

Blog Post

Florida Board of Pharmacy Initiates Work on International Export Pharmacy Permit Application and Rules

July 23, 2019

By [Martin R. Dix](#)

International export pharmacies took another step forward towards a separate, distinct licensure in Florida as the Florida Board of Pharmacy held a specially called [Rules Sub-Committee Meeting](#) on June 27, 2019, to address the Board's responsibilities under House Bill 19, which went into effect on July 1, 2019. Section 465.0157, FS, establishes an "international export pharmacy" permit as part of the governor's initiative to try to bring less expensive drugs from Canada to Florida residents. An international export pharmacy is a pharmacy located outside of the United States that holds an active and unencumbered permit under Chapter 465, FS [The Florida Pharmacy Practice Act], to export prescription drugs from their location into this state under the program. These pharmacies will also need to be registered as exporters with the Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics before they can export drugs into this state.

Only drugs that meet FDA standards relating to safety, effectiveness, misbranding and adulteration, and ones that do not violate U.S. patent laws can be imported. Even then, not all prescription drugs may be imported. The law excludes:

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- A controlled substance as defined in 21 U.S.C. s. 802
- A biological product as defined in 42 U.S.C. s. 262
- An infused drug
- An intravenously injected drug
- A drug that is inhaled during surgery
- A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health

The Board also worked through a draft international export pharmacy permit application and adjusted the language to reflect the international nature of the application to the extent allowed by Florida law. The rules will be housed in Chapter 64B16-33, FAC. The Rules Sub-Committee anticipates seeing the revised draft application and a rule outline at its August 2019 meeting.

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