

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 493 Pharmacy  
**SPONSOR(S):** Roach  
**TIED BILLS:** IDEN./SIM. BILLS: SB 444

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		DesRochers	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

The Florida Pharmacy Act (Act) regulates the practice of pharmacy in Florida. The Board of Pharmacy (Board) adopts rules to implement the provisions of the Act and sets standards of practice within the state. Any person who operates a pharmacy in Florida must have a permit in one of the seven categories: community pharmacy, institutional pharmacy, nuclear pharmacy, special pharmacy, internet pharmacy, nonresident sterile compounding pharmacy, or special sterile compounding pharmacy. A pharmacist must be present and on duty for the prescription department of a pharmacy to be considered open; however the prescription department is not considered closed if the pharmacist briefly leaves to tend to personal needs or counsel patients.

HB 493 creates a new pharmacy permit category for the operation of a remote site pharmacy. A remote site pharmacy is a location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site prescription department manager. In addition to meeting all the requirements in rule and statute for permitting pharmacies, a remote pharmacy must be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy; maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days; display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance; maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request; and designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote-site pharmacy may not dispense Schedule II controlled substances listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote-site pharmacy as often as the Board's schedule states. During remote site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

The bill authorizes a pharmacist to serve as the prescription department manager for up to three remote site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

The bill authorizes a registered pharmacy technician working in a remote site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

The bill has a significant, negative fiscal impact on DOH and no impact on local governments. See Fiscal Analysis.

The bill provides an effective date of July 1, 2024.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

#### Pharmacy Regulation

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.<sup>1</sup> The Board of Pharmacy (Board) is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.<sup>2</sup> Any person who operates a pharmacy in Florida must have a permit, and as of June 30, 2023, there were 10,901 permitted pharmacies in the state.<sup>3</sup> The following permits are issued by the Department of Health (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.<sup>4</sup>
- 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.<sup>5</sup>
- 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.<sup>6</sup>
- 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.<sup>7</sup>
- 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.<sup>8</sup>
- 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.<sup>9</sup>
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.<sup>10</sup>

A pharmacy must pass an on-site inspection for a permit to be issued,<sup>11</sup> and the permit is valid only for the name and address to which it is issued.<sup>12</sup>

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<sup>1</sup> Chapter 465, F.S.

<sup>2</sup> Sections 465.005, 465.0155, and 465.022, F.S.

<sup>3</sup> Department of Health, *2024 Agency Legislative Bill Analysis for House Bill 493*, (Nov. 20, 2023), on file with the Healthcare Regulation Subcommittee.

<sup>4</sup> Sections 465.003(20)(a)1. and 465.018, F.S.

<sup>5</sup> Sections 465.003(20)(a)2. and 465.019, F.S.

<sup>6</sup> Sections 465.003(20)(a)3. and 465.0193, F.S.

<sup>7</sup> Sections 465.003(20)(a)4. and 465.0196, F.S.

<sup>8</sup> Sections 465.003(20)(a)5. and 465.0197, F.S.

<sup>9</sup> Section 465.0158, F.S.

<sup>10</sup> Rules 64B16-28.100 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.

<sup>11</sup> *Id.*

<sup>12</sup> Rule 64B16-28.100, F.A.C.

## Regulation of Pharmacists and Pharmacy Technicians

### Pharmacists

#### *Licensure Requirements*

A pharmacist is a person who is licensed under the act to practice the profession of pharmacy.<sup>13</sup> To be licensed as a pharmacist in Florida, a person must:<sup>14</sup>

- Be at least 18 years of age;
- Complete an application and remit an examination fee;
- Hold a degree from an accredited and approved school or college of pharmacy;<sup>15</sup>
- Have completed a Board-approved internship; and
- Successfully complete the Board-approved examination.

During each biennial licensure renewal cycle, a pharmacist must complete at least 30 hours of Board-approved continuing education.<sup>16</sup> If a pharmacist is certified to administer vaccines or epinephrine, the pharmacist must complete a 3-hour continuing education course on the safe and effective administration of vaccines and epinephrine autoinjections as a part of the biennial licensure renewal.<sup>17</sup>

#### *Scope of Practice*

The practice of the profession of pharmacy includes:<sup>18</sup>

- Compounding,<sup>19</sup> 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 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>20</sup>
- Administering epinephrine injections;<sup>21</sup> and
- Administering antipsychotic medications by injection.<sup>22</sup>

Pharmacists are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.<sup>23</sup>

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<sup>13</sup> Section 465.003(19), F.S.

<sup>14</sup> Section 465.007, F.S. 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>15</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.

<sup>16</sup> Section 465.009, F.S.

<sup>17</sup> Section 465.009(6), F.S.

<sup>18</sup> Section 465.003(22), F.S.

<sup>19</sup> Rule 64B16-27.700, F.A.C., defines compounding a professional act by a pharmacist incorporating ingredients to create a finished product for dispensing to a patient or to a practitioner for administration to a patient. The American Pharmacists Association, citing the U.S. Pharmacopeia Convention (USP) defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice." See <https://www.pharmacist.com/Practice/Patient-Care-Services/Compounding/Compounding-FAQs> (last visited Jan. 21, 2024).

<sup>20</sup> See s. 465.189, F.S.

<sup>21</sup> *Id.*

<sup>22</sup> Section 465.1893, F.S.

<sup>23</sup> *Supra* note 18.

Only a pharmacist or registered intern may:<sup>24</sup>

- Supervise or be responsible for the controlled substance inventory;
- Receive verbal prescriptions from a prescriber;
- Interpret and identify prescription contents;
- Engage in consultation with a health care practitioner regarding the interpretation of a prescription and date in a patient's profile record;
- Engage in professional communication with health care practitioners;
- Advise or consult with a patient, both as to the prescription and the patient profile record; and
- Perform certain duties related to the preparation of parenteral and bulk solutions.

Pharmacists must perform the final check of a completed prescription, thereby assuming complete responsibility for its preparation and accuracy.<sup>25</sup> A pharmacist must be personally available at the time of dispensing.<sup>26</sup> A prescription department is considered closed if a Florida-licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:<sup>27</sup>

- Consult, respond to inquiries, or provide assistance to customers or patients;
- Attend to personal hygiene needs; or
- Perform functions for which the pharmacist is responsible provided that such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

### *Prescription Department Managers*

Each community pharmacy must have designate a licensed pharmacist as a prescription department manager.<sup>28</sup> The prescription drug manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring that the all regulations of the practice of the profession of pharmacy are followed.<sup>29</sup> A pharmacist may only serve as the prescription department manager of one pharmacy.<sup>30</sup> However, the Board may grant an exception based on circumstances, such as the proximity of the pharmacies and the workload of the pharmacist.

### Pharmacy Technicians

#### *Registration Requirements*

Pharmacy technicians assist pharmacists in dispensing medications and are accountable to a supervising pharmacist who is legally responsible for the care and safety of the patients served.<sup>31</sup> A person must register with DOH to practice as a pharmacy technician. To register, an individual must:<sup>32</sup>

- Be at least 17 years of age;
- Submit an application and remit an application fee; and
- Complete a Board-approved pharmacy technician training program.<sup>33</sup>

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<sup>24</sup> Rule 64B16-27.1001(1)-(2), F.A.C. Section 465.003(12), F.S., defines a pharmacy intern as a person who is currently registered in, and attending, or is a graduate of a duly accredited college or school of pharmacy and is properly registered with DOH. The American Pharmacist Association, citing the U.S.

<sup>25</sup> Rule 64B16-27.1001(3), F.A.C.

<sup>26</sup> Rule 64B16-27.1001(4), F.A.C.

<sup>27</sup> Section 465.003(20)(b), F.S.

<sup>28</sup> Rules 64B16-27.104 and 64B16-27.450, F.A.C.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> Pharmacy Technician Certification Board, *Pharmacy Technicians*, available at [https://www.ptcb.org/who-we-serve/pharmacy-technicians#\\_Wj1PsGyouUk](https://www.ptcb.org/who-we-serve/pharmacy-technicians#_Wj1PsGyouUk) (last visited on Jan. 21, 2024).

<sup>32</sup> Section 465.014(2), F.S.

<sup>33</sup> An individual is exempt from the training program if he or she was registered as a pharmacy technician before January 1, 2011, and either worked as a pharmacy technician at least 1,500 hours under a licensed pharmacist or received certification from an accredited pharmacy technician program.

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours, 4 of which must be live.<sup>34</sup>

### *Pharmacy Technician Training Programs*

A pharmacy technician may only be registered with DOH if he or she completes a Board-approved training program. These include pre-approved training programs that were accredited on or before December 1, 2018, by certain accreditation entities, such as the Accreditation Council on Pharmacy Education, as well as pharmacy technician training programs provided by a branch of the United States Armed Forces whose curriculum was developed on or before June 1, 2018.<sup>35</sup>

The Board may review and approve other training programs that do not meet the criteria for pre-approval. Such programs must be licensed by the Commission for Independent Education or equivalent licensing authority or be within the public school system of this state, and offer a course of study that includes:<sup>36</sup>

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the Health Insurance Portability and Accountability Act (HIPAA);
- Relevant federal and state law;
- Pharmaceutical topics, including medical terminology, abbreviations, and symbols; medication safety and error prevention; and prescriptions and medication orders;
- Records management and inventory control, including pharmaceutical supplies, medication labeling, medication packaging and storage, controlled substances, and adjudication and billing;
- Interpersonal relations and ethics, including diversity of communications, empathetic communications, ethics governing pharmacy practice, patient and caregiver communications; and
- Pharmaceutical calculations.

The training program must provide the Board with educational and professional background of its faculty.<sup>37</sup> A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.<sup>38</sup>

The Board may also review and approve employer-based pharmacy technician training programs. An employer-based program must be offered by a Florida-permitted pharmacy, or affiliated group of pharmacies under common ownership.<sup>39</sup> The program must consist of 160 hours of training over a period of no more than 6 months and may only be provided to the employees of that pharmacy.<sup>40</sup> The employer-based training program must:<sup>41</sup>

- Meet the same qualifications as required for non-employment based pharmacy technician training programs as indicated above;
- Provide an opportunity for students to evaluate learning experiences, instructional methods, facilitates, and resources;
- Ensure that self-directed learning experience, such as home study or web-based courses, evaluate the participant's knowledge at the completion of the learning experience; and
- Designate a person to assume responsibility for the registered pharmacy technician training program.

### *Scope of Practice*

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<sup>34</sup> Section 465.014(6), F.S.

<sup>35</sup> Rule 64B16-26.351(1)-(2), F.A.C.

<sup>36</sup> Rule 64B16-26.351(3)(b), F.A.C.

<sup>37</sup> Rule 64B16-26.351(3)(e), F.A.C.

<sup>38</sup> *Id.*

<sup>39</sup> Rule 64B16-26.351(4), F.A.C.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

A registered pharmacy technician may not engage in the practice of the profession of pharmacy; however, a licensed pharmacist may delegate those duties, tasks, and functions that do not fall within the definition of the practice of professional pharmacy.<sup>42</sup> Registered pharmacy technicians' responsibilities include:<sup>43</sup>

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, and pouring of prescription medication;
- Initiation of communication with a prescribing practitioner regarding requests for prescription refill authorization, obtaining clarification on missing or illegible information on prescriptions, and confirmation of information such as names, medication, strength, directions, and refills;
- Acceptance of authorization for prescription renewals; and
- Any other mechanical, technical, or administrative tasks which do not themselves constitute the practice of the profession of pharmacy.

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician,<sup>44</sup> and is responsible for acts performed by persons under his or her supervision.<sup>45</sup> A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.<sup>46</sup> If technological means are used by a pharmacist to supervise the pharmacy technician(s), the technological means must be sufficient for the pharmacist to provide the personal assistance, direction, and approval required to meet the standard of practice for the delegated tasks.<sup>47</sup>

The Board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from:<sup>48</sup>

- Receiving new verbal prescriptions or any change in the medication, strength, or directions of an existing prescription;
- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Monitoring prescription drug usage;
- Transferring a prescription;
- Overriding clinical alerts without first notifying the pharmacist;
- Preparing a copy of a prescription or reading a prescription to any person for the purpose of providing reference concerning treatment of the patient for whom the prescription was written;
- Engaging in patient counseling; or
- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.

A registered pharmacy technician must wear an identification badge with a designation as a "registered pharmacy technician" and identify herself or himself as a registered pharmacy technician in telephone or other forms of communication.<sup>49</sup>

### Pharmacist-to-Technician Ratios

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<sup>42</sup> Section 465.014(1), F.S.

<sup>43</sup> Rule 64B16-27.420(1), F.A.C.

<sup>44</sup> Direct supervision means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction, and approval throughout the time the delegated tasks are being performed (r. 64B16-27.4001(2)(a), F.A.C.)

<sup>45</sup> Rule 64B16-27.1001(7), F.A.C.

<sup>46</sup> Rule 64B16-27.4001(2)(b), F.A.C.

<sup>47</sup> *Id.*

<sup>48</sup> Rule 64B16-27.420(2), F.A.C.

<sup>49</sup> Rule 64B16-27.100(2), F.A.C.

When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient populations.<sup>50</sup>

Current law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by Board rules.<sup>51</sup> The guidelines include the following restrictions:<sup>52</sup>

- A pharmacist engaging in sterile compounding may supervise up to 3 registered pharmacy technicians.
- A pharmacist who is not engaged in sterile compounding may supervise up to 4 registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to 6 registered pharmacy technicians, as long as the pharmacist or pharmacy is not involved in sterile compounding.
- In a pharmacy that dispenses medicinal drugs in a physically separate area<sup>53</sup> of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to 6 registered pharmacy technicians.

In all other situations, the Board rules provide the prescription department manager or the consultant pharmacist of record with the discretion to use their independent professional judgment to determine and set the appropriate pharmacist-technician supervision ratios.<sup>54</sup>

## Telehealth

Telehealth means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide the following, nonexhaustive types of health care services:<sup>55</sup>

- assessment, diagnosis, consultation, treatment, and monitoring of a patient;
- transfer of medical data;
- patient and professional health-related education;
- public health services; and
- health administration.

Telehealth providers mean any Florida-licensed or Florida-certified individual who provides health care and related services using telehealth, including pharmacists. Current law also recognizes telehealth providers who are licensed under a multistate health care licensure compact of which Florida is a member state. Current law lets health care professionals not licensed in Florida to use telehealth as long as they register with the applicable Board (e.g., The Board of Pharmacy) and provides health care services within the applicable scope of practice (e.g., the practice of pharmacy) established by Florida law or rule (e.g., the Florida Pharmacy Act).<sup>56</sup>

Current law specifies that the delivery of health care services occurs at the place of the patient's location (or the patient's county of residence).<sup>57</sup> A telehealth provider must document the health care services provided to a patient via telehealth in the patient's medical record.<sup>58</sup>

Current law holds telehealth providers to the duty to practice in a manner consistent with their scope of practice and the prevailing professional standard of practice for a health care professional who provides in-person health care services to patients in this state. A nonphysician telehealth provider (e.g., a

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<sup>50</sup> Rule 64B16-27.410(1), F.A.C.

<sup>51</sup> Section 465.014(1), F.S.

<sup>52</sup> Rule 64B16-27.410, F.A.C.

<sup>53</sup> A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

<sup>54</sup> Rule 64B16-27.410(7), F.A.C.

<sup>55</sup> s. 456.47(1)(a), F.S.

<sup>56</sup> *Id.*, ss. 456.47(4), (6), F.S. Registration is not required in the event an out-of-state licensed health care professional provides telehealth services in response to an emergency medical condition or in consultation with a Florida-licensed health care professional who has ultimate authority over the diagnosis and care of the patient.

<sup>57</sup> s. 456.47(5), F.S.

<sup>58</sup> s. 456.47(3), F.S.

pharmacist) using telehealth and acting within his or her relevant scope of practice is not in violation of the practice of medicine or an attempt to practice medicine without a license to practice in Florida.<sup>59</sup>

## Telepharmacy

Telepharmacy is the provision of pharmaceutical care by pharmacies and pharmacists through the use of telepharmacy technologies to patients or their agents at a distance.<sup>60</sup> Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.<sup>61</sup>

## **Effect of Proposed Changes**

HB 493 creates a remote-site pharmacy permit. A remote-site pharmacy includes every location where medicinal drugs are dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of prescription department manager.

## **Remote Site Pharmacy**

The bill requires a DOH-issued permit to operate a remote-site pharmacy. A remote-site pharmacy must:

- Be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy;<sup>62</sup>
- Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 30 days;
- Display a sign, visible by the public, which indicates that the facility is a remote site pharmacy and that it is under 24-hour video surveillance;
- Maintain a policies and procedures manual which must be made available to the Board of Pharmacy or its agent upon request. The policies and procedures manual must include at the very least all of the following:
  - A description of how the pharmacy will comply with federal and state laws and rules.
  - The procedures for supervising the remote site pharmacy and counseling its patients.
  - The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site pharmacy.
  - The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.
  - The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote-site pharmacy's operation.
  - The procedures for use of the state prescription drug monitoring program by the prescription department manager before they may authorize the dispensing of any controlled substance.
  - The procedures for maintaining a perpetual inventory of the controlled substances listed in Schedule II of s. 893.03, F.S.
  - The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site pharmacy.
- Designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

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<sup>59</sup> s. 456.47(2), F.S.

<sup>60</sup> National Association of Boards of Pharmacy, "Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy," <https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/> (last visited Jan. 21, 2024). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.

<sup>61</sup> E. Alexander et al, *ASHP Statement on Telepharmacy*, 74 AM J HEALTH-SYSTEM PHARM., e236 (May 2017), available at <https://academic.oup.com/ajhp/article-abstract/74/9/e236/5102780?redirectedFrom=fulltext> (last visited Jan. 21, 2024).

<sup>62</sup> The bill defines a supervising pharmacy as a Florida-licensed pharmacy that employs or contracts with a Florida-licensed pharmacist who remotely supervises a registered pharmacy technician at a remote site pharmacy at a ratio of one pharmacist to up to six registered pharmacy technicians.



DOH must issue a permit if the Board certifies that an application for a permit complies with the laws and rules governing pharmacies.

### Operation of a Remote Site Pharmacy

The bill authorizes a remote-site pharmacy to store, hold, and dispense all medicinal drugs, including proprietary drugs and controlled substances. However, a remote site pharmacy may not dispense Schedule II controlled substances<sup>63</sup> listed in s. 893.03 unless a pharmacist is present at the remote-site pharmacy.

The prescription department manager must visit the remote site pharmacy as often as the Board schedule states. During remote-site pharmacy visits, the prescription department manager must inspect the pharmacy, address personnel matters, and provide clinical services for patients.

Generally, a remote-site pharmacy may not be open when the supervising pharmacy is closed. However, the bill creates two exceptions. First, when a pharmacist employed by or under contract with a supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote site pharmacy may be open. Second, when a pharmacy under contract with the supervising pharmacy is present at the remote-site pharmacy or is providing remote supervision as required under the bill, the remote-site pharmacy may be open.

Generally, a registered pharmacist cannot serve as the prescription department manager in more than one location. However, the bill authorizes a pharmacist to serve as the prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacy. The maximum allowable pharmacist-pharmacy technician ratio is 1:6.

### Pharmacy Technicians

The bill authorizes a registered pharmacy technician working in a remote-site pharmacy under the remote supervision of a pharmacist to fill, compound, and dispense medicinal drugs.

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<sup>63</sup> Section 893.03(2), F.S., defines a Schedule II drug as a substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment, and the abuse of the substance may lead to severe psychological or physical dependence.

## Board of Pharmacy

The bill grants the Board of Pharmacy rulemaking authority to adopt rules as necessary to specify additional criteria for a remote-site pharmacy. Any additional criteria adopted by the board must be limited to rules concerning one or more of the following:

- Application requirements.
- Structural and equipment requirements.
- Training requirements.
- Inventory recordkeeping and storage requirements.

The bill provides an effective date of July 1, 2024.

### B. SECTION DIRECTORY:

**Section 1:** Amends s. 465.003, F.S., relating to definitions.

**Section 2:** Amends s. 465.014, F.S., relating to pharmacy technician.

**Section 3:** Amends s. 465.015, F.S., relating to violations and penalties.

**Section 4:** Creates s. 465.0198, F.S., relating to remote-site pharmacy permits.

**Section 5:** Amends s. 465.022, F.S., relating to pharmacies; general requirements; fees.

**Section 6:** Provides an effective date of July 1, 2024.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

None.

#### 2. Expenditures:

According to DOH, the Department will require 7 FTEs to implement the provisions of this bill.<sup>64</sup>

- 2 FTEs (Government Analyst II) to process new permit applications.
- 4 FTEs (1 Senior Attorney, 2 Government Analyst II, and 2 Investigation Specialist II) to handle complaints, investigations, and prosecution cases.
- 1 FTE (System Project Consultant) to establish and maintain additional transactions in the Enforcement Information Database System (LEIDS), the Online Service Portal (Versa Online) the License Verification Search Site, and the Board of Pharmacy website.

According to DOH, the total estimated annual cost is \$982,229 in the following categories:<sup>65</sup>

#### Annual Estimated Cost

- Salary: \$759,732/Recurring
- Salary Rate: 533,325 units of rate
- Expense: \$62,125/Recurring + \$46,613/Non-recurring
- Human Resources: \$2,519
- Contracted Services: \$111,240/Non-recurring

Because the bill does not authorize a fee for this new permit type, it is unclear how DOH will cover the costs of implementing its provisions.

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<sup>64</sup> *Supra*, FN 3 at p. 6-7.

<sup>65</sup> *Id.* at 7-8.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

None.

**D. FISCAL COMMENTS:**

None.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

The Board has sufficient rulemaking authority to implement the provisions of the bill.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES**