Committee on Health Policy

CS/HB 19 — Prescription Drug Importation Programs

by Health and Human Services Committee and Rep. Leek and others (CS/CS/SB 1528 by Appropriations Committee; Health Policy Committee; and Senators Bean and Gruters)

The bill establishes two programs to import prescription drugs approved by the federal Food and Drug Administration (FDA) into the state, contingent on federal approval:

- The Canadian Prescription Drug Importation Program (CPDI Program) established by the Agency for Health Care Administration (AHCA) and the International Prescription Drug Importation Program (IPDI Program) established by the Department of Business and Professional Regulation (DBPR) in collaboration with the Department of Health (DOH).
- The CPDI Program focuses on providing savings and options for specific public programs identified in the bill:
  - Recipients in the Medicaid program;
  - Clients of free clinics and county health departments;
  - Inmates in the custody of the Department of Corrections;
  - Clients treated in developmental disability centers; and
  - Patients treated in certain state mental health facilities.
- The bill establishes eligibility criteria for the types of prescription drugs which may be imported and the requirements for entities that may export or import prescription drugs. The eligibility criteria cover:
  - Importation process;
  - Safety standards;
  - Testing requirements;
  - Drug distribution requirements; and
  - Penalties for violations of program requirements.
- Both programs must also adhere to federal product tracing requirements known as *track and trace* as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq. The bill includes a testing process with random sampling and batch testing of drugs as they enter the state under either program.
- Bond requirements and other financial responsibility requirements provisions were added for the following program contractors with their program noted:
  - Vendors (CPDI Program);
  - Pharmacy permittees (IPDI Program);
  - Wholesale distributor permittees (IPDI);
  - Nonresident prescription drug manufacturer licensees or permittees (IPDI); and
  - International prescription drug wholesale distribution permittees (IPDI).

  The fees for the new licenses and permits that are created under this bill are handled in a separate fee bill as required by the State Constitution. The specific financial requirements for each of these licenses or permits will be set by rule by the AHCA and DBPR.
- Both programs have an immediate suspension provision allowing either the AHCA or the DBPR to immediately suspend the importation of a specific drug or the importation of drugs by a specific importer if either a specific drug or a specific importer is in violation of any provision of the bill or any federal or state law or regulation. The suspension may

be lifted if, after conducting an investigation, the AHCA or DBPR determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the state.

- The bill requires federal approval, followed by state legislative review of an implementation and funding plan, before either program can begin. The IPDI Program requires specific federal approval as there is not any current federal legislation authorizing such a program.
- CS/HB 19 is linked to HB 7073, which authorizes DBPR and DOH to charge fees relating to new permits created in this bill for the IPDI Program.

If approved by the Governor, these provisions take effect July 1, 2019.
Vote: Senate 27-13; House 93-20