

Amendment No. 2 (for drafter's use only)

| | <u>Senate</u> | CHAMBER ACTION | <u>House</u> |
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ORIGINAL STAMP BELOW

11 Representative(s) Johnson, Gay, and Kelly offered the
12 following:

14 **Amendment (with title amendment)**

15 Remove from the bill: Everything after the enacting clause
16
17 and insert in lieu thereof:

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

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

25 465.003 Definitions.--As used in this chapter, the
26 term:

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

31 (13)(12) "Practice of the profession of pharmacy"

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1 includes compounding, dispensing, and consulting concerning
2 contents, therapeutic values, and uses of any medicinal drug;
3 ~~and~~ consulting concerning therapeutic values and interactions
4 of patent or proprietary preparations, whether pursuant to
5 prescriptions or in the absence and entirely independent of
6 such prescriptions or orders; and other pharmaceutical
7 services. For purposes of this subsection, "other
8 pharmaceutical services" means the monitoring of the patient's
9 drug therapy and assisting the patient in the management of
10 his or her drug therapy, and includes review of the patient's
11 drug therapy and communication with the patient's prescribing
12 health care provider as licensed under chapter 458, chapter
13 459, chapter 461, or chapter 466, or similar statutory
14 provision in another jurisdiction, or such provider's agent or
15 such other persons as specifically authorized by the patient,
16 regarding the drug therapy. However, nothing in this
17 subsection may be interpreted to permit an alteration of a
18 prescriber's directions, the diagnosis or treatment of any
19 disease, the initiation of any drug therapy, the practice of
20 medicine, or the practice of osteopathic medicine, unless
21 otherwise permitted by law."Practice of the profession of
22 pharmacy"~~The phrase~~ also includes any other act, service,
23 operation, research, or transaction incidental to, or forming
24 a part of, any of the foregoing acts, requiring, involving, or
25 employing the science or art of any branch of the
26 pharmaceutical profession, study, or training, and shall
27 expressly permit a pharmacist to transmit information from
28 persons authorized to prescribe medicinal drugs to their
29 patients.

30 Section 3. Paragraph (c) of subsection (2) of section
31 465.015, Florida Statutes, is amended, and a new subsection

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1 (4) is added to that section and present subsection (4) of
2 that section is amended and renumbered as subsection (5), to
3 read:

4 465.015 Violations and penalties.--

5 (2) It is unlawful for any person:

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

9 (4) It is unlawful for records maintained by a
10 pharmacy relating to the filling of prescriptions and the
11 dispensing of medicinal drugs, 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, to be accessed, used, or
15 maintained by the operator or owner of the data communication
16 device unless specifically authorized by s. 465.017.

17 (5)(~~4~~) Any person who violates any provision of
18 subsection (1), ~~or~~ subsection (3), or subsection (4) is guilty
19 of a misdemeanor or the first degree, punishable as provided
20 in s. 775.082, or s. 775.083. Any person who violates any
21 provision of subsection (2) is guilty of a felony of the third
22 degree, punishable as provided in s. 775.082, s. 775.083, or
23 s. 775.084. In any warrant, information, or indictment, it
24 shall not be necessary to negative any exceptions, and the
25 burden of any exception shall be upon the defendant.

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

29 465.016 Disciplinary actions.--

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

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

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

15 465.016 Disciplinary actions.--

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

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

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

23 465.017 Authority to inspect.--

24 (2) Except as permitted by this chapter, and chapters
25 406, 409, 455, 499, and 893, records maintained by ~~in~~ a
26 pharmacy relating to the filling of prescriptions and the
27 dispensing of medicinal drugs shall not be furnished, except
28 upon the written authorization of the patient, to any person
29 other than to the patient for whom the drugs were dispensed,
30 ~~or her or his legal representative, or to the department~~
31 ~~pursuant to existing law,~~ or, in the event that the patient is

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1 incapacitated or unable to request such ~~said~~ records, her or
2 his spouse; to the department pursuant to law; to health care
3 practitioners and pharmacists consulting with or dispensing to
4 the patient, including physicians who are part of independent
5 practice associations, physician hospital organizations, or
6 other such organized provider groups; or to insurance carriers
7 or other payors authorized by the patient to receive such
8 records. For purposes of this section, the pharmacy
9 permitholder shall be considered the custodian of records
10 maintained in a pharmacy. The pharmacy owner may use such
11 records in the aggregate without patient identification data,
12 regardless of where such records are held, for purposes
13 reasonably related to the business and practice of pharmacy
14 except upon the written authorization of such patient. Such
15 records may be furnished in any civil or criminal proceeding,
16 upon the issuance of a subpoena from a court of competent
17 jurisdiction and proper notice to the patient or her or his
18 legal representative by the party seeking such records. Such
19 records or any part thereof, if transmitted through a data
20 communication device not under the control or ownership of a
21 pharmacy or affiliated company or not directly between a
22 pharmacy and a treating practitioner, may not be accessed,
23 used, or maintained by the operator or owner of the data
24 communication device unless specifically authorized by this
25 section. It is the intent of this subsection to allow the use
26 and sharing of such records to improve patient care, provided
27 the pharmacist acts in the best interests of her or his
28 patient. Nothing in this subsection may be construed to
29 authorize or expand solicitation or marketing to patients or
30 potential patients in any manner not otherwise specifically
31 authorized by law.

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

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

19 Section 7. Section 465.014, Florida Statutes, is
20 amended to read:

21 465.014 Pharmacy technician.--No person other than a
22 licensed pharmacist or pharmacy intern may engage in the
23 practice of the profession of pharmacy, except that a licensed
24 pharmacist may delegate to nonlicensed pharmacy technicians
25 those duties, tasks, and functions which do not fall within
26 the purview of s. 465.003(13)(12). All such delegated acts
27 shall be performed under the direct supervision of a licensed
28 pharmacist who shall be responsible for all such acts
29 performed by persons under his or her supervision. A pharmacy
30 technician, under the supervision of a pharmacist, may
31 initiate or receive communications with a practitioner or his

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1 or her agent, on behalf of a patient, regarding refill
2 authorization requests. No licensed pharmacist shall
3 supervise more than one pharmacy technician unless otherwise
4 permitted by the guidelines adopted by the board. The board
5 shall establish guidelines to be followed by licensees or
6 permittees in determining the circumstances under which a
7 licensed pharmacist may supervise more than one but not more
8 than three pharmacy technicians.

9 Section 8. Paragraph (c) of subsection (2) of section
10 465.015, Florida Statutes, is amended to read:

11 465.015 Violations and penalties.--

12 (2) It is unlawful for any person:

13 (c) To sell or dispense drugs as defined in s.
14 465.003(8)(~~7~~)without first being furnished with a
15 prescription.

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

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

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1 drugs occurs. The permittee shall notify the department
2 within 10 days of any change of the licensed pharmacist
3 responsible for such duties.

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

6 468.812 Exemptions from licensure.--

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

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

24 499.003 Definitions of terms used in ss.

25 499.001-499.081.--As used in ss. 499.001-499.081, the term:

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

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

4 499.012 Wholesale distribution; definitions; permits;
5 general requirements.--

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

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

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

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

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

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

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

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

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

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

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

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

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1 which must be submitted to the agency or entity quarterly.
2 (VI) The contract provider or subcontractor may
3 administer or dispense the prescription drugs only to the
4 eligible patients of the agency or entity or must return the
5 prescription drugs for or to the agency or entity. The
6 contract provider or subcontractor must require proof from
7 each person seeking to fill a prescription or obtain treatment
8 that the person is an eligible patient of the agency or entity
9 and must, at a minimum, maintain a copy of this proof as part
10 of the records of the contractor or subcontractor required
11 under sub-sub-subparagraph (V).

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

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

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

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

30 b. The sale, purchase, or trade of a prescription drug
31 or an offer to sell, purchase, or trade a prescription drug

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1 for emergency medical reasons.~~For purposes of this~~
2 ~~sub-subparagraph~~ ~~subparagraph~~, the term "emergency medical
3 reasons" includes transfers of prescription drugs by a retail
4 pharmacy to another retail pharmacy to alleviate a temporary
5 shortage.

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

13 d. The revocation of a sale or the return of a
14 prescription drug to the person's prescription drug wholesale
15 supplier.

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

21 f. The transfer of a prescription drug by a person
22 authorized to purchase or receive prescription drugs to a
23 person licensed or permitted to handle reverse distributions
24 or destruction under the laws of the jurisdiction in which the
25 person handling the reverse distribution or destruction
26 receives the drug.

27 ~~3. The dispensing of a prescription drug pursuant to a~~
28 ~~prescription.~~

29 ~~3.4.~~ The distribution of prescription drug samples by
30 manufacturers' representatives or distributors'
31 representatives conducted in accordance with s. 499.028. ~~or~~

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1 ~~4.5.~~ The sale, purchase, or trade of blood and blood
2 components intended for transfusion. As used in this
3 subparagraph section, the term "blood" means whole blood
4 collected from a single donor and processed either for
5 transfusion or further manufacturing, and the term "blood
6 components" means that part of the blood separated by physical
7 or mechanical means.

8 5. The lawful dispensing of a prescription drug in
9 accordance with chapter 465.

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

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

16
17

18 ===== T I T L E A M E N D M E N T =====

19 And the title is amended as follows:

20 remove from the title of the bill: everything before the
21 enacting clause

22

23 and insert in lieu thereof:

24

A bill to be entitled

25

An act relating to pharmacy practice; providing

26

a short title; amending s. 465.003, F.S.;

27

defining the term "data communication device";

28

revising the definition of the term "practice

29

of the profession of pharmacy"; amending s.

30

465.015, F.S.; providing penalties for

31

unauthorized use of pharmacy records when

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1 transmitted through a data communication
2 device; conforming cross-references; amending
3 ss. 465.014, 465.0196, 468.812; amending s.
4 465.016, F.S.; authorizing the redispensing of
5 unused or returned unit-dose medication by
6 correctional facilities under certain
7 conditions; providing that using or releasing a
8 patient's records except as authorized by
9 chapter 455 or chapter 465, F.S., constitutes a
10 ground for disciplinary action against a
11 pharmacist, for which there are penalties;
12 amending s. 465.017, F.S.; providing additional
13 persons to whom and entities to which records
14 relating to the filling of prescriptions and
15 the dispensing of medicinal drugs that are
16 maintained by a pharmacy may be furnished;
17 specifying authorized uses of patient records
18 by pharmacy owners; providing restrictions on
19 such records when transmitted through a data
20 communication device; clarifying the use of
21 records for research; restricting the use of
22 records for compliance services; amending ss.
23 465.014, 465.015, 465.0196, 468.812, and
24 499.003, F.S.; correcting cross references, to
25 conform; amending s. 499.012, F.S.; redefining
26 the term "wholesale distribution," relating to
27 the distribution of prescription drugs, to
28 provide for the exclusion of certain
29 activities; providing effective dates.
30
31