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By the Committee on Health Policy; and Senator Rodriguez

588-02182-21 2021700c1

A bill to be entitled An act relating to telehealth; amending s. 409.908, F.S.; requiring the Agency for Health Care Administration to reimburse the use of telehealth services under certain circumstances and subject to certain limitations; requiring providers to include certain documentation in patient records and notes; authorizing certain out-of-state providers to receive reimbursement for telehealth services; providing an exception; amending s. 456.47, F.S.; revising the definition of the term "telehealth"; authorizing telehealth providers to prescribe specified controlled substances through telehealth under certain circumstances; authorizing nonphysician health care practitioners to satisfy a certain supervision requirement through telehealth; amending ss. 458.347 and 459.022, F.S.; revising the definition of the term "supervision"; amending s. 465.003, F.S.; revising the definition of the term "pharmacy"; revising construction of the term "not present and on duty"; amending s. 465.014, F.S.; authorizing registered pharmacy technicians to compound and dispense medicinal drugs under certain circumstances; providing an exception to certain supervision limitations; amending s. 465.015, F.S.; providing applicability; exempting certain registered pharmacy technicians from specified prohibitions; creating s. 465.0198, F.S.; defining the term "supervising pharmacy"; providing for the permitting of remote-site pharmacies;

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requiring a licensed or consultant pharmacist to serve as the prescription department manager of a remote site; requiring remote-site pharmacies to notify the Department of Health of a change in the pharmacy's prescription department manager within a specified timeframe; providing requirements for remote-site pharmacies; providing that remote-site pharmacies are not considered pharmacy locations for purposes of network access in managed care programs; authorizing remote-site pharmacies to store, hold, and dispense medicinal drugs; prohibiting remote-site pharmacies from performing centralized prescription filling; requiring prescription department managers to visit remote sites, based on a certain schedule, to perform specified tasks; authorizing registered pharmacists to serve as prescription department managers for up to three remote-site pharmacies under certain circumstances; amending s. 465.022, F.S.; exempting registered pharmacists serving as prescription department managers for remote-site pharmacies from certain practice limitations; amending s. 465.0265, F.S.; providing applicability; amending s. 465.1893, F.S.; providing additional long-acting medications pharmacists may administer under certain circumstances; revising requirements for a continuing education course such pharmacists must complete; amending s. 468.1225, F.S.; revising minimum procedures and equipment requirements for fitting and selling hearing aids; amending s. 468.1265, F.S.;

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revising a prohibition on the sale or distribution of hearing aids through the mail; amending s. 484.0501, F.S.; revising minimum procedures and equipment requirements for fitting and selling hearing aids; amending s. 484.054, F.S.; revising a prohibition on the sale or distribution of hearing aids through the mail; amending s. 893.05, F.S.; prohibiting telehealth providers from prescribing specified controlled substances through telehealth; providing an effective date.

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Be It Enacted by the Legislature of the State of Florida:

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Section 1. Present subsections (22) through (26) of section 409.908, Florida Statutes, are redesignated as subsections (23) through (27), respectively, and a new subsection (22) is added to that section, to read:

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409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate

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for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

- (22) Subject to any limitations or directions provided in the General Appropriations Act, the agency shall reimburse the use of telehealth as defined by s. 456.47, to include services provided in real time, services provided using store-and-forward technologies, and remote patient monitoring services to the extent that these technologies are available.
- (a) Providers using any modality described in this subsection must ensure that treatment services are medically necessary and performed within a provider's scope of practice and any applicable supervision requirements.
- (b) Providers must include documentation regarding the use of telehealth in the medical record or progress notes for each encounter with a recipient.

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(c) Out-of-state providers who are registered under s.

456.47(4) and enrolled in Florida Medicaid as an out-of-state provider may be reimbursed for telehealth services provided to recipients in this state.

(d) Reimbursement under this subsection does not cover the purchase of any general telecommunications equipment that is not specific to or used solely for the provision of telehealth, including, but not limited to, computers, tablets, cell phones, smartphones, or any other similar equipment or device.

Section 2. Paragraph (a) of subsection (1) and paragraph (c) of subsection (2) of section 456.47, Florida Statutes, are amended, and paragraph (f) is added to subsection (2) of that section, to read:

456.47 Use of telehealth to provide services.

- (1) DEFINITIONS.—As used in this section, the term:
- (a) "Telehealth" means the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide or supervise the provision of 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 includes does not include audio-only telephone calls, personal e-mail messages, or facsimile transmissions, and any other nonpublic-facing telecommunications technology.
 - (2) PRACTICE STANDARDS.—
- (c) A telehealth provider, acting within the scope of his or her practice and in accordance with chapter 893, may not use telehealth to prescribe a controlled substance <u>listed in</u>

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Schedule III, Schedule IV, or Schedule V of s. 893.03 unless the controlled substance is prescribed for the following:

- 1. The treatment of a psychiatric disorder;
- 2. Inpatient treatment at a hospital licensed under chapter
 150 395;
 - 3. The treatment of a patient receiving hospice services as defined in s. 400.601; or
 - 4. The treatment of a resident of a nursing home facility as defined in s. 400.021.
 - (f) A nonphysician health care practitioner, including, but not limited to, an advanced practice registered nurse, a certified registered nurse anesthetist, or a physician assistant, who is required to maintain a formal supervisory relationship with a physician may satisfy such requirement through telehealth.

Section 3. Paragraph (f) of subsection (2) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.-

- (2) DEFINITIONS.—As used in this section:
- (f) "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 telehealth as defined in s. 456.47(1) telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.
 - Section 4. Paragraph (f) of subsection (2) of section

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459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.-

- (2) DEFINITIONS.—As used in this section:
- (f) "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 telehealth as defined in s. 456.47(1) telecommunication. The boards shall establish rules as to what constitutes responsible supervision of the physician assistant.

Section 5. Subsection (11) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

- (11) (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy, and a remote-site pharmacy.
- 1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- 2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
- 3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification

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of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
- 5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).
- 6. The term "remote-site pharmacy" or "remote site" includes 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.
- (b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" <u>may</u> shall not be construed to prevent <u>any of the following:</u>
- $\underline{1.}$ A pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers.
 - 2. A pharmacist from, attending to personal hygiene needs.

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3. A pharmacist from, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

4. An off-site pharmacist, acting in the capacity of a prescription department manager, from remotely supervising a registered pharmacy technician at a remote-site pharmacy.

Section 6. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13), and a registered pharmacy technician operating under remote supervision of an off-site pharmacist under s. 465.0198 may compound and dispense medicinal drugs under such supervision. All such delegated acts must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision. A registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician, except as provided in s. 465.0198 or unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or

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permittees in determining the circumstances under which a licensed pharmacist may supervise more than one pharmacy technician.

Section 7. Paragraph (b) of subsection (1) and paragraph (b) of subsection (2) of section 465.015, Florida Statutes, are amended to read:

465.015 Violations and penalties.-

- (1) It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:
- (b) In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs. This paragraph does not apply to any person who owns, operates, maintains, opens, establishes, conducts, or has charge of a remote site pursuant to s. 465.0198.
 - (2) It is unlawful for any person:
- (b) To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist, or is not a registered pharmacy technician at a remote-site pharmacy acting under remote supervision of a licensed pharmacist pursuant to s. 465.0198.

Section 8. Section 465.0198, Florida Statutes, is created to read:

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465.0198 Remote-site pharmacy permits.

- (1) As used in this section, the term "supervising pharmacy" means a pharmacy licensed in this state which employs a licensed pharmacist who remotely supervises a registered pharmacy technician at a remote-site pharmacy.
- (2) Any person desiring a permit to operate a remote-site pharmacy must apply to the department. If the board certifies that the application complies with the laws and rules of the board, the department must issue the permit. A permit may not be issued unless a licensed pharmacist or consultant pharmacist is designated as the prescription department manager responsible for the oversight of the remote site. The permittee must notify the department within 10 days after any change of the prescription department manager.
- (3) A remote-site pharmacy must comply with all of the following:
- (a) Be jointly owned by or operated under a contract with a supervising pharmacy.
- (b) Maintain a video surveillance system that records continuously 24 hours per day and retain video surveillance recordings for at least 45 days.
- (c) 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.
- (d) Maintain a policies and procedures manual, which must be made available to the board or its agent upon request, and must include, but need not be limited to, all of the following:
- 1. A description of how the pharmacy will comply with federal and state laws and rules.

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2. The procedures for supervising the remote site and counseling its patients.

- 3. The procedures for reviewing the prescription drug inventory and drug records maintained by the remote site.
- 4. The policies and procedures for providing security adequate to protect the confidentiality and integrity of patient information.
- 5. The written plan for recovery from an event that interrupts or prevents the prescription department manager from supervising the remote site's operation.
- 6. 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.
- 7. The procedures for maintaining a perpetual inventory of the controlled substances listed in s. 893.03(2).
- 8. The specific duties, tasks, and functions that registered pharmacy technicians are authorized to perform at the remote site.
- (4) A remote-site pharmacy is not considered a pharmacy location for purposes of network access in managed care programs.
- (5) A remote-site pharmacy may store, hold, or dispense any medicinal drug.
- (6) A remote-site pharmacy may not perform centralized prescription filling as defined in s. 465.003(16).
- (7) The prescription department manager must visit the remote site, based on a schedule determined by the board, to inspect the pharmacy, address personnel matters, and provide

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clinical services for patients.

(8) 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. Paragraph (c) of subsection (11) of section 465.022, Florida Statutes, is amended to read:

465.022 Pharmacies; general requirements; fees.-

- (11) A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:
- (c) A registered pharmacist may not serve as the prescription department manager in more than one location, except as authorized under s. 465.0198, unless approved by the board.

Section 10. Subsection (1) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.-

(1) A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner 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. This subsection does not apply to a remote-site pharmacy.

Section 11. Section 465.1893, Florida Statutes, is amended to read

465.1893 Administration of long-acting antipsychotic

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medication by injection.-

- (1) (a) A pharmacist, at the direction of a physician licensed under chapter 458 or chapter 459, may administer a long-acting antipsychotic medication or an extended-release medication indicated to treat opioid use disorder, alcohol use disorder, or other substance use disorder or dependency, including, but not limited to, buprenorphine, naltrexone, or other medications that have been approved by the United States Food and Drug Administration by injection to a patient if the pharmacist:
- 1. Is authorized by and acting within the framework of an established protocol with the prescribing physician.
- 2. Practices at a facility that accommodates privacy for nondeltoid injections and conforms with state rules and regulations regarding the appropriate and safe disposal of medication and medical waste.
 - 3. Has completed the course required under subsection (2).
- (b) A separate prescription from a physician is required for each injection administered by a pharmacist under this subsection.
- (2)(a) A pharmacist seeking to administer a long-acting antipsychotic medication described in paragraph (1)(a) by injection must complete an 8-hour continuing education course offered by:
- 1. A statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credit or the American Osteopathic Association (AOA) Category 1-A continuing medical

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education (CME) credit; and

- 2. A statewide association of pharmacists.
- (b) The course may be offered in a distance learning format and must be included in the 30 hours of continuing professional pharmaceutical education required under s. 465.009(1). The course shall have a curriculum of instruction that concerns the safe and effective administration of behavioral health, addiction, and antipsychotic medications by injection, including, but not limited to, potential allergic reactions to such medications.

Section 12. Subsections (1) through (4) of section 468.1225, Florida Statutes, are amended to read:

468.1225 Procedures, equipment, and protocols.-

- (1) The following minimal procedures <u>must</u> shall be used when a licensed audiologist fits and sells a hearing aid <u>unless</u> the client is 18 years of age or older and provides a medical clearance or a waiver of medical examination:
- (a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency when indicated.
 - (b) Effective masking when indicated.
- (c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit when indicated.
- (2) The following equipment <u>must shall</u> be used <u>unless the</u> <u>client is 18 years of age or older and provides a medical</u> clearance or a waiver of medical examination:

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(a) A wide range audiometer $\underline{\text{that}}$ which meets the specifications of the American National Standards Institute for diagnostic audiometers when indicated.

- (b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination when indicated.
- (3) A final fitting ensuring physical and operational comfort of the hearing aid must shall be made when indicated.
- (4) A licensed audiologist who fits and sells hearing aids must shall obtain the following medical clearance: If, upon inspection of the ear canal with an otoscope in the common procedure of fitting a hearing aid or and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client must shall be instructed to see a physician, and a hearing aid may shall not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no longer observable and the client signs a medical waiver, a hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical or surgical correction.

Section 13. Section 468.1265, Florida Statutes, is amended to read:

468.1265 Sale or distribution of hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer who is younger than 18 years of age. Any person who violates this section commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

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Section 14. Subsections (1) through (4) of section 484.0501, Florida Statutes, are amended to read:

484.0501 Minimal procedures and equipment.-

- (1) The following minimal procedures <u>must</u> shall be used in the fitting and selling of hearing aids <u>unless the client is 18</u> years of age or older and provides a medical clearance or a waiver of medical examination:
- (a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency.
 - (b) Effective masking when indicated.
- (c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit.
- (2) The following equipment <u>must</u> <u>shall</u> be used <u>unless the</u> <u>client is 18 years of age or older and provides a medical</u> clearance or a waiver of medical examination:
- (a) A wide range audiometer $\underline{\text{that}}$ which meets the specifications of the American National Standards Institute for diagnostic audiometers.
- (b) A speech audiometer or a master hearing aid in order to determine the most comfortable listening level and speech discrimination.
- (3) For clients younger than 18 years of age, a final fitting ensuring physical and operational comfort of the hearing aid <u>must shall</u> be made. For all other clients, such final fitting must be made when indicated.
 - (4) The following medical clearance must shall be obtained:

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If, upon inspection of the ear canal with an otoscope in the common procedure of a hearing aid fitter or and upon interrogation of the client, there is any recent history of infection or any observable anomaly, the client must shall be instructed to see a physician, and a hearing aid may shall not be fitted until medical clearance is obtained for the condition noted. If, upon return, the condition noted is no longer observable and the client signs a medical waiver, a hearing aid may be fitted. Any person with a significant difference between bone conduction hearing and air conduction hearing must be informed of the possibility of medical correction.

Section 15. Section 484.054, Florida Statutes, is amended to read:

484.054 Sale or distribution of hearing aids through mail; penalty.—It is unlawful for any person to sell or distribute hearing aids through the mail to the ultimate consumer who is younger than 18 years of age. Any violation of this section constitutes a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

Section 16. Paragraph (e) is added to subsection (1) of section 893.05, Florida Statutes, to read:

893.05 Practitioners and persons administering controlled substances in their absence.—

(1)

(e) A telehealth provider as defined in s. 456.47 may not prescribe through telehealth a controlled substance listed in Schedule I or Schedule II of s. 893.03.

Section 17. This act shall take effect July 1, 2021.