

1 A bill to be entitled
2 An act relating to pharmacy practice; providing
3 a short title; amending s. 465.003, F.S.;
4 defining the term "data communication device";
5 revising the definition of the term "practice
6 of the profession of pharmacy"; amending s.
7 465.015, F.S.; providing penalties for
8 unauthorized use of pharmacy records when
9 transmitted through a data communication
10 device; conforming cross-references; amending
11 ss. 465.014, 465.0196, 468.812; amending s.
12 465.016, F.S.; authorizing the redispensing of
13 unused or returned unit-dose medication by
14 correctional facilities under certain
15 conditions; providing that using or releasing a
16 patient's records except as authorized by
17 chapter 455 or chapter 465, F.S., constitutes a
18 ground for disciplinary action against a
19 pharmacist, for which there are penalties;
20 amending s. 465.017, F.S.; providing additional
21 persons to whom and entities to which records
22 relating to the filling of prescriptions and
23 the dispensing of medicinal drugs that are
24 maintained by a pharmacy may be furnished;
25 specifying authorized uses of patient records
26 by pharmacy owners; providing restrictions on
27 such records when transmitted through a data
28 communication device; clarifying the use of
29 records for research; restricting the use of
30 records for compliance services; amending ss.
31 465.014, 465.015, 465.0196, 468.812, and

1 499.003, F.S.; correcting cross references, to
2 conform; amending s. 499.012, F.S.; redefining
3 the term "wholesale distribution," relating to
4 the distribution of prescription drugs, to
5 provide for the exclusion of certain
6 activities; providing effective dates.

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

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10 Section 1. This act may be cited as the "Pharmacy
11 Patient Privacy Act of 1999."

12 Section 2. Subsection (12) of section 465.003, Florida
13 Statutes, is amended, subsections (4) through (14) of said
14 section are renumbered as subsections (5) through (15),
15 respectively, and a new subsection (4) is added to said
16 section, to read:

17 465.003 Definitions.--As used in this chapter, the
18 term:

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

23 (13)(12) "Practice of the profession of pharmacy"
24 includes compounding, dispensing, and consulting concerning
25 contents, therapeutic values, and uses of any medicinal drug;
26 and consulting concerning therapeutic values and interactions
27 of patent or proprietary preparations, whether pursuant to
28 prescriptions or in the absence and entirely independent of
29 such prescriptions or orders; and other pharmaceutical
30 services. For purposes of this subsection, "other
31 pharmaceutical services" means the monitoring of the patient's

1 drug therapy and assisting the patient in the management of
2 his or her drug therapy, and includes review of the patient's
3 drug therapy and communication with the patient's prescribing
4 health care provider as licensed under chapter 458, chapter
5 459, chapter 461, or chapter 466, or similar statutory
6 provision in another jurisdiction, or such provider's agent or
7 such other persons as specifically authorized by the patient,
8 regarding the drug therapy. However, nothing in this
9 subsection may be interpreted to permit an alteration of a
10 prescriber's directions, the diagnosis or treatment of any
11 disease, the initiation of any drug therapy, the practice of
12 medicine, or the practice of osteopathic medicine, unless
13 otherwise permitted by law."Practice of the profession of
14 pharmacy"~~The phrase~~ also includes any other act, service,
15 operation, research, or transaction incidental to, or forming
16 a part of, any of the foregoing acts, requiring, involving, or
17 employing the science or art of any branch of the
18 pharmaceutical profession, study, or training, and shall
19 expressly permit a pharmacist to transmit information from
20 persons authorized to prescribe medicinal drugs to their
21 patients.

22 Section 3. Paragraph (c) of subsection (2) of section
23 465.015, Florida Statutes, is amended, and a new subsection
24 (4) is added to that section and present subsection (4) of
25 that section is amended and renumbered as subsection (5), to
26 read:

27 465.015 Violations and penalties.--

28 (2) It is unlawful for any person:

29 (c) To sell or dispense drugs as defined in s.

30 465.003(8)(7) without first being furnished with a
31 prescription.

1 (4) It is unlawful for records maintained by a
2 pharmacy relating to the filling of prescriptions and the
3 dispensing of medicinal drugs, if transmitted through a data
4 communication device not under the control or ownership of a
5 pharmacy or affiliated company or not directly between a
6 pharmacy and a treating practitioner, to be accessed, used, or
7 maintained by the operator or owner of the data communication
8 device unless specifically authorized by s. 465.017.

9 ~~(5)(4)~~ Any person who violates any provision of
10 subsection (1), ~~or~~ subsection (3), or subsection (4) is guilty
11 of a misdemeanor or the first degree, punishable as provided
12 in s. 775.082, or s. 775.083. Any person who violates any
13 provision of subsection (2) is guilty of a felony of the third
14 degree, punishable as provided in s. 775.082, s. 775.083, or
15 s. 775.084. In any warrant, information, or indictment, it
16 shall not be necessary to negative any exceptions, and the
17 burden of any exception shall be upon the defendant.

18 Section 4. Effective upon this act becoming a law,
19 paragraph (1) of subsection (1) of section 465.016, Florida
20 Statutes, is amended to read:

21 465.016 Disciplinary actions.--

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

24 (1) Placing in the stock of any pharmacy any part of
25 any prescription compounded or dispensed which is returned by
26 a patient; however, in a hospital, nursing home, correctional
27 facility, or extended care facility in which unit-dose
28 medication is dispensed to inpatients, each dose being
29 individually sealed and the individual unit dose or unit-dose
30 system labeled with the name of the drug, dosage strength,
31 manufacturer's control number, and expiration date, if any,

1 the unused unit dose of medication may be returned to the
2 pharmacy for redispensing. Each pharmacist shall maintain
3 appropriate records for any unused or returned medicinal
4 drugs.

5 Section 5. Paragraph (q) is added to subsection (1) of
6 section 465.016, Florida Statutes, to read:

7 465.016 Disciplinary actions.--

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

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

12 Section 6. Subsection (2) of section 465.017, Florida
13 Statutes, is amended and new subsections (3) and (4) of said
14 section are added to read:

15 465.017 Authority to inspect.--

16 (2) Except as permitted by this chapter, and chapters
17 406, 409, 455, 499, and 893, records maintained by ~~in~~ a
18 pharmacy relating to the filling of prescriptions and the
19 dispensing of medicinal drugs shall not be furnished, except
20 upon the written authorization of the patient, to any person
21 other than to the patient for whom the drugs were dispensed,
22 ~~or her or his legal representative, or to the department~~
23 ~~pursuant to existing law,~~ or, in the event that the patient is
24 incapacitated or unable to request such ~~said~~ records, her or
25 his spouse; to the department pursuant to law; to health care
26 practitioners and pharmacists consulting with or dispensing to
27 the patient, including physicians who are part of independent
28 practice associations, physician hospital organizations, or
29 other such organized provider groups; or to insurance carriers
30 or other payors authorized by the patient to receive such
31 records. For purposes of this section, the pharmacy

1 permitholder shall be considered the custodian of records
2 maintained in a pharmacy. The pharmacy owner may use such
3 records in the aggregate without patient identification data,
4 regardless of where such records are held, for purposes
5 reasonably related to the business and practice of pharmacy
6 ~~except upon the written authorization of such patient.~~ Such
7 records may be furnished in any civil or criminal proceeding,
8 upon the issuance of a subpoena from a court of competent
9 jurisdiction and proper notice to the patient or her or his
10 legal representative by the party seeking such records. Such
11 records or any part thereof, if transmitted through a data
12 communication device not under the control or ownership of a
13 pharmacy or affiliated company or not directly between a
14 pharmacy and a treating practitioner, may not be accessed,
15 used, or maintained by the operator or owner of the data
16 communication device unless specifically authorized by this
17 section. It is the intent of this subsection to allow the use
18 and sharing of such records to improve patient care, provided
19 the pharmacist acts in the best interests of her or his
20 patient. Nothing in this subsection may be construed to
21 authorize or expand solicitation or marketing to patients or
22 potential patients in any manner not otherwise specifically
23 authorized by law.

24 (3) Nothing in subsection (2) may be construed to
25 prohibit a pharmacy permit holder from providing to a
26 researcher records maintained by the pharmacy relating to the
27 filling of prescriptions and the dispensing of medicinal drugs
28 on behalf a patient who is a participant in a research project
29 or clinical investigation supervised by an institutional
30 review board, consistent with the informed consent
31 requirements of 21 CFR 50 and 45 CFR 56.

1 (4) Nothing in subsection (2) may be construed to
2 prohibit a pharmacy permit holder from providing records
3 maintained by the pharmacy relating to the filling of
4 prescriptions and the dispensing of medicinal drugs to
5 entities performing compliance services, provided that the
6 patients are given the opportunity to either enroll or
7 disenroll from the compliance service program. For purposes of
8 this subsection, compliance service programs do not include
9 direct marketing of any pharmaceutical product to the patients
10 involved in the program.

11 Section 7. Section 465.014, Florida Statutes, is
12 amended to read:

13 465.014 Pharmacy technician.--No person other than a
14 licensed pharmacist or pharmacy intern may engage in the
15 practice of the profession of pharmacy, except that a licensed
16 pharmacist may delegate to nonlicensed pharmacy technicians
17 those duties, tasks, and functions which do not fall within
18 the purview of s. 465.003~~(13)~~~~(12)~~. All such delegated acts
19 shall be performed under the direct supervision of a licensed
20 pharmacist who shall be responsible for all such acts
21 performed by persons under his or her supervision. A pharmacy
22 technician, under the supervision of a pharmacist, may
23 initiate or receive communications with a practitioner or his
24 or her agent, on behalf of a patient, regarding refill
25 authorization requests. No licensed pharmacist shall
26 supervise more than one pharmacy technician unless otherwise
27 permitted by the guidelines adopted by the board. The board
28 shall establish guidelines to be followed by licensees or
29 permittees in determining the circumstances under which a
30 licensed pharmacist may supervise more than one but not more
31 than three pharmacy technicians.

1 Section 8. Paragraph (c) of subsection (2) of section
2 465.015, Florida Statutes, is amended to read:

3 465.015 Violations and penalties.--

4 (2) It is unlawful for any person:

5 (c) To sell or dispense drugs as defined in s.
6 465.003(8)~~(7)~~without first being furnished with a
7 prescription.

8 Section 9. Section 465.0196, Florida Statutes, is
9 amended to read:

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

27 Section 10. Subsection (3) of section 468.812, Florida
28 Statutes, is amended to read:

29 468.812 Exemptions from licensure.--

30 (3) The provisions of this act relating to orthotics
31 or pedorthics do not apply to any licensed pharmacist or to

1 any person acting under the supervision of a licensed
2 pharmacist. The practice of orthotics or pedorthics by a
3 pharmacist or any of the pharmacist's employees acting under
4 the supervision of a pharmacist shall be construed to be
5 within the meaning of the term "practice of the profession of
6 pharmacy" as set forth in s. 465.003(13)(~~12~~), and shall be
7 subject to regulation in the same manner as any other pharmacy
8 practice. The Board of Pharmacy shall develop rules regarding
9 the practice of orthotics and pedorthics by a pharmacist. Any
10 pharmacist or person under the supervision of a pharmacist
11 engaged in the practice of orthotics or pedorthics shall not
12 be precluded from continuing that practice pending adoption of
13 these rules.

14 Section 11. Subsection (19) of section 499.003,
15 Florida Statutes, is amended to read:

16 499.003 Definitions of terms used in ss.

17 499.001-499.081.--As used in ss. 499.001-499.081, the term:

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

24 Section 12. Paragraph (a) of subsection (1) and
25 subsection (5) of section 499.012, Florida Statutes, 1998
26 Supplement, are amended to read:

27 499.012 Wholesale distribution; definitions; permits;
28 general requirements.--

29 (1) As used in this section, the term:
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1 (a) "Wholesale distribution" means distribution of
2 prescription drugs to persons other than a consumer or
3 patient, but does not include:

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

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

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

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

26 d. The sale, purchase, trade, or other transfer of a
27 prescription drug from or for any federal, state, or local
28 government agency or any entity eligible to purchase
29 prescription drugs at public health services prices pursuant
30 to s. 602 of Pub. L. No. 102-585 to a contract provider or its
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1 subcontractor for eligible patients of the agency or entity
2 under the following conditions:

3 (I) The agency or entity must obtain written
4 authorization for the sale, purchase, trade, or other transfer
5 of a prescription drug under this sub-subparagraph from the
6 Secretary of Health or his or her designee.

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

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

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

16 (V) The contract provider and subcontractor must
17 maintain and produce immediately for inspection all records of
18 movement or transfer of all the prescription drugs belonging
19 to the agency or entity, including, but not limited to, the
20 records of receipt and disposition of prescription drugs. Each
21 contractor and subcontractor dispensing or administering these
22 drugs must maintain and produce records documenting the
23 dispensing or administration. Records that are required to be
24 maintained include, but are not limited to, a perpetual
25 inventory itemizing drugs received and drugs dispensed by
26 prescription number or administered by patient identifier,
27 which must be submitted to the agency or entity quarterly.

28 (VI) The contract provider or subcontractor may
29 administer or dispense the prescription drugs only to the
30 eligible patients of the agency or entity or must return the
31 prescription drugs for or to the agency or entity. The

1 contract provider or subcontractor must require proof from
2 each person seeking to fill a prescription or obtain treatment
3 that the person is an eligible patient of the agency or entity
4 and must, at a minimum, maintain a copy of this proof as part
5 of the records of the contractor or subcontractor required
6 under sub-sub-subparagraph (V).

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

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

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

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

25 b. The sale, purchase, or trade of a prescription drug
26 or an offer to sell, purchase, or trade a prescription drug
27 for emergency medical reasons.~~For purposes of this~~
28 sub-subparagraph ~~subparagraph~~, the term "emergency medical
29 reasons" includes transfers of prescription drugs by a retail
30 pharmacy to another retail pharmacy to alleviate a temporary
31 shortage.

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

8 d. The revocation of a sale or the return of a
9 prescription drug to the person's prescription drug wholesale
10 supplier.

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

16 f. The transfer of a prescription drug by a person
17 authorized to purchase or receive prescription drugs to a
18 person licensed or permitted to handle reverse distributions
19 or destruction under the laws of the jurisdiction in which the
20 person handling the reverse distribution or destruction
21 receives the drug.

22 ~~3. The dispensing of a prescription drug pursuant to a~~
23 ~~prescription.~~

24 ~~3.4.~~ The distribution of prescription drug samples by
25 manufacturers' representatives or distributors'
26 representatives conducted in accordance with s. 499.028. ~~or~~

27 ~~4.5.~~ The sale, purchase, or trade of blood and blood
28 components intended for transfusion. As used in this
29 subparagraph ~~section~~, the term "blood" means whole blood
30 collected from a single donor and processed either for
31 transfusion or further manufacturing, and the term "blood

1 components" means that part of the blood separated by physical
2 or mechanical means.

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

5 (5) The department may adopt rules governing the
6 recordkeeping, storage, and handling with respect to each of
7 the distributions of prescription drugs specified in
8 subparagraphs (1)(a)~~1.-4.1., 2., 4., and 5.~~

9 Section 13. Except as otherwise provided herein, this
10 act shall take effect July 1, 1999.

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