.011, only the information received from the department that is relevant to an identified active investigation that prompted the request for the information.

2. Upon a court order authorizing the release of patient information under s. 893.055(5)(b)2.

(6) An agency or person who obtains any information pursuant to this section must maintain the confidential and exempt status of that information and may not disclose such information unless authorized by law. Information shared with a state attorney pursuant to paragraph (3)(f), ~~or~~ paragraph (3)(h), or with the Attorney General or his or her designee pursuant to subparagraph (3)(e)2. may be released only in response to a discovery demand if such information is directly related to the ~~criminal~~ case for which the information was requested. Unrelated information may be released only upon an order of a court of competent jurisdiction.

Section 3. The amendments to ss. 893.055 and 893.0551, Florida Statutes, made by this act shall stand repealed on June 30, 2021, unless reviewed and saved from repeal through reenactment by the Legislature. If such amendments are not saved from repeal, the text of ss. 893.055 and 893.0551, Florida Statutes, shall revert to that in existence on June 30, 2019, except that any amendments to such text other than by this act shall be preserved and continue to operate to the extent that

such amendments are not dependent upon the portions of text which expire pursuant to this section.

Section 4. This act shall take effect July 1, 2019.

An act relating to mental health; amending s. 394.4615, F.S.; requiring service providers to disclose information from a clinical record under certain circumstances relating to threats to cause serious bodily injury or death; requiring a law enforcement agency that receives notification of a specific threat to take appropriate action; providing immunity for service providers for certain actions; amending s. 394.463, F.S.; revising deadlines for submission of documentation regarding involuntary examinations; requiring that additional information be included in reports to the department; requiring the department to report to the Governor and Legislature on data collected from such reports; amending s. 394.917, F.S.; revising the purpose of civil commitment of sexually violent predators to the department after completion of their criminal incarceration sentences; amending s. 456.059, F.S.; requiring psychiatrists to disclose certain patient communications for purposes of notifying law enforcement agencies of certain threats; requiring the notified law enforcement agency to take appropriate action to prevent the risk of harm to the victim; providing psychiatrists with immunity from specified liability and actions under certain circumstances; amending s. 490.0147, F.S.; requiring psychologists to disclose certain patient or client communications for purposes of notifying law enforcement agencies of

certain threats; requiring the notified law enforcement agency to take appropriate action to prevent the risk of harm to the victim; providing psychologists with immunity from specified liability and actions under certain circumstances; amending s. 491.0147, F.S.; requiring certain license holders and certificate holders to disclose certain patient or client communications for purposes of notifying law enforcement agencies of certain threats; requiring the notified law enforcement agency to take appropriate action to prevent the risk of harm to the victim; providing such persons with immunity from specified liability and actions; amending s. 1012.583, F.S.; revising responsibilities of the Department of Education and the Statewide Office for Suicide Prevention; revising criteria for designation as a Suicide Prevention Certified School; requiring that the department, schools, and school districts post certain information regarding such schools be posted on their respective websites; reenacting ss. 490.009 and 491.009, F.S., relating to discipline of psychologists and other licensed therapists, to incorporate amendments made by the act; providing an effective date.

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

Section 1. Present subsections (4) through (11) of section 394.4615, Florida Statutes, are renumbered as subsections (5)

through (12), respectively, paragraph (a) of subsection (3) is amended, and a new subsection (4) is added to that section, to read:

394.4615 Clinical records; confidentiality.—

(3) Information from the clinical record may be released in the following circumstances:

(a) When a patient has communicated to a service provider a specific threat to cause serious bodily injury or death to an identified or a readily available person, if the service provider reasonably believes, or should reasonably believe according to the standards of his or her profession, that the patient has the apparent intent and ability to imminently or immediately carry out such threat ~~declared an intention to harm other persons~~. When such communication ~~declaration~~ has been made, the administrator may authorize the release of sufficient information to provide adequate warning to the person threatened with harm by the patient.

For the purpose of determining whether a person meets the criteria for involuntary outpatient placement or for preparing the proposed treatment plan pursuant to s. 394.4655, the clinical record may be released to the state attorney, the public defender or the patient’s private legal counsel, the court, and to the appropriate mental health professionals, including the service provider identified in s. 394.4655(7)(b)2., in accordance with state and federal law.

(4) Information from the clinical record must be released when a patient has communicated to a service provider a specific threat to cause serious bodily injury or death to an identified

or a readily available person, if the service provider reasonably believes, or should reasonably believe according to the standards of his or her profession, that the patient has the apparent intent and ability to imminently or immediately carry out such threat. When such communication has been made, the administrator must authorize the release of sufficient information to communicate the threat to law enforcement. A law enforcement agency that receives notification of a specific threat under this subsection must take appropriate action to prevent the risk of harm, including, but not limited to, notifying the intended victim of such threat or initiating a risk protection order. A service provider's authorization to release information from a clinical record when communicating a threat pursuant to this section may not be the basis of any legal action or criminal or civil liability against the service provider.

Section 2. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended, and subsection (4) is added to that section, to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A circuit or county court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination and specifying the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on written or oral sworn testimony that includes specific facts that support the findings. If other

less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The order of the court shall be made a part of the patient's clinical record. A fee may not be charged for the filing of an order under this subsection. A facility accepting the patient based on this order must send a copy of the order to the department within 5 ~~the next~~ working days ~~day~~. The order may be submitted electronically through existing data systems, if available. The order shall be valid only until the person is delivered to the facility or for the period specified in the order itself, whichever comes first. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, which must be made a part of the patient's clinical record. Any facility accepting the patient based on this report must send a copy of the report to the department within 5 ~~the next~~ working days ~~day~~.

3. A physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, or

clinical social worker may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means, such as voluntary appearance for outpatient evaluation, are not available, a law enforcement officer shall take into custody the person named in the certificate and deliver him or her to the appropriate, or nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any facility accepting the patient based on this certificate must send a copy of the certificate to the department within 5 ~~the next~~ working days ~~day~~. The document may be submitted electronically through existing data systems, if applicable.

When sending the order, report, or certificate to the department, a facility shall at a minimum provide information about which action was taken regarding the patient under paragraph (g), which information shall also be made a part of the patient's clinical record.

(4) DATA ANALYSIS.—Using data collected under paragraph (2)(a), the department shall, at a minimum, analyze data on the initiation of involuntary examinations of children, identify any patterns or trends and cases in which involuntary examinations are repeatedly initiated on the same child, study root causes

for such patterns, trends, or repeated involuntary examinations, and make recommendations for encouraging alternatives to and eliminating inappropriate initiations of such examinations. The department shall submit a report on its findings and recommendations to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1 of each odd numbered year.

Section 3. Subsection (2) of section 394.917, Florida Statutes, is amended to read:

394.917 Determination; commitment procedure; mistrials; housing; counsel and costs in indigent appellate cases.—

(2) If the court or jury determines that the person is a sexually violent predator, upon the expiration of the incarcerative portion of all criminal sentences and disposition of any detainers, the person shall be committed to the custody of the Department of Children and Families for control, care, ~~and~~ treatment, and rehabilitation of criminal offenders, until such time as the person's mental abnormality or personality disorder has so changed that it is safe for the person to be at large. At all times, persons who are detained or committed under this part shall be kept in a secure facility segregated from patients of the department who are not detained or committed under this part.

Section 4. Section 456.059, Florida Statutes, is amended to read:

456.059 Communications confidential; exceptions.—Communications between a patient and a psychiatrist, as defined in s. 394.455, shall be held confidential and may ~~shall~~ not be disclosed except upon the request of the patient or the

patient's legal representative. Provision of psychiatric records and reports are ~~shall be~~ governed by s. 456.057. Notwithstanding any other provision of this section or s. 90.503, when ~~where~~:

(1) A patient is engaged in a treatment relationship with a psychiatrist;

(2) Such patient has communicated to the psychiatrist a specific threat to cause serious bodily injury or death to an identified or a readily available person ~~made an actual threat to physically harm an identifiable victim or victims~~; and

(3) The treating psychiatrist makes a clinical judgment that the patient has the apparent intent and ability to imminently or immediately carry out such threat ~~capability to commit such an act and that it is more likely than not that in the near future the patient will carry out that threat~~,

the psychiatrist may disclose patient communications to the extent necessary to warn any potential victim ~~or~~ and must disclose patient communications to the extent necessary to communicate the threat to a law enforcement agency. A law enforcement agency that receives notification of a specific threat under this subsection must take appropriate action to prevent the risk of harm, including, but not limited to, notifying the intended victim of such threat or initiating a risk protection order. A psychiatrist's disclosure of confidential communications when communicating a threat pursuant to this section may not be the basis of any legal action or criminal or civil liability against the psychiatrist ~~No civil or criminal action shall be instituted, and there shall be no liability on account of disclosure of otherwise confidential~~

~~communications by a psychiatrist in disclosing a threat pursuant to this section~~.

Section 5. Section 490.0147, Florida Statutes, is amended to read:

490.0147 Confidentiality and privileged communications.—

(1) Any communication between a psychologist ~~any person licensed under this chapter~~ and her or his patient or client is ~~shall be~~ confidential. This privilege may be waived under the following conditions:

(a) ~~(1)~~ When the psychologist ~~person licensed under this chapter~~ is a party defendant to a civil, criminal, or disciplinary action arising from a complaint filed by the patient or client, in which case the waiver shall be limited to that action~~.~~;

(b) ~~(2)~~ When the patient or client agrees to the waiver, in writing, or when more than one person in a family is receiving therapy, when each family member agrees to the waiver, in writing~~.~~; or

(c) ~~(3)~~ When a patient or client has communicated to the psychologist a specific threat to cause serious bodily injury or death to an identified or readily available person, and the psychologist makes a clinical judgment that the patient or client has the apparent intent and ability to imminently or immediately carry out such threat and the psychologist ~~there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society and the person licensed under this chapter~~ communicates the information ~~only~~ to the potential victim~~, appropriate family member, or law enforcement or other appropriate authorities~~. A disclosure of

confidential communications by a psychologist when communicating a threat pursuant to this subsection may not be the basis of any legal action or criminal or civil liability against the psychologist.

(2) Such privilege must be waived, and the psychologist shall disclose patient or client communications to the extent necessary to communicate the threat to a law enforcement agency, if a patient or client has communicated to the psychologist a specific threat to cause serious bodily injury or death to an identified or readily available person, and the psychologist makes a clinical judgment that the patient or client has the apparent intent and ability to imminently or immediately carry out such threat. A law enforcement agency that receives notification of a specific threat under this subsection must take appropriate action to prevent the risk of harm, including, but not limited to, notifying the intended victim of such threat or initiating a risk protection order. A psychologist's disclosure of confidential communications when communicating a threat pursuant to this subsection may not be the basis of any legal action or criminal or civil liability against the psychologist.

Section 6. Section 491.0147, Florida Statutes, is amended to read:

491.0147 Confidentiality and privileged communications.—Any communication between any person licensed or certified under this chapter and her or his patient or client is ~~shall be~~ confidential.

(1) This privilege ~~secrecy~~ may be waived under the following conditions:

(a) ~~(1)~~ When the person licensed or certified under this chapter is a party defendant to a civil, criminal, or disciplinary action arising from a complaint filed by the patient or client, in which case the waiver shall be limited to that action.

(b) ~~(2)~~ When the patient or client agrees to the waiver, in writing, or, when more than one person in a family is receiving therapy, when each family member agrees to the waiver, in writing.

(c) ~~(3)~~ When a patient or client has communicated to the person licensed or certified under this chapter a specific threat to cause serious bodily injury or death to an identified or readily available person, and the person licensed or certified under this chapter makes a clinical judgment that the patient or client has the apparent intent and ability to imminently or immediately carry out such threat~~, in the clinical judgment of the person licensed or certified under this chapter, there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society~~ and the person licensed or certified under this chapter communicates the information ~~only~~ to the potential victim~~, appropriate family member, or law enforcement or other appropriate authorities. There shall be no liability on the part of, and no cause of action of any nature shall arise against, a person licensed or certified under this chapter for the disclosure of otherwise confidential communications under this subsection~~. A disclosure of confidential communications by a person licensed or certified under this chapter when communicating a threat pursuant to this subsection may not be the basis of any legal action or criminal

or civil liability against such person.

(2) This privilege must be waived, and the person licensed or certified under this chapter shall disclose patient or client communications to the extent necessary to communicate the threat to a law enforcement agency, if a patient or client has communicated to such person a specific threat to cause serious bodily injury or death to an identified or readily available person, and the person licensed or certified under this chapter makes a clinical judgment that the patient or client has the apparent intent and ability to imminently or immediately carry out such threat. A law enforcement agency that receives notification of a specific threat under this subsection must take appropriate action to prevent the risk of harm, including, but not limited to, notifying the intended victim of such threat or initiating a risk protection order. A disclosure of confidential communications by a person licensed or certified under this chapter when communicating a threat pursuant to this subsection may not be the basis of any legal action or criminal or civil liability against such person.

Section 7. Section 1012.583, Florida Statutes, is amended to read:

1012.583 Continuing education and inservice training for youth suicide awareness and prevention.—

(1) By July 1, 2019 ~~Beginning with the 2016-2017 school year~~, the Department of Education, in consultation with the Statewide Office for Suicide Prevention and suicide prevention experts, shall develop a list of approved youth suicide awareness and prevention training materials and suicide screening instruments that may be used for training in youth

suicide awareness, suicide ~~and~~ prevention, and suicide screening for instructional personnel in elementary school, middle school, and high school. The approved list of materials:

(a) Must identify available standardized suicide screening instruments appropriate for use with a school-age population and which have validity and reliability and include information about obtaining instruction in the administration and use of such instruments.

(b) ~~(a)~~ Must include training on how to identify appropriate mental health services and how to refer youth and their families to those services.

(c) ~~(b)~~ May include materials currently being used by a school district if such materials meet any criteria established by the department.

(d) ~~(c)~~ May include programs that instructional personnel can complete through a self-review of approved youth suicide awareness and prevention materials.

(2) A school ~~that chooses to incorporate 2 hours of training offered pursuant to this section~~ shall be considered a "Suicide Prevention Certified School~~.~~" if it:

(a) Incorporates 2 hours of training offered pursuant to this section. The training must be included in the existing continuing education or inservice training requirements for instructional personnel and may not add to the total hours currently required by the department. A school that chooses to participate in the training must require all instructional personnel to participate.

(b) Has at least two school-based staff members certified or otherwise deemed competent in the use of a suicide screening

instrument approved under subsection (1) and has a policy to use such suicide risk screening instrument to evaluate a student's suicide risk before requesting the initiation of, or initiating, an involuntary examination due to concerns about that student's suicide risk.

(3) A school that meets the criteria in subsection (2) ~~participates in the suicide awareness and prevention training pursuant to this section~~ must report its compliance ~~participation~~ to the department. The department shall keep an updated record of all Suicide Prevention Certified Schools and shall post the list of these schools on the department's website. Each school shall also post on its own website whether it is a Suicide Prevention Certified School, and each school district shall post on its district website a list of the Suicide Prevention Certified Schools in that district.

(4) A person has no cause of action for any loss or damage caused by an act or omission resulting from the implementation of this section or resulting from any training required by this section unless the loss or damage was caused by willful or wanton misconduct. This section does not create any new duty of care or basis of liability.

(5) The State Board of Education may adopt rules to implement this section.

Section 8. For the purpose of incorporating the amendment made by this act to section 490.0147, Florida Statutes, in a reference thereto, paragraph (u) of subsection (1) of section 490.009, Florida Statutes, is reenacted to read:

490.009 Discipline.—

(1) The following acts constitute grounds for denial of a

license or disciplinary action, as specified in s. 456.072(2):

(u) Failing to maintain in confidence a communication made by a patient or client in the context of such services, except as provided in s. 490.0147.

Section 9. For the purpose of incorporating the amendment made by this act to section 491.0147, Florida Statutes, in a reference thereto, paragraph (u) of subsection (1) of section 491.009, Florida Statutes, is reenacted to read:

491.009 Discipline.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(u) Failure of the licensee, registered intern, or certificateholder to maintain in confidence a communication made by a patient or client in the context of such services, except as provided in s. 491.0147.

Section 10. This act shall take effect July 1, 2019.

An act relating to stroke centers; amending s. 395.3038, F.S.; revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; removing provisions requiring the agency to adopt rules establishing the criteria for such list; amending s. 395.30381, F.S.; revising provisions relating to the statewide stroke registry to conform to changes made by the act; amending s. 395.3039, F.S.; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act; amending s. 395.3041, F.S.; requiring specified protocols to consider the capability of an emergency receiving facility to improve outcomes for certain patients; clarifying applicability; providing an effective date.

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

Section 1. Subsection (1), paragraph (a) of subsection (2), and subsection (3) of section 395.3038, Florida Statutes, are amended to read:

395.3038 State-listed stroke centers; notification of hospitals.—

(1) The agency shall make available on its website and to the department a list of the name and address of each hospital that <u>is certified by a nationally recognized certifying</u>

organization as ~~meets the criteria for~~ an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center. The list of stroke centers must include only those hospitals that have submitted documentation to the agency verifying their certification as an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, which may include, but is not limited to, any stroke center that offers and performs mechanical endovascular therapy consistent with the standards identified by a nationally recognized guidelines-based organization approved by the agency. Each hospital that has attested in an affidavit to the agency that it meets the criteria in this subsection must be certified ~~that attest in an affidavit submitted to the agency that the hospital meets the named criteria, or those hospitals that attest in an affidavit submitted to the agency that the hospital is certified as an acute stroke ready center, a primary stroke center, or a comprehensive stroke center~~ by a nationally recognized accrediting organization by July 1, 2021.

(2)(a) If a hospital no longer chooses to be certified by a nationally recognized certifying organization or has not attained certification consistent with ~~meet~~ the criteria in subsection (1) as ~~for~~ an acute stroke ready center, a primary stroke center, a thrombectomy-capable stroke center, or a comprehensive stroke center, the hospital shall notify the agency and the agency shall immediately remove the hospital from the list of stroke centers.

~~(3) The agency shall adopt by rule criteria for an acute stroke ready center, a primary stroke center, and a~~

~~comprehensive stroke center which are substantially similar to the certification standards for the same categories of stroke centers of a nationally recognized accrediting organization.~~

Section 2. Section 395.30381, Florida Statutes, is amended to read:

395.30381 Statewide stroke registry.—

(1) Subject to a specific appropriation, the department shall contract with a private entity to establish and maintain a statewide stroke registry to ensure that the stroke performance measures required to be submitted under subsection (2) are maintained and available for use to improve or modify the stroke care system, ensure compliance with standards and nationally recognized guidelines, and monitor stroke patient outcomes.

(2) Each acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, and comprehensive stroke center shall regularly report to the statewide stroke registry information containing ~~specified by the department, including~~ nationally recognized stroke performance measures.

(3) The department shall require the contracted private entity to use a nationally recognized platform to collect data from each stroke center on the stroke performance measures required in subsection (2). The contracted private entity shall provide regular reports to the department on the data collected.

(4) A ~~No~~ liability of any kind or character for damages or other relief shall not arise or be enforced against any acute stroke ready center, primary stroke center, thrombectomy-capable stroke center, or comprehensive stroke center by reason of having provided such information to the statewide stroke registry.

Section 3. Section 395.3039, Florida Statutes, is amended to read:

395.3039 Advertising restrictions.—A person may not advertise to the public, by way of any medium whatsoever, that a hospital is a state-listed ~~primary or comprehensive~~ stroke center unless the hospital has submitted documentation to the agency verifying that it is certified and meets the criteria ~~provided notice to the agency~~ as required in s. 395.3038 ~~by this act~~.

Section 4. Subsections (1), (3), and (4) of section 395.3041, Florida Statutes, are amended to read:

395.3041 Emergency medical services providers; triage and transportation of stroke victims to a stroke center.—

(1) By June 1 of each year, the department shall send the list of acute stroke ready centers, primary stroke centers, thrombectomy-capable stroke centers, and comprehensive stroke centers to the medical director of each licensed emergency medical services provider in the ~~this~~ state.

(3) The medical director of each licensed emergency medical services provider shall develop and implement assessment, treatment, and transport-destination protocols for stroke patients with the intent to assess, treat, and transport stroke patients to the most appropriate hospital. Such protocols must consider the capability of an emergency receiving facility to improve outcomes for those patients suspected of having an emergent large vessel occlusion.

(4) Each emergency medical services provider licensed under chapter 401 must comply with ~~all sections of~~ this section ~~act~~.

Section 5. This act shall take effect July 1, 2019.

Health

Sorted by Bill Number

HB 7 **Direct Health Care Agreements** Duggan

Direct Health Care Agreements: Expands scope of direct primary care agreements to direct health care agreements. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

5/2/2019 SENATE Read Third Time; Passed (Vote: 40 Yeas / 0 Nays)
5/2/2019 HOUSE Ordered enrolled
5/2/2019 HOUSE Enrolled Text (ER) Filed

Compare

HB 843 Health Care (Rodriguez (AM))
04/29/2019 HOUSE Enrolled Text (ER) Filed

SB 7078 Health Care (Health Policy)
04/26/2019 SENATE Read Second Time; Substituted for HB 0843; Laid on Table, Refer to HB 0843

Identical

SB 1520 Direct Health Care Agreements (Bean)
05/01/2019 SENATE Read Second Time; Substituted for HB 0007; Laid on Table, Refer to HB 0007

HB 19 **Prescription Drug Importation Programs** Leek

Prescription Drug Importation Programs: Requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; establishing an international export pharmacy permit for participation in the International Prescription Drug Importation Program; authorizing the department to inspect international export pharmacy permittees; providing that the importation of a prescription drug under the International Prescription Drug Importation Program is not a prohibited act under that chapter; requiring the agency, in collaboration with the Department of Business and Professional Regulation and the Department of Health, to negotiate a federal arrangement to operate a pilot program for importing prescription drugs into this state, etc. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

4/29/2019 HOUSE Ordered engrossed, then enrolled
4/29/2019 HOUSE Engrossed Text (E1) Filed
4/29/2019 HOUSE Enrolled Text (ER) Filed

Compare

SB 1528 Canadian Prescription Drug Importation Program (Bean)
04/26/2019 SENATE Read Second Time; Substituted for HB 0019; Laid on Table, Refer to HB 0019

Similar

SB 1452 Prescription Drug Importation Programs (Gruters)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

Linked

HB 7073 Permit and Inspection Fees (Health Quality Subcommittee)
04/26/2019 HOUSE Enrolled Text (ER) Filed

HB 21 **Hospital Licensure** Fitzenhagen

Hospital Licensure; Revising the Agency for Health Care Administration's rulemaking authority with respect to minimum standards for hospitals; requiring hospitals that provide certain services to meet specified licensure requirements; revising duties and responsibilities of the agency relating to issuance of licenses to health care facilities and health service providers, etc. Effective Date: 7/1/2019

Current Committee of Reference: No Current Committee

4/29/2019 HOUSE Ordered engrossed, then enrolled
4/29/2019 HOUSE Engrossed Text (E1) Filed
4/29/2019 HOUSE Enrolled Text (ER) Filed

Compare

SB 1712 Hospital Licensure (Harrell)
04/26/2019 SENATE Read Second Time; Substituted for HB 0021; Laid on Table, Refer to HB 0021

HB 23 **Telehealth** Yarborough

Telehealth: Establishing standards of practice for telehealth providers; authorizing certain telehealth providers to use telehealth to prescribe certain controlled substances under specified circumstances; providing registration requirements for out-of-state telehealth providers, etc. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee
4/29/2019 HOUSE Ordered engrossed, then enrolled
4/29/2019 HOUSE Engrossed Text (E1) Filed
4/29/2019 HOUSE Enrolled Text (ER) FIled

Compare

HB 947 Telehealth (Ausley)
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

Similar

SB 1526 Telehealth (Harrell)
04/26/2019 SENATE Read Second Time; Substituted for HB 0023; Laid on Table, Refer to HB 0023

Linked

HB 7067 Registration Fees (Health Quality Subcommittee)
04/29/2019 HOUSE Enrolled Text (ER) Filed

SB 182 **Medical Use of Marijuana** Brandes

Medical Use of Marijuana; Medical Use of Marijuana; Redefining the term “marijuana delivery device” to provide an exception to the requirement that such devices must be purchased from a medical marijuana treatment center for devices that are intended for the medical use of marijuana by smoking; redefining the term “medical use” to include the possession, use, or administration of marijuana in a form for smoking; restricting the smoking of marijuana in enclosed indoor workplaces; requiring a qualified physician to submit specified documentation to the Board of Medicine and the Board of Osteopathic Medicine upon determining that smoking is an appropriate route of administration for a qualified patient, other than a patient diagnosed with a terminal condition, etc. APPROPRIATION: $2,596,664.00 Effective Date: 3/18/2019

Current Committee of Reference: No Current Committee
3/13/2019 SENATE Enrolled Text (ER) Filed
3/13/2019 Signed by Officers and presented to Governor (Governor must act on this bill by 03/20/19)
3/18/2019 Approved by Governor; Chapter No. 2019-001

Compare

SB 372 Smoking Marijuana for Medical Use (Farmer, Jr.)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration
SB 1322 Availability of Marijuana for Medical Use (Brandes)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration
HB 7015 Medical Use of Marijuana (Health & Human Services Committee)
03/13/2019 HOUSE Read Second Time; Substituted for SB 0182; Laid on Table, Refer to SB 0182
HB 7117 Medical Use of Marijuana (Health & Human Services Committee)
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

HB 213 **Immunization Registry** Massullo, Jr.

Immunization Registry; Revising provisions relating to the communicable disease prevention and control program under the Department of Health; providing that certain students who obtain vaccinations from a college or university student health center or clinic in the state may refuse to be included in the immunization registry; requiring a specified consent to treatment form to contain a certain notice; revising school-entry health requirements to require students to have a certificate of immunization on file with the department's immunization registry; requiring each district school board and the governing authority of each private school to establish and enforce a policy requiring the age-appropriate screening of students for scoliosis, etc. Effective Date: 1/1/2021

Current Committee of Reference: No Current Committee
5/1/2019 HOUSE Ordered engrossed, then enrolled
5/1/2019 HOUSE Engrossed Text (E1) Filed
5/2/2019 HOUSE Enrolled Text (ER) Filed

Similar

SB 354 Immunization Registry (Montford)
04/24/2019 SENATE Read Third Time; Substituted for HB 0213; Laid on Table, Refer to HB 0213

SB 322 **Health Plans** Simpson

Health Plans; Revising eligibility requirements for multiple-employer welfare arrangements; authorizing health insurers and health maintenance organizations to create new health insurance policies and health maintenance contracts meeting certain criteria for essential health benefits under the federal Patient

Protection and Affordable Care Act (PPACA); revising applicability of requirements relating to preexisting conditions, etc. Effective Date: Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law

Current Committee of Reference: No Current Committee

5/1/2019 SENATE In returning messages
5/3/2019 SENATE Received from Messages; Concurred in House amendment (819705); Passed (Vote: 23 Yeas / 13 Nays)
5/3/2019 SENATE Ordered engrossed, then enrolled

Compare

SB 418 Essential Health Benefits Under Health Plans (Simpson)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 1422 Health Plans (Gruters)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

Similar

HB 997 Health Plans (Gregory)
05/01/2019 HOUSE Laid on Table

HB 369 **Substance Abuse Services** Caruso

Substance Abuse Services: Authorizes DCF & AHCA to grant exemptions from disqualification for service provider personnel to work in certain treatment programs, facilities, or recovery residences; revises background screening requirements & exemptions from disqualification for certain service provider personnel; provides qualifications for peer specialists; authorizes DCF to approve certain credentialing entities to certify peer specialists; provides for review of certain decisions made by department-recognized credentialing entities; provides certain prohibitions & penalties. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

5/3/2019 SENATE Read Third Time; Amendment Withdrawn (624706); Passed (Vote: 37 Yeas / 0 Nays)
5/3/2019 HOUSE Ordered enrolled
5/3/2019 HOUSE Enrolled Text (ER) Filed

Compare

SB 528 Mental Health and Substance Use Disorders (Rouson)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

HB 1187 Mental Health and Substance Use Disorders (Stevenson)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

Similar

SB 900 Substance Abuse Services (Harrell)
05/02/2019 SENATE Withdrawn from Appropriations; Placed on Calendar, on 2nd reading; Placed on Special Order Calendar, 05/02/19; Read Second Time; Substituted for HB 0369; Laid on Table, Refer to HB 0369

HB 375 **Prescription Drug Monitoring Program** Pigman

Prescription Drug Monitoring Program: Authorizes DOH to enter into reciprocal agreements to share prescription drug monitoring information with specified federal agencies; exempts from requirement to check patient's dispensing history the prescribing of or dispensing controlled substance to patients admitted to hospice for alleviation of pain related to terminal condition or to patients receiving palliative care for terminal illnesses. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

5/2/2019 SENATE Withdrawn from Health Policy; Appropriations; Placed on Calendar, on 2nd Reading; Substituted for SB 0592; Read Second Time; Placed on Third Reading, 05/03/19
5/3/2019 SENATE Read Third Time; Passed (Vote: 39 Yeas / 0 Nays)
5/3/2019 HOUSE Ordered enrolled

Compare

SB 592 Prescription Drug Monitoring Program (Albritton)
05/02/2019 SENATE Read Second Time; Substituted for HB 0375; Laid on Table, Refer to HB 0375

HB 1253 Prescription Drug Monitoring Program (Mariano)
05/03/2019 HOUSE Enrolled Text (ER) Filed

HB 411 **Nonemergency Medical Transportation Services** Perez

Nonemergency Medical Transportation Services; Authorizing certain transportation network companies to provide nonemergency medical transportation services to a Medicaid recipient under certain

circumstances; requiring the Agency for Health Care Administration to update its regulations, policies, or other guidance by a specified date to reflect such authorization; providing limitations on requirements for transportation network companies and transportation network company drivers; providing construction, etc. Effective Date: 7/1/2019

Current Committee of Reference: No Current Committee

5/1/2019 HOUSE Ordered engrossed, then enrolled
5/1/2019 HOUSE Engrossed Text (E2) Filed
5/2/2019 HOUSE Enrolled Text (ER) Filed

Identical

SB 302 Nonemergency Medical Transportation Services (Brandes)
04/29/2019 SENATE Read Second Time; Substituted for HB 0411; Laid on Table, Refer to HB 0411

HB 449 **Alzheimer's Disease** Plakon

Alzheimer's Disease: Increases membership of Alzheimer's Disease Advisory Committee; revises representative requirements of committee; requires committee to submit annual report to specified parties that includes certain information & recommendations; requires Department of Elderly Affairs to review & update Alzheimer's disease state plan every 3 years in collaboration with certain parties; provides requirements for plan; establishes specified memory disorder clinic; provides that certain clinics shall not receive decreased funding for specified reason. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

4/26/2019 SENATE Withdrawn from Children, Families, and Elder Affairs; Appropriations Subcommittee on Health and Human Services; Appropriations; Placed on Calendar, on 2nd Reading; Substituted for SB 0860; Read Second Time; Read Third Time; Passed (Vote: 40 Yeas / 0 Nays)
4/26/2019 HOUSE Ordered enrolled
4/26/2019 HOUSE Enrolled Text (ER) Filed

Similar

SB 860 Alzheimer's Disease (Stargel)
04/26/2019 SENATE Read Second Time; Substituted for HB 0449; Laid on Table, Refer to HB 0449

HB 451 **Nonopioid Alternatives** Plakon

Nonopioid Alternatives: Requires DOH to develop & publish on its website educational pamphlet regarding use of nonopioid alternatives for treatment of pain; provides requirements for health care practitioners. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

4/30/2019 SENATE Read Third Time; Passed (Vote: 40 Yeas / 0 Nays)
4/30/2019 HOUSE Ordered enrolled
4/30/2019 HOUSE Enrolled Text (ER) Filed

Similar

SB 630 Nonopioid Alternatives (Perry)
04/29/2019 SENATE Read Second Time; Substituted for HB 0451; Laid on Table, Refer to HB 0451

HB 487 **Carrying of Firearms by Tactical Medical Professionals** Smith (D)

Carrying of Firearms by Tactical Medical Professionals; Exempting certain licensed medical professionals from specified provisions concerning the carrying of firearms; requiring certain policies and procedures for law enforcement agencies; providing such professionals have no duty to retreat in certain circumstances; providing immunities and privileges for such professionals; providing construction; requiring the appointing law enforcement agency to issue to tactical medical professionals any firearm or ammunition, etc. Effective Date: 7/1/2019

Current Committee of Reference: No Current Committee

5/1/2019 HOUSE Ordered engrossed, then enrolled
5/1/2019 HOUSE Engrossed Text (E1) Filed
5/2/2019 HOUSE Enrolled Text (ER) Filed

Similar

SB 722 Carrying of Firearms by Tactical Medical Professionals (Hooper)
04/29/2019 SENATE Read Second Time; Substituted for HB 0487; Laid on Table, Refer to HB 0487

HB 501 **Alternative Treatment Options for Veterans** Ponder

Alternative Treatment Options for Veterans: Authorizes DVA to contract with state university or Florida College System institution to furnish specified alternative treatment options for veterans; provides university or institution responsibilities; provides requirements for provision of alternative treatment options

& related assessment data; provides eligibility requirements; requires direction & supervision by certain licensed providers; requires annual report to Governor & Legislature. Effective Date: July 1, 2019
Current Committee of Reference: No Current Committee
5/2/2019 SENATE Read Third Time; Passed (Vote: 40 Yeas / 0 Nays)
5/2/2019 HOUSE Ordered enrolled
5/2/2019 HOUSE Enrolled Text (ER) Filed
Similar

SB 1518	Alternative Treatment Options for Veterans (Wright) 05/01/2019 SENATE Read Second Time; Substituted for HB 0501; Laid on Table, Refer to HB 0501

HB 523 **Halifax Hospital Medical Center, Volusia County** Santiago
Halifax Hospital Medical Center, Volusia County: Authorizes district to establish, own construct, operate, manage, & maintain hospitals, facilities, & services within & beyond boundaries of district under certain conditions; provides ad valorem taxes and non-ad valorem special assessments be expended only within the boundaries of district; authorizes district to contract to carry out provisions of act; authorizes district to own & operate certain facilities & provide certain services throughout the state. Effective Date: upon becoming a law
Current Committee of Reference: No Current Committee
5/1/2019 SENATE Withdrawn from Rules; Placed on Calendar, on 2nd Reading; Read Second Time; Read Third Time; Passed (Vote: 39 Yeas / 0 Nays)
5/1/2019 HOUSE Ordered enrolled
5/1/2019 HOUSE Enrolled Text (ER) Filed

HB 549 **Continuing Education for Dentists** Sirois
Continuing Education for Dentists: Requires minimum of 2 hours of continuing education on prescribing of controlled substances. Effective Date: July 1, 2019
Current Committee of Reference: No Current Committee
4/23/2019 SENATE Withdrawn from Health Policy; Innovation, Industry, and Technology; Rules; Placed on Calendar, on 2nd Reading; Read Second Time; Substituted for SB 0648; Read Third Time; Passed (Vote: 36 Yeas / 0 Nays)
4/23/2019 HOUSE Ordered enrolled
4/23/2019 HOUSE Enrolled Text (ER) Filed
Identical

SB 648	Continuing Education for Dentists (Mayfield) 04/23/2019 SENATE Read Third Time; Substituted for HB 0549; Laid on Table, Refer to HB 0549

SB 732 **Office Surgery** Flores
Office Surgery; Authorizing the Department of Health to issue an emergency order suspending or restricting the registration of certain facilities upon specified findings; requiring an office in which a physician performs certain procedures or office surgeries to register with the department; requiring an office and physicians practicing at the office to meet certain financial responsibility requirements, etc. Effective Date: 1/1/2020
Current Committee of Reference: No Current Committee
5/1/2019 HOUSE Read Third Time; Passed (Vote: 114 Yeas / 0 Nays)
5/1/2019 SENATE Ordered enrolled
5/1/2019 SENATE Enrolled Text (ER) Filed
Similar

HB 933	Office Surgery (Rodriguez (Ant)) 05/01/2019 HOUSE Laid on Table

HB 831 **Electronic Prescribing** Mariano
Electronic Prescribing; Requiring certain health care practitioners to electronically generate and transmit prescriptions for medicinal drugs upon license renewal or by a specified date; authorizing the Department of Health, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine, the Board of Dentistry, the Board of Nursing, and the Board of Optometry, to adopt rules; revising the authority for electronic prescribing software to display information regarding a payor's formulary under certain circumstances, etc. Effective Date: 1/1/2020
Current Committee of Reference: No Current Committee
5/2/2019 HOUSE Ordered engrossed, then enrolled
5/2/2019 HOUSE Engrossed Text (E1) Filed

5/2/2019 HOUSE Enrolled Text (ER) Filed

Identical

SB 1192 Electronic Prescribing (Bean)
05/01/2019 SENATE Read Third Time; Substituted for HB 0831; Laid on Table, Refer to HB 0831

HB 843 **Health Care** Rodriguez (AM)

Health Care; Establishing the Dental Student Loan Repayment Program to support dentists who practice in public health programs located in certain underserved areas; requiring the Department of Health to establish the Donated Dental Services Program to provide comprehensive dental care to certain eligible individuals; requiring a hospital to notify a patient's primary care provider within a specified timeframe after the patient's admission; requiring a licensed facility, upon placing a patient on observation status, to immediately notify the patient of such status using a specified form; prohibiting certain health maintenance organizations from employing step-therapy protocols under certain circumstances, etc. Effective Date: 7/1/2019

Current Committee of Reference: No Current Committee

4/29/2019 HOUSE Ordered engrossed, then enrolled
4/29/2019 HOUSE Engrossed Text (E1) Filed
4/29/2019 HOUSE Enrolled Text (ER) Filed

Compare

HB 7 Direct Health Care Agreements (Duggan)
05/02/2019 HOUSE Enrolled Text (ER) Filed

HB 25 Ambulatory Care Services (Stevenson)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

HB 319 Patient Safety and Quality Measures (Grant (M))
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 434 Ambulatory Surgical Centers (Harrell)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

HB 465 Dental Services (Grant (M))
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

HB 559 Prescription Drug Utilization Management (Massullo, Jr.)
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

SB 716 Dental Services (Hooper)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

HB 813 Hospital Observation Status (Tomkow)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 882 Restrictive Covenants (Gruters)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 1126 Pediatric Cardiac Technical Advisory Panel (Harrell)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

HB 1207 Pediatric Cardiac Technical Advisory Panel (Beltran)
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

HB 1243 Hospital or Group Practice Mergers, Acquisitions, and Other Transactions (Burton)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 1520 Direct Health Care Agreements (Bean)
05/01/2019 SENATE Read Second Time; Substituted for HB 0007; Laid on Table, Refer to HB 0007

SB 1540 Recovery Care Services (Lee)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

SB 7080 Public Records and Meetings/Interstate Medical Licensure Compact (Health Policy)
05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration

Similar

SB 7078 Health Care (Health Policy)
04/26/2019 SENATE Read Second Time; Substituted for HB 0843; Laid on Table, Refer to HB 0843

HB 1113 **Health Insurance Savings Programs** Renner

Health Insurance Savings Programs: Authorizes health insurers to provide shared savings incentive programs in which insureds receive cash payment as incentive to save on certain nonemergency health

care services; provides shared savings incentive amount does not institute income to insureds; provides that shared savings incentives are not administrative expenses for insurers; provides tax reductions for insurers. Effective Date: January 1, 2020

Current Committee of Reference: No Current Committee

5/3/2019 SENATE In returning messages
5/3/2019 SENATE Received from Messages; Concurred in House amendment (205125); Passed (Vote: 37 Yeas / 1 Nay)
5/3/2019 HOUSE Ordered enrolled

Compare

SB 524 Health Insurance Savings Programs (Diaz)
04/30/2019 SENATE Read Second Time; Substituted for HB 1113; Laid on Table, Refer to HB 1113

HB 1253 **Prescription Drug Monitoring Program** Mariano

Prescription Drug Monitoring Program: Requires DOH to develop unique identifier for each patient; authorizes AG to introduce as evidence in certain actions specified information from prescription drug monitoring program; authorizes certain individuals to authenticate records; authorizes AG to have access to records for active investigations or pending civil or criminal litigation in certain cases; provides that certain information may only be released pursuant to discovery request. Effective Date: July 1, 2019

Current Committee of Reference: No Current Committee

5/3/2019 SENATE Read Third Time; Passed (Vote: 39 Yeas / 0 Nays)
5/3/2019 HOUSE Ordered enrolled
5/3/2019 HOUSE Enrolled Text (ER) Filed

Compare

HB 375 Prescription Drug Monitoring Program (Pigman)
05/03/2019 HOUSE Ordered enrolled

Similar

SB 1700 Prescribed Controlled Substances (Lee)
05/02/2019 SENATE Read Second Time; Substituted for HB 1253; Laid on Table, Refer to HB 1253

SB 1418 **Mental Health** Powell

Mental Health; Requiring service providers to disclose information from a clinical record under certain circumstances relating to threats to cause seriously bodily injury or death; requiring, rather than authorizing, psychiatrists to disclose certain patient communications for purposes of notifying potential victims and law enforcement agencies of certain threats; revising responsibilities of the Department of Education and the Statewide Office for Suicide Prevention, etc. Effective Date: Upon becoming a law

Current Committee of Reference: No Current Committee

5/1/2019 HOUSE Read Third Time; Passed (Vote: 113 Yeas / 0 Nays)
5/1/2019 SENATE Ordered enrolled
5/1/2019 SENATE Enrolled Text (ER) Filed

Compare

HB 363 Pub. Rec./Admission to Mental Health Facilities (Silvers)
05/01/2019 HOUSE Laid on Table

SB 642 Public Safety (Brandes)
05/01/2019 SENATE Read Second Time; Substituted for HB 7125; Laid on Table, Refer to HB 7125

SB 7048 Disclosure of Confidential Records (Children, Families, and Elder Affairs)
05/03/2019 HOUSE Indefinitely postponed and withdrawn from consideration

HB 7125 Public Safety (Judiciary Committee)
05/03/2019 HOUSE Ordered engrossed, then enrolled

Similar

HB 361 Mental Health (Silvers)
05/01/2019 HOUSE Laid on Table

SB 1460 **Stroke Centers** Book

Stroke Centers; Revising the criteria for hospitals to be included on the state list of stroke centers by the Agency for Health Care Administration; revising provisions relating to the statewide stroke registry to conform to changes made by the act; revising provisions prohibiting the advertisement of a hospital as a state-listed stroke center, unless certain conditions are met, to conform to changes made by the act, etc. Effective Date: 7/1/2019

Current Committee of Reference: No Current Committee
5/1/2019 HOUSE Read Third Time; Passed (Vote: 114 Yeas / 0 Nays)
5/1/2019 SENATE Ordered enrolled
5/1/2019 SENATE Enrolled Text (ER) Filed
Compare

HB 993	Stroke Centers (Plakon) 05/01/2019 HOUSE Laid on Table

HB 7025 **OGSR/Treatment-based Drug Court Programs** Oversight, Transparency & Public Management Subcommittee

OGSR/Treatment-based Drug Court Programs: Removes scheduled repeal of exemption from public records requirements for certain information relating to screenings for participation in treatment-based drug court programs, behavioral health evaluations, & subsequent treatment status reports. Effective Date: October 1, 2019
Current Committee of Reference: No Current Committee
4/23/2019 SENATE Immediately certified
4/23/2019 HOUSE Ordered enrolled
4/23/2019 HOUSE Enrolled Text (ER) Filed
Identical

SB 7010	OGSR/Treatment-based Drug Court Programs (Judiciary) 04/10/2019 SENATE Read Second Time; Substituted for HB 7025; Laid on Table, Refer to HB 7025

HB 7073 **Permit and Inspection Fees** Health Quality Subcommittee

Permit and Inspection Fees: Requires initial & renewal fees for international export pharmacy permits; requires late renewal fees & annual permit & inspection fees for international prescription drug wholesale distributors. Effective Date: on the same date that HB 19 or similar legislation takes effect
Current Committee of Reference: No Current Committee
4/26/2019 SENATE Read Second Time; Read Third Time; Passed (Vote: 35 Yeas / 0 Nays)
4/26/2019 HOUSE Ordered enrolled
4/26/2019 HOUSE Enrolled Text (ER) Filed
Compare

SB 1452	Prescription Drug Importation Programs (Gruters) 05/03/2019 SENATE Indefinitely postponed and withdrawn from consideration
SB 1528	Canadian Prescription Drug Importation Program (Bean) 04/26/2019 SENATE Read Second Time; Substituted for HB 0019; Laid on Table, Refer to HB 0019

Linked

HB 19	Prescription Drug Importation Programs (Leek) 04/29/2019 HOUSE Enrolled Text (ER) Filed

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ENROLLED

HB 7025 2019 Legislature

An act relating to a review under the Open Government Sunset Review Act; amending s. 397.334, F.S., which provides an exemption from public records requirements for certain information relating to screenings for participation in treatment-based drug court programs, behavioral health evaluations, and subsequent treatment status reports; removing the scheduled repeal of the exemption; providing an effective date.

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

Section 1. Subsection (10) of section 397.334, Florida Statutes, is amended to read:

397.334 Treatment-based drug court programs.—

(10)(a) Information relating to a participant or a person considered for participation in a treatment-based drug court program which is contained in the following records is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

1. Records created or compiled during screenings for participation in the program.

2. Records created or compiled during substance abuse screenings.

3. Behavioral health evaluations.

4. Subsequent treatment status reports.

(b) Such confidential and exempt information may be disclosed:

1. Pursuant to a written request of the participant or person considered for participation, or his or her legal representative.

2. To another governmental entity in the furtherance of its responsibilities associated with the screening of a person considered for participation in or the provision of treatment to a person in a treatment-based drug court program.

(c) Records of a service provider which pertain to the identity, diagnosis, and prognosis of or provision of service to any person shall be disclosed pursuant to s. 397.501(7).

(d) This exemption applies to such information described in paragraph (a) relating to a participant or a person considered for participation in a treatment-based drug court program before, on, or after the effective date of this exemption.

~~(e) This subsection is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.~~

Section 2. This act shall take effect October 1, 2019.

An act relating to permit and inspection fees; amending s. 465.0157, F.S.; requiring initial and renewal fees for international export pharmacy permits; amending s. 499.012, F.S.; requiring late renewal fees for international prescription drug wholesale distributors; amending s. 499.041, F.S.; requiring annual permit and inspection fees for international prescription drug wholesale distributors; providing a contingent effective date.

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

Section 1. Subsection (4) of section 465.0157, Florida Statutes, as created by HB 19, is renumbered as subsection (5), and a new subsection (4) is added to that section to read:

465.0157 International export pharmacy permit.—

(4) The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).

Section 2. Paragraph (d) of subsection (5) of section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(5)

(d) A permit issued under this part may be renewed by making application for renewal on forms furnished by the

department and paying the appropriate fees.

1. If a prescription drug wholesale distributor, ~~or~~ an out-of-state prescription drug wholesale distributor, or an international prescription drug wholesale distributor renewal application and fee are submitted and postmarked later than 45 days before the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee.

2. If any other renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

3. A permittee who submits a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

4. Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

Section 3. Paragraph (i) is added to subsection (2) of section 499.041, Florida Statutes, and subsection (8) of that section is amended, to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(i) The fee for an international prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(8) The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee or an international prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.

Section 4. This act shall take effect on the same date that HB 19 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.