Amendment No.

CHAMBER ACTION

Senate House

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Representative Patronis offered the following:

Amendment to Amendment (204433) (with directory and title amendments)

Remove line 2284 and insert:

(32) "Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(43) ~~(42)~~ "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active 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) ~~(45)~~, or subsection (53) ~~(52)~~.

(54) ~~(53)~~ "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. ~~e.~~

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 85. Paragraph (i) is added to subsection (3) of section 499.01212, Florida Statutes, to read:

499.01212 Pedigree paper.—

(3) EXCEPTIONS.—A pedigree paper is not required for:

(i) The wholesale distribution of prescription drugs contained within a medical convenience kit if:

1. The medical convenience kit is assembled in an establishment that is registered as a medical device manufacturer with the United States Food and Drug Administration;

2. The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;

3. The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and

4. The drugs contained in the medical convenience kit are:

a. Intravenous solutions intended for the replenishment of fluids and electrolytes;

b. Products intended to maintain the equilibrium of water and minerals in the body;

c. Products intended for irrigation or reconstitution;

d. Anesthetics; or

e. Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

D I R E C T O R Y A M E N D M E N T

Remove lines 2880-2881 and insert:

Section 86. Subsections (32) through (54) of section 499.003, Florida Statutes, are renumbered as subsections (33) through (55), respectively, present subsection (42) and

paragraph (a) of present subsection (53) are amended, and a new subsection (32) is added to that subsection, to read:

T I T L E A M E N D M E N T

Remove line 3530 and insert:

499.003, F.S.; defining the term "medical convenience kit" for purposes of pt. I of ch. 499, F.S.; providing an exception to applicability of the term; removing a requirement that certain