



CS/HB 19 Prescription Drug Importation Programs

- **CS/HB 19** authorizes prescription drug importation programs that would give Floridians access to safe, effective, FDA-approved drugs from countries with good track records with the United States, including Canada.
- The bill establishes the **Canadian Prescription Drug Importation Program** within the Agency for Health Care Administration (AHCA) to allow state health care programs to import safe and effective prescription drugs from eligible Canadian suppliers at lower cost to the state.
 - AHCA must apply for and receive federal approval before it can implement the program.
- The bill also establishes the **International Prescription Drug Importation Program** within the Department of Business and Professional Regulation (DBPR) and the Department of Health (DOH) to import safe and effective drugs from other countries into the state, for use by all consumers.
 - These other countries must be ones the federal government has recognized as adhering to current good manufacturing practices for pharmaceutical products, either through a current mutual recognition agreement, cooperation agreement, or memorandum of understanding, or through some other federal mechanism.
 - Foreign suppliers must obtain appropriate licensing or permitting in Florida to participate in the program, and as such, will be subject to Florida's laws and regulations. The bill poses additional requirements for importers, exporters, and activities under the program to ensure safety of prescription drugs imported into the state.
 - To implement the program, DBPR and DOH must first negotiate a federal arrangement or obtain federal guidance on the program.
- The bill requires DBPR to immediately suspend importation of a specific prescription drug or importation by a specific entity if it discovers that any prescription drug or activity is in violation of the program requirements. DBPR may lift the suspension if after an investigation it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into the state.
- The bill also outlines the importation process, the safety standards that must be adhered to, drug distribution requirements, and measures that may be taken against those who violate any program requirements.
- Under the bill, both programs require cooperation at the federal level before prescription drug importation under the programs can begin.
- The bill increases patient choices and allows safe and effective drugs from other countries to be sold in Florida.