

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 679 Telepharmacy
SPONSOR(S): Health Quality Subcommittee; Ponder
TIED BILLS: **IDEN./SIM. BILLS:** SB 848

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Siples	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.

Telepharmacy is generally defined as the provision of pharmaceutical care through the use of communication technologies. A pharmacist may provide such services as dispensing of medications, medication therapy management, clinical consultation, and patient counseling through telepharmacy. A number of states have adopted laws or regulations authorizing the use of telepharmacy to provide services to individuals who may have limited access to pharmaceutical care.

CS/HB 679 authorizes the Department of Health (DOH) to issue a permit for the operation of a remote dispensing site pharmacy. A remote dispensing site pharmacy is a location where medicinal drugs are dispensed by a registered pharmacy technician who is electronically supervised by an off-site prescription department manager. The bill requires that a registered pharmacy technician employed at a remote dispensing site pharmacy have at least 2,080 hours of experience.

In addition to meeting all the requirements in rule and statute for permitting pharmacies, a remote dispensing pharmacy must, among other things:

- Be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy;
- Display a sign, visible by the public, which indicates that the facility is a remote dispensing site pharmacy and that it is under 24-hour video surveillance;
- Be located in a rural area and at least 10 miles from an existing community pharmacy; and
- Designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility.

DOH must perform an onsite inspection of the remote dispensing pharmacy prior to issuing a permit. A remote dispensing site pharmacy may not dispense or store Schedule II medicinal drugs, and the pharmacy technician may not perform sterile or nonsterile compounding of drugs.

The bill creates an exception to the requirement that a pharmacist be present and on duty for a prescription department of a pharmacy to be considered open. Under the bill, a prescription department may be considered open if an off-site prescription manager remotely supervises a pharmacy technician at a remote dispensing site pharmacy. A pharmacist may utilize telepharmacy to meet his or her obligation to be present and on duty and to supervise the pharmacy technician.

The prescription drug manager must visit the remote dispensing site pharmacy as required by the Board. A pharmacist may serve as a prescription department manager for one remote site dispensing pharmacy; however, a pharmacist may serve as a prescription department manager for up to two remote site dispensing pharmacies if they are under common control.

The bill will have an indeterminate, recurring negative fiscal impact on DOH and an insignificant, nonrecurring fiscal impact on DOH. The bill will have no impact on local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0679a.HQS

DATE: 1/18/2018

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.¹ 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.² Any person who operates a pharmacy in Florida must have a permit, and as of June 30, 2017, there were 9,835 permitted pharmacies in the state.³ 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.⁴
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.⁵
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.⁶
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.⁷
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.⁸
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.⁹
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.¹⁰

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

¹ Chapter 465, F.S.

² Sections 465.005, 465.0155, and 465.022, F.S.

³ Department of Health, *2018 Agency Legislative Bill Analysis for House Bill 679*, (Nov. 15, 2018), on file with the Health Quality Subcommittee.

⁴ Sections 465.003(11)(a)1. and 465.018, F.S.

⁵ Sections 465.003(11)(a)2. and 465.019, F.S.

⁶ Sections 465.003(11)(a)3. and 465.0193, F.S.

⁷ Sections 465.003(11)(a)4. and 465.0196, F.S.

⁸ Sections 465.003(11)(a)5. and 465.0197, F.S.

⁹ Section 465.0158, F.S.

¹⁰ Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.

¹¹ Id.

¹² 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.¹³ To be licensed as a pharmacist in Florida, a person must:¹⁴

- 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;¹⁵
- 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.¹⁶ 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.¹⁷

Scope of Practice

The practice of the profession of pharmacy includes:¹⁸

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

¹³ Section 465.003(10), F.S.

¹⁴ 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.

¹⁵ 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.

¹⁶ Section 465.009, F.S.

¹⁷ Section 465.009(6), F.S.

¹⁸ Section 465.003(13), F.S.

¹⁹ 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 <http://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding> (last visited January 9, 2018).

²⁰ See s. 465.189, F.S.

²¹ Id.

²² Section 465.1893, F.S.

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.²³

Only a pharmacist or registered intern may:²⁴

- 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.²⁵ A pharmacist must be personally available at the time of dispensing.²⁶ 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:²⁷

- 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.²⁸ 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.²⁹ A pharmacist may only serve as the prescription department manager of one pharmacy.³⁰ 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.³¹ A person must register with DOH to practice as a pharmacy technician. To register, an individual must:³²

²³ *Supra* note 18.

²⁴ 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.

²⁵ Rule 64B16-27.1001(3), F.A.C.

²⁶ Rule 64B16-27.1001(4), F.A.C.

²⁷ Section 465.003(11)(b), F.S.

²⁸ Rules 64B16-27.104 and 64B16-27.450, F.A.C.

²⁹ *Id.*

³⁰ *Id.*

³¹ Pharmacy Technician Certification Board, *Pharmacy Technicians*, available at <https://www.ptcb.org/who-we-serve/pharmacy-technicians#.Wj1PsGyouUk> (last visited on December 22, 2017).

³² Section 465.014(2), F.S.

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

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.³⁴

Pharmacy Technician Training Programs

A pharmacy technician may only be registered with DOH if it 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, 2017.³⁵

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:³⁶

- 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.³⁷ A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.³⁸

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.³⁹ 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.⁴⁰ The employer-based training program must:⁴¹

³³ 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.

³⁴ Section 465.014(6), F.S.

³⁵ Rule 64B16-26.351(1)-(2), F.A.C.

³⁶ Rule 64B16-26.351(3)(b), F.A.C.

³⁷ Rule 64B16-26.351(3)(e), F.A.C.

³⁸ Id.

³⁹ Rule 64B16-26.351(4), F.A.C.

⁴⁰ Id.

⁴¹ Id.

- 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.⁴² Registered pharmacy technicians' responsibilities include:⁴³

- 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,⁴⁴ and is responsible for acts performed by persons under his or her supervision.⁴⁵ A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.⁴⁶

The Board specifies, by rule, certain acts that registered pharmacy technicians are prohibited from:⁴⁷

- 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

⁴² Section 465.014(1), F.S.

⁴³ Rule 64B16-27.420(1), F.A.C.

⁴⁴ 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.)

⁴⁵ Rule 64B16-27.1001(7), F.A.C.

⁴⁶ Rule 64B16-27.4001(2)(b), F.A.C.

⁴⁷ Rule 64B16-27.420(2), F.A.C.

- Engaging in any other act that requires the exercise of a pharmacist's professional judgment.

A registered pharmacy technicians 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.⁴⁸

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.⁴⁹ The guidelines include the following restrictions.⁵⁰

- 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 area⁵¹ of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to 6 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, treatment⁵² and prevention of disease and injuries⁵³, 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.⁵⁴

More specific definitions vary by state and occasionally by profession.⁵⁵ There are, however, common elements among the varied definitions of telehealth.

⁴⁸ Rule 64B16-27.100(2), F.A.C.

⁴⁹ Section 465.014(1), F.S.

⁵⁰ Rule 64B16-27.410, F.A.C.

⁵¹ 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.

⁵² 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 January 2, 2018).

⁵³ 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 January 2, 2018).

⁵⁴ 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 January 2, 2018).

⁵⁵ 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 January 2, 2018)

Telehealth generally consists of synchronous and/or asynchronous transmittal of information.⁵⁶ Synchronous refers to the live⁵⁷ transmission of information between patient and provider during the same time period.⁵⁸ Asynchronous telehealth is the transfer of data over a period of time, and typically in separate time frames.⁵⁹ 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, i.e., the provider.⁶⁰ A spoke site is a remote site where the patient is presented during the telehealth encounter.⁶¹ 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 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.⁶²

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.⁶³ Telepharmacy operations include, but are not limited to, drug review and monitoring, dispensing of medications, medication therapy management, clinical consultation, and patient counseling.⁶⁴

In 2001, North Dakota became the first state to regulate telepharmacy.⁶⁵ North Dakota created a pilot project using telepharmacy to save rural pharmacies from closing and to provide telepharmacy services to underserved rural communities in that state.⁶⁶ 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.⁶⁷ A pharmacist supervises the pharmacy technician and speaks with patients using real-time communications

⁵⁶ The majority of telehealth definitions allow for both synchronous and asynchronous transmittal of information. Some definitions however omit asynchronous from the definition of telehealth.

⁵⁷ This is also referred to as “real time” or “interactive” telehealth.

⁵⁸ American Telemedicine Association, *Telemedicine Glossary*, available at <http://thesource.americantelemed.org/resources/telemedicine-glossary> (last visited on January 2, 2018). The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

⁵⁹ 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.

⁶⁰ Id.

⁶¹ Id.

⁶² 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 January 2, 2018).

⁶³ 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 January 2, 2018). Telepharmacy technologies means secure electronic communications, information exchange, or other methods that meet state and federal requirements.

⁶⁴ 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?sschecked=true> (last visited January 2, 2018).

⁶⁵ 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: 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 January 2, 2018).

⁶⁶ 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 January 5, 2018).

⁶⁷ Id at 582.

technology.⁶⁸ Almost 80,000 rural citizens had pharmacy services established, restored, or retained under the pilot project.⁶⁹

At least 23 states have enacted laws or regulations that allow for the use of telepharmacy and/or remote dispensing since 2001.⁷⁰ 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 areas⁷¹ while others restrict it by facility type such as rural health centers.⁷² 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.⁷³

Rural Areas

There are a number of rural areas in Florida in which access to health care may be limited. Both the state and federal government have advanced policy and programs to ensure that individuals residing in rural communities have access to quality health care. The Office of Rural Health, within DOH, is tasked with actively fostering the provision of health care services in rural areas and serving as a catalyst for improved health services to residents in these areas.⁷⁴ A rural area is an area with a population density of less than 100 individuals per square mile or an area defined by the most recent United States census as rural.⁷⁵ DOH has designated the following counties as rural areas:⁷⁶

⁶⁸ Id.

⁶⁹ 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 January 5, 2018).

⁷⁰ *Supra* note 65. 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.

⁷¹ Id. For example, Colorado requires that a telepharmacy outlet be more than twenty miles from the nearest prescription drug outlet or another telepharmacy outlet. (COLO. REV. STAT. s. 12-12.5-102 (2017)).

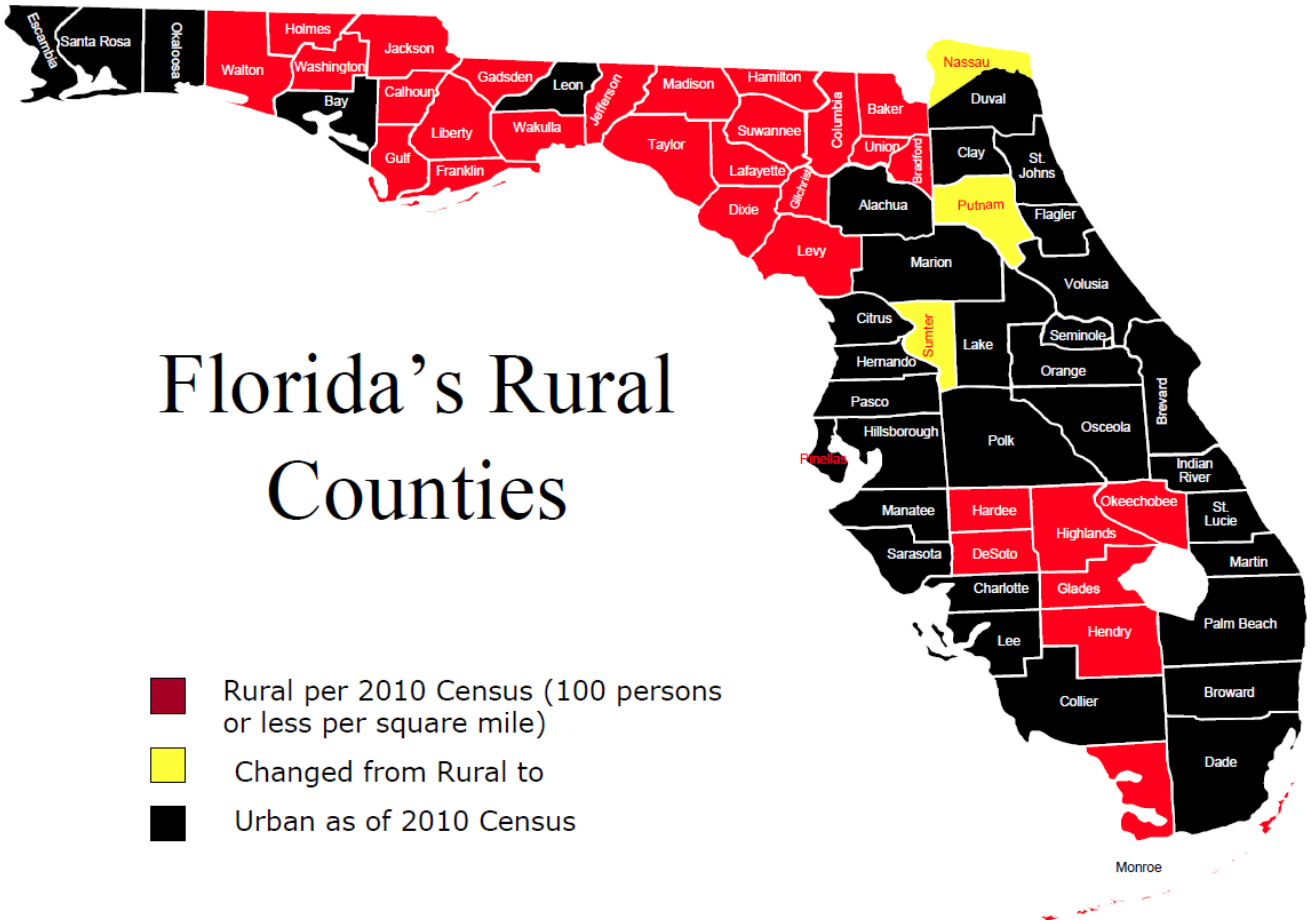
⁷² Id. For example, Wisconsin limits the operation of a remote dispensing site to a health care facility, office or clinic of a practitioner, county jail, rehabilitation facility, state prison, county house of correction, juvenile correctional facility, juvenile detention center, or residential care center for children and youth. (Wis. Admin. Code s. Phar. 7.095(3)).

⁷³ 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).

⁷⁴ Section 381.0405.

⁷⁵ Section 381.0406(2)(a), F.S.

⁷⁶ Department of Health, *Florida's Rural Counties*, available at http://www.floridahealth.gov/programs-and-services/community-health/rural-health/_documents/ruralcountiespdf.12.pdf (last visited January 18, 2018). For a list of counties, see http://www.floridahealth.gov/programs-and-services/community-health/rural-health/_documents/rual-counties-2000-2010.pdf (last visited January 18, 2018).



Effect of Proposed Changes

CS/HB 679 creates a remote dispensing site pharmacy permit. A remote dispensing site pharmacy is a location where medicinal drugs are dispensed by a registered pharmacy technician who is electronically supervised by an off-site prescription department manager.

Remote Dispensing Site Pharmacy

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

- Be jointly owned by a supervising pharmacy or operated under contract with a supervising pharmacy;⁷⁷
- Display a sign, visible by the public, which indicates that the facility is a remote dispensing site pharmacy and that it is under 24-hour video surveillance;
- Retain video surveillance recordings for at least 45 days;
- Be located in a rural area, which is defined as a having a population density of less than 100 people per square mile or designated as rural by the most recent United States census;⁷⁸
- Be located at least 10 miles from an existing community pharmacy;

⁷⁷ The bill defines a supervising pharmacy as a Florida-licensed pharmacy that employs a Florida-licensed pharmacist who remotely supervises a registered pharmacy technician at a remote dispensing site pharmacy.

⁷⁸ Section 381.0406, F.S.

- Designate a licensed pharmacist or consultant pharmacist as the prescription department manager responsible for oversight of the facility; and
- Pass an onsite inspection by DOH.

DOH must issue a permit if the Board certifies that an application for a permit complies with the laws and rules governing pharmacies. A remote dispensing site pharmacy will not lose its permit if a community pharmacy subsequently opens within 10 miles of its location. For purposes of network access in managed care, a remote dispensing site pharmacy is not considered a pharmacy.

Operation of a Remote Dispensing Site Pharmacy

The bill authorizes a remote dispensing site pharmacy to store, hold, and dispense all medicinal drugs; however, it may not store, hold, or dispense Schedule II controlled substances.⁷⁹ It may not perform centralized prescription filling, which is the filing of a prescription by one pharmacy upon the request of another pharmacy.⁸⁰

The bill creates an exception to the requirement that a pharmacist be present and on duty for a prescription department of a pharmacy to be considered open. Under the bill, a prescription department may be considered open if an off-site prescription manager remotely supervises a pharmacy technician at a remote dispensing site pharmacy. A pharmacist may utilize telepharmacy to meet his or her obligation to be present and on duty and to supervise the pharmacy technician.

A remote dispensing site pharmacy must maintain a policy and procedures manual that addresses:

- How the pharmacy will comply with federal and state laws, rules, and regulations;
- The procedure for supervising the remote dispensing site pharmacy and counseling its patients;
- The procedure for reviewing the prescription drug inventory and drug records;
- The policy and procedure for providing appropriate security to protect the confidentiality and integrity of patient information;
- A written plan for recovery from an event that interrupts or prevents the pharmacist from supervising the remote dispensing site pharmacy's operation;
- The procedure by which the supervising pharmacist consults the state prescription drug management program before authorizing the dispensing of any controlled substance and reports the dispensing of a controlled substance;⁸¹ and
- The duties, tasks, and functions that a registered pharmacy technician is authorized to perform.

The prescription drug manager must visit the remote dispensing site pharmacy, pursuant to a schedule established by the Board, to inspect the pharmacy, address personnel matters, and provide clinical services to patients. A pharmacist may serve as a prescription department manager for one remote site dispensing pharmacy; except that a pharmacist may serve as a pharmacy department manager for up to two remote site dispensing pharmacies if they are under common control.

Pharmacy Technicians

The bill authorizes a registered pharmacy technician working in a remote site dispensing pharmacy under the electronic supervision of a pharmacist to compound and dispense medicinal drugs. A registered pharmacy technician employed by a remote dispensing site pharmacy must have completed

⁷⁹ 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.

⁸⁰ Section 465.003(16), F.S. It also includes the performance of other pharmacy duties by one pharmacy on behalf of another pharmacy, such as drug utilization review, claims adjudication, and obtaining refill authorizations.

⁸¹ Pursuant to s. 893.055, F.S., each time a controlled substance is dispensed, the dispenser must submit certain information to the state's prescription drug management program by the close of the next business day.

at least 2,080 hours of pharmacy experience prior to commencing employment. The bill prohibits a registered pharmacy technician from performing sterile or nonsterile compounding.

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

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 dispensing site pharmacy permits.

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

Section 6: Amends s. 465.0265, F.S., relating to centralized prescription filing.

Section 7: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill will have an indeterminate, negative fiscal impact on DOH due to a recurring increase in costs and workload associated with issuing the remote dispensing site pharmacy permit and regulating permittees.⁸² Pursuant to 465.022(14), the Board is authorized to set an initial permit fee of no more than \$250, and a biennial renewal fee of no more than \$250, which may be used to offset these costs. DOH will also incur an insignificant, nonrecurring negative fiscal impact associated with the development of an application form and updates to the Licensing and Enforcement Information Database System, which current resources can absorb.⁸³

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:

⁸² Florida Department of Health, *2018 Agency Legislative Bill Analysis for Senate Bill 848*, (Nov. 13, 2017), on file with the Health Quality Subcommittee. SB 848 is substantively similar to HB 679.

⁸³ *Id.*

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:

Section 465.005, F.S., grants the Board of Pharmacy broad rulemaking authority to implement the provisions of ch. 465, F.S. Therefore, no additional rulemaking authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 16, 2018, the Health Quality Subcommittee adopted a strike-all amendment that did the following:

- Required a remote dispensing site pharmacy to pass an onsite inspection to qualify for a permit;
- Required that a remote dispensing site pharmacy be located in an area defined as rural under s. 381.0406, F.S., (less than 100 people per square mile or designated as rural by the most recent U.S. census);
- Removed exceptions that would have allowed a remote dispensing site pharmacy to be located within 10 miles of an existing community pharmacy;
- Prohibited a remote dispensing site pharmacy from storing or dispensing Schedule II drugs;
- Required the policies and procedures manual of a remote dispensing site pharmacy to contain procedures to comply with the requirements of the prescription drug monitoring program;
- Established a minimum experience requirement for a pharmacy technician employed at a remote dispensing site pharmacy of at least 2,080 hours of experience within the 2 years immediately preceding employment; and
- Prohibited a pharmacy technician working at a remote dispensing site pharmacy from performing sterile and nonsterile compounding.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.