By Representative Gay

A bill to be entitled

An act relating to pharmacy practice; amending s. 465.003, F.S.; defining the term "data communication device"; revising the definition of the term "practice of the profession of pharmacy"; amending s. 465.016, F.S.; authorizing the redispensing of unused or returned unit-dose medication by correctional facilities under certain conditions; providing a ground for which a pharmacist may be subject to discipline by the Board of Pharmacy; amending s. 465.017, F.S.; providing additional persons to whom and entities to which records relating to the filling of prescriptions and the dispensing of medicinal drugs that are maintained by a pharmacy may be furnished; specifying authorized uses of patient records by pharmacy owners; providing restrictions on such records when transmitted through a data communication device; amending ss. 465.014, 465.015, 465.0196, 468.812, and 499.003, F.S.; correcting cross references, to conform; amending s. 499.012, F.S.; redefining the term "wholesale distribution," relating to the distribution of prescription drugs, to provide for the exclusion of certain activities; creating s. 499.072, F.S.; creating the Drug Regulation Advisory Group; providing membership; providing terms of office; providing for meetings, for reimbursement of expenses, and for purposes and duties of the

group; authorizing the Department of Health to publish compliance policy guidelines that include recommendations of the group; providing effective dates.

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

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

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

(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 such bridge, router, switch, or gateway.

(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 pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means evaluation and monitoring of the patient's health as it relates to drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient and the patient's prescribing health care provider as licensed under chapter 458, chapter

459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, unless otherwise permitted by law. "Practice of the profession of pharmacy" ~~The phrase~~ also includes any other act, service, operation, research, 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. "Practice of the profession of pharmacy" also includes the administering of immunizations by a pharmacist within the framework of an established protocol under a supervisory practitioner who is a physician licensed under chapter 458 or chapter 459 or by written agreement with a county health department. Each protocol must contain specific procedures to address any unforeseen allergic reaction to an immunization. A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability insurance, and not until the pharmacist has completed training in immunizations as may be required by the board. The decision by a supervisory practitioner to enter into such a protocol is a professional decision of the practitioner, and no person may interfere with a supervisory practitioner's decision as to whether to enter into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as

an employee without the written approval of the owner of the pharmacy.

Section 2. Effective upon this act becoming a law, paragraph (l) of subsection (1) of section 465.016, Florida Statutes, is amended to read:

465.016 Disciplinary actions.--

(1) The following acts shall be grounds for disciplinary action set forth in this section:

(l) Placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing. Each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.

Section 3. Paragraph (q) is added to subsection (1) of section 465.016, Florida Statutes, to read:

465.016 Disciplinary actions.--

(1) The following acts shall be grounds for disciplinary action set forth in this section:

(q) Using or releasing a patient's records except as authorized by this chapter and chapter 455.

Section 4. 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 such ~~said~~ records, her or his spouse; to the department pursuant to law; to health care practitioners and pharmacists consulting with or dispensing to the patient; or to insurance carriers or other payors authorized by the patient to receive such records. For purposes of this section, records held in a pharmacy shall be considered owned by the owner of the pharmacy. The pharmacy owner may use such records in the aggregate without patient identification data, regardless of where such records are held, for purposes reasonably related to the business and practice of 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. It is the intent of this subsection to allow the use and sharing of such records to improve patient care, provided the pharmacist acts in the best

interests of her or his patient. Nothing in this subsection may be construed to authorize or expand solicitation or marketing to patients or potential patients in any manner not otherwise specifically authorized by law.

Section 5. 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)~~(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 in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

Section 6. 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 7. 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)~~(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.

Section 8. 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 9. 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 10. Paragraph (a) of subsection (1) and subsection (5) of section 499.012, Florida Statutes, 1998 Supplement, are amended to read:

499.012 Wholesale distribution; definitions; permits; general requirements.--

(1) As used in this section, the term:

(a) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.014:

a. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

b. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

2. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

a. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

b. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to s. 602 of Pub. L. No. 102-585 to a contract provider or its

subcontractor for eligible patients of the agency or entity under the following conditions:

(I) The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this sub-subparagraph from the Secretary of Health. This written authorization must be based on a favorable recommendation by the Drug Regulation Advisory Group after the group has reviewed the agency's or entity's submission to the department of a detailed plan and justification for the sale, purchase, trade, or other transfer of a prescription drug under this sub-subparagraph and must enhance the public's health by improving needed access, quality, or safety because current patient drug delivery systems are inadequate.

(II) The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

(III) In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

(IV) A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

(V) The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be

maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity monthly.

(VI) The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-sub-subparagraph (V).

(VII) The prescription drugs transferred pursuant to this sub-subparagraph may not be billed to Medicaid.

(VIII) In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this sub-subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this sub-subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

c.~~b.~~ The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons.~~;~~ For purposes of this sub-subparagraph ~~subparagraph~~, the term "emergency medical reasons" includes transfers of prescription drugs by a retail

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

pharmacy to another retail pharmacy to alleviate a temporary shortage.

d.~~c.~~ The transfer ~~purchase or acquisition~~ of a prescription drug acquired by a medical director on behalf of a licensed ~~an~~ emergency medical services provider to that ~~medical director for use by~~ emergency medical services provider and its transport vehicles for use in accordance with the provider's license under ~~providers acting within the scope of their professional practice pursuant to~~ chapter 401.

e.~~d.~~ The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

f.~~e.~~ The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

g.~~f.~~ The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

~~3. The dispensing of a prescription drug pursuant to a prescription;~~

h.~~4.~~ The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.~~; or~~

i.~~5.~~ The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this sub-subparagraph ~~section~~, the term "blood" means whole blood

collected from a single donor and processed either for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

3. The lawful dispensing of a prescription drug in accordance with chapter 465.

(5) The department may adopt rules governing the recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in subparagraphs (1)(a)1. and ~~,~~2.~~, 4., and 5.~~

Section 11. Section 499.072, Florida Statutes, is created to read:

499.072 Drug Regulation Advisory Group.--

(1) There is created the Drug Regulation Advisory Group, which is an independent advisory group composed of at least 13 members appointed by the Secretary of Health and including:

(a) One member representing the prescription drug wholesale industry in this state.

(b) One member representing pharmaceutical manufacturers, who may represent pharmaceutical manufacturers nationwide.

(c) One member who is a practicing pharmacist.

(d) One member representing the Agency for Health Care Administration.

(e) One member who is a physician licensed under chapter 458 or chapter 459.

(f) One consumer representative.

(g) One member representing the cosmetic industry.

(h) One member representing the compressed medical gas industry.

(i) One member representing the medical device manufacturing industry.

(j) The Executive Director of the Board of Pharmacy, who shall be an ex officio member.

(k) One member representing the department, who shall chair group meetings.

(l) One member representing hospitals.

(m) One member representing the long-term care industry.

(2) Members shall be appointed for terms of 4 years, except for the Executive Director of the Board of Pharmacy and the departmental representative, who may serve indefinitely. Members of the group may be reappointed. A vacancy in membership that occurs before the expiration of a term shall be filled by a member appointed by the Secretary of Health for a full term.

(3) The group shall meet upon request of the department, but no more than four times a year. Members of the group shall serve without compensation, but may be reimbursed for per diem and travel expenses as provided in s. 112.061.

(4) The purposes and duties of the Drug Regulation Advisory Group include, but are not limited to:

(a) Making recommendations to the Secretary of Health regarding authorizations for the sale, purchase, trade, or other transfer of a prescription drug under s. 499.012(1)(a)2.

(b) Making recommendations to the department regarding enforcement priorities under this chapter.

(c) Briefing the department on industry trends that affect this chapter.

(d) Providing information and guidance on issues submitted by the department to the group.

(e) Facilitating the dissemination of relevant information concerning current issues affecting the public health within the scope and responsibility of this chapter.

(5) The department may publish compliance policy guidelines that set forth enforcement priorities or other recommendations of the Drug Regulation Advisory Group when that is in the best interests of the public health.

Section 12. Except as otherwise provided herein, this act shall take effect July 1, 1999.

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HOUSE SUMMARY

Defines the term "data communication device" and expands the definition of "practice of the profession of pharmacy" to include other pharmaceutical services relating to drug therapy and administration of immunizations under certain circumstances. Authorizes the redispensing of unused or returned unit-dose medication by correctional facilities under certain conditions. Provides that using or releasing a patient's records except as authorized by chapter 465 or chapter 455, F.S., constitutes a ground for disciplinary action against a pharmacist. Provides additional persons to whom and entities to which records relating to the filling of prescriptions and the dispensing of medicinal drugs that are maintained by a pharmacy may be furnished. Specifies authorized uses of patient records by pharmacy owners. Provides restrictions on such records when transmitted through a data communication device. Redefines the term "wholesale distribution," relating to the distribution of prescription drugs, to provide for the exclusion of certain activities. Creates the Drug Regulation Advisory Group and provides for its members and their terms of office. Provides for meetings, for reimbursement of expenses, and for purposes and duties of the group. Authorizing the Department of Health to publish compliance policy guidelines that include recommendations of the group. See bill for details.