Committee on Health Policy

CS/CS/SB 1604 — Drugs, Devices, and Cosmetics

by Appropriations Committee; Health Policy Committee; and Senator Grimsley

The bill updates the Florida Drug and Cosmetic Act (Act) to bring it into conformity with the federal Food, Drug and Cosmetic Act (federal act). Recent amendments to the federal act preempted Florida's regulatory structure. The bill replaces provisions relating to pedigree papers with federal requirements for a transaction history, transaction information, or transaction statement for the manufacture and distribution of prescription drugs. Certain activities are exempted from the definition of wholesale distribution in order to conform regulatory oversight in Florida to the federal regulatory scheme.

The bill provides for administrative efficiencies and cost savings by:

- Eliminating the distinction between primary and secondary wholesalers and the supplemental information required of a secondary wholesaler for initial and renewal permitting for in-state and out-of-state prescription drug wholesale distributors;
- Allowing certain key personnel to submit an affidavit that information submitted on a previous personal statement remains unchanged;
- Modifying the requirement for a surety bond;
- Authorizing the Department of Business and Professional Regulation (DBPR) to contract with a vendor or enter into interagency agreements for electronic fingerprinting;
- Authorizing a pending application to expire;
- Authorizing certain permits to be issued for up to four-year periods; and
- Exempting licensed hospices from the requirement to obtain a medical oxygen retail establishment permit in order to provide medical oxygen to its patients based upon a prescription or order from an authorized practitioner.

The bill establishes a nonresident prescription drug repackager permit, along with the requirement to obtain such a permit if a repackager located outside the state distributes its repackaged prescription drugs into the state. This repackager is also required to comply with provisions applicable to prescription drug manufacturers. The DBPR must establish a virtual prescription drug manufacturer permit and a virtual out-of-state prescription drug manufacturer permit for manufacturers that do not physically manufacture and possess their prescription drugs.

The bill creates the "Victoria Siegel Controlled Substance Safety Education and Awareness Act." This act requires the Department of Health to develop and disseminate a pamphlet of educational information relating to controlled substances, encourage health care providers to disseminate and display information about controlled substance safety, encourage consumers to discuss the risks of controlled substance use with their health care providers, and create a systematic approach to increasing public awareness regarding controlled substance safety.

The bill also authorizes an academic medical research institution to conduct research on cannabidiol and Low-THC cannabis.

If approved by the Governor, these provisions take effect July 1, 2016.
Vote: Senate 39-0; House 117-0