

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Rules

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BILL: HB 7073

INTRODUCER: Health Quality Subcommittee and Representatives Plakon and Leek

SUBJECT: Permit and Inspection Fees

DATE: April 21, 2019

REVISED: \_\_\_\_\_

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ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. <u>Brown</u>	<u>Phelps</u>	<u>RC</u>	<b>Favorable</b>

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**I. Summary:**

HB 7073, which is linked to HB 19, authorizes the Department of Health’s (DOH) Board of Pharmacy and the Department of Business and Professional Regulation (DBPR) to charge fees relating to new permits created under HB 19.

HB 19 seeks to create an International Prescription Drug Importation Program, subject to the negotiation of a “federal arrangement or upon obtaining federal guidance,” along with the following permits: an international export pharmacy permit under the Board of Pharmacy and an international prescription drug wholesale distributor permit under the DBPR.

The Florida Constitution requires that legislation that imposes or authorizes new state taxes or fees,<sup>1</sup> or that raises existing state taxes or fees,<sup>2</sup> must be approved by two-thirds of the membership of each house of the Legislature, and the tax or fee provisions must be passed in a separate bill that contains no other subject.<sup>3</sup> HB 7073 authorizes the imposition of fees for permits created under HB 19 or similar legislation. As such, the Florida Constitution may require that such a fee provision must be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

HB 7073 has an indeterminate positive fiscal impact on the DOH and the DBPR.

The bill will be effective on the same date that HB 19 or similar legislation takes effect.<sup>4</sup>

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<sup>1</sup> FLA. CONST. art. VII, s. 19(a).

<sup>2</sup> FLA. CONST. art. VII, s. 19(b).

<sup>3</sup> FLA. CONST. art. VII, s. 19(e).

<sup>4</sup> As of this writing, HB 19 provides an effective date of July 1, 2019. See: <http://www.flsenate.gov/Session/Bill/2019/00019> (last visited April 21, 2019)

## II. Present Situation:

### Permit Fees

#### *Drugs, Devices, and Cosmetics*

The DBPR's Division of Drugs, Devices, and Cosmetics protects public health, safety, and welfare from adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics by enforcing part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.<sup>5</sup> The Florida Drug and Cosmetic Act conforms to federal Food and Drug Administration drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.<sup>6</sup> Florida has 18 distinct permits based on the type of entity and intended activity and includes permits for entities within the state, out of state, or even outside of the United States.<sup>7</sup>

Section 499.041, F.S., provides a schedule of fees for the DBPR to follow and establishes ranges of fees for each permitting type and category. For prescription drug wholesale distributor permits, the DBPR must set the annual permit fee between \$300 and \$800 and must charge out-of-state prescription drug wholesale distributors an on-site inspection fee between \$1,000 and \$3,000. Section 499.012, F.S., also sets a \$100 late renewal fee for prescription drug wholesale distributors.

#### *Pharmacies*

The Board of Pharmacy (Board) within the DOH regulates the practice of pharmacy, which includes licensing and monitoring pharmacists and pharmacies to ensure safe practice.<sup>8</sup> To operate a pharmacy, an entity must first obtain a pharmacy permit from the Board.<sup>9</sup> Under current law, the costs of regulation of health care professions must be borne by the licensees and licensure applicants.<sup>10</sup> As such, s. 465.022(14), F.S., requires the Board to set the following fees for pharmacy permits:

- Initial permit fee not to exceed \$250.
- Biennial permit fee not to exceed \$250.
- Delinquent fee not to exceed \$100.
- Change of location fee not to exceed \$100.

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<sup>5</sup> FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited April 21, 2019).

<sup>6</sup> Section 499.01, F.S.

<sup>7</sup> A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. *See* s. 499.01(1), F.S.

<sup>8</sup> Chapter 465, F.S.; FLORIDA BOARD OF PHARMACY, <https://floridaspharmacy.gov/> (last visited April 21, 2019).

<sup>9</sup> Section 465.022, F.S.

<sup>10</sup> Section 456.025(1), F.S.

### **International Prescription Drug Importation Program**

HB 19 seeks to create the following two new permit categories for participation in an International Prescription Drug Importation Program that HB 19 also seeks to create:<sup>11</sup>

- An international prescription drug wholesale distributor permit under the DBPR; and
- An international export pharmacy permit under the Board.

Currently, the DBPR and the Board cover the cost of regulating wholesale distributors and pharmacies through permitting fees. Creating new permits would increase regulatory costs for DBPR and the Board. Without authorization to charge permitting fees, the DBPR and the Board would likely not have adequate resources to cover the costs associated with regulating these new entities under the provisions of HB 19.

### **III. Effect of Proposed Changes:**

The bill, which is linked to HB 19, authorizes the DBPR and the Board to charge the following fees for new permits created by HB 19:

- The Board may charge international export pharmacies initial permit and renewal fees up to \$250, delinquent fees up to \$100, and change of location fees up to \$100.
- The DBPR must charge international prescription drug wholesale distributors an annual permit fee between \$300 and \$800, an annual on-site inspection fee within a range between \$1,000 and \$3,000, and a late permit renewal fee of \$100.

These are consistent with permit fees that the DBPR and the Board currently charge for similar entities. These fees would offset costs associated with regulating these new entities under the provisions of HB 19.

The bill becomes effective on the same date as HB 19 or similar legislation takes effect.

### **IV. Constitutional Issues:**

#### **A. Municipality/County Mandates Restrictions:**

None.

#### **B. Public Records/Open Meetings Issues:**

None.

#### **C. Trust Funds Restrictions:**

None.

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<sup>11</sup> HB 19 provides that, notwithstanding the federal Food, Drug, and Cosmetic Act, the DBPR, in collaboration with the DOH, must negotiate a “federal arrangement” to operate an International Prescription Drug Importation Program for importing prescription drugs into the state. Under HB 19, implementation of the program is contingent upon such “federal arrangement or upon obtaining federal guidance.” It is unclear what sort of federal arrangement or federal guidance might authorize the program because such a program appears to be currently illegal under federal law, and there appears to be no authority for any executive branch agency to waive the provisions of federal law that make such a program illegal.

**D. State Tax or Fee Increases:**

Article VII, s. 19, of the Florida Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, s. 19(d)(1), of the Florida Constitution defines “fee” to mean “any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service.”

HB 7073 authorizes the imposition of fees for permits created under HB 19 or similar legislation. As such, the Florida Constitution may require that such a fee provision must be approved in a stand-alone bill by two-thirds of the membership of each house of the Legislature.

**E. Other Constitutional Issues:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

If an International Prescription Drug Importation Program is ever implemented under HB 19, entities seeking the permits created under HB 19 would incur the fees authorized under HB 7073. Applicants for an international export pharmacy would have to pay initial and biennial renewal permit fees of up to \$250 to the Board. Additionally, applicants for an international prescription drug wholesale distributor would have to pay an annual permit fee between \$300 and \$800 and an annual onsite inspection fee between \$1,000 and \$3,000 to the DBPR.

**C. Government Sector Impact:**

If an International Prescription Drug Importation Program is ever implemented under HB 19, HB 7073 would generate additional revenues for the Board and the DBPR. The additional revenue the Board or DBPR would receive is indeterminate because the number of entities that may choose to apply for such permits is not known.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 465.0157, 499.012, and 499.041.

**IX. Additional Information:**

**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.

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This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

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