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.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1128
INTRODUCER:	Senator Stargel
SUBJECT:	Pharmacy
DATE:	January 29, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Pre-meeting**
2.			AP	
3.			RC	

I. Summary:

SB 1128 establishes a Class III institutional pharmacy permit. A Class III institutional pharmacy may dispense, distribute, compound, fill prescriptions, and prepare prepackaged drug products, for an affiliated hospital and entities under common control that are also permitted under the Florida Pharmacy Act. A Class III institutional pharmacy is exempt from permitting under the Florida Drug and Cosmetic Act.

The bill expands the pharmacists eligible for two seats on the Board of Pharmacy to include a pharmacist engaged in the practice of pharmacy in a Class III institutional pharmacy.

The effective date of the bill is July 1, 2018.

II. Present Situation:

Pharmacy

The practice of pharmacy, and the licensure of pharmacies, are regulated by ch. 465, F.S. The "practice of the profession of pharmacy" includes:

- Compounding, dispensing, and consulting the consumer concerning the contents, therapeutic values, and uses of any medicinal drug; and
- Other pharmaceutical services.[1,2]

[1] Section 465.003(13), F.S.

[2] "Other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. . . .The "practice of the profession of pharmacy" also includes any other act, service,

The Board of Pharmacy

The Board of Pharmacy (Board) is created within the Department of Health (DOH). The Board consists of nine members appointed for four year terms by the Governor, and confirmed by the Senate. Seven members of the Board must be licensed pharmacists who are residents of Florida and who have been engaged in the practice of pharmacy in this state for at least four years and, to the extent possible, represent the various pharmacy practice settings.[3]

The Board members must include the following, of which one member must be 60 years of age or older:

- Two pharmacists currently engaged in practice in a community pharmacy;
- Two pharmacists currently engaged in practice in a Class II institutional pharmacy or a Modified Class II institutional pharmacy;
- Three pharmacists must be licensed in this state irrespective of practice setting; and
- Two resident consumer members who are not pharmacists, not connected with the practice of the pharmacy, drug manufacturing or drug wholesaling.[4]

The Board is authorized to make rules to regulate the practice of professional pharmacy in pharmacies meeting minimum requirements for safe practice.[5] All pharmacies must obtain a permit before operating, unless exempt. This is true whether opening a new establishment, or simply changing locations or owners.[6]

The general application and permitting process for a business establishment to obtain a pharmacy permit requires the submission of the following information to the DOH:

- General drug safety measures;
- Minimum standards for the physical facilities of pharmacies;
- Safe storage of floor-stock drugs;
- Functions of the pharmacist, and consultant pharmacist[7] in an institutional pharmacy, consistent with the size and scope of the pharmacy;
- Procedures for the safe storage and handling of radioactive drugs;
- Procedures for the distribution and disposition of drug samples or complimentary medicinal drugs;[8]
- Procedures for the transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy;
- Minimum equipment which a pharmacy must at all times possess to fill prescriptions properly; and

operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults. Section 465.003(13), F.S.

[3] Section 465.004, F.S.

[4] *Supra* note 1.

[5] Sections 465.002, and 465.0155, F.S.

[6] Rule 64B16-28.100(1), F.A.C.

[7] Section 465.003(3), F.S.

[8] Section 499.028, F.S.

- Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.[9]

The Practice of Pharmacy

There are seven types of pharmacies eligible for various operating permits issued by the DOH:
- Community pharmacy;[10]
- Institutional pharmacy;[11]
- Nuclear pharmacy;[12]
- Special pharmacy;[13]
- Internet pharmacy;[14]
- Non-resident sterile compounding pharmacy;[15] and
- Special sterile compounding pharmacy.[16]

Institutional Pharmacies

An "institutional pharmacy" includes any pharmacy located in a health care institution, which includes a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[17] Institutional pharmacy permits are required for any pharmacy located in any health care institution.[18]

All institutional pharmacies must designate a consultant pharmacist;[19] and he or she is responsible for maintaining all drug records required by law, and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical tests when such tests are necessary for the proper performance of his or her responsibilities. Such laboratory or clinical tests may be ordered only with regard to patients residing in a nursing home; and then only when authorized by the medical director. The consultant pharmacist must have completed additional

[9] Section 465.022, F.S., and Rule 64B16-28-100, F.A.C.
[10] The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. *See* s. 465.003(11)(a)1., and s. 465.018, F.S.
[11] *See* ss. 465.003(11)(a)2., and 465.019, F.S.
[12] The term "nuclear pharmacy" includes 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 chapter 395 or the nuclear medicine facilities of such hospitals. *See* s. 465.003(11)(a)3., and s. 465.0193, F.S.
[13] The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection. *See* s. 465.003(11)(a)4., and s. 465.0196, F.S.
[14] The term "internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. *See* ss. 465.003(11)(a)5., and 465.0197, F.S.
[15] The term "nonresident sterile compounding pharmacy" includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility, must hold a nonresident sterile compounding permit *See* s. 465.0158, F.S.
[16] *See* Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.
[17] Section 465.003(11)(a)2., F.S.
[18] Rule 64B16-28.100(3), F.A.C.
[19] *See* ss. 465.003(11), and 465.0125, F.S.

training, and demonstrate additional qualifications in the practice of institutional pharmacy, as is required by the board in addition to licensure as a registered pharmacist.[20,21]

Currently there are three types of institutional pharmacy permits issued by the Board to institutional pharmacies: Institutional Class I, Class II, and Modified Class II.[22]

Institutional Class I Pharmacy

A Class I institutional pharmacy is an institutional pharmacy in which all medicinal drugs are administered from individual prescription containers to an individual patients; and in which medicinal drugs are not dispensed on the premises, except a licensed nursing homes[23] may purchase medical oxygen for administration to residents.[24]

Institutional Class II Pharmacy

A Class II institutional pharmacy is a pharmacy that 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 the institution, for use on the premises of the institution. A Class II institutional pharmacy is required to be open sufficient hours to meet the needs of the hospital facility. The consultant pharmacist of record is responsible for establishing a written policy and procedure manual for the implementation. An Institutional Class II Pharmacy may elect to participate in the Cancer Drug Donation Program.[25]

Modified Institutional Class II Pharmacy Permits

Modified Institutional Class II pharmacies are those institutional 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 specialized type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility;[26] and provide the following pharmacy services:

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[20] Section 465.0125, F.S.

[21] The consultant pharmacist must also conduct Drug Regimen Reviews required by Federal or State law, inspect the facility, and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist must monitor the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications are available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and in the monthly facility inspection. A licensed consultant pharmacist may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct any services additional or supplemental to regular drug regimen reviews, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations. The Board office must be notified in writing within ten days of any change in the consultant pharmacist of record. *See* Rule 64B16-28.100(3)(b), and 64B16-28.501, F.A.C.

[22] Section 465.019, F.S.

[23] *See* part II, ch. 400, F.S.

[24] Section 465.019(2)(a), F.S.

[25] The Department of Health, *Institutional Pharmacy Permit Application Information*, *available at:* http://floridaspharmacy.gov/licensing/institutional-pharmacy-permit/ (last visited Jan. 5, 2018).

[26] Rule 64B16-28.702, F.A.C.

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 shall provide 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 shall provide 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 shall provide onsite consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.[27]

All Modified Class II Institutional Pharmacies must be under the control and supervision of a certified consultant pharmacist. The consultant pharmacist of record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. [28]

Pharmaceutical Distribution in Florida

The Department of Business and Professional Regulation (DBPR) is charged with, among other things, regulating the distribution of prescription drugs into and within Florida against fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs under the Florida Drug and Cosmetic Act.[29]

In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers,[30] prescription drug repackagers, and prescription drug wholesale distributors,[31] to obtain permits. In total, Florida has 18 distinct permits for prescription drug manufacturers and wholesale distributors.[32]

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[27] *Id.*
[28] *See supra* note 25.
[29] *See* part I, ch. 499, F.S., and specifically s. 499.002, F.S.
[30] Sections 499.01(2)(a),(c), F.S.
[31] Sections 499.01(2)(e)(f)(g)(h), F.S.
[32] Section 499.01(1), F.S. Before operating, a permit is required for each person and establishment that intends to operate as a: prescription drug manufacturer; prescription drug repackager; nonresident prescription drug manufacturer; nonresident prescription drug repackager; prescription drug wholesale distributor; out-of-state prescription drug wholesale distributor; retail pharmacy drug wholesale distributor; restricted prescription drug distributor; complimentary drug distributor; freight forwarder; veterinary prescription drug retail establishment; veterinary prescription drug wholesale distributor; limited prescription drug veterinary wholesale distributor; over-the-counter drug manufacturer; device manufacturer; A cosmetic manufacturer; third party logistics provider; or health care clinic establishment.

Prescription Drug Repackaging Permit and Restricted Prescription Drug Distributor Permit

Within the pharmaceutical supply chain, a repackager removes a drug from its container and places it in another, usually smaller, container for sale to a distributor or dispenser. At the end of the supply chain, a dispenser provides the drug to the patient. A dispenser may be a community pharmacy (i.e. a retail chain pharmacy), an institutional pharmacy, a health care facility, or a doctor's office.[33]

A prescription drug repackager permit is required for any person that repackages a prescription drug in this state. A person that operates an establishment permitted as a prescription drug repackager may engage in distribution of prescription drugs repackaged at that establishment and must comply with all of the provisions of this part and the rules adopted under this part that apply to a prescription drug manufacturer. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.[34]

A health care entity,[35] permitted as a restricted prescription drug distributor,[36] 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 its own use under the following conditions:[37]

- The hospital or health care entity is under common control;[38]
- 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 DOH 30 days in advance of its intent to repackage.

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.[39] 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.[40] Eligible health care entities who receive

[33] Section 499.01(2)(b), F.S.
[34] *Id*.
[35] A "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 [community pharmacy]. *See* s. 499.003(21), F.S. A "closed pharmacy" means a pharmacy that is licensed under ch. 465, F.S., and purchases prescription drug for use by a limited patient population and not for wholesale distribution or sale to the public. *See* s. 499.003(8), F.S.
[36] A restricted prescription drug distributor permit is required for the distribution of a prescription drug that is not considered wholesale distribution. *See* s. 499.01(2)(h)1.a., F.S. Several exemptions from the definition of wholesale distribution could be applicable to the discussion, including s. 499.003(48)(a)3, (b)6, and (i), F.S.
[37] Section 499.01(5), F.S.
[38] Section 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
[39] 42 U.S.C. s. 256(b); *See also* 340B Health, *Overview of the 340B Drug Pricing Program, available at* https://www.340bhealth.org/340b-resources/340b-program/overview/ (last visited Jan. 24, 2018).
[40] *Id.*

distributions of such drugs must obtain a restricted drug distributor-governmental entities permit from DBPR allowing them to receive and distribute the discounted drugs.[41]

The following six categories of hospitals are eligible to participate in the program:
- 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.[42] 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)[43]; FQHC "look-alikes"[44]; 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.[45]

III. Effect of Proposed Changes:

The bill creates a new type of institutional pharmacy – the "Class III institutional pharmacy"; and describes it as an institutional pharmacy, including central distribution facilities, which is affiliated with a hospital and provides the same services as those authorized for Class II institutional pharmacies. The bill authorizes a Class III institutional pharmacy to:
- Dispense, distribute, compound, and fill prescriptions for medicinal drugs;
- Prepare prepackaged drug products;
- Conduct other pharmaceutical services for affiliated hospitals and entities under common control, each of which must be permitted under ch. 465, F.S., to possess medicinal drugs; and
- Provide medicinal drugs, drug products, and pharmaceutical services to an entity under common control that holds an active health care clinic establishment permit.[46]

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[41] Rule 61N-1.023, F.A.C.
[42] *See supra* note 43.
[43] 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. *See* U.S. Health Resources & Services Administration, *Federally Qualified Health Centers, available at* https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html (last visited Jan. 24, 2018).
[44] 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. *See* U.S. Health Resources & Services Administration, *Federally Qualified Health Centers Look Alike, available at* https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc-look-alikes/index.html (last visited Jan. 24, 2018).
[45] See *supra*, note 43.
[46] *See* s. 499.01(2)(r), F.S.

Sections 1 and 3 amend ss. 465.003, and 465.019, F.S., respectively, to modify the definition for the "practice of the profession of pharmacy" to include the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

The bill includes definitions for a "central distribution facility" and "common control" for ch. 465, F.S. It defines "central distribution facility" as a facility under common control with a hospital, holding a Class III institutional pharmacy permit, which may dispense, distribute, compound, or fill prescriptions for medicinal drugs, prepare prepackaged drug products, and conduct other pharmaceutical services. It 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.

Section 465.019, F.S., provides that the dispensing or distribution of a medicinal drug by a Class III institutional pharmacy is not considered wholesale distribution as defined in the Florida Drug and Cosmetic Act. It also requires a Class III institutional pharmacy to maintain policies and procedures that identify or address:

- 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; and
- Medicinal drugs and prepackaged drug products that may not be safely distributed among Class III institutional pharmacies.

The bill allows up to a 24 hour supply of medicinal drugs to be prescribed to outpatients in a hospital emergency department that does not have a Community Pharmacy Permit, if the hospital holds a Class III institutional pharmacy permit, similar to the authority granted to a Class II institutional pharmacy. The bill also treats Class III permits similar to Class II permits with respect to institutional formulary systems and substitutions of interchangeable biosimilar products.

Section 5 amends s. 499.003, F.S., to change the definition of "prepackaged drug product." The term means a drug that originally was in finished packaged form, sealed by a manufacturer, and was placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to ch. 465, F.S. The revised definition removes the phrase that this is done for the purpose of dispensing in the establishment in which the prepackaged occurred.

Section 6 amends s. 499.01, F.S., to exempt entities holding a Class III institutional pharmacy permit or a health care clinic establishment permit from the requirement for Prescription Drug Repackager permits or Restricted Prescription Drug Distributor permits for the distribution of medicinal drugs or prepackaged drug products between the establishments if they are under common control.

The bill also provides that a Restricted Prescription Drug Distributor permit is not required for a hospital covered by s. 340B of the Public Health Service Act, if the hospital arranges for a prescription drug distributor to distribute prescription drugs covered under that act directly to a contract pharmacy.

The bill removes the exemption for a health care entity with a Prescription Drug Repackager permit from obtaining a Restricted Prescription Drug Distributor permit. It is no longer necessary due to the elimination of the requirement for a Prescription Drug Repackager permit for health care entities and hospitals with Class III institutional pharmacy permits under common control.

Section 2 amends s. 465.004, F.S., to expand the qualifications of two persons eligible to serve on the Board to include a person engaged in the practice of professional pharmacy in a Class II institutional pharmacy, a Modified Class II institutional pharmacy, or a Class III institutional pharmacy.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The DBPR may see a reduction in licensure revenues as health care institutions who obtain a Class III Institutional Pharmacy permit will no longer requiring permits from the DBPR in the following permit categories:

- Restricted Prescription Drug Distributor- Health Care Establishment (HCE),
- Restricted Prescription Drug Distributor- Governmental Programs, and
- Prescription Drug Repackager.[47]

[47] Department of Business and Professional Regulation, *House Bill 675 Analysis (similar to SB 1128),* (January 5, 2018), (on file with the Senate Committee on Health Policy).

B. Private Sector Impact:

The private sector could realize a reduction in expenditures on permitting fees based on the ability to obtain one Class III institutional pharmacy permit exempting them from other permitting requirements under ch. 499, F.S.

C. Government Sector Impact:

The creation of Class III institutional pharmacy permit may result in additional expenditures for the DOH and the Board with respect to licensure and enforcement.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The provision within s. 499.01(5), F.S., that is being replaced with the Class III institutional pharmacy permit authorized repacking and distribution activities of prescription drugs for "own use" which is a term of art for antitrust considerations. This term is not used for the authorized activities under the Class III institutional pharmacy permit.[48]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.003, 465.004, 465.019, 465.0252, 499.003, and 499.01.

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.

[48] *See Abbott Laboratories v. Portland Retail Druggists*, 425 U.S. 1 (1976).