By Senator Crist

20-358-98 See HB

1 A bill to be entitled 2 An act relating to pharmacy practice; amending s. 465.003, F.S.; defining the term "data 3 4 communication device"; revising the definition 5 of the term "practice of the profession of 6 pharmacy"; amending s. 465.017, F.S.; providing 7 additional persons and entities to whom records relating to the filling of prescriptions and 8 9 the dispensing of medicinal drugs which are maintained by a pharmacy may be furnished; 10 providing restrictions on such records when 11 12 transmitted through a data communication device; amending ss. 465.014, 465.015, 13 465.0196, 468.812, and 499.003, F.S.; 14 conforming cross-references; providing an 15 effective date. 16

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

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Section 1. Subsections (4) through (11), (13), and (14) of section 465.003, Florida Statutes, are renumbered as subsections (5) through (12), (14), and (15), respectively, present subsection (12) is renumbered as subsection (13) and amended, and a new subsection (4) is added to that section, to read:

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

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(4) "Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any bridge, router, switch, or gateway.

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(13)(12) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug and consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders, and other related cognitive services. The phrase also includes any other act, service, operation, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

Section 2. Subsection (2) of section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect.--

(2) Except as permitted by this chapter, and chapters 406, 409, 455, 499, and 893, records maintained by in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished, except upon the written authorization of the patient, to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse; to the department pursuant to existing law; to treating practitioners and other pharmacists when, in the professional judgment of the pharmacist, such release protects or benefits the patient's health, well-being, or treatment; or, to insurance carriers or other payors authorized by the

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30 31 patient to receive such records. For purposes of this section, records held in a pharmacy shall be considered held by the owner of the pharmacy except upon the written authorization of such patient. Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records. Such records or any part thereof, if transmitted through a data communication device and not directly between a pharmacy and a treating practitioner, may not be accessed, used, or maintained by the operator or owner of the data communication device unless specifically authorized by this section.

Section 3. Section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician. -- No person other than a licensed pharmacist or pharmacy intern may engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to nonlicensed pharmacy technicians those duties, tasks, and functions which do not fall within the purview of s. $465.003(13)\frac{(12)}{(12)}$. All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A 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. No licensed pharmacist shall supervise more than one pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees

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in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

Section 4. Paragraph (c) of subsection (2) of section 465.015, Florida Statutes, is amended to read:

465.015 Violations and penalties. --

- (2) It is unlawful for any person:
- (c) To sell or dispense drugs as defined in s. 465.003(8)(7) without first being furnished with a prescription.

Section 5. Section 465.0196, Florida Statutes, is amended to read:

465.0196 Special pharmacy permits. -- Any person desiring a permit to operate a pharmacy which does not fall within the definitions set forth in s. $465.003(11)\frac{(10)}{(10)}(a)1.$ 2., and 3. shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for such duties.

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Section 6. Subsection (3) of section 468.812, Florida

Statutes, is amended to read:

468.812 Exemptions from licensure.--

(3) The provisions of this act relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003(13)(12), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics shall not be precluded from continuing that practice pending adoption of these rules.

Section 7. Subsection (19) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss.

499.001-499.081.--As used in ss. 499.001-499.081, the term:

(19) "Legend drug," "prescription drug," or "medicinal drug" means any drug, including, but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8)(7), s. 499.007(12), or s. 499.0122(1)(b) or (c).

Section 8. This act shall take effect July 1 of the year in which enacted.

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4	Provides additional persons and entities to whom records relating to the filling of prescriptions and the dispensing of medicinal drugs which are maintained by a pharmacy may be furnished, and provides restrictions on such records when transmitted through a data communication device. Provides and revises definitions,
5	pharmacy may be furnished, and provides restrictions on
6	communication device. Provides and revises definitions, to conform. (See bill for details.)
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