CHAMBER ACTION

<u>Senate</u> <u>House</u>

Representative Flores offered the following:

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Amendment (with title amendment)

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Between lines 963 and 964, insert:

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Section 24. Subsections (32) through (54) of section 499.003, Florida Statutes, are renumbered as subsections (33) through (55), respectively, present subsection (42) is amended, and a new subsection (32) is added to that section, to read:

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

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(32) "Medical convenience kit" means a package or unit that contains combination products as described in 21 C.F.R. s. 3.2(e)(2).

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(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 049855

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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) $\frac{(45)}{(45)}$, or subsection (53) $\frac{(52)}{(52)}$.

Section 25. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.

- (1) As used in this section, the term:
- (a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(45)(45) or (53)(52), or s. 499.007(13).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 26. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.-

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(54)(53).

Section 27. Paragraph (d) of subsection (4) of section 499.0121, Florida Statutes, is amended to read:

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499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

- (4) EXAMINATION OF MATERIALS AND RECORDS.-
- (d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37)(36).

Section 28. Paragraphs (a) and (b) of subsection (2) of section 499.01211, Florida Statutes, are amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.-

- (2) The State Surgeon General, or his or her designee, and the Secretary of Health Care Administration, or her or his designee, shall be members of the council. The State Surgeon General shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:
- (a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. $499.003(47)\frac{(46)}{(46)}$.

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52)(51).

Section 29. Subsection (1) of section 499.03, Florida Statutes, is amended to read:

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

- (1) A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(33)(32), or prescription drug as defined in s. 499.003(43)(42), unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:
- (a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;
- (b) A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

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- (c) A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;
- (d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;
- (e) An officer or employee of a federal, state, or local government; or
- (f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

Section 30. Paragraphs (i) and (m) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.-

- (1) The department shall adopt rules to implement and enforce this part with respect to:
- (i) Additional conditions that qualify as an emergency medical reason under s. $499.003(54)\frac{(53)}{(53)}(b)2$.
- (m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. $499.003(54)\frac{(53)}{(53)}(a)-(d)$.
- Section 31. Subsection (1) of section 794.075, Florida Statutes, is amended to read:
 - 794.075 Sexual predators; erectile dysfunction drugs.-
- (1) A person may not possess a prescription drug, as defined in s. 499.003(43)(42), for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

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Bill No. CS/CS/HB 1503 (2010)

Amendment No.

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128	TITLE AMENDMENT
129	Remove line 125 and insert:
130	by practitioners licensed under ch. 466, F.S.; amending s.
131	499.003, F.S.; defining the term "medical convenience kit" for
132	purposes of the Florida Drug and Cosmetic Act; conforming cross-
133	references; amending ss. 409.9201, 465.0265, 499.0121,
134	499.01211, 499.03, 499.05, and 794.075, F.S.; conforming cross-
135	references; amending s.