HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/HB 675	**FINAL HOUSE FLOOR ACTION:**	
SUBJECT/SHORT TITLE	Pharmacies	113 **Y's** 0 **N's**	
SPONSOR(S):	Health & Human Services Committee; Brodeur	**GOVERNOR'S ACTION:**	Approved
COMPANION BILLS:	CS/SB 1128		

SUMMARY ANALYSIS

CS/HB 675 passed the House on March 1, 2018, and subsequently passed the Senate on March 9, 2018.

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice. The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice within the state. Any person who operates a pharmacy in Florida must have a permit from the Department of Health (DOH). Pharmacy permits may only be issued to a single location. An entity that operates pharmacies at multiple locations must obtain a permit for each location outside a ½-mile radius.

An institutional pharmacy permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. DOH issues three different classes of permits for institutional pharmacies: Class I, Class II, and Modified Class II permits.

The Florida Drug and Cosmetic Act authorizes the Department of Business and Professional Regulation (DBPR) to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida. Institutional pharmacy permit holders must obtain additional permits from DBPR to distribute drugs. Entities that operate multiple permitted institutional pharmacies must obtain permits from DBPR for each of its permitted locations.

Section 340B of the Public Health Services Act is a federal program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices directed at serving primarily low income and vulnerable populations. Eligible organizations include six categories of hospitals: Disproportionate Share Hospitals; Children's hospitals; Cancer hospitals exempt from the Medicare prospective payment system; Sole community hospitals; Rural Referral Centers; and Critical Access Hospitals.

CS/HB 675 creates a Class III institutional pharmacy permit (Class III permit) for hospital-affiliated institutional pharmacies, including central distribution facilities, that provide the same services authorized by a Class II permit. The bill exempts Class III permit holders from obtaining additional permits from DBPR to distribute medical drugs or prepackaged drug products between certain entities under common control.

The bill also exempts hospitals that participate in the Section 340B Drug Discount Program from obtaining a Restricted Prescription Drug Distributor permit when arranging for a prescription drug wholesale distributor to distribute prescription drugs covered by the Section 340B Drug Discount Program directly to its contract pharmacy.

The bill has an indeterminate, negative fiscal impact on the DBPR. See fiscal analysis section.

The bill was approved by the Governor on March 23, 2018, ch. 2018-95, L.O.F., and will become effective on July 1, 2018.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Practice of Pharmacy

The Florida Pharmacy Act (act) regulates the practice of pharmacy and contains the minimum requirements for safe practice.[1] The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice within the state.[2] Any person who operates a pharmacy in Florida must have a permit from the Department of Health (DOH). Pharmacy permits may only be issued to a single location. An entity that operates pharmacies at multiple locations must obtain a permit for each location outside a ½-mile radius.[3]

The following permits are issued by DOH:

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[4]
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[5]
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.[6]
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[7]
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[8]
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.[9]
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[10]

[1] Chapter 465, F.S.
[2] Sections 465.005, 465.0155, and 465.022, F.S.
[3] Rule 64B16-28.113, F.A.C.
[4] Sections 465.003(11)(a)1. and 465.018, F.S.
[5] Sections 465.003(11)(a)2. and 465.019, F.S.
[6] Sections 465.003(11)(a)3. and 465.0193, F.S.
[7] Sections 465.003(11)(a)4. and 465.0196, F.S.
[8] Sections 465.003(11)(a)5. and 465.0197, F.S.
[9] Section 465.0158, F.S.
[10] Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.

DOH issues three different classes of permits for institutional pharmacies:

- Institutional Class I: An Institutional Class I pharmacy is a pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provide the individual patient prescriptions.
- Institutional Class II: An Institutional Class II pharmacy is a pharmacy which employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility. A consultant pharmacist of record shall also be responsible for establishing written policy and procedure manual for the implementation of the general requirements set forth in Rule 64B16- 28.702, F.A.C.
- Modified Class II: Modified Institutional Class II pharmacies are those pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements. Modified Class II Institutional pharmacies are designated as Type "A", Type "B" and Type "C" according to the type of specialized pharmaceutical delivery system utilized[11]:
    - Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist provides on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.
    - Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist provides on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.
    - Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist provides onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

Florida Regulation of Drug Distribution

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[12] 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. Florida has 18 distinct permits for these entities.[13]

[11] 64B16-28.702
[12] S. 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[13] 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.

Institutional pharmacy permit holders must obtain additional permits from DBPR to distribute drugs. Entities that operate multiple permitted institutional pharmacies must obtain permits from DBPR for each of its permitted locations.

Prescription Drug Manufacturer Permit

A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[14] A person that operates an establishment permitted as a prescription drug manufacturer may engage in distribution of prescription drugs for which the person is the manufacturer.[15] The distribution of drugs includes the selling, purchasing, trading, delivering, handling storing, and receiving of drugs.[16] Distribution of drugs does not include the administration or dispensing of drugs. The manufacturing of drugs includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[17]

Restricted Prescription Drug Distributor Permit

A restricted prescription drug distributor permit is required for:[18]

- Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.
- A blood establishment located in this state which collects blood and blood components only from volunteer donors[19] or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug that does not include the distribution of blood and blood components intended for transfusion to a health care entity.
- Any person located in this state who engages in the distribution of a prescription drug that is not considered "wholesale distribution."

The following activities are not considered wholesale distribution if conducted in accordance with a restricted drug distributor permit:[20]

- The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.
- The distribution of a prescription drug or an offer to distribute a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law.
- The distribution of a prescription drug among hospitals or other health care entities that are under common control.[21]
- The distribution of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to

[14] Id.
[15] Id.
[16] S. 499.003(16), F.S.
[17] S. 499.003(28), F.S.
[18] S. 499.01(2)(h), F.S.
[19] S. 381.06014, F.S. defines volunteer donor as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion, and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under 21 C.F.R. s. 606.121.
[20] S. 499.003(48)(a), F.S.
[21] S. 499.003(48)(a)2., F.S. defines common control as the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity if:

- The agency or entity obtains written authorization for the distribution of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.
- The contract provider or subcontractor is authorized by law to administer or dispense prescription drugs.
- In the case of a subcontractor, the agency or entity is a party to and execute the subcontract.
- The contract provider and subcontractor maintains and produces immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs.
- The contract provider or subcontractor administers or dispenses the prescription drugs only to the eligible patients of the agency or entity or returns the prescription drugs for or to the agency or entity.

There are six classifications for restricted prescription drug distributor permits:[22]

- Restricted Prescription Drug Distributor – Charitable Organization: Required for a charitable organization to possess or transfer prescription drugs, including prescription drug samples.
- Restricted Prescription Drug Distributor – Health Care Entity: Required for a hospital or health care entity[23] for the limited purpose of transferring prescription drugs among hospitals or other health care entities that are under common control[24] or members of a group purchasing organization.[25]
- Restricted Prescription Drug Distributor – Reverse Distributor: Required for persons engaged in the handling, processing and removal of expired or otherwise adulterated or unsuitable prescription drugs on behalf of licensed pharmacies, practitioners, wholesalers, or other persons authorized to possess prescription drugs for return to the manufacturer or source of the prescription drug or for destruction.
- Restricted Prescription Drug Distributor – Destruction: Required for a person to take possession in Florida of a prescription drug for arranging for its destruction; other than the manufacturer of that drug or a permitted Restricted Prescription Drug Distributor – Reverse Distributor.
- Restricted Prescription Drug Distributor – Government Programs: Required for a state or local government agency, or any entity eligible to purchase prescription drugs at public health services prices pursuant to Veterans Health Care Act of 1992, to distribute its prescription drugs to a contract provider or its subcontractor for administering or dispensing to eligible patients of the entity under the eligible program.
- Restricted Prescription Drug Distributor – Institutional Research: Required for a licensed pharmacy of a university to transfer prescription drugs to practitioner or non-practitioner researchers for university sponsored research.

<u>Prescription Drug Repackager Permit</u>

A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.[26] Repackaging includes the repacking or otherwise changing the container, wrapper, or

[22] Rule 61N-1.023, F.S.
[23] "Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. See s. 499.003(21), F.S.
[24] Supra, FN 21.
[25] S. 499.003(48)(a)1., F.S
[26] S. 499.01(2)(b), F.S.

labeling to further the distribution of the drug, device, or cosmetic,[27] but does not include pharmacies operating in compliance with ch. 465 and rules adopted under that chapter.[28] A person that operates an establishment permitted as a prescription drug repackager must comply with all of the requirements that apply to a prescription drug manufacturer.[29]

A health care entity[30] permitted as a restricted prescription drug distributor is exempt from obtaining a prescription drug repackager permit for the repackaging of prescription drugs for that health care entity's own use or for distribution to other hospitals or health care entities in the state for their own use under the following conditions:[31]

- The hospital or health care entity is under common control;[32]
- The prescription drugs are repackaged in accordance with current state and federal good manufacturing practices;
- The prescription drugs are labeled in accordance with state and federal law; and
- The distributor notifies the department 30 days in advance of its intent to repackage.

Health Care Clinic Establishment Permit

A health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number.[33] The health care clinic establishment must employ a qualifying practitioner[34] at each establishment.[35]

Section 340B Discount Drug Program

Section 340B of the Public Health Services Act is a federal program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices directed at serving primarily low income and vulnerable populations.[36] Eligible health care organizations are required to register with the Health Resources and Services Administration within the federal Department of Health and Human Services and meet established eligibility requirements.[37] Eligible health care entities who receive distributions of such drugs must obtain a restricted drug distributor- governmental entities permit from DBPR allowing them to receive and distribute the discounted drugs.[38]

[27] S. 499.003(44), F.S.
[28] S. 499.003(45), F.S.
[29] Supra, FN 26.
[30] Supra, FN 19.
[31] S. 499.01(5), F.S.
[32] S. 499.01(5)(b), F.S. defines "common control" as the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise
[33] S. 499.01(2)(r), F.S.
[34] A qualifying practitioner is a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug or one of the following licensed health care practitioners: acupuncturist, medical doctor, osteopathic physician, chiropractor, podiatrist, naturopathy practitioner, optometrist, nurse, pharmacists, dentist, dental hygienist, speech language pathologist, audiologist, nursing home administrator, occupational therapist, dietitian, athletic trainer, orthoptist, pedorthotist, prosthestist, midwife, electrologist, massage therapist, clinical lab personnel, medical physicists, clinical social worker, marriage and family therapist, mental health counselor, optician, physical therapist, and psychologist. See s. 456.001, F.S.
[35] Supra, FN 34.
[36] 42 U.S. Code § 256b; Overview of the 340B Drug Pricing Program. Available at: https://www.340bhealth.org/340b-resources/340b-program/overview/ (Last visited January 12, 2018).
[37] Id.
[38] Rule 61N-1.023, F.S.

The following six categories of hospitals are eligible to participate in the program[39]:

- Disproportionate Share Hospitals (DSH);
- Children's hospitals;
- Cancer hospitals exempt from the Medicare prospective payment system;
- Sole community hospitals;
- Rural Referral Centers; and
- Critical Access Hospitals (CAH)

Hospitals in each of the categories must be owned or operated by state or local government, a public or private non-profit corporation which is formally granted governmental powers by state or local government, or a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare.[40] In addition, with the exception of CAHs, hospitals must meet payer-mix criteria related to the Medicare DSH program. There are also eleven categories of non-hospital covered entities that are eligible based on receiving federal funding. They include federally qualified health centers (FQHCs)[41]; FQHC "look-alikes"[42]; state-operated AIDS drug assistance programs; the Ryan White Comprehensive AIDS Resources Emergency Act clinics and programs; tuberculosis, black lung, family planning, and sexually transmitted disease clinics; hemophilia treatment centers; Title X public housing primary care clinics; homeless clinics; Urban Indian clinics; and Native Hawaiian health centers.[43]

Effect of the Bill

CS/HB 675 creates a Class III institutional pharmacy permit (Class III permit) for hospital-affiliated institutional pharmacies, including central distribution facilities that provide the same services authorized by a Class II permit. The bill authorizes Class III permits to:

- Dispense, distribute, compound, and fill prescriptions for medicinal drugs.
- Prepare prepackaged drug products.
- Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under ch. 465 to possess medicinal drugs.
- Provide the aforementioned services to an entity under common control that holds an active health care clinic establishment permit as required under ch. 499.

The bill defines prepackaged drug product as a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to ch. 465 for the purpose of dispensing or by a facility holding a Class III permit.

The bill defines a central distribution facility as a facility under common control with a hospital holding a Class III institutional pharmacy permit that may dispense, distribute, compound, or fill prescriptions for medicinal drugs; prepare prepackaged drug products; and conduct other pharmaceutical services.

The bill defines common control as the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

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[39] Supra, FN 30.
[40] Id.
[41] Federally Qualified Health Centers are community-based health care providers that receive funds from the HRSA Health Center Program to provide primary care services in underserved areas. Available at: https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html
[42] Federally Qualified Health Center Look-Alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program, but do not receive Health Center Program funding. Available at: https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc-look-alikes/index.html (Last visited January 12, 2018)
[43] Supra, FN 30.

The bill requires a Class III permit holder to maintain policies and procedures addressing:

- The consultant pharmacist responsible for pharmaceutical services.
- Safe practices for the preparation, dispensing, prepackaging, distribution, and transportation of medicinal drugs and prepackaged drug products.
- Recordkeeping to monitor the movement, distribution, and transportation of medicinal drugs and prepackaged drug products.
- Recordkeeping of pharmacy staff responsible for each step in the preparation, dispensing, prepackaging, transportation, and distribution of medicinal drugs and prepackaged drug products.
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III permit holders.

The bill requires pharmacists in a Class III institutional pharmacy to notify a person presenting a prescription when substituting a biological product[44] for the one prescribed by entering the substitution in the institution's written medical record system or electronic medical record system.

The bill allows up to a 24-hour supply of medicinal drugs to be prescribed to outpatients of an emergency department in a hospital that does not have a Community Pharmacy permit if it has a Class III permit.

The bill allows a Class III permit holder to establish an institutional formulary system identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by its pharmacists.

The bill exempts entities under common control that hold either a Class III permit or Health Care Clinic Establishment permit holders from obtaining a Restricted Prescription Drug Distributor permit and Prescription Drug Repackager permit in order to distribute medical drugs or prepackaged drug products between themselves. Under the bill, a hospital-affiliated institutional pharmacy with multiple locations permitted as a Class III pharmacy will no longer be required to obtain additional permits from DBPR for each of its permitted locations that are under common control.

The bill removes the exemption for a health care entity with a Prescription Drug Repackager permit from obtaining a Restricted Prescription Drug Distributor permit, as it is no longer necessary due to the bill's removal of the requirement for a Prescription Drug Repackager permit for health care entities and hospitals with Class III permits under common control.

The bill exempts hospitals that participate in the Section 340B Drug Discount Program from obtaining a Restricted Prescription Drug Distributor permit when arranging for a prescription drug wholesale distributor to distribute prescription drugs covered by the Section 340B Drug Discount Program directly to its contract pharmacy.

The bill allows the Governor to appoint a pharmacist currently engaged in the practice of pharmacy in a Class III institutional pharmacy to the Florida Board of Pharmacy.

The bill provides an effective date of July 1, 2018.

[44] "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. See s. 351 of the federal Public Health Service Act, 42 U.S.C. s. 262.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

DBPR will experience an indeterminate, negative fiscal impact due to the decrease in licensure revenues created by the exemption granted to qualifying Class III institutional pharmacy permit holders from obtaining permits from DBPR.[45]

It is unknown how many pharmacies will take advantage of the exemption. Using a range of percentages of pharmacies that may be exempt, it is estimated the DBPR revenue loss will be between $61,200 and $220,800 biennially. The following table illustrates possible revenue loss scenarios using the current number of pharmacies licensed by DBPR.

Licensure Type	License Count by License Type as of 1/1/18	Renewal Fee Per License Type	Possible Reduction in Licenses: 25%		Possible Reduction In Licenses: 50%		Possible Reduction in Licenses: 75%		Possible Reduction in Licenses: 90%	
			License Reduction	Revenue Reduction	License Reduction	Revenue Reduction	License Reduction	Revenue Reduction	License Reduction	Revenue Reduction
Restricted Prescription Drug Distributor- Health	122	$600/ biennially	31	$ 18,600	61	$ 36,600	92	$ 55,200	110	$ 66,000
Restricted Prescription Drug Distributor-	203	$600/ biennially	51	$ 30,600	102	$ 61,200	152	$ 91,200	183	$109,800
Prescription Drug Repackager	33	$1,500/ biennially	8	$ 12,000	17	$ 25,500	25	$ 37,500	30	$ 45,000
Totals	**358**		**90**	**$ 61,200**	**180**	**$123,300**	**269**	**$183,900**	**323**	**$220,800**

DOH should not experience a significant increase in revenues due to the new permit type. The Class III designation is not a separate pharmacy permit, but rather a modifier that is associated with the institutional pharmacy permit number in DOH's licensing database. Pharmacies that qualify for Class III institutional pharmacy permits must already hold an institutional pharmacy permit under current law. Therefore, current permit holders would only need to have their designation changed to a Class III designation by DOH rather than obtaining a new permit.[46]

2. Expenditures:

DBPR should not experience an increase in expenditures.

DOH should not experience an increase in expenditures associated with the new permit type. The Class III designation is not a separate pharmacy permit, but rather a modifier that is associated with the institutional pharmacy permit number in DOH's licensing database. Accordingly, there is no fiscal impact associated with adding this modifier to the licensing database and issuing pharmacy permits with the Class III designation.[47]

[45] Dep't of Business and Professional Regulation, *2018 Agency Bill Analysis-HB 675, January 5,2018* (on file with Health Quality Subcommittee staff).
[46] Dep't of Health, *2018 Agency Bill Analysis-HB 675, November 15, 2018*; E-mail correspondence with agency, January 5, 2018 (on file with Health Quality Subcommittee staff).
[47] Id.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacies that obtain a Class III permit will no longer be required to pay licensure fees to obtain additional permits from DBPR.

D. FISCAL COMMENTS:

None.