

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 Appropriations

BILL: CS/SB 848

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Telepharmacy

DATE: February 26, 2018

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Loe</u>	<u>Hansen</u>	<u>AP</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 848 creates a new pharmacy permit specific to remote dispensing site pharmacies (RDSP). The bill defines “remote dispensing site pharmacy” and provides exceptions to current law for the operation of an RDSP. In an RDSP, a registered pharmacy technician may dispense medicinal drugs under the supervision of an offsite pharmacist. The bill establishes requirements for RDSP permits including:

- Ownership and video surveillance for remote supervision by a Florida licensed pharmacist;
- A restriction that a remote dispensing site pharmacy must be located in a rural area and may not be located within 10 miles of a community pharmacy, with exceptions; and
- Policies and procedures that an RDSP must maintain.

The bill allows an RDSP to store, hold, and dispense all medicinal drugs,¹ including controlled substances listed in s. 893.03(3)-(5), F.S., but restricts an RDSP from storing, holding, and dispensing schedule II narcotic controlled substances. The bill restricts an RDSP from performing centralized prescription filling² and a registered pharmacy technician working in an RDSP from performing sterile or complex nonsterile compounding.

¹ “Medicinal drugs” are defined in s. 465.003(8), F.S., as those substances or preparations commonly known as “prescription” or “legend” drugs, which are required by federal or state law to be dispensed only on a prescription.

² “Centralized prescription filling” is defined in s. 465.003(16), F.S., as the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

The bill will increase costs in the DOH by an indeterminate amount; however, these costs will be absorbed within existing resources of the DOH.

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

II. Present Situation:

Pharmacy Regulation

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.³ 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.⁴ Any person who operates a pharmacy in Florida must have a permit, and as of July 1, 2017, there were 9,835 permitted pharmacies in the state.⁵ The Department of Health (DOH) issues the following permits:

- 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.⁶
- 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.⁷
- 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.⁸
- 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.⁹
- 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.¹⁰
- 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.¹¹

³ Chapter 465, F.S.

⁴ Sections 465.005, 465.0155, and 465.022, F.S.

⁵ Department of Health, *Senate Bill 848 Analysis* (Nov. 13, 2017) (on file with the Senate Committee on Health Policy).

⁶ Sections 465.003(11)(a)1. and 465.018, F.S.

⁷ Sections 465.003(11)(a)2. and 465.019, F.S.

⁸ Sections 465.003(11)(a)3. and 465.0193, F.S.

⁹ Sections 465.003(11)(a)4. and 465.0196, F.S.

¹⁰ Sections 465.003(11)(a)5. and 465.0197, F.S.

¹¹ Section 465.0158, F.S.

- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.¹²

A pharmacy must pass an on-site inspection for a permit to be issued,¹³ and the permit is valid only for the name and address to which it is issued.¹⁴

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.¹⁵ To be licensed as a pharmacist in Florida, a person must:¹⁶

- 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;¹⁷
- 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 courses.¹⁸ If a pharmacist is certified to administer vaccines or epinephrine, the pharmacist must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine autoinjections as a part of the biennial licensure renewal.¹⁹

Scope of Practice

The practice of the profession of pharmacy includes:²⁰

- Compounding,²¹ dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;

¹² 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.

¹³ Id.

¹⁴ Rule 64B16-28.100, F.A.C.

¹⁵ Section 465.003(10), F.S.

¹⁶ 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.

¹⁷ If the applicant has graduated from a four-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.

¹⁸ Section 465.009, F.S.

¹⁹ Section 465.009(6), F.S.

²⁰ Section 465.003(13), F.S.

²¹ Rule 64B16-27.700, F.A.C., defines compounding as 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

- 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;²²
- Administering epinephrine injections;²³ and
- Administering antipsychotic medications by injection.²⁴

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.²⁵

Only a pharmacist or registered intern may:²⁶

- 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.²⁷ A pharmacist must be personally available at the time of dispensing.²⁸ 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:²⁹

- 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 if such activities are performed in a manner that is consistent with the pharmacist's responsibility to provide pharmacy services.

course of professional practice." See <http://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding> (last visited Feb. 1, 2018).

²² See s. 465.189, F.S.

²³ Id.

²⁴ Section 465.1893, F.S.

²⁵ Supra note 21.

²⁶ 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.

²⁷ Rule 64B16-27.1001(3), F.A.C.

²⁸ Rule 64B16-27.1001(4), F.A.C.

²⁹ Section 465.003(11)(b), F.S.

Prescription Department Managers

Each community pharmacy must designate a licensed pharmacist as a prescription department manager.³⁰ The prescription department manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring that all regulations of the practice of the profession of pharmacy are followed.³¹ A pharmacist may only serve as the prescription department manager of one pharmacy.³² 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.³³ A person must register with DOH to practice as a pharmacy technician. To register, an individual must:³⁴

- Be at least 17 years of age;
- Submit an application and pay an application fee; and
- Complete a board-approved pharmacy technician-training program.³⁵

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours.³⁶

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 April 1, 2017, 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 April 1, 2017.³⁷

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:³⁸

- Introduction to pharmacy and health care systems;

³⁰ Rules 64B16-27.104 and 64B16-27.450, F.A.C.

³¹ *Id.*

³² *Id.*

³³ Pharmacy Technician Certification Board, Pharmacy Technicians, available at <https://www.ptcb.org/who-we-serve/pharmacy-technicians#.WnjALPwUIPZ> (last visited on Feb. 1, 2018).

³⁴ Section 465.014(2), F.S.

³⁵ 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.

³⁶ Section 465.014(6), F.S.

³⁷ Rule 64B16-26.351(1)-(2), F.A.C.

³⁸ Rule 64B16-26.351(3)(b), F.A.C.

- Confidentiality;
- Patient rights and the Health Insurance Portability and Accountability Act (HIPAA);
- Relevant state and federal 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.³⁹ A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.⁴⁰

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.⁴¹ The program must include 160 hours of training over a period of no more than six months and may be provided only to the employees of that pharmacy.⁴² The employer-based training program must:⁴³

- 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

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.⁴⁴ Registered pharmacy technicians' responsibilities include:⁴⁵

- Retrieval of prescription files;
- Data entry;
- Label preparation;

³⁹ Rule 64B16-26.351(3)(e), F.A.C.

⁴⁰ Id.

⁴¹ Rule 64B16-26.351(4), F.A.C.

⁴² Id.

⁴³ Id.

⁴⁴ Section 465.014(1), F.S.

⁴⁵ Rule 64B16-27.420(1), F.A.C.

- 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 that do not themselves constitute the practice of the profession of pharmacy.

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician⁴⁶ and is responsible for acts performed by persons under his or her supervision.⁴⁷ A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.⁴⁸

The board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from performing, which include:⁴⁹

- 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.⁵⁰

⁴⁶ 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 (Rule 64B16-27.4001(2)(a), F.A.C.)

⁴⁷ Rule 64B16-27.1001(7), F.A.C.

⁴⁸ Rule 64B16-27.4001(2)(b), F.A.C.

⁴⁹ Rule 64B16-27.420(2), F.A.C.

⁵⁰ Rule 64B16-27.100(2), F.A.C.

Pharmacist-to-Technician Ratios

Florida law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by guidelines adopted by the board.⁵¹ The guidelines include the following restrictions:⁵²

- A pharmacist engaging in sterile compounding may supervise up to three registered pharmacy technicians.
- A pharmacist who is not engaged in sterile compounding may supervise up to four registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to six 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 area⁵³ of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to six registered pharmacy technicians.

Telehealth

There is no universally accepted definition of telehealth. In broad terms, telehealth is:

The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment,⁵⁴ and prevention of disease and injuries,⁵⁵ research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.⁵⁶

Definitions that are more specific vary by state and occasionally by profession; however,⁵⁷ there are common elements among the varied definitions of telehealth.

⁵¹ Section 465.014(1), F.S.

⁵² Rule 64B16-27.410, F.A.C.

⁵³ A “physically separate area” is a part of the pharmacy that is separated by a permanent wall or other barrier, which restricts access between the two areas.

⁵⁴ The University of Florida’s Diabetes Institute utilizes telehealth to deliver treatment to children with diabetes and other endocrine problems who live in Volusia County. This allows the children to receive specialized treatment without the necessity of traveling from Volusia County to Gainesville. The Florida Department of Health’s Children’s Medical Services underwrites the program. See <https://ufhealth.org/diabetes-center-excellence/telemedicine> (last visited on Feb. 1, 2018).

⁵⁵ The University of South Florida has partnered with American Well to provide health care services to the residents of the Villages via telehealth. The goal is to reduce hospital admissions, readmission rates, and pharmacy costs, while maintaining Medicare beneficiaries in their homes rather than long-term care settings. See <http://hscweb3.hsc.usf.edu/blog/2012/06/22/usf-health-and-american-well-to-bring-telehealth-to-seniors-living-at-the-villages/> (last visited on Feb. 1, 2018).

⁵⁶ World Health Organization, *Telemedicine: Opportunities and Developments in Member States*, Global Observatory for Ehealth Series- Volume 2, Section 1.2, page 9 (2010), available at http://apps.who.int/iris/bitstream/10665/44497/1/9789241564144_eng.pdf (last visited on Feb. 1, 2018).

⁵⁷ Center for Connected Health Policy, The National Telehealth Policy Resource Center, *State Telehealth Laws and Medicaid Program Policies* (August 2016), available at http://www.cchpca.org/sites/default/files/resources/50%20STATE%20COMPLETE%20REPORT%20PASSWORD%20AUG%202016_1.pdf (last visited on Feb. 1, 2018).

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.⁵⁸ Synchronous refers to the live⁵⁹ transmission of information between patient and provider during the same time period.⁶⁰ Asynchronous telehealth is the transfer of data over a period of time and typically in separate time frames.⁶¹ This is commonly referred to as “store and forward.” Definitions of telehealth also commonly contain restrictions related to the location where telehealth may be used. For example, the use of the “hub and spoke” model is a common location restriction. A hub site is the location from which specialty or consultative services originate from the provider.⁶² A spoke site is a remote site where the patient is presented during the telehealth encounter.⁶³ Under this model, health services may be provided through telehealth only if the patient is located at a designated spoke site and the provider is located at a designated hub site.

Telehealth is not a type of health care service but rather is a mechanism for the delivery of health care services. Health care professionals use telehealth as a platform to provide traditional health care services in a non-traditional manner. These services include, among others, preventative medicine and the treatment of chronic conditions.⁶⁴

Telepharmacy

Telepharmacy is the provision of pharmaceutical care by pharmacies and pharmacists using telepharmacy technologies to patients or their agents at a distance.⁶⁵ Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.⁶⁶

In 2001, North Dakota became the first state to regulate telepharmacy.⁶⁷ North Dakota created a pilot project using telepharmacy to save rural pharmacies from closing and to provide

⁵⁸ The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information, but some definitions omit asynchronous from the definition of telehealth.

⁵⁹ This is also referred to as “real time” or “interactive” telehealth.

⁶⁰ American Telemedicine Association, Telemedicine Glossary, *available at* <http://thesource.americantelemed.org/resources/telemedicine-glossary> (last visited on Feb. 1, 2018). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

⁶¹ *Id.* A common example of synchronous telehealth is the transfer of X-rays or MRI images from one health care provider to another health care provider for review in the future.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ U.S. Department of Health and Human Services, Report to Congress: E-Health and Telemedicine, (August 2016), *available at* <https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf> (last visited Feb. 1, 2018).

⁶⁵ National Association of Boards of Pharmacy, “Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy,” (Aug. 2017), *available at* <https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/> (last visited Feb. 1, 2018). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.

⁶⁶ E. Alexander et al, ASHP Statement on Telepharmacy, 74 Am J Health-System Pharm., e236 (May 2017), *available at* <http://www.ajhp.org/content/74/9/e236?sso-checked=true> (last visited Feb. 1, 2018).

⁶⁷ George Tzanetakos et al, RUPRI Center for Rural Health Policy Analysis, University of Iowa College of Public Health, Rural Policy Brief: Telepharmacy Rules and Statutes: A 50-State Survey, Brief No. 2017-4, (April 2017), *available at* <https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2017/Telepharmacy%20Rules%20and%20Statutes.pdf> (last visited Feb. 1, 2018).

telepharmacy services to underserved rural communities in that state.⁶⁸ The pilot project authorized community pharmacies to open and operate telepharmacy sites in rural communities without a pharmacist being physically present to supervise a registered pharmacy technician working at the remote site.⁶⁹ A pharmacist supervises the pharmacy technician and speaks with patients using real-time communications technology.⁷⁰ Almost 80,000 rural citizens had pharmacy services established, restored, or retained under the pilot project.⁷¹

At least 23 states have enacted laws or regulations that allow for the use of telepharmacy and/or remote dispensing sites since 2001.⁷² The regulation of telepharmacy and remote dispensing varies by state. Some states geographically limit the provision of telepharmacy services to ensure that remote dispensing sites are only established in rural areas or medically underserved areas⁷³ while others restrict it by facility type such as rural health centers.⁷⁴ Many states have included minimum staffing and education requirements, such as requiring a minimum level of experience for the pharmacy technicians or limiting the number of pharmacy technicians that a pharmacist may supervise.⁷⁵

III. Effect of Proposed Changes:

Section 1 amends s. 465.003, F.S., to define an RDSP to include every location where medicinal drugs are prepared by a registered pharmacy technician who is electronically supervised by an offsite pharmacist and dispensed pursuant to s. 465.014(1), F.S., to the patient after verification, certification, and counseling by the pharmacist. The bill exempts an RDSP from the requirement to close when a pharmacist is not present and on duty if the pharmacist is remotely supervising a registered pharmacy technician at an RDSP.

Section 2 amends s. 465.014(1), F.S., to allow a registered pharmacy technician to dispense medicinal drugs at an RDSP when operating under electronic supervision of an offsite Florida licensed pharmacist.

Section 3 amends s. 465.015, F.S., to exempt any person who owns, operates, maintain, opens, establishes, conducts, or has charge of an RDSP from the requirement that a licensed pharmacist

⁶⁸ Daniel L. Friesner et al, Do Remote Community Telepharmacies Have Higher Medication Error Rates than Traditional Community Pharmacies? Evidence from the North Dakota Telepharmacy Project, 51 J Am Pharm Assoc., 580 (Sept./Oct. 2011), available at https://www.ndsu.edu/fileadmin/telepharmacy/APhA_article_2011_-_Copy.pdf (last visited Feb. 1, 2018).

⁶⁹ Id at 582.

⁷⁰ Id.

⁷¹ National Association of Boards of Pharmacy, Telepharmacy: The New Frontier of Patient Care and Professional Practice, 46 Innovations 46 (June/July 2017), available at https://nabp.pharmacy/wp-content/uploads/2016/07/Innovations_June_July_Final.pdf (last visited Feb.1, 2018).

⁷² Supra note 678. These states include Alaska, Colorado, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Minnesota, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, Wisconsin, and Wyoming.

⁷³ Id. For example, Colorado requires that a telepharmacy outlet be more than 20 miles from the nearest prescription drug outlet or another telepharmacy outlet. (Colo. Rev. Stat. s. 12-12.5-102 (2017)).

⁷⁴ Id. For example, Wisconsin limits the operation of a remote dispensing site to a health care facility, office or clinic of a practitioner, county jail, rehabilitation facility, state prison, county house of correction, juvenile correctional facility, juvenile detention center, or residential care center for children and youth. (Wis. Admin. Code s. Phar. 7.095(3)).

⁷⁵ Id. For example, Illinois requires a pharmacy technician to have at least one year of experience and prohibits a pharmacist from supervising more than three sites that are simultaneously open. (Ill. Admin. Code tit. 68, s. 1330.510).

or registered intern must fill, compound, or dispense any prescription or medicinal drugs. The bill also exempts a registered pharmacy technician working in an RDSP from the restriction on dispensing medicinal medications without an active pharmacist's license or without being a registered pharmacy intern.

Section 4 creates s. 465.0198, F.S., to allow for the operation of RDSPs. The bill:

- Requires any person desiring to operate an RDSP to apply to the DOH for a permit. To receive a permit, the application must comply with the laws and board rules governing pharmacy and must designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the RDSP. The bill requires an RDSP to notify the DOH within 10 days if the prescription department manager changes.
- Requires an RDSP to pass an onsite inspection before receiving an initial permit or changing locations. The DOH is required to inspect the RDSP within 90 days before issuing the permit.
- Establishes requirements for an RDSP, including that:
 - An RDSP be jointly owned, or operated under contract with, a supervising pharmacy. A “supervising pharmacy” is defined as a licensed pharmacy in Florida that employs a Florida licensed pharmacist who remotely supervises the registered pharmacy technician at the RDSP.
 - An RDSP must be under 24-hour video surveillance, display a sign indicating that the RDSP is an RDSP and is under video surveillance, and must keep video surveillance recordings for at least 45 days.
 - An RDSP must be located in a rural area⁷⁶ and at least 10 miles from an existing community pharmacy unless the RDSP is located in a hospital or a clinic. For the purposes of this requirement, a “clinic” is defined as an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, excluding a mobile clinic and a portable equipment provider. The bill specifies that an RDSP may not lose its permit if a community pharmacy opens within 10 miles of the RDSP subsequent to the opening of the RDSP.
 - The prescription department manager or other pharmacist employed by the supervising pharmacy visits the RDSP on a schedule determined by the board to inspect the pharmacy, address personnel matters, and provide clinic services for patients.
 - A registered pharmacy technician must have completed at least 2,080 hours of experience at a pharmacy within the two years immediately preceding the date on which the registered pharmacy technician begins employment at the RDSP.
- Allows an RDSP to store, hold, and dispense all medicinal drugs⁷⁷ including schedule III-V controlled substances listed in s. 893.03(3)-(5), F.S.
- Restricts an RDSP from storing, holding, or dispensing schedule II narcotic controlled substances and performing centralized prescription filling.⁷⁸
- Restricts a registered pharmacy technician from performing sterile or complex nonsterile compounding.

⁷⁶ As defined in s. 381.0406, F.S. A map of rural counties is available at <http://www.floridahealth.gov/programs-and-services/community-health/rural-health/documents/ruralcountiespdf.12.pdf>. (Last visited on Feb. 6, 2018).

⁷⁷ Supra note 1

⁷⁸ Supra note 2

- Requires an RDSP to maintain a policy and procedures manual that must be made available to the board upon request. The manual must include:
 - A description of how the RDSP will comply with state and federal laws, rules, and regulations.
 - The procedure for supervising the RDSP and counseling its patients before the dispensing of any medicinal drug.
 - The procedure for reviewing the prescription drug inventory and drug records maintained by the RDSP.
 - The policy and procedure for providing appropriate security to protect the confidentiality and integrity of patient information.
 - The written plan for recovery from an event that interrupts or prevents the pharmacist from supervising the RDSP's operation.
 - The procedure by which the supervising pharmacist consults the state prescription drug-monitoring program (PDMP) before authorizing any controlled substance for dispensing and reports the dispensing of controlled substances to the PDMP.
 - The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the RDSP.

Section 5 amends s. 460.022, F.S., to allow a Florida licensed pharmacist to serve as a prescription manager for up to two RDSPs that are under common control and to make a technical change.

Section 6 amends s. 465.0265, F.S., to conform its provisions to the restriction on RDSPs performing centralized prescription filling.

Section 7 establishes 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:

None.

B. Private Sector Impact:

CS/SB 848 may have an indeterminate fiscal impact on persons who open and run an RDSP pursuant to the provisions of the bill. It may also have an indeterminate fiscal impact on community pharmacies that are nearby but beyond the 10-mile zone.

C. Government Sector Impact:

The DOH will incur indeterminate costs to establish the RDSP permit and regulate permitted RDSPs; however, these costs will be absorbed within existing resources of the DOH.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Lines 158-162 of the bill specify that a RDSP may store, hold, and dispense medicinal drugs listed as a controlled substance in schedules III-V but may not store, hold, and dispense narcotic controlled substances listed in schedule II. The bill does not specify whether an RDSP may store, hold, and dispense nonnarcotic schedule II controlled substances. The bill should be clarified to specify whether an RDSP may or may not store, hold, and dispense nonnarcotic controlled substances listed in schedule II.

Lines 201-203 of the bill restrict a registered pharmacy technician working in an RDSP from performing sterile and complex nonsterile compounding. The use of the term “complex” nonsterile compounding implies that a pharmacy technician may perform noncomplex nonsterile compounding at an RDSP. However, it is unclear what the definitions of “complex” and “noncomplex” nonsterile compounding include. The bill should be amended to clarify what compounding, if any, a registered pharmacy technician is authorized to perform at an RDSP.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.003, 465.014, 465.015, 465.022, and 465.0265.

This bill creates section 465.0198 of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS by Health Policy on February 6, 2018:**

The CS changes the title of the bill to Telepharmacy and:

- Tightens the regulation of RDSPs by:
 - Requiring that RDSPs be supervised by Florida licensed pharmacists;

- Restricting a pharmacy technician at an RDSP from performing sterile or complex nonsterile compounding;
- Restricting a pharmacy technician at an RDSP from dispensing narcotic drugs listed as a schedule II controlled substance; and
- Requiring a registered pharmacy technician who works in a RDSP to have certain experience.
- Requires all RDSPs to be located in rural areas (as defined in s. 381.0406, F.S.) and be located at least 10 miles from an existing community pharmacy unless the RDSP is located in a hospital or a clinic.
- Requires each RDSP to be inspected by the DOH before being issued an initial permit or a permit for a change of location.
- Specifies that the section establishing RDSPs does not alter supervisory requirements for pharmacy technicians.
- Removes the provision that an RDSP may not be counted toward network adequacy in managed care programs.
- Makes a number of technical changes to clean up the bill's provisions.

B. Amendments:

None.