The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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

BILL:	SB 700
INTRODUCER:	Senator Rodriguez
SUBJECT:	Telehealth
DATE:	February 16, 2021
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 700:

- Authorizes the Agency for Health Care Administration (AHCA), subject to limitations in the General Appropriations Act, to reimburse for telehealth services involving store-and-forward technology and remote patient monitoring services under the Medicaid program.
- Expands the definition of "telehealth" in s. 456.47, F.S., to include:
  - A telehealth provider's supervision of health care services through the use of synchronous and asynchronous telecommunications technology.
  - Telephone calls, emails, fax transmissions, and other nonpublic-facing telecommunications.
- Provides that a nonphysician health care practitioner who is required to maintain a formal supervisory relationship with a physician may satisfy such a requirement through telehealth.
- Authorizes registered out-of-state telehealth providers who are physicians to formally supervise nonphysician health care practitioners in this state through telehealth, but specifies that such supervision may not be for the provision of any health care service that requires "direct supervision" under Florida laws or rules.
- Authorizes a telehealth provider, practicing in a manner consistent with his or her scope of practice, to prescribe Schedule III, IV, and V controlled substances through telehealth.
- Prohibits the prescription of Schedule I and II controlled substances through telehealth.
- Creates a new type of pharmacy establishment, a "remote-site pharmacy," where medicinal drugs are compounded or dispensed by a registered pharmacy technician (RPT) who is remotely supervised by an off-site pharmacist acting in the capacity of prescription department manager.
- Authorizes an off-site pharmacist to remotely supervise an RPT at a remote-site pharmacy and authorizes an RPT operating under such remote supervision to compound and dispense drugs.

- Provides for permitting and regulation of remote-site pharmacies by the Department of Health (DOH).
- Provides requirements for remote-site pharmacies.
- Prohibits a remote-site pharmacy from performing centralized prescription filling.
- Authorizes a pharmacist to serve as prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacies and requiring him or her to visit the remote site on a schedule as determined by the Board of Pharmacy (BOP).

The bill provides an effective date of July 1, 2021.

II. Present Situation:

This section will discuss the following topics in order:

- Telehealth
  - Terminology.
  - Florida telehealth providers.
- Telemedicine coverage under Florida Medicaid.
- Controlled substance prescribing through telehealth.
  - Controlled substances generally.
  - Federal law.
  - Federal guidance during the Covid-19 public health emergency.
  - Florida law.
  - Florida DOH Emergency Order No. 20-002.
- Physician supervision.
  - Physician supervision laws and rules governing the practice of advanced practice registered nurses, certified registered nurse anesthetists, and physician assistants
  - Advanced practice registered nurses (APRNs).
  - Certified registered nurse anesthetists (CRNAs).
  - Physician supervision of CRNA's and anesthesiologist assistants (AAs) as a condition of participation in Medicare.
  - Physician assistants (PAs).
  - Physician assistant licensure.
  - Physician assistant scope of practice and physician supervision.
- Regulation of pharmacy establishments.
  - Pharmacy permitting.
  - Centralized prescription filling.
  - Prescription department managers.
- Regulation of pharmacists.
  - Pharmacist licensure requirements.
  - Pharmacist scope of practice.
  - Pharmacists with a broader scope of practice.
  - Consultant pharmacists.
  - Collaborative pharmacy practice for chronic health conditions.
  - Testing or screening for and treatment of minor, nonchronic health conditions.
  - Pharmacist supervision of registered pharmacy interns.

- Registered pharmacy technicians.
  - Pharmacy technician registration requirements.
  - Pharmacy technician training programs.
  - Pharmacy technician scope of practice.
  - Pharmacist supervision of pharmacy technicians.
- The federal Health Insurance Portability and Accountability Act (HIPAA).
  - HIPAA Privacy Rule.
  - HIPAA Security Rule.
  - HIPAA Breach Notification Rule.
  - Notice of nonenforcement discretion during a public health emergency.
- Jurisdiction and venue for telehealth-related actions.

Telehealth

Terminology

Section 456.47, F.S., defines the term "telehealth" as the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, 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. The term does not include audio-only telephone calls, e-mail messages, or facsimile transmissions.

"Synchronous" telehealth refers to the live, real-time, or interactive transmission of information between a patient and a health care provider during the same time period. The use of live video to evaluate and diagnosis a patient would be considered synchronous telehealth.

"Asynchronous" telehealth refers to the transfer of data between a patient and a health care provider over a period of time and typically in separate time frames. This is commonly referred to as "store-and-forward."

Store-and-forward allows for the electronic transmission of medical information, such as digital images, documents, and pre-recorded videos through telecommunications technology to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service after the data has been collected.[1] The transfer of X-rays or MRI images from one health care provider to another health care provider for review in the future would be considered asynchronous telehealth through store-and-forward technology.

"Remote monitoring" refers to the collection, transmission, evaluation, and communication of individual health data to a health care provider from the patient's location through technology such as wireless devices, wearable sensors, implanted health monitors, smartphones, and mobile apps.[2] Remote monitoring can be useful for ongoing condition monitoring and chronic disease

[1] Center for Connected Health Policy, National Telehealth Policy Resource Center, *Store-and-Forward (Asynchronous) available at* https://www.cchpca.org/about/about-telehealth/store-and-forward-asynchronous (last visited Feb. 13, 2021).
[2] American Telemedicine Association, Telehealth: Defining 21st Century Care, *available at* https://f.hubspotusercontent30.net/hubfs/5096139/Files/Resources/ATA_Telehealth_Taxonomy_9-11-20.pdf (last visited Feb. 13, 2021).

management. Depending upon the patient's needs, remote monitoring can be synchronous or asynchronous.

"Non-public facing communication technology" is a technology that, as a default, allows only the intended parties to participate in the communication. For example, Zoom, Skype, Apple FaceTime, and Facebook Messenger video chat.[3] Typically, these technologies employ end-to-end encryption, which allows only an individual and the person with whom the individual is communicating to see what is transmitted. In contrast, public-facing products such as TikTok, Facebook Live, or a public chat room are not acceptable forms of remote communication for telehealth because they are designed to be open to the public or allow wide or indiscriminate access to the communication.

Florida Telehealth Providers

In 2019, the Legislature passed and the Governor approved CS/CS/HB 23 which created s. 456.47, F.S. The bill became effective on July 1, 2019.[4] It authorized Florida-licensed health care providers[5] to use telehealth to deliver health care services within their respective scopes of practice. The bill also authorized out-of-state health care providers to use telehealth to deliver health care services to Florida patients if they register with the DOH or the applicable board[6] and meet certain eligibility requirements.[7] A registered out-of-state telehealth provider may use telehealth, within the relevant scope of practice established by Florida law and rule, to provide health care services to Florida patients but is prohibited from opening an office in Florida and from providing in-person health care services to patients located in Florida.

Telehealth providers who treat patients located in Florida must be one of the licensed health care practitioners listed below[8] and be either Florida-licensed, licensed under a multi-state health care licensure compact of which Florida is a member state, or registered as an out-of-state telehealth provider:

- Behavioral Analyst.
- Acupuncturist.
- Allopathic physician.
- Osteopathic physician.
- Chiropractor.
- Podiatrist.
- Optometrist.
- Nurse.

[3] U.S. Department for Health and Human Services Office for Civil Rights, FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency (Mar. 2020) *available at* https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf (Feb. 14, 2021).
[4] Chapter 2019-137, s. 6, Laws of Fla.
[5] Section 467.47(1)(b), F.S.
[6] Under s. 456.001(1), F.S., the term "board" is defined as any board, commission, or other statutorily created entity, to the extent such entity is authorized to exercise regulatory or rulemaking functions within the DOH or, in some cases, within the DOH's Division of Medical Quality Assurance.
[7] Section 467.47(4), F.S.
[8] Section 467.47(1)(b), F.S. These are professionals licensed under s. 393.17; part III, ch. 401; ch. 457; ch. 458; ch. 459; ch. 460; ch. 461; ch. 463; ch. 464; ch. 465; ch. 466; ch. 467; part I, part III, part IV, part V, part X, part XIII, and part XIV, ch. 468; ch. 478; ch. 480; part II and part III, ch. 483; ch. 484; ch. 486; ch. 490; or ch. 491.

- Pharmacist.
- Dentist.
- Dental Hygienist.
- Midwife.
- Speech Therapist.
- Occupational Therapist.
- Radiology Technician.
- Electrologist.
- Orthotist.
- Pedorthist.
- Prosthetist.
- Medical Physicist.
- Emergency Medical Technician.
- Paramedic.
- Massage Therapist.
- Optician.
- Hearing Aid Specialist.
- Clinical Laboratory Personnel.
- Respiratory Therapist.
- Psychologist.
- Psychotherapist.
- Dietician/Nutritionist.
- Athletic Trainer.
- Clinical Social Worker.
- Marriage and Family Therapist.
- Mental Health Counselor.

The Legislature also passed 2019 HB 7067 that would have required an out-of-state telehealth provider to pay an initial registration fee of $150 and a biennial registration renewal fee of $150, but the bill was vetoed by the Governor and did not become law.[9]

On March 16, 2020, Surgeon General Scott Rivkees executed DOH Emergency Order 20-002 authorizing certain out-of-state physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S.[10] This emergency order was extended[11] and will

[9] Transmittal Letter from Governor Ron DeSantis to Secretary of State Laurel Lee (June 27, 2019) *available at* https://www.flgov.com/wp-content/uploads/2019/06/06.27.2019-Transmittal-Letter-3.pdf (last visited Feb. 14, 2021).
[10] Department of Health, State of Florida, *Emergency Order DOH No. 20-002* (Mar. 16, 2020) *available at* http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf (last visited Feb. 14, 2021).
[11] Department of Health, State of Florida, *Emergency Order DOH No. 20-011* (June 30, 2020) *available at* https://floridahealthcovid19.gov/wp-content/uploads/2020/06/DOH-Emergency-Order-DOH-No.-20-011.pdf (last visited Feb. 14, 2021).

remain in effect until the expiration of the Governor's Executive Order No. 20-52 and extensions thereof.[12]

Five days later, the Surgeon General executed DOH Emergency Order 20-003[13] to also authorize certain out-of-state clinical social workers, marriage and family therapists, mental health counselors, and psychologists to provide telehealth in Florida without the need to register as a telehealth provider under s. 456.47(4), F.S. This emergency order was also extended[14] and will remain in effect until the expiration of Executive Order No. 20-52 and extensions thereof.

Florida Medicaid Program

Florida Medicaid is the health care safety net for low-income Floridians. The national Medicaid program is a partnership of federal and state governments established to provide coverage for health services for eligible persons. Florida's program is administered by the AHCA and financed through state and federal funds.[15]

The majority of Florida Medicaid recipients receive their services through a managed care plan contracted with the AHCA under the Statewide Medicaid Managed Care (SMMC) program.[16] The SMMC program has two components, the Managed Medical Assistance (MMA) program and the Long-term Care program. Florida's SMMC offers a health care package covering both acute and long-term care.[17] The SMMC benefits are authorized by federal authority and are specifically required in ss. 409.973 and 409.98, F.S. The AHCA contracts with managed care plans on a regional basis to provide services to eligible recipients. The MMA program, which covers most medical and acute care services for managed care plan enrollees, was fully implemented in August 2014 and was re-procured for a period beginning December 2018 and ending in 2023.[18] The minority of Florida Medicaid recipients receive their services through the fee-for-service delivery system.

[12] Under s. 252.36(2), F.S., no state of emergency declared pursuant to the Florida Emergency Management Act, may continue for more than 60 days unless renewed by the Governor. The state of emergency declared in Executive Order 20-52, was extended by Executive Orders 20-114, 20- 166, 20-192, 20-213, 20-276, and 20-316. Executive Order 20-316 will remain in effect until Feb. 27, 2020. Office of the Governor, State of Florida, *Executive Order 20-316* (Dec. 29, 2020) *available at* https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-316.pdf (last visited Feb. 9, 2021).
[13] Department of Health, State of Florida, *Emergency Order DOH No. 20-003* (Mar. 21, 2020) *available at* https://s33330.pcdn.co/wp-content/uploads/2020/03/DOH-EO-20-003-3.21.2020.pdf (last visited Feb. 14, 2021).
[14] Department of Health, State of Florida, *Emergency Order DOH No. 20-005* (Apr. 21, 2020) *available at* https://s33330.pcdn.co/wp-content/uploads/2020/04/DOH-Emergency-Order-20-005-extending-20-003.pdf (last visited Feb. 14, 2021).
[15] Section 20.42, F.S.
[16] Agency for Health Care Administration, *Senate Bill 348 Fiscal Analysis* (Feb. 1, 2021) (on file with Senate Committee on Health Policy).
[17] *Id.*
[18] *Id.*

Telemedicine Coverage under the Florida Medicaid Program[19]

Medicaid managed care plans have broad flexibility in covering telemedicine services, including remote patient monitoring and store-and-forward services. The AHCA has encouraged plans to ensure the use of services via telemedicine is maximized.

Under the fee-for-service delivery system, the AHCA covers physicians, APRNs, PAs, and clinic providers through telemedicine (which the AHCA defines as live, two-way communication). Covered medical services include evaluation, diagnostic, and treatment recommendations for services included on the AHCA's practitioner fee schedule to the extent telemedicine is designated in the American Medical Association's Current Procedural Terminology (national coding standards). The AHCA reimburses services using telemedicine at the same rate detailed on the practitioner fee schedule. The AHCA also covers behavioral health evaluation, diagnostic, and treatment recommendation services through telemedicine.

On March 18, 2020, the AHCA issued a Florida Medicaid Health Care Alert to provide telemedicine guidance for all medical and behavioral health care providers during the COVID-19 public health emergency. Throughout the duration of the public health emergency, the AHCA has expanded telehealth to include store-and-forward and remote patient monitoring modalities rendered by licensed physicians, APRNs, and PAs functioning within their scope of practice. The AHCA has also expanded services provided through telemedicine through the fee-for-service delivery system to include certain therapies, medication management, behavioral health, and medication-assisted treatment services.

Controlled Substance Prescribing through Telehealth

Controlled Substances Generally

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. The scheduling of substances in Florida law is generally consistent with the federal scheduling of substances under 21 U.S.C. s. 812:

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples include heroin and lysergic acid diethylamide (LSD).
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples include cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples include lysergic acid; ketamine; and some anabolic steroids.

[19] Agency for Health Care Administration, Florida Medicaid Health Care Alert, *Medicaid Telemedicine Guidance for Medical and Behavioral Health Providers* (Mar. 18, 2020) *available at* https://ahca.myflorida.com/Medicaid/pdffiles/provider_alerts/2020_03/Medicaid_Telemedicine_Guidance_20200318.pdf (last visited Feb. 15, 2021).

- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples include alprazolam, diazepam, and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples include low dosage levels of codeine, certain stimulants, and certain narcotic compounds.

Federal Law[20]

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008[21] amended the federal Controlled Substances Act, to prohibit a practitioner from issuing a "valid prescription" for a controlled substance through the Internet without having first conducted at least one in-person medical evaluation, except in certain circumstances. Thereafter, the prescriber may prescribe controlled substances to that patient via Internet or a phone call. The Act offers seven exceptions to the in-person exam. One such exception occurs when the Secretary of the federal Department of Health and Human Services (HHS) has declared a public health emergency.

Federal Guidance During the COVID-19 Public Health Emergency

On January 31, 2020, the Secretary of HHS issued a public health emergency.[22] On March 16, 2020, the federal Drug Enforcement Agency (DEA) published a COVID-19 Information page on the Diversion Control Division website, authorizing DEA-registered practitioners, authorized designated DEA-registered practitioners to issue prescriptions for all Schedule II-V controlled substances to patients without first conducting an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.
- The evaluation is conducted using an audio-visual, real-time, two-way interactive communication system.
- The practitioner is acting in accordance with applicable federal and state law.[23]

[20] 21 U.S.C. s. 829.
[21] Public Law No. 110-435 (2008).
[22] Determination that a Public Health Emergency Exists, Alex M. Azar II, Secretary of U.S. Department of Health and Human Services (January 31, 2020) *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (last visited Feb. 9, 2021).
[23] Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, *COVID-19 Information Page*, *available at* https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Feb. 9, 2021). Letter from Thomas Prevoznik, Deputy Assistant Administrator, Diversion Control Division, U.S. Department of Justice Drug Enforcement Administration, to DEA Qualifying Practitioners and Other Practitioners, (Mar. 31, 2020) *available at* https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf (last visited Feb. 9, 2021).

Florida Law

Section 456.44, F.S., as amended by 2018 CS/CS/HB 21,[24] authorizes prescribers to prescribe a three-day supply of a Schedule II opioid[25] or up to a seven-day supply if medically necessary. The prescribing limits on Schedule II opioids do not apply to prescriptions for acute pains related to: cancer, a terminal condition, pain treated with palliative care, or a traumatic injury with an Injury Severity Score of 9 or higher.[26]

That section also requires a prescriber and dispenser to report to and review the Prescription Drug Monitoring Program database to review a patient's controlled substance dispensing history prior to prescribing or dispensing a Schedule II-IV controlled substance for patients 16 years older.[27] These limitations and requirements apply to practitioners providing services in-person and through telehealth.

Section 456.47(2)(c), F.S., as created by 2019 CS/CS/HB 23[28], prohibits telehealth providers from prescribing any controlled substance unless the controlled substance is prescribed for:

- The treatment of a psychiatric disorder;
- Inpatient treatment at a licensed hospital;
- The treatment of a patient receiving hospice services; or
- The treatment of a resident of a nursing home facility.

Florida DOH Emergency Order No. 20-002

The same day that the HHS Secretary authorized qualified prescribers to prescribe Schedule II-V controlled substances, Surgeon General Rivkees issued DOH Emergency Order No. 20-002[29], which suspended s. 456.47(2)(c), F.S., and authorized specified Florida-licensed prescribers[30] to issue a renewal prescription for a Schedule II-IV controlled substance only for an existing patient for the purpose of treating chronic nonmalignant pain without conducting another physical examination of the patient. This emergency order was extended[31] and will remain in effect until the expiration of Executive Order No. 20-52 and extensions thereof.[32]

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[24] Chapter 2018-13, Laws of Fla.
[25] All opioids are controlled substances. Opioids range in classification between Schedule I and Schedule V.
[26] Section 456.44(1)(a), F.S.
[27] Section 893.055, F.S.
[28] Chapter 2019-137, Laws of Fla.
[29] Department of Health, State of Florida, *Emergency Order DOH No. 20-002* (Mar. 16, 2020) *available at* http://floridahealthcovid19.gov/wp-content/uploads/2020/03/filed-eo-doh-no.-20-002-medical-professionals-03.16.2020.pdf (last visited Feb. 14, 2021).
[30] Physicians, osteopathic physicians, physician assistants, or advanced practice registered nurses that have designated themselves as a controlled substance prescribing practitioner on their practitioner profiles pursuant to s. 456.44, F.S.
[31] Department of Health, State of Florida, *Emergency Order DOH No. 20-011* (June 30, 2020) *available at* https://floridahealthcovid19.gov/wp-content/uploads/2020/06/DOH-Emergency-Order-DOH-No.-20-011.pdf (last visited Feb. 14, 2021).
[32] Under s. 252.36(2), F.S., no state of emergency declared pursuant to the Florida Emergency Management Act, may continue for more than 60 days unless renewed by the Governor. The state of emergency declared in Executive Order 20-52, was extended by Executive Orders 20-114, 20- 166, 20-192, 20-213, 20-276, and 20-316. Executive Order 20-316 will remain in effect until Feb. 27, 2020. Office of the Governor, State of Florida, *Executive Order 20-316* (Dec. 29, 2020) *available at* https://www.flgov.com/wp-content/uploads/orders/2020/EO_20-316.pdf (last visited Feb. 9, 2021).

Physician Supervision

The Board of Medicine (BOM) defines levels of physician supervision.[33] Unless otherwise provided by law or rule, the definitions listed below will apply to all supervised licensees:

"Direct supervision" requires the physical presence of the supervising licensee on the premises so that the supervising licensee is reasonably available as needed.

"Indirect supervision" requires only that the supervising licensee practice at a location which is within close physical proximity of the practice location of the supervised licensee and that the supervising licensee must be readily available for consultation as needed. "Close physical proximity" shall be within 20 miles or 30 minutes unless otherwise authorized by the BOM.

"Immediate Supervision" requires the physical presence of the supervising licensee in the same room as the supervised licensee.

The Board of Osteopathic Medicine (BOOM) has no similar rule.

Physician Supervision Laws and Rules governing the practice of Advanced Practice Registered Nurses, Certified Registered Nurse Anesthetists, and Physician Assistants

	APRNs	CRNAs (specialized APRNs)	PAs
Federal Conditions		42 CFR s. 482.52 As a condition of a hospital's participation in the Medicare program, a CRNA or an AA who administers anesthesia must be under the supervision of an anesthesiologist (a physician specialist) who is immediately available if needed, unless the CRNA or AA is located in a state that has opted out of the supervision requirements. Florida has not opted out. An operating practitioner or an anesthesiologist is "immediately available" when they are physically located within the same area as the CRNA and are not otherwise occupied in a way that prevents an immediate hands-on intervention.[34]	

[33] Fla. Admin. Code R. 64B8-2.001 (2020).
[34] Centers for Medicare & Medicaid Services, Medicare Learning Network MLN Booklet, *Advanced practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants* (Apr. 2020) *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Medicare-Information-For-APRNs-AAs-PAs-Text-Only.pdf (last visited Feb. 14, 2021).

	APRNs	CRNAs (specialized APRNs)	PAs
		Note: Beginning in March 2020, the federal Centers for Medicare and Medicaid began to waive the requirements that a CRNA is under the supervision of a physician in order to allow CRNAs to function to the fullest extent allowed by states and free up physicians to expand the capacity of both CRNAs and physicians throughout the public health emergency.[35]	
Florida Statutes	s. 464.012(3), F.S. A written protocol with an osteopathic or allopathic physician, or dentist that must be maintained on site at the location where he or she practices.	s. 464.012(3), F.S. A written protocol with an osteopathic or allopathic physician that must be maintained on site at the location where he or she practices. s. 464.012(3)(b), F.S. An established protocol approved by the medical staff of the facility in which the anesthetic service is performed.	s. 458.347(1)(f), F.S. "Supervision" means responsible supervision and control. Except in cases of emergency, supervision requires the easy availability or physical presence of the licensed physician for consultation and direction of the actions of the physician assistant. For the purposes of this definition, the term "easy availability" includes the ability to communicate by way of telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.
Florida Rules	BON Rule 64B9-4.001(14), F.A.C. General Supervision – supervision whereby a practitioner currently licensed under Chapter 458, 459, or 466, F.S., authorizes procedures being carried out but need not be present when such procedures are performed. The APRN must be able to contact the practitioner when needed for consultation and advice either in person or by communication devices.	BON Rule 64B9-4.001(14), F.A.C. General Supervision – supervision whereby a practitioner currently licensed under Chapter 458, 459, or 466, F.S., authorizes procedures being carried out but need not be present when such procedures are performed. The APRN must be able to contact the practitioner when needed for consultation and advice either in person or by communication devices.	BOM Rule 64B8-30.012(2), F.A.C. The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. Furthermore, the supervising physician must be certain that the physician assistant is knowledgeable and skilled in performing the tasks and procedures assigned. BOOM Rule 64B15-6.001(3)

[35] Centers for Medicare & Medicaid Services, Newsroom, *Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address Covid-19 Patient Surge* (Mar. 30, 2020) *available at* https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19 (last visited Feb. 12, 2012).

	APRNs	CRNAs (specialized APRNs)	PAs
			The term "responsible supervision" as used herein refers to the ability of the supervising physician to responsibly exercise control and provide direction over the services of the physician assistant. In providing supervision, the supervising physician shall periodically review the physician assistant's performance. It requires the easy availability or physical presence of the supervising physician to the physician assistant. In determining whether supervision is adequate, the following factors should be considered: (a) The complexity of the task; (b) The risk to the patient; (c) The background, training and skill of the physician assistant; (d) The adequacy of the direction in terms of its form; (e) The setting in which the tasks are performed; (f) The availability of the supervising physician; (g) The necessity for immediate attention; and, (h) The number of other persons that the supervising physician must supervise.

Advanced Practice Registered Nurses (APRNs)

In Florida, an advanced practice registered nurse (APRN),[36] is licensed in one of five roles:

- Advanced nursing practitioner (ANP);
- Certified nurse midwife (CNM);
- Certified registered nurse anesthetist (CRNA);
- Clinical nurse specialist (CNS); and
- Psychiatric nurse specialist (PNS).[37]

[36] Section 464.003(3), F.S.
[37] *Id*.

According to the Annual Report and Long-Range Plan 2019-2020,[38] published by the DOH's Division of Medical Quality Assurance, Florida has 32,215 current and active APRNs who are regulated under the Nurse Practice Act.[39] The Board of Nursing (BON), provides by rule the criteria for an applicant to be licensed as an APRN and the applicable regulatory standards for APRN nursing practices. Additionally, the BON is responsible for administratively disciplining an APRN who commits an act prohibited.[40]

To be eligible for licensure as an APRN, an applicant must:

- Be licensed as a registered nurse;
- Have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills; and
- Submit proof that the applicant holds a current national advanced practice certification from a BON-approved nursing specialty board.[41]

To be a BON-approved nursing specialty board, that board must:[42]

- Attest to the competency of nurses in a clinical specialty area;
- Require a written examination prior to certification;
- Require nurses to complete a formal program prior to eligibility for examination;
- Maintain program accreditation or review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing special.

All APRNs must carry malpractice insurance or demonstrate proof of financial responsibility. Any applicant for licensure must submit proof of coverage or financial responsibility as a prerequisite to licensure/certification and biennial renewal.[43] The APRN must have professional liability coverage of at least $100,000 per claim, with a minimum annual aggregate of at least $300,000; or an unexpired irrevocable letter of credit in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000 and which is payable to the APRN as beneficiary.[44]

To begin practicing as an APRN in Florida, the APRN must establish a written protocol with an osteopathic or allopathic physician, or dentist, that must be maintained on site at the location where he or she practices,[45] unless the APRN is in autonomous practice. The osteopathic or allopathic physicians, or dentist, must maintain supervision for directing the specific course of

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[38] Department of Health, Medical Quality Assurance, *Annual Report and Long-Range Plan 2019-2020, available at* http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/2019-2020-annual-report.pdf (last visited Feb. 11, 2020).
[39] Part I, ch. 464, F.S.
[40] Sections 464.018 and 456.072, F.S.
[41] Section 464.012(1), F.S., and Fla. Admin. Code R. 64B9-4.002 (2021).
[42] Fla. Admin. Code R. 64B9-4.002(3) (2020).
[43] Section 456.048, F.S.
[44] Fla. Admin. Code R. 64B9-4.002 (2021). *Requirements for Licensure. See* Financial Responsibility, form number DH-MQA 1186, (Jan. 2009), incorporated by reference and *available at* http://www.flrules.org/Gateway/reference.asp?No=Ref-07539 (last visited Feb. 11, 2021)
[45] Section 464.012(3), F.S. The DOH may, by rule, also require that a copy of the protocol be filed with the DOH along with the notice required to be filed by physicians under s. 458.348, F.S.

medical care and treatment the APRN provides. An APRN, within the established framework of the written protocol, may:

- Prescribe, dispense, administer, or order any drug;[46]
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Order any medication for administration to a patient in a hospital or nursing home;
- Manage selected medical problems specified in the protocol;
- Order physical and occupational therapy;
- Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses;
- Monitor and manage patients with stable chronic diseases;
- Establish behavioral problems; and
- Medical diagnoses and treatment recommendations.[47]

An APRN who is also a certified nurse midwife[48] may, to the extent authorized by his or her established written protocol and approved by the medical staff of the health care facility he or she performs midwifery services, or the back-up physician when the delivery is performed at home, perform the following additional medical nursing functions:

- Superficial minor surgical procedures.
- Patient management during labor and delivery to include amniotomy, episiotomy, and repair.
- Ordering, initiating, and performing appropriate anesthetic procedures.
- Postpartum examination.
- Ordering appropriate medications.
- Providing family-planning services and well-woman care.
- Managing the medical care of the normal obstetrical patient and the initial care of a newborn patient.

An APRN who is a clinical nurse specialist may perform any of the following additional medical nursing acts and functions within the framework of his or her established written protocol:

- The assessment of the health status of individuals and families using methods appropriate to the population and area of practice;
- The diagnosis of human responses to actual or potential health problems;
- Planning of health promotion, disease prevention, and therapeutic intervention in collaboration with the patient;
- Implementation of therapeutic interventions based on the nurse specialist's area of expertise and within the scope of the APRN's practice, including:
    - Direct nursing care;
    - Counseling;
    - Teaching;
    - Collaboration with other licensed health care providers;
    - Coordination of health care as necessary; and

[46] Section 464.012(3)(a), F.S., requires that for the APRN to prescribe or dispense controlled substance as defined in s. 893.03, F.S., he or she must have graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area.
[47] Sections 464.012 and 464.003(2), F.S. In the case of multiple supervising physicians in the same group, an APRN must enter into a written supervisory protocol with at least one physician within the physician group practice.
[48] Section 467.003(2), F.S.

- Evaluation of the patient for the effectiveness of care.

An APRN psychiatric nurse,[49] within the framework of an established written protocol with a psychiatrist, may prescribe additional psychotropic controlled substances for the treatment of mental disorders.

When a physician enters into an established written protocol with an APRN, where the protocol calls for the APRN to perform general or specialized APRN medical acts and functions, the physician must submit a notice, within 30 days of entering into the protocol, to the BOM or Board of Osteopathic Medicine (BOOM), as appropriate; and must also notify the appropriate board within 30 days after the termination of the protocol. The notice must contain:

- The physician's name and license number;
- A statement that the physician has entered into a written protocol with ___ number of APRNs.[50]

There are no limits on the number of APRNs that a physician may have written protocol with or on the number of physicians an APRN may have a written protocols with.[51]

However, a physician who supervises APRNs in a medical office, other than the physician's primary practice location,[52] where the APRN is not under onsite or direct physician supervision, must comply with the following location limits:

- A physician who is engaged in "primary health care"[53] may not supervise more than four offices, in addition to his or her primary practice location;
- A physician who is engaged in "specialty health care"[54] may not supervise more than two offices, in addition to his or her primary practice location;
- A physician who is engaged in dermatologic or skin care services, include aesthetic skin care services other than plastic surgery, must:
  - Submit to the appropriate board the addresses of all locations, not his or her primary location, where he or she is supervising or has a written protocol with APRNs;
  - Be board certified or board eligible in dermatology or plastic surgery as recognized by the appropriate board.[55]
  - Arrange for all such locations, not the physician's primary practice, to be within 25 miles of the primary practice, or in a county that is contiguous to the county of the primary practice, but in no event may any of the locations be more than 75 miles from the primary practice; and

[49] Section 394.455(36), F.S.
[50] Section 459.025(1), F.S.
[51] *See* ss. 464.012, 458.348, and 459.025, F.S.
[52] Sections 458.348(3) and 459.025(3), F.S. An physician's "primary practice location" is the physician's address reflected on his or her profile published pursuant to s. 456.041, F.S.
[53] Sections 458.348(3)(a) and 459.025(3)(a),F.S., "Primary health care" means health care services that are commonly provided to patients without referral from another practitioner, including obstetrical and gynecological services, and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.
[54] Sections 458.348(3)(b) and 459.025(3)(b),F.S., "specialty health care" means health care services that are commonly provided to patients with a referral from another practitioner and excludes practices providing primarily dermatologic and skin care services, which include aesthetic skin care services.
[55] Sections 458.3312 and 459.0152, F.S.

- Supervise no more than one practice location other than his or her primary practice.[56]

Certified Registered Nurse Anesthetists (CRNAs)

An APRN who is also a CRNA may, to the extent authorized by his or her established written protocol with the supervising physician, at the facility in which he or she provides anesthetic services, perform any of the following:

- Determine patient health status as it relates to risk factors for anesthesia management;
- Determine the appropriate type of anesthesia;
- Order pre-anesthetic medication;
- Perform procedures used to render a patient insensible to pain during the performance of a surgical, obstetrical, therapeutic, or diagnostic procedure, including ordering and administering:
  - Regional anesthesia;
  - Spinal anesthesia;
  - General anesthesia;
  - Inhalation agents;
  - Intravenous agents; and
  - Hypnosis techniques.
- Monitor procedures indicated as pertinent to the anesthetic health care management of the patient;
- Provide life support functions during anesthesia, including:
  - Induction;
  - Intubation;
  - The use of appropriate mechanical supportive devices; and
  - The management of fluid, electrolyte, and blood component balances.
- Recognize and provide corrective action for abnormal patient responses to anesthesia;
- Recognize and treat cardiac arrhythmias while the patient is under anesthetic care;
- Participate in the management of the patient while in the recovery area, including ordering the administration of fluids and drugs; and
- Place special peripheral and central venous and arterial lines for blood sampling and monitoring, as needed.

Physician Supervision of CRNA's and Anesthesiologist Assistants (AAs) as a Condition of Participation in Medicare

As a condition of a hospital's participation in the Medicare program, a CRNA or an AA who administers anesthesia must be under the supervision of an anesthesiologist (a physician specialist) who is immediately available if needed, unless the CRNA or AA is located in a state that has opted out of the supervision requirements.[57] Florida has not opted out.

[56] Sections 458.348(3)(c) and 459.025(3)(c), F.S.
[57] 42 CFR s. 482.52.

An operating practitioner or an anesthesiologist is "immediately available" when he or she is physically located within the same area as the CRNA or AA and is not otherwise occupied in a way that prevents an immediate hands-on intervention.[58]

As of February 1, 2021, 19 states and Guam have opted out of the federal physician supervision requirement, including Arizona, Oklahoma, Iowa, Nebraska, Idaho, Minnesota, New Hampshire, New Mexico, Kansas, North Dakota, Washington, Alaska, Oregon, Montana, South Dakota, Wisconsin, California, Colorado, and Kentucky.[59] A state may opt out if the state's governor sends a letter to the federal Centers for Medicare & Medicaid Services requesting exemption from physician supervision of CRNAs. The governor's letter must attest that he or she has consulted with the state boards of medicine and nursing about issues relating to access to, and the quality of, anesthesia services in the state and has concluded that it is in the best interests of the state's citizens to opt-out of the federal physician supervision requirement. The opt-out must be consistent with state law.[60]

Physician Assistants

Physician Assistants (PAs) are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the BOM for PAs licensed under ch. 458, F.S., or the BOOM for PAs licensed under ch. 459, F.S.[61]

The Council consists of five members, appointed as follows:[62]

- The chairperson of the BOM appoints one member who is a physician and member of the BOM who supervises a PA in his or her practice;
- The chairperson of the BOOM appoints one member who is a physician and member of the BOOM who supervises a PA in his or her practice; and
- The State Surgeon General, or his or her designee, appoints three PAs licensed under chs. 458 or 459, F.S.

The Council is responsible for:[63]

- Recommending PAs to the DOH for licensure;
- Developing rules for the boards' consideration[64] regulating the use of PAs by physicians;
- Developing rules to ensure the continuity of supervision in each practice setting;
- Making recommendations to the boards on matters relating to PAs;

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[58] Centers for Medicare & Medicaid Services, Medicare Learning Network MLN Booklet, *Advanced practice Registered Nurses, Anesthesiologist Assistants, and Physician Assistants* (Apr. 2020) *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Medicare-Information-For-APRNs-AAs-PAs-Text-Only.pdf (last visited Feb. 14, 2021).

[59] American Association of Nurse Anesthetists, *Certified Registered Nurse Anesthetist Fact Sheet (Feb. 1, 2021) available at* https://www.aana.com/membership/become-a-crna/crna-fact-sheet (last visited Feb. 11, 2021).

[60] 42 CFR s. 482.52(c).

[61] Sections 458.347 and 459. 022, F.S.

[62] Sections 458.347(9) and 459. 022(9), F.S. Members of the Board of Medicine and the Board of Osteopathic Medicine are appointed by the Governor and confirmed by the Senate. *See* ss. 458.307, F.S., and 459.004, F.S., respectively.

[63] *Id.*

[64] *See* ss. 458.347(9)(c)2. and 459.022(9)(c)2., F.S.

- Addressing the concerns and problems of practicing PAs in order to improve safety in the clinical practices of PAs;[65] and
- Denying, restricting, or placing conditions on the license of a PA who fails to meet the licensing requirements.[66]

Physician Assistant Licensure

An applicant for a PA license must be at least 18 years of age. The DOH must issue a license to a person who has been certified by the Council as having met all of the following requirements:[67]

- Completed an approved PA training program;[68]
- Obtained a passing score on the National Commission on Certification of Physician Assistants (NCCPA) exam;
- Acknowledged any prior felony convictions;
- Submitted to a background screening and have no disqualifying offenses;[69]
- Acknowledged any previous revocation or denial of licensure in any state; and
- Provided a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs must renew their licenses biennially. During each biennial renewal cycle, a PA must complete 100 hours of continuing medical education or must demonstrate current certification issued by the National Commission on Certification of Physician Assistants.[70] To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially and must take a re-certification examination every 10 years.[71]

Physician Assistant Scope of Practice and Physician Supervision

A PA is licensed to perform only those medical services delegated to him or her by his or her supervising allopathic or osteopathic physician.[72] PAs may only practice under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a working relationship.[73] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[74] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[75]

Upon employment as a PA, a licensed PA must notify the DOH in writing within 30 days after such employment or after any subsequent changes of his or her supervising physician. The

[65] *Id.*
[66] Sections 458.347(9)(d) and 459. 022(9)(d), F.S.
[67] Sections 458.347(7) and 459.022(7), F.S.
[68] *See* Fla. Admin. Code R. 64B8-30.012 and 64B15.004 (2020).
[69] Sections 456.0135, F.S.
[70] Sections 458.347(7)(c) and 459.022(7)(c), F.S.
[71] National Commission on Certification of Physician Assistants, *Maintaining Certification*, *available at* https://www.nccpa.net/CertificationProcess (last visited Feb. 15, 2021).
[72] Sections 458.347(4) and 459.022(4), F.S.
[73] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[74] Fla. Admin. Code R. 64B8-30.012 and 64B15-6.010 (2020).
[75] Sections 458.347(15) and 459.022(15), F.S.

notification must include the full name, Florida medical license number, specialty, and address of the supervising physician.[76]

Supervision of a PA requires the physician to exercise responsible supervision and control and, except in cases of emergency, requires the "easy availability" or physical presence of the physician for consultation and direction of the actions of the PA. "Easy availability" is defined in current law as the ability to communicate by way of telecommunication, and the law further directs the BOM and BOOM to establish rules as to what constitutes responsible supervision of a PA.[77]

The boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[78]

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[79]

A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[80] A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the negative formulary established by the Council[81] but only under the following circumstances:
    - The PA identifies himself or herself as a PA and advises of his or her right to see a physician before the prescription is written or dispensed;

[76] Sections 458.458.347(7) and 459.022(7), F.S.
[77] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[78] Fla. Admin. Code R. 64B8-2.001, 64B8-30.001, and 64B15-6.001 (2020).
[79] *See* Sections 458.347(3) and 459.022(3), F.S.
[80] *Id.*
[81] Sections 458.347(4)(f) and 459.022(e), F.S., directs the Council to establish a negative formulary listing the medical drugs that a PA may not prescribe. The negative formulary in Florida Administrative Code Rule 64B8-30.008, and 64B15-6.0038, prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.

- The supervising physician must be registered as a dispensing practitioner[82] and have notified the DOH on an approved form of his or her intent to delegate prescriptive authority or to change prescriptive authority; and
- The PA must have completed 10 hours of continuing medical education in the specialty practice in which the PA has prescriptive authority with each licensure renewal, and three of the 10 hours must be on the safe and effective prescribing of controlled substances.

- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;[83] and
- Perform any other service that is not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[84]

Regulation of Pharmacy Establishments

Pharmacy Permitting

The Florida Pharmacy Act regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[85] The BOP is tasked with adopting rules to implement the provisions of the act and setting standards of practice within the state.[86] Any person who operates a pharmacy in Florida must have a permit. The 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.[87]
- 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.[88]
- 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.[89]
- 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.[90]
- 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.[91]

[82] *See* s. 465.0276, F.S.
[83] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.
[84] Sections 458.347(4) and 459.022(e), F.S.
[85] Chapter 465, F.S.
[86] Sections 465.005, 465.0155, and 465.022, F.S.
[87] Sections 465.003(11)(a)1. and 465.018, F.S.
[88] Sections 465.003(11)(a)2. and 465.019, F.S.
[89] Sections 465.003(11)(a)3. and 465.0193, F.S.
[90] Sections 465.003(11)(a)4. and 465.0196, F.S.
[91] Sections 465.003(11)(a)5. and 465.0197, F.S.

- 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.[92]
- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[93]

A pharmacy must pass an on-site inspection for a permit to be issued,[94] and the permit is valid only for the name and address to which it is issued.[95]

Centralized Prescription Filling

Section 465.003(16), F.S., defines the term "centralized prescription filling" as the filling (measuring the medicine and putting the right dosage into a bottle) 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.

Pharmacies acting as the central-fill pharmacy must have the same owner as the originating pharmacy (where the prescription is initially presented) or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.[96]

Prescription Department Managers[97]

A prescription department manager is responsible for maintaining all drug records, providing for the security of the prescription department, and ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy. A pharmacist may only serve as the prescription department manager of one pharmacy location. However, the BOP may grant an exception based on circumstances, such as the proximity of the pharmacy locations and the workload of the pharmacist.

All community, internet, special parenteral and enteral, special closed system, nuclear and, if applicable, special sterile compounding pharmacy permittees must continuously maintain a designated prescription department manager who is a licensed pharmacist at all times the pharmacy is open and in operation.

[92] Section 465.0158, F.S.
[93] Fla. Admin. Code R. 64B16-2.100 and 64B16-28.802 (2020). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.
[94] *Id.*
[95] Fla. Admin. Code R. 64B16-28.100 (2020).
[96] Fla. Admin. Code R. 64B16-28.450(2) (2020).
[97] Fla. Admin. Code R. 64B16-27.450 (2020).

Regulation of Pharmacists

Pharmacist Licensure Requirements

To be licensed as a pharmacist in Florida, a person must:[98]

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[99]
- Have completed a BOP-approved internship; and
- Successfully complete the BOP-approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial licensure renewal period.[100] Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of their renewal.[101] Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for their renewal.[102]

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:[103]

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of a medicinal drug;
- Consultation concerning therapeutic values and interactions of patented or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy;
- Reviewing, and making recommendations regarding the patient's drug therapy and health care status in communication with the patient's prescribing health care provider as authorized by the patient;
- Initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement;[104]
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[105]
- Administering epinephrine injections;[106]

[98] Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. See s. 465.0075, F.S.
[99] 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 BOP-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.
[100] Section 465.009, F.S.
[101] Section 465.009(6), F.S.
[102] Section 465.1893, F.S.
[103] Section 465.003(13), F.S.
[104] Section 465.1865, F.S.
[105] *See* s. 465.189, F.S.
[106] *Id.*

- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;[107]
- Administering antipsychotic medications by injection;[108]
- Ordering and dispensing over-the-counter drugs approved by the FDA;[109]
- Ordering and dispensing within his or her professional judgment, subject to specified conditions:[110]
  - Certain oral analgesics for mild to moderate pain;
  - Anti-nausea preparations;
  - Certain antihistamines and decongestants;
  - Certain topical antifungal/antibacterial;
  - Topical anti-inflammatory preparations containing an amount of hydrocortisone not exceeding 2.5 percent;
  - Otic antifungal/antibacterial;
  - Salicylic acid;
  - Vitamins;
  - Ophthalmics;
  - Certain histamine H2 antagonists;
  - Acne products; and
  - Topical antivirals for herpes simplex infections of the lips.

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.[111]

Only a pharmacist or registered pharmacy intern may:[112]
- 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.[113] A pharmacist must be personally available at the time of dispensing.[114] A prescription department is considered closed if a Florida-

[107] A Class III institutional pharmacy are those pharmacies affiliated with a hospital. *See* s. 465.019(2)(d), F.S.
[108] Section 465.1893, F.S.
[109] Section 465.186, F.S.
[110] Fla. Admin. Code R. 64B16-27.220 (2020).
[111] Section 465.003(13), F.S.
[112] Fla. Admin. Code R. 64B16-27.1001(1)-(2) (2020). 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.
[113] Fla. Admin. Code R. 64B16-27.1001(3) (2020).
[114] Fla. Admin. Code R. 64B16-27.1001(4) (2020).

licensed pharmacist is not present and on duty unless the pharmacist leaves the prescription department to:[115]

- 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.

Pharmacists with a Broader Scope of Practice

There are three categories of pharmacists that have broader scopes of practice than other pharmacists:

- The consultant pharmacist;[116]
- The pharmacist working under a collaborative pharmacy practice agreement with a physician to treat chronic health conditions;[117] and
- A pharmacist authorized to test or screen for and treat minor, nonchronic health conditions.[118]

Consultant Pharmacists

A consultant pharmacist works within the framework of a written collaborative practice agreement between the pharmacist and any of the following who are authorized to prescribe medicinal drugs:[119]

- A health care facility medical director;
- A medical, osteopathic, or podiatric physician; or
- A dentist.[120]

The consultant pharmacist may provide medication management services only in the following health care facilities:[121]

- Ambulatory surgical centers;
- Hospitals;
- Alcohol or chemical dependency treatment centers;
- Inpatient hospices;
- Nursing homes;
- Ambulatory care centers; or
- Nursing homes within a continuing care facility.

A consultant pharmacist may only provide medication management services, conduct patient assessments, and order and evaluate laboratory or clinical testing for patients of the health care practitioner with whom the consultant pharmacist has a written collaborative practice

[115] Section 465.003(11)(b), F.S.
[116] Sections 465.003(3) and 465.0125, F.S.
[117] Section 465.1865, F.S.
[118] Section 465.1895, F.S.
[119] Section 465.0125, F.S.
[120] *Id.*
[121] Section 465.1865, F.S.

agreement.[122] The written collaborative practice agreement must outline the circumstances under which the consultant pharmacist may:

- Order and evaluate any laboratory or clinical tests to promote and evaluate patient health and wellness, and monitor drug therapy and treatment outcomes.
- Conduct patient assessments as appropriate to evaluate and monitor drug therapy.
- Modify or discontinue medicinal drugs as outlined in the agreed upon patient-specific order or preapproved treatment protocol under the direction of a physician. However, a consultant pharmacist may not modify or discontinue medicinal drugs prescribed by a health care practitioner who does not have a written collaborative practice agreement with the consultant pharmacist.
- Administer medicinal drugs.

A consultant pharmacist must maintain drug, patient care, and quality assurance records and, with the collaborating practitioner, must maintain written collaborative practice agreements that must be available upon request from or upon inspection by the DOH. A consultant pharmacist is not authorized to diagnose any disease or condition.[123]

Collaborative Pharmacy Practice for Chronic Health Conditions

A collaborative pharmacy practice agreement is a written agreement between a pharmacist who is certified by the BOP and a medical or osteopathic physician in which the collaborating physician authorizes a pharmacist to provide specified patient care to the physician's patients named in the agreement. A chronic health condition is defined as:

- Arthritis;
- Asthma;
- Chronic obstructive pulmonary diseases;
- Type 2 diabetes;
- Human immunodeficiency virus or acquired immune deficiency syndrome;
- Obesity; or
- Any other chronic condition adopted in rule by the BOP in consultation with the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM).[124]

The terms and conditions of the collaborative pharmacy practice agreement must be appropriate to the pharmacist's training, and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A collaborative pharmacy practice agreement must include the following:

- The name(s) of the collaborating physician's patient or patients for whom a pharmacist may provide services;
- Each chronic health condition to be collaboratively managed;
- Specific medicinal drug or drugs to be managed by the pharmacist for each patient;
- Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests;

[122] Section 465.0125(1), F.S.
[123] Section 465.0125(1)(c)-(d), F.S.
[124] Section 465.1865(1)(a)-(b), F.S.

- Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur;
- Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures, including procedures for patient notification and medical records transfers; and
- A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.[125]

A pharmacist may not modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a collaborative pharmacy practice agreement. A physician may not delegate the authority to initiate or prescribe a controlled substance to a pharmacist.[126]

Testing or Screening for and Treatment of Minor, Nonchronic Health Conditions

The scope of practice for a pharmacist, within the framework of an established written protocol with a supervising medical or osteopathic physician, may also include the testing or screening for and treatment of minor, nonchronic health conditions, which are defined as short-term conditions that are generally managed with minimal treatment or self-care, and include:

- Influenza;
- Streptococcus;
- Lice;
- Skin conditions such as ring worm and athletes foot; and
- Minor, uncomplicated infections.[127]

The written protocol between a supervising physician and a pharmacist who has been certified by the BOP to provide the services listed above must include particular terms and conditions imposed by the supervising physician. The terms and conditions must be appropriate to the pharmacist's training. A pharmacist who enters into such a protocol with a supervising physician must submit the protocol to the BOP. At a minimum, the protocol must include:

- Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.
- The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.
- The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.
- A process and schedule for the physician to review the pharmacist's actions under the protocol.
- A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.

[125] Section 465.1865(3)(a), F.S.
[126] Section 465.1865(4)-(5), F.S.
[127] Section 465.1895(1), F.S.

- Any other requirements as established by the BOP in consultation with the BOM and the BOOM.[128]

A pharmacist authorized to test and screen for and treat minor, nonchronic conditions under a protocol must provide evidence of current certification by the BOP to his or her supervising physician. A supervising physician must review the pharmacist's actions in accordance with the protocol.[129]

Pharmacist Supervision of Registered Pharmacy Interns

A person seeking licensure as a pharmacist must submit proof that he or she has completed an internship program.[130] To become a registered pharmacy intern, a person must be certified by the BOP and enrolled in an intern program at an accredited school or college of pharmacy or as a graduate of an accredited school or college of pharmacy and not yet licensed as a pharmacist in Florida.[131]

A pharmacist is responsible for any delegated act performed by a registered pharmacy intern employed or supervised by the pharmacist.[132] A registered intern may fill, compound, or dispense prescriptions or medicinal drugs only under the "direct and immediate personal supervision" of a licensed pharmacist.[133]

Regulation of Pharmacy Technicians

Pharmacy Technician 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.[134] A person must register with the DOH to practice as a pharmacy technician. To register, an individual must:[135]

- Be at least 17 years of age;
- Submit an application and pay an application fee; and
- Complete a BOP-approved pharmacy technician training program.[136]

The pharmacy technician must renew the registration biennially. For each renewal cycle, a pharmacy technician must complete 20 continuing education hours.[137]

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[128] Section 465.1895(5)(a), F.S.
[129] Section 465.1895(5)(b), F.S.
[130] Section 465.007(1)(c), F.S.
[131] Section 465.013, F.S. *See also* Fla. Admin. Code R. 64B16-26.2032 (2020) (U.S. pharmacy students/graduates); Fla. Admin. Code R. 64B16-26.2033 (2020) (foreign pharmacy graduates).
[132] Fla. Admin. Code R. 64B16-27.430 (2020).
[133] Sections 465.015(1)(b) and (2)(b), F.S.
[134] Section 465.014(1), F.S.
[135] Section 465.014(2), F.S.
[136] 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 pharmacists or received certification from an accredited pharmacy technician program.
[137] Section 465.014(6), F.S.

Pharmacy Technician Training Programs

The BOP has preapproved certain training programs that have been accredited by certain accreditation agencies or provided by a branch of the United States Armed Forces.[138] The BOP 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:

- Introduction to pharmacy and health care systems;
- Confidentiality;
- Patient rights and the federal 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. [139]

The training program must provide the BOP with educational and professional background of its faculty.[140] A licensed pharmacist or registered pharmacy technician with appropriate expertise must be involved with planning and instruction and must supervise learning experiences.[141]

The BOP 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. [142] 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.[143] The employer-based training program must:

- 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. [144]

[138] Fla. Admin. Code R. 64B16-26.351(1)-(2) (2020).
[139] Fla. Admin. Code R. 64B16-26.351(3)(b) (2020).
[140] Fla. Admin. Code R. 64B16-26.351(3)(e) (2020).
[141] *Id.*
[142] Fla. Admin. Code R. 64B16-26.351(4) (2020).
[143] *Id.*
[144] *Id.*

Pharmacy Technician 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.[145] The BOP specifies, by rule, certain acts that registered pharmacy technicians are prohibited from performing, which include:

- 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.[146]

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.[147]

Pharmacist Supervision of Pharmacy Technicians

A licensed pharmacist must directly supervise the performance of a registered pharmacy technician[148] and is responsible for acts performed by persons under his or her supervision.[149] A pharmacist may use technological means to communicate with or observe a registered pharmacy technician who is performing delegated tasks.[150]

Florida law prohibits a pharmacist from supervising more than one registered pharmacy technician, unless otherwise permitted by guidelines adopted by the BOP.[151] The guidelines include the following restrictions:[152]

[145] Section 465.014(1), F.S.
[146] Fla. Admin. Code R. 64B16-27.420(2) (2020).
[147] Fla. Admin. Code R. 64B16-27.100(2) (2020).
[148] 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 (Fla. Admin. Code R. 64B16-27.4001(2)(a))
[149] Fla. Admin. Code R. 64B16-27.1001(7) (2020).
[150] Fla. Admin. Code R. 64B16-27.4001(2)(b) (2020).
[151] Section 465.014(1), F.S.
[152] Fla. Admin. Code R. 64B16-27.410 (2020).

- 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 six registered pharmacy technicians.
- In a pharmacy that does not dispense medicinal drugs, a pharmacist may supervise up to eight 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[153] of the pharmacy from which medicinal drugs are not dispensed, a pharmacist may supervise up to eight registered pharmacy technicians.

The Federal Health Insurance Portability and Accountability Act (HIPAA)[154]

HIPAA Privacy Rule[155]

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. The HIPAA Privacy Rule sets national standards for when protected health information (PHI) may be used and disclosed.

Only certain entities and their business associates are subject to HIPAA's provisions. These "covered entities" include: health plans, health care providers; and health care clearinghouses.

The Privacy Rule gives individuals privacy and confidentiality rights with respect to their protected PHI, including rights to examine and obtain a copy of their health records in the form and manner they request, and to ask for corrections to their information. Also, the Privacy Rule permits the use and disclosure of health information needed for patient care and other important purposes.

The Privacy Rule protects PHI held or transmitted by a covered entity or its business associate, in any form, whether electronic, paper, or verbal. PHI includes information that relates to any of the following:

- The individual's past, present, or future physical or mental health or condition;
- The provision of health care to the individual; or
- The past, present, or future payment for the provision of health care to the individual.

HIPAA Security Rule[156]

The HIPAA Security Rule specifies safeguards that covered entities and their business associates must implement to protect electronic PHI (ePHI) confidentiality, integrity, and availability.

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[153] 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.

[154] Centers for Medicare & Medicaid Services, Medicare Learning Network Fact Sheet, HIPAA Basics for Providers: Privacy, Security, and Breach Notification Rules (Sept. 2018) *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/HIPAAPrivacyandSecurityTextOnly.pdf (last visited Feb. 14, 2021).

[155] 45 C.F.R. Part 160 and Subparts A and E of Part 164.

[156] 45 C.F.R. Part 160 and Subparts A and C of Part 164.

Covered entities and business associates must develop and implement reasonable and appropriate security measures through policies and procedures to protect the security of ePHI they create, receive, maintain, or transmit. Each entity must analyze the risks to ePHI in its environment and create solutions appropriate for its own situation. What is reasonable and appropriate depends on the nature of the entity's business as well as its size, complexity, and resources.

Under the Security Rule, covered entities must:

- Ensure the confidentiality, integrity, and availability of all ePHI they create, receive, maintain, or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the ePHI;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce.

When developing and implementing Security Rule compliant safeguards, covered entities and their business associates may consider all of the following:

- Size, complexity, and capabilities;
- Technical, hardware, and software infrastructure;
- The costs of security measures; and
- The likelihood and possible impact of risks to ePHI.

Covered entities must review and modify security measures to continue protecting ePHI in a changing environment.

HIPAA Breach Notification Rule[157]

The HIPAA Breach Notification Rule requires covered entities to notify affected individuals; the federal HHS; and, in some cases, the media of a breach of unsecured PHI. Generally, a breach is an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of PHI.

The impermissible use or disclosure of PHI is presumed to be a breach unless the covered entity demonstrates a low probability that the PHI has been compromised based on a risk assessment of, at a minimum, the following factors:

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
- The unauthorized person who used the PHI or to whom the disclosure was made;
- Whether the PHI was actually acquired or viewed; and
- The extent to which the risk to the PHI has been mitigated.

Most notifications must be provided without unreasonable delay and no later than 60 days following the breach discovery. Notifications of smaller breaches affecting fewer than 500 individuals may be submitted to HHS annually. The Breach Notification Rule also requires business associates of covered entities to notify the covered entity of breaches at or by the business associate.

[157] 45 C.F.R. Subpart D.

Notification of Enforcement Discretion during Public Health Emergency

Covered health care providers acting in good faith will not be subject to penalties for violations of the HIPAA Privacy Rule, the HIPAA Security Rule, or the HIPAA Breach Notification Rule that occur in the good faith provision of telehealth during the public health emergency.[158]

On March 17, 2020, the federal Department of Health & Human Services (HHS) Office for Civil Rights (OCR) issued a Notification of Enforcement of Discretion, meaning that the OCR may exercise its enforcement discretion and not pursue penalties for HIPPA violations against health care providers that serve patients through everyday communication technologies during the public health emergency.[159] If a provider follows the terms of the Notification and any applicable OCR guidance, it will not face HIPAA penalties if it experiences a hack that exposes protected health information from a telehealth session.[160]

Jurisdiction and Venue for Telehealth-related Actions[161]

For purposes of s. 456.47, F.S., any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the DOH, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County.

III. Effect of Proposed Changes:

Section 1 amends s. 409.908, F.S., to require the AHCA to reimburse Medicaid providers for the use of telehealth, including services provided in real time, store-and-forward technologies, and remote patient monitoring services, subject to any limitations or directions provided in the General Appropriations Act. Currently, Medicaid health plans have broad flexibility in covering telemedicine services, including remote patient monitoring and store-and-forward services. Throughout the duration of the public health emergency, the AHCA has expanded services under the fee-for-service delivery system to cover store-and-forward and remote patient monitoring modalities rendered by licensed physicians, APRNs, and PAs functioning within their scope of practice.

The bill requires providers to ensure that such technologies are medically necessary and performed within a provider's scope of practice and within applicable supervision requirements. The bill requires providers to document the use of telehealth in the patient's medical record or progress notes. The AHCA already requires this of providers.

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[158] U.S. Department for Health and Human Services Office for Civil Rights, *FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency* (Mar. 2020) *available at* https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf (Feb. 14, 2021).

[159] Press Release, U.S. Department of Health and Human Services, *OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency* (Mar. 17, 2021) *available at* https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html (last visited Feb. 14, 2021).

[160] U.S. Department for Health and Human Services Office for Civil Rights, *FAQs on Telehealth and HIPAA during the COVID-10 nationwide public health emergency* (Mar. 2020) *available at* https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf (Feb. 14, 2021).

[161] Section 456.47(5), F.S.

The bill authorizes out-of-state providers who are registered under section 456.47(4), F.S., and enrolled in Florida Medicaid as an out-of-state provider to be reimbursed for telehealth services provided to recipients in this state.

The reimbursements required and authorized in Section 1 do not cover the purchase of telecommunications equipment used for the provision of telehealth, such as computers, tablets, or smartphones.

Section 2 amends s. 456.47, F.S., to expand the definition of "telehealth" to include:

- A telehealth provider's supervision of health care services through the use of synchronous and asynchronous telecommunications technology.
- Telephone calls, emails, fax transmissions, and other nonpublic-facing telecommunications. Under current law, audio-only telephone calls, email messages, and fax transmissions are explicitly excluded from the definition of telehealth.

Section 2 authorizes a telehealth provider,[162] acting within the scope of his or her practice, to prescribe controlled substances listed in Schedule III, Schedule IV, and Schedule V of s. 893.03, F.S. The telehealth provider must also comply with chapter 893 by consulting and reporting to the Prescription Drug Monitoring Program database. This change removes the prohibition on prescribing controlled substances via telehealth.[163]

Section 2 authorizes a non-physician health care practitioner,[164] including, but not limited to, an APRN, a CRNA, or a PA, who is required to maintain a formal supervisory relationship with a physician, to satisfy that requirement through telehealth. This would authorize the synchronous and asynchronous remote supervision of non-physician health care practitioners by in-state physicians.

Section 2 also authorizes an out-of-state physician registered to provide telehealth services in Florida to use telehealth to engage in a formal supervisory relationship with a nonphysician health care practitioner in this state, including, but not limited to an APRN, a CRNA, or a PA. Such supervision may not be for the provision of any health care service that requires direct supervision under Florida law or rules.

The bill's language providing that "such supervision may not be for the provision of any health care service that requires direct supervision" in lines 164-166 and the exclusion of that provision at line 153 could be interpreted to mean that lines 148-153 authorize the synchronous and asynchronous remote supervision of non-physician health care practitioners by in-state

[162] Section 456.47(1)(b), F.S. defines the term "telehealth provider" as any individual who provides health care and related services using telehealth and who is licensed or certified under s. 393.17; part III of chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part III, part IV, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; who is licensed under a multistate health care licensure compact of which Florida is a member state; or who is registered under and complies with subsection (4).

[163] Section 456.47(2)(c).

[164] Section 456.001(4) defines the term "health care practitioner" for purposes of ch. 456, as any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part I or part II of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

physicians through telehealth, regardless of whether direct supervision is required elsewhere in the statutes or in rule.[165]

SB 700 does not provide guidance as to what constitutes a "formal" supervisory relationship and certain supervisory relationships may be required by federal law or federal or state rules. Under the Florida Statutes, the following practitioners may also be affected in their practice or in the provision of specified services:

- Anesthesiologist Assistants (ss. 458.3475 and 459.023, F.S.)
- Emergency Medical Technicians (ss. 458.348 and 459.025, F.S.)
- Paramedics (ss. 458.348 and 459.025, F.S.)
- Any practitioner authorized to perform electrolysis (ss. 458.348 and 459.025, F.S.)
- Medical Assistants (s. 458.3485, F.S.)
- Certified Chiropractic Physician Assistants under supervision of a licensed chiropractic physician (s. 460.4165, F.S.)
- Certified Podiatric X-ray Assistants (ss. 461.0135 and 468.302, F.S.)
- Basic X-ray Machine Operator-podiatric Medicine (ss. 461.0135 and 468.302, F.S.)
- Retired Volunteer Nurses (s. 464.0205, F.S.)
- Midwifes providing collaborative prenatal and postpartal care to pregnant women not at low risk in their pregnancy, labor, and delivery (s. 467.015, F.S.)
- Laryngectomized individuals rendering guidance and instruction to other laryngectomized individuals. (s. 468.1115, F.S.)
- Optician Apprentices (s. 484.007, F.S.)
- Pharmacists (ch. 465, F.S. *See* Present Situation of this analysis.)

Under s. 456.47(4)(e), F.S., a registered out-of-state telehealth provider must maintain professional liability coverage or financial responsibility that includes coverage or responsibility for "telehealth services provided to patients" not located in the provider's home state. Under the bill, it is unclear if such coverage or responsibility would extend to services provided to patients not located in the provider's home state if those services were provided by a practitioner under the remote physician supervision of a registered-out-of-state telehealth provider.

For purposes of s. 456.47, F.S., any act that constitutes the delivery of health care services is deemed to occur at the place where the patient is located at the time the act is performed or in the patient's county of residence. Venue for a civil or administrative action initiated by the DOH, the appropriate board, or a patient who receives telehealth services from an out-of-state telehealth provider may be located in the patient's county of residence or in Leon County. These provisions would apply to in-state and out-of-state physicians who remotely supervise health care practitioners in Florida.

The bill does not define the term "physician" as an allopathic physician or osteopathic physician, so the term would include chiropractic physicians and podiatric physicians.

[165] The *expressio unius est exclusion alterius* principle of statutory construction suggests that when one or more things of a class are expressly mentioned, others of the same class are excluded.

Sections 3 and 4 amend ss. 458.347 and 459.022, F.S., the practice acts for allopathic and osteopathic PAs, respectively, to revise the definitions of the terms "supervision" and "easy availability." In both sections, the bill replaces "telecommunication" with "telehealth as defined in s. 456.47(1), F.S.," to incorporate the definition of the term as amended by section 2 of this bill.

Section 5 amends **s.** 465.003, F.S., to create a new type of pharmacy establishment. Section 5 expands the definition of "pharmacy" to include "remote-site pharmacies." The term "remote-site pharmacy" or "remote site" is defined as every location where medicinal drugs are compounded or dispensed by a registered pharmacy technician who is remotely supervised by an off-site pharmacist acting in the capacity of a prescription department manager.

Section 5 also clarifies that an off-site pharmacist, acting in the capacity of a prescription department manager, is not prohibited from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

Section 6 amends s. 465.014, F.S., to authorize a registered pharmacy technician operating under the remote supervision of an off-site pharmacist under s. 456.0198, F.S., to compound and dispense medicinal drugs under such remote supervision.

Section 6 also specifies that a licensed pharmacist may supervise more than one registered pharmacy technician as provided in s. 465.0198, F.S., as created in section 8 of this bill.

Section 7 amends s. 465.015, F.S., to conform provisions to changes made by the act and make lawful the remote supervision of a registered pharmacy technician at a remote-site pharmacy.

Section 8 creates s. 465.0198, F.S., and establishes the permitting of and regulation of remote-site pharmacies.

The term "supervising pharmacy" is defined as a pharmacy licensed in this state which employs a licensed pharmacist who remotely supervises a registered pharmacy technician at a remote-site pharmacy.

The bill requires a person desiring a permit to operate a remote-site pharmacy to apply to the DOH. If the BOP certifies that the application complies with the laws and rules of the BOP,[166] the DOH must issue the permit. To obtain a permit, a licensed pharmacist or a consultant pharmacist must be designated as the prescription department manager responsible for the oversight of the remote site. The permittee must notify the DOH within 10 days after any change of the prescription department manager.

A remote-site pharmacy must:
- Be jointly owned 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 45 days.

[166] The BOP has rulemaking authority under s. 465.005, F.S., to implement the provisions of chapter 465.

- Display a sign visible to the public indicating that the location is a remote-site pharmacy and that the facility is under 24-hour video surveillance.
- Maintain a policies and procedures manual, which must be made available to the BOP or its agent upon request. The manual must contain, at a minimum, 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 and counseling its patients,
  - The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site,
  - 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's operation,
  - The procedures for use of the state prescription drug monitoring program by the prescription department manager before he or she may authorize the dispensing of any controlled substance,
  - The procedures for maintaining a perpetual inventory of the controlled substances listed in s. 893.03(2), F.S., and
  - The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site.

The bill specifies that a remote-site pharmacy is not considered a pharmacy location for purposes of network access in managed care programs. The bill authorizes a remote-site pharmacy to store, hold, or dispense any medicinal drug, but prohibits centralized prescription filling. The bill requires a prescription department manager to visit the remote site, based on a schedule adopted by the BOP, to inspect the pharmacy, address personnel matters, and provide clinical services for patients. The BOP must adopt a rule that defines such a schedule.

A registered pharmacist may serve as the prescription department manager for up to three remote-site pharmacies that are under common control of the same supervising pharmacy.

Section 9 amends s. 465.022, F.S., to conform to changes made by the bill and to make an exception for registered pharmacists to serve as the prescription department manager for more than one location (remote-site pharmacies) as authorized under s. 465.0198, F.S., as created by section 8.

Section 10 amends s. 465.0265, F.S., to conform to changes made by the bill and clarify that provisions relating to centralized prescription filling do not apply to remote-site pharmacies. Under s. 456.0198(7), F.S., as created by section 8, remote-site pharmacies are prohibited from performing centralized prescription filling.

Section 11 amends s. 893.05, F.S., to prohibit telehealth providers from prescribing Schedule I or Schedule II controlled substances through telehealth. Currently, telehealth providers may prescribe Schedule II drugs through telehealth only for the treatment of a psychiatric disorder, inpatient treatment at a hospital, the treatment of a patient receiving hospice services, or the

treatment of a resident in a nursing home facility.[167] No provider may prescribe a Schedule I drug.

Section 12 provides an effective date of July 1, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill has an indeterminate fiscal impact on the private sector.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the AHCA, which will be responsible for reimbursing for specified telehealth services covered under Florida Medicaid. The bill also has an indeterminate fiscal impact on the DOH, which will be responsible for the permitting and regulation of remote-site pharmacies. The supervision requirements in the bill could require the DOH and its applicable boards to update rules. At this time, neither the AHCA nor the DOH has provided a bill analysis.

[167] Section 456.47(2)(c), F.S.

VI. Technical Deficiencies:

SB 700 authorizes physicians to use telehealth to engage in formal supervisory relationships with nonphysician health care practitioners, but it does not provide guidance as to what constitutes a "formal" supervisory relationship.

"Formal supervisory relationships" are referenced twice in the Florida Statutes. Sections 458.348 and 459.025, F.S., directly mention the formal supervisory relationship between an emergency medical technician or a paramedic and medical or osteopathic physicians, respectively. In that situation, the physician must submit written notice of the relationship to the BOM or the BOOM, as applicable. The notice must contain the following statement:

> "I, (name and professional license number of physician) , of (address of physician) have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with (number of persons) emergency medical technician(s), (number of persons) paramedic(s), or (number of persons) advanced practice registered nurse(s)."

Those sections suggest that a formal supervisory relationship is a relationship that exists in writing and is reported to the appropriate board. The bill should be amended to clarify what constitutes a formal supervisory relationship between a physician and a health care practitioner.

Section 11 of the bill amends s. 893.05, F.S., to prohibit telehealth providers from prescribing through telehealth a Schedule I or Schedule II controlled substance. This prohibition should be relocated to subsection (2) of section 456.47(2), F.S., where the provision of health care services using telehealth is addressed.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.908, 456.47, 458.347, 459.022, 465.003, 465.014, 465.015, 465.022, 465.0265, and 893.05.

This bill creates section 465.0198 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.