

**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 Health Policy

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BILL: SB 1170

INTRODUCER: Senator Brandes

SUBJECT: Automated Pharmacy Systems

DATE: March 22, 2019

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	<b>Pre-meeting</b>
2.	_____	_____	IT	_____
3.	_____	_____	RC	_____

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**I. Summary:**

SB 1170 amends s. 465.0235, F.S., to permit a licensed community pharmacy to provide outpatient pharmacy services for the dispensing of medicinal drugs through the use of an automated pharmacy system (APS) not located at the community pharmacy, if specific requirements are met.

The bill takes effect July 1, 2019.

**II. Present Situation:**

**The Practice of Pharmacy**

Pharmacy is the third largest health profession behind nursing and medicine.<sup>1</sup> The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists and pharmacies pursuant to ch. 465, F.S.<sup>2</sup> There are seven types of pharmacies eligible for various operating permits issued by the DOH:

- Community pharmacy;
- Institutional pharmacy;<sup>3</sup>
- Nuclear pharmacy;<sup>4</sup>

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<sup>1</sup> American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Mar. 18, 2019).

<sup>2</sup> Sections 465.004 and 465.005, F.S.

<sup>3</sup> See ss. 465.003(11)(a)2. and 465.019, F.S.

<sup>4</sup> 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 ch. 395, F.S., or the nuclear medicine facilities of such hospitals. See ss. 465.003(11)(a)3. and 465.0193, F.S.

- Special pharmacy;<sup>5</sup>
- Internet pharmacy;<sup>6</sup>
- Non-resident sterile compounding pharmacy;<sup>7</sup> and
- Special sterile compounding pharmacy.<sup>8</sup>

### Community Pharmacy

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.<sup>9</sup> A community pharmacy permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.<sup>10</sup> Any person desiring a permit to operate a community pharmacy must apply to the DOH. If the BOP certifies that an application complies with the laws and the rules governing pharmacies, the DOH must issue the permit.

No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager.<sup>11</sup> A registered pharmacist may not serve as the prescription department manager in more than on location unless approved by the BOP.<sup>12</sup> Permits issued by the DOH are not transferable.<sup>13</sup> Passing an on-site inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The DOH must make the inspection within 90 days before issuance of the permit.<sup>14</sup>

The BOP may suspend or revoke the permit of, or may refuse to issue a permit to:

- Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;
  - Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit;
- or

<sup>5</sup> 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* ss. 465.003(11)(a)4., and 465.0196, F.S.

<sup>6</sup> 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.

<sup>7</sup> 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, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit *See* s. 465.0158, F.S.

<sup>8</sup> *See* Fla. Admin. Code Rule 64B16-2.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.

<sup>9</sup> *See* ss. 465.003(11)(a)1. and 465.018, F.S.

<sup>10</sup> Fla. Admin. Code Rule 64B16-28.100(2) (2019).

<sup>11</sup> Section 465.018(2), F.S.

<sup>12</sup> Section 465.022(11)(c), F.S.

<sup>13</sup> Section 465.022(13), F.S.

<sup>14</sup> Section 465.018(6), F.S.

- Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.<sup>15</sup>

A community pharmacy that dispenses controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07, F.S., and must make the record available to the DOH or law enforcement agencies upon request.<sup>16</sup>

### **Pharmacist Licensure**

A person desiring to be licensed in Florida as a pharmacist must:<sup>17</sup>

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>18</sup>
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.

A pharmacist must complete at least 30 hours of board-approved continuing education during each biennial renewal period.<sup>19</sup> Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.<sup>20</sup> Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.<sup>21</sup>

### **Pharmacist Scope of Practice**

In Florida, the “practice of the profession of pharmacy” includes:<sup>22</sup>

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient’s drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient’s drug therapy and communication with the

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<sup>15</sup> Section 465.018(3), F.S.

<sup>16</sup> Section 465.018(7), F.S.

<sup>17</sup> Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

<sup>18</sup> If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist. Section 465.007(1)(b)2., F.S.

<sup>19</sup> Section 465.009, F.S.

<sup>20</sup> Section 465.009(6), F.S.

<sup>21</sup> Section 465.1893, F.S.

<sup>22</sup> Section 465.003(13), F.S.

patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;

- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;<sup>23</sup>
- Administering epinephrine injections;<sup>24</sup>
- Administering antipsychotic medications by injection at the direction of a physician;<sup>25</sup> and,
- Other pharmaceutical services.<sup>26,27</sup>

A pharmacist may not alter a prescriber's directions, diagnose or treating any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.<sup>28</sup>

### **Automated Pharmacy Systems (APS)**

An APS is a mechanical system that delivers prescription drugs received from a Florida-licensed pharmacy and maintains related transaction information.<sup>29</sup> A mechanical pharmacy system performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.<sup>30</sup>

A community pharmacy may use an automated pharmacy system provided that:

- The APS is:
  - Located within the prescription department, adjacent to the prescription department, or is located on the establishment<sup>31</sup> of the licensed pharmacy, and its operation under the supervision of a pharmacist;
  - Not located within the prescription department, but must be operated as an extension of the licensed pharmacy, and does not require an independent, separate community pharmacy permit;
  - Not located within the prescription department, but must have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit

<sup>23</sup> See s. 465.189, F.S.

<sup>24</sup> *Id.*

<sup>25</sup> Section 465.1893, F.S.

<sup>26</sup> Section 465.003(13), F.S.

<sup>27</sup> "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 chs. 458, 459, 461, or 466, F.S., 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, 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.

<sup>28</sup> *Supra* note 22.

<sup>29</sup> Section 465.003(17), F.S.

<sup>30</sup> Fla. Admin. Code Rule 64B16-28.141(1)(a) (2019).

<sup>31</sup> An "Establishment" is one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. Fla. Admin. Code Rule 64B16-28.141(1)(b) (2019).

- number of the community pharmacy that is responsible for the operation of the automated pharmacy system.
- The pharmacy develops and maintains a policy and procedure manual;
  - The APS ensures that each prescription is dispensed in compliance with the definition of dispense as defined by s. 465.003, F.S., and the practice of the profession of pharmacy. The system must include:
    - A mechanism to ensure that the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product, and the means of communication may include in-person, electronic, digital, or telephonic.
  - The APS must maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.
  - The APS must provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system must have a process in place to isolate affected lot numbers, including an intermix of drug product lot numbers.<sup>32</sup>

Any pharmacy may also provide pharmacy services through the use of an APS that need not be located at the same location as the pharmacy at the following locations:

- A long-term care facility;<sup>33</sup>
- A hospice licensed care facility;<sup>34</sup> or,
- A state correctional institution.<sup>35, 36</sup>

Medicinal drugs stored in bulk, or unit of use, in an APS servicing a long-term care facility, hospice, or correctional institution are part of the inventory of the pharmacy providing pharmacy services, and drugs delivered by the APS are considered to have been dispensed by that pharmacy.<sup>37</sup>

The operation of an APS must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an APS, the pharmacist need not be physically present at the site of the APS and may supervise the system electronically. The Florida-licensed pharmacist is required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.<sup>38</sup>

The BOP must adopt rules governing the use of an APS, which must specify:

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<sup>32</sup> Fla. Admin. Code Rule 64B16-28,141(2), (2019).

<sup>33</sup> A “Long-term care facility” means a nursing home facility, assisted living facility, adult family-care home, board and care facility, or any other similar residential adult care facility. Section 400.0060(6), F.S.

<sup>34</sup> Section 400.601(6), F.S., defines a “hospice residential unit” as a homelike living facility, and includes a facility licensed under chs. 395 or 429. F.S., that is operated by a hospice for the benefit of its patients and is considered by a patient who lives there to be his or her primary residence.

<sup>35</sup> A “State correctional institution” means any prison, road camp, prison industry, prison forestry camp, or any prison camp or prison farm or other correctional facility, temporary or permanent, in which prisoners are housed, worked, or maintained, under the custody and jurisdiction of the Department of Corrections. See 944.02 (8), F.S.

<sup>36</sup> Section 465.0235(1), F.S.

<sup>37</sup> Section 465.0235(2), F.S.

<sup>38</sup> Section 465.0235(3), F.S.

- Recordkeeping requirements;
- Security requirements; and
- Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication, and the automated pharmacy system identifies:
  - The dispensing pharmacy;
  - The prescription number;
  - The name of the patient; and
  - The name of the prescribing practitioner.<sup>39</sup>

### III. Effect of Proposed Changes:

SB 1170 amends s. 465.0235, F.S., to permit a licensed community pharmacy<sup>40</sup> to provide outpatient pharmacy services for dispensing of medicinal drugs through the use of an automated pharmacy system (APS) not located at the same location as the community pharmacy if the requirements of Florida Administrative Code Rule 64B-28.141, and all of the following are met:

- The APS is under the supervision and control of the community pharmacy;
- The community pharmacy providing services through the APS notifies the BOP of the location of the APS and any changes in such location;
- The APS is under the supervision and control of a licensed pharmacist<sup>41</sup> who is available and accessible for patient counseling before the dispensing of any medicinal drug;
- The APS does not contain or dispense any controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S., or 21 U.S.C. s. 812;
- The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling; and
- The APS ensures the confidentiality of personal health information.

The bill provides that medicinal drugs stored in bulk, or unit of use, in an APS for outpatient dispensing are part of the inventory of the community pharmacy operating the APS and considered to have been dispensed by that pharmacy.

The bill deletes obsolete language regarding the BOP adopting rules governing the use of APS's.

The bill takes effect July 1, 2019.

### IV. Constitutional Issues:

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

None.

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<sup>39</sup> Section 465.0235(5), F.S.

<sup>40</sup> See note 9.

<sup>41</sup> Section 465.003(10), F.S., defines pharmacist as a person licensed under ch. 465, F.S., to practice the profession of pharmacy.

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

None.

**C. Trust Funds Restrictions:**

None.

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

None.

**E. Other Constitutional Issues:**

None.

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

None.

**B. Private Sector Impact:**

There may be an indeterminate cost, or a savings, to the public of having medicinal drugs readily available for dispensing at various locations other than the community pharmacy location.

**C. Government Sector Impact:**

None.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 465.0235 of the Florida Statutes.

**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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