By the Committee on Health Regulation; and Senator Latvala

588-03799-12 20121006c1

A bill to be entitled

An act relating to health care; creating s. 383.146, F.S.; providing definitions; providing requirements for screening newborns for critical congenital heart disease; providing an exception; requiring that the physician, midwife, or other person attending the newborn maintain a record if the screening has not been performed and attach a written objection signed by the parent or guardian; requiring appropriate documentation of the screening completion in the medical record; requiring that each hospital and each licensed birth center designate a lead physician and a licensed health care provider, respectively, to provide programmatic oversight for the screening; requiring that the screening for critical congenital heart disease be conducted on all newborns in hospitals and birth centers in this state; authorizing the Department of Health to adopt rules to administer the screening program; providing powers and duties of the department; amending s. 499.003, F.S.; revising the definitions of the terms "distribute" or "distribution," "drug," "establishment," "prescription drug," and "wholesale distribution"; amending s. 499.01, F.S.; deleting provisions relating to an exemption from nonresident prescription drug manufacturer permit requirements; deleting provisions relating to an exemption from out-of-state prescription drug wholesale distributor permit requirements for intracompany sale or transfer of

prescription drugs; authorizing certain business entities to pay for prescription drugs obtained by practitioners licensed under ch. 466, F.S.; providing an exemption from permit requirements for the distribution into this state of prescription drug active pharmaceutical ingredients for incorporation into prescription drugs in finished dosage form; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring compliance with certain recordkeeping requirements; exempting compliance with pedigree paper requirements; providing an exemption from permit requirements for distribution into this state of limited quantities of a prescription drug that has not been repackaged for research and development or to a holder of a letter of exemption issued by the Department of Business and Professional Regulation for research, teaching, or testing; granting the department authority to define the term "limited quantities" by rule and limit therein the number of transactions and amount of prescription drugs distributed into the state; requiring a distributor claiming such exemption to maintain a valid license, permit, or registration in the state from which the prescription drug was distributed; requiring all purchasers and recipients of such prescription drugs to ensure the products are not resold or used on humans except in lawful clinical

trials and biostudies; requiring compliance with certain recordkeeping requirements; exempting compliance from pedigree paper requirements; providing labeling requirements for active pharmaceutical ingredients distributed within the state for teaching, testing, research, and development; exempting from out-of-state prescription drug wholesale distributor permit requirements intracompany transactions or the sale of prescription drugs from an out-of-state distributor to a distributor in this state if both distributors conduct wholesale distributions under the same business name; requiring compliance with recordkeeping and pedigree paper requirements; allowing distributors and recipients of prescription drugs claiming exemption from certain permitting requirements to maintain on file their FDA registration number, resident state distributor license or permit number, and most recent resident state or FDA inspection report; providing that persons claiming such exemptions are subject to part I of ch. 499, F.S., the Florida Drug and Cosmetic Act; requiring persons claiming such exemptions to make all records regarding prescription drug distribution available to the department, upon request, within 48 hours; requiring submission of a report of mishandled or adulterated prescription drugs within 14 days after receipt of such drugs; authorizing the department to adopt rules; providing that failure to comply with requirements or rules governing such exemptions

constitutes unlawful purchase or receipt of a prescription drug from a person not authorized to distribute prescription drugs to that purchaser or recipient; providing that knowing failure to comply with such requirements constitutes unlawful sale, distribution, purchase, trade, holding, or offering of a drug; providing penalties; providing construction with respect to federal and state laws relating to controlled substances; providing that a prescription drug repackager permit is not required for certain restricted prescription drug distributor permitholders that distribute prescription drugs to certain hospitals or other health care entities; exempting certain restricted prescription drug distributors from product registration requirements; providing an effective date.

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

Section 1. Section 383.146, Florida Statutes, is created to read:

383.146 Newborn screening for critical congenital heart disease.—

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

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

(b) "Newborn" means an age range from birth through 29 days.

(c) "Screening" means measuring blood oxygen saturation using pulse oximetry to determine whether a newborn needs

additional diagnostic evaluation for critical congenital heart disease.

(2) REQUIREMENTS FOR SCREENING OF NEWBORNS; REFERRAL FOR ONGOING SERVICES.—

(a) Each licensed hospital that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(b) Each licensed birth center that provides maternity and newborn care services shall ensure that, prior to discharge, all newborns are screened for the detection of critical congenital heart disease.

(c) If the parent or legal guardian of the newborn objects to the screening, the screening must not be completed, notwithstanding any other provision of this section. In such case, the physician, midwife, or other person who is attending the newborn shall maintain a record that the screening has not been performed and attach a written objection that must be signed by the parent or guardian.

(d) For home births, the health care provider in attendance is responsible for the screening.

(e) Appropriate documentation of the screening completion, results, interpretation, and recommendations must be placed in the medical record within 24 hours after completion of the screening procedure.

(f) Each hospital shall formally designate a lead physician who is responsible for programmatic oversight of newborn congenital heart disease screening. Each licensed birth center shall designate a licensed health care provider to provide such

programmatic oversight. Such physician or health care provider shall ensure that the appropriate referrals are completed following a positive screening test result.

(g) By October 1, 2012, screening for critical congenital heart disease must be conducted on all newborns in hospitals and birth centers in this state following birth admission.

(3) RULES.—After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state be screened for critical congenital heart disease. The department shall adopt such additional rules as are necessary for the administration of this section, including rules providing definitions of terms, rules relating to the methods used and time or times for testing as accepted medical practice indicates, rules relating to charging and collecting fees for the administration of the newborn screening program required by this section, rules for processing requests and releasing test and screening results, and rules requiring mandatory reporting of the results of tests and screenings for this condition to the department.

(4) POWERS AND DUTIES OF THE DEPARTMENT.—The department shall administer and provide services required pursuant to this section and shall:

(a) Furnish to all physicians, county health departments, perinatal centers, birth centers, and hospitals forms on which the results of tests for critical congenital heart disease shall be reported to the department.

(b) Have the authority to charge and collect fees sufficient to administer the newborn screening program required

under this section.

Section 2. Subsections (17), (19), (20), and (43), and paragraph (a) of subsection (54) of section 499.003, Florida Statutes, are amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(17) "Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(19) "Drug" means an article that is:

(a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c) Intended to affect the structure or any function of the body of humans or other animals; or

(d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that

furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20) "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(54) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) Any of the following activities, which is not a

violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a. The agency or entity must obtain written authorization

for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the State Surgeon General or his or her designee.

b. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c. In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

~~d. A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.~~

d.~~e.~~ The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.~~f.~~ The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum,

maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d ~~sub-subparagraph c~~.

f.~~g.~~ In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

Section 3. Paragraphs (c), (e), and (t) of subsection (2) of section 499.01, Florida Statutes, are amended, and subsections (3) and (4) are added to that section, to read:

499.01 Permits.—

(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 wholesale 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 wholesale distributor under this part, except s. 499.01212.

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 or third party logistics provider permit pursuant to this section to

engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

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 product wholesaled 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 nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited quantities intended for research and development and not for resale, or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subparagraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; the out-of-state license, permit, or registration number; and, if available, a copy of the~~

~~most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall specify by rule the allowable number of transactions within a given period of time and the amount of active pharmaceutical ingredients that qualify as limited quantities for purposes of this exemption. The failure to comply with the requirements of this subparagraph, or rules adopted by the department to administer this subparagraph, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14).~~

(e) *Out-of-state prescription drug wholesale distributor permit.*—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond 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.

~~1.~~ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

~~2. An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor, in its state of residence, to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.~~

(t) *Health care clinic establishment permit.*—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1. An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2. The health care clinic establishment must employ a qualifying practitioner at each establishment.

3. In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4. The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5. A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified

Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6. This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license. A professional corporation or limited liability company composed of dentists and operating as authorized in s. 466.0285 may pay for prescription drugs obtained by a practitioner licensed under chapter 466, and the licensed practitioner is deemed the purchaser and owner of the prescription drugs.

(3)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. Any distributor claiming exemption from permitting

requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b) A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define the term "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3. Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and

recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4. The immediate package or container of any active pharmaceutical ingredient distributed into the state which is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c) An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(d) Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1. A record of the FDA establishment registration number, if any;

2. The resident state prescription drug wholesale distribution license, permit, or registration number; and

3. A copy of the most recent resident state or FDA inspection report, for all distributors and establishments whom they purchase or receive prescription drugs under this

subsection.

(e) All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f) A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g) The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h) This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(4) A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity that repackages prescription drugs in this state for its own use or distributes prescription drugs to a hospital or other health care entity in the state for its own use pursuant to s. 499.003(54)(a)3. if the restricted prescription drug distributor:

(a) Notifies the department in writing of its intention to engage in repackaging under this exemption 30 days before actually engaging in the repackaging of prescription drugs at the permitted establishment;

(b) Is under common control with the hospital or other health care entity to which the restricted prescription drug distributor distributes prescription drugs. For purposes of this paragraph, the term "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(c) Repackages the prescription drugs in accordance with federal and state current good manufacturing practices; and

(d) Labels the prescription drugs in accordance with state and federal laws and rules.

The restricted prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

Section 4. This act shall take effect July 1, 2012.