

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7073 PCB HQS 19-05 Permit and Inspection Fees

SPONSOR(S): Health Quality Subcommittee, Plakon and Leek

TIED BILLS: HB 19 **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	14 Y, 0 N	Gilani	McElroy
1) Appropriations Committee	25 Y, 3 N	Keith	Pridgeon
2) Health & Human Services Committee	10 Y, 6 N	Gilani	Calamas

SUMMARY ANALYSIS

HB 19 creates two new permits for the International Prescription Drug Importation Program: an international export pharmacy under the Department of Health's Board of Pharmacy and an international prescription drug wholesale distributor under the Department of Business and Professional Regulation (DBPR).

HB 7073, which is linked to HB 19, authorizes the Board of Pharmacy and DBPR to charge fees relating to the new permits.

The bill has an indeterminate, significant positive fiscal impact on DOH and DBPR.

The bill will be effective on the same date that HB 19 or similar legislation takes effect.

This bill authorizes a new state fee, requiring a two-thirds vote of the membership of the House. See Section III.A.2. of the analysis.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Legislation Imposing or Raising State Fees or Taxes

The Florida Constitution provides that no state tax or fee may be imposed, authorized, or raised by the Legislature except through legislation approved by two-thirds of the membership of each house of the Legislature.¹ For purposes of this requirement, a “fee” is any charge or payment required by law, including any fee or charge for services and fees or costs for licenses and to “raise” a fee or tax means to:²

- Increase or authorize an increase in the rate of a state tax or fee imposed on a percentage or per mill basis;
- Increase or authorize an increase in the amount of a state tax or fee imposed on a flat or fixed amount basis; or
- Decrease or eliminate a state tax or fee exemption or credit.

A bill that imposes, authorizes, or raises any state fee or tax may only contain the fee or tax provision(s) and may not contain any other subject.³

The constitutional provision does not authorize any state tax or fee to be imposed if it is otherwise prohibited by the constitution and does not apply to any tax or fee authorized or imposed by a county, municipality, school board, or special district.⁴

Permit Fees

Drugs, Devices, and Cosmetics

The Department of Business and Professional Regulation’s (DBPR) 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.⁵ The Florida Drug and Cosmetic Act conforms to FDA drug laws and regulations and authorizes DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.⁶ 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.⁷

Section 499.041, F.S., provides a schedule of fees for DBPR to follow and establishes ranges of fees for each permitting type and category. For prescription drug wholesale distributor permits, DBPR must

¹ Fla. Const. art. VII, s. 19(a)-(b). The amendment appeared on the 2018 ballot as Amendment 5.

² Fla. Const. art. VII, s. 19(d).

³ Fla. Const. art. VII, s. 19(e).

⁴ Fla. Const. art. VII s. 19(c).

⁵ FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited Mar. 7, 2019).

⁶ S. 499.01, F.S.

⁷ 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. S. 499.01(1), F.S.

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 Department of Health (DOH), regulates the practice of pharmacy, which includes licensing and monitoring pharmacists and pharmacies to ensure safe practice.⁸ To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.⁹ Under current law, the costs of regulation of health care professions must be borne by the licensees and licensure applicants.¹⁰ 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.

International Prescription Drug Importation Program

HB 19 creates the following two new permit categories for participation in the International Prescription Drug Importation Program:

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

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

Effect of the Bill

The bill, which is linked to HB 19, authorizes 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.
- DBPR must charge international prescription drug wholesale distributors an annual permit fee between \$300 and \$800, an annual on-site inspection fee between \$1,000 and \$3,000, and a late permit renewal fee of \$100.

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

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

⁸ Ch. 465, F.S.; FLORIDA BOARD OF PHARMACY, <https://floridaspharmacy.gov/> (last visited Mar. 10, 2019).

⁹ S. 465.022, F.S

¹⁰ S. 456.025(1), F.S.

B. SECTION DIRECTORY:

- Section 1:** Amends s. 465.017, F.S., relating to international export pharmacy permit, created by HB 19.
- Section 2:** Amends s. 499.012, F.S., relating to permit application requirements.
- Section 3:** Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.
- Section 4:** Provides an effective date contingent on the passage of HB 19 or similar legislation.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill will generate additional revenues for the Board and DBPR. Applicants for an international export pharmacy will have to pay initial and biennial renewal permit fees of up to \$250 to the Board. Analysis of the revenue impact of HB 7073 was requested of DOH, however, no DOH analysis has been provided.

Additionally, applicants for an international prescription drug wholesale distributor will have to pay an annual permit fee between \$300 and \$800, and an annual onsite inspection fee between \$1,000 and \$3,000 to DBPR.¹¹ The additional revenue the Board or DBPR will receive is indeterminate because the number of entities that choose to apply for such permits is not known at this time.

2. Expenditures:

DBPR and the Board will incur costs associated with regulating these newly permitted entities. The number of applicants for an international export pharmacy or international prescription drug wholesale distributor is indeterminate at this time. However, the revenues generated by the permit fees authorized in the bill may be sufficient to cover costs associated with the implementation of HB 19.¹²

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

International export pharmacies and international prescription drug wholesale distributors will have to pay fees related to permitting, but in exchange will be able to export prescription drugs into the state under the International Prescription Drug Importation Program. To the extent that such parties participate in the program and export prescription drugs into the state, they may experience an increase in revenue that is currently not available to them.

D. FISCAL COMMENTS:

None.

¹¹ Florida Department of Business and Professional Regulation, Agency Analysis for 2019 HB 7073, p. 4 (March 14, 2019)(on file with Appropriations Committee staff)

¹² *Id.*

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

Article VII, s. 19 of the Florida Constitution requires the imposition, authorization, or raising of a state tax or fee be contained in a separate bill that contains no other subject and be approved by two-thirds of the membership of each house of the Legislature. As such, the bill appears to implicate Art. VII, s. 19 of the Florida Constitution because the bill authorizes a state fee.

B. RULE-MAKING AUTHORITY:

DBPR and the Board have sufficient rulemaking authority in current law to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES