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Bill No. CS/HB 287

Amendment No. \_\_\_\_ (for drafter's use only)

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

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

**Amendment (with title amendment)**

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

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

Section 2. Subsection (12) of section 465.003, Florida Statutes, is amended, subsections (4) through (14) of said section 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"

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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. Effective upon this act becoming a law,  
 31 paragraph (1) of subsection (1) of section 465.016, Florida

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1 Statutes, is amended to read:

2 465.016 Disciplinary actions.--

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

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

17 Section 4. Paragraph (q) is added to subsection (1) of  
18 section 465.016, Florida Statutes, to read:

19 465.016 Disciplinary actions.--

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

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

24 Section 5. Subsection (2) of section 465.017, Florida  
25 Statutes, is amended to read:

26 465.017 Authority to inspect.--

27 (2) Except as permitted by this chapter, and chapters  
28 406, 409, 455, 499, and 893, records maintained by ~~in~~ a  
29 pharmacy relating to the filling of prescriptions and the  
30 dispensing of medicinal drugs shall not be furnished, except  
31 upon the written authorization of the patient, to any person

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1 other than to the patient for whom the drugs were dispensed,  
2 ~~or her or his legal representative, or to the department~~  
3 ~~pursuant to existing law,~~ or, in the event that the patient is  
4 incapacitated or unable to request such said records, her or  
5 his spouse; to the department pursuant to law; to health care  
6 practitioners and pharmacists consulting with or dispensing to  
7 the patient, including physicians who are part of independent  
8 practice associations, physician hospital organizations, or  
9 other such organized provider groups; to entities that provide  
10 compliance services; to insurance carriers or other payors  
11 authorized by the patient to receive such records; or to a  
12 health care researcher, investigator, or sponsor investigator  
13 where use of the information is for a research project or  
14 clinical investigation regulated under 21 C.F.R. ss. 50 and 56  
15 or 45 C.F.R s. 46. For purposes of this section, records held  
16 in a pharmacy shall be considered owned by the owner of the  
17 pharmacy. The pharmacy owner may use such records in the  
18 aggregate without patient identification data, regardless of  
19 where such records are held, for purposes reasonably related  
20 to the business and practice of pharmacy or health care  
21 research that meets the requirements of s. 455.667(5)(d)  
22 ~~except upon the written authorization of such patient.~~ Such  
23 records may be furnished in any civil or criminal proceeding,  
24 upon the issuance of a subpoena from a court of competent  
25 jurisdiction and proper notice to the patient or her or his  
26 legal representative by the party seeking such records. Such  
27 records or any part thereof, if transmitted through a data  
28 communication device not under the control or ownership of a  
29 pharmacy or affiliated company or not directly between a  
30 pharmacy and a treating practitioner, may not be accessed,  
31 used, or maintained by the operator or owner of the data

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1 communication device unless specifically authorized by this  
 2 section. It is the intent of this subsection to allow the use  
 3 and sharing of such records to improve patient care, provided  
 4 the pharmacist acts in the best interests of her or his  
 5 patient. Nothing in this subsection may be construed to  
 6 authorize or expand solicitation or marketing to patients or  
 7 potential patients in any manner not otherwise specifically  
 8 authorized by law.

9 Section 6. Section 465.014, Florida Statutes, is  
 10 amended to read:

11 465.014 Pharmacy technician.--No person other than a  
 12 licensed pharmacist or pharmacy intern may engage in the  
 13 practice of the profession of pharmacy, except that a licensed  
 14 pharmacist may delegate to nonlicensed pharmacy technicians  
 15 those duties, tasks, and functions which do not fall within  
 16 the purview of s. 465.003(13)~~(12)~~. All such delegated acts  
 17 shall be performed under the direct supervision of a licensed  
 18 pharmacist who shall be responsible for all such acts  
 19 performed by persons under his or her supervision. A pharmacy  
 20 technician, under the supervision of a pharmacist, may  
 21 initiate or receive communications with a practitioner or his  
 22 or her agent, on behalf of a patient, regarding refill  
 23 authorization requests. No licensed pharmacist shall  
 24 supervise more than one pharmacy technician unless otherwise  
 25 permitted by the guidelines adopted by the board. The board  
 26 shall establish guidelines to be followed by licensees or  
 27 permittees in determining the circumstances under which a  
 28 licensed pharmacist may supervise more than one but not more  
 29 than three pharmacy technicians.

30 Section 7. Paragraph (c) of subsection (2) of section  
 31 465.015, Florida Statutes, is amended to read:



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

12 Section 10. Subsection (19) of section 499.003,  
 13 Florida Statutes, is amended to read:

14 499.003 Definitions of terms used in ss.

15 499.001-499.081.--As used in ss. 499.001-499.081, the term:

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

22 Section 11. Paragraph (a) of subsection (1) and  
 23 subsection (5) of section 499.012, Florida Statutes, 1998  
 24 Supplement, are amended to read:

25 499.012 Wholesale distribution; definitions; permits;  
 26 general requirements.--

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

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

31 1. Any of the following activities, which is not a

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1 violation of s. 499.005(21) if such activity is conducted in  
2 accordance with s. 499.014:

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

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

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

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

29 (I) The agency or entity must obtain written  
30 authorization for the sale, purchase, trade, or other transfer  
31 of a prescription drug under this sub-subparagraph from the



1 Secretary of Health or his or her designee.  
2           (II) The contract provider or subcontractor must be  
3 \_\_\_\_\_  
4 drugs.  
5           (III) In the case of a subcontractor, the agency or  
6 \_\_\_\_\_  
7           (IV) A contract provider or subcontractor must  
8 maintain separate and apart from other prescription drug  
9 \_\_\_\_\_  
10 its possession.  
11           (V) The contract provider and subcontractor must  
12 \_\_\_\_\_  
13 movement or transfer of all the prescription drugs belonging  
14 to the agency or entity, including, but not limited to, the  
15 \_\_\_\_\_  
16 Each contractor and subcontractor dispensing or administering  
17 these drugs must maintain and produce records documenting the  
18 \_\_\_\_\_  
19 maintained include, but are not limited to, a perpetual  
20 inventory itemizing drugs received and drugs dispensed by  
21 \_\_\_\_\_  
22 which must be submitted to the agency or entity quarterly.  
23           (VI) The contract provider or subcontractor may  
24 \_\_\_\_\_  
25 eligible patients of the agency or entity or must return the  
26 prescription drugs for or to the agency or entity. The  
27 \_\_\_\_\_  
28 each person seeking to fill a prescription or obtain treatment  
29 that the person is an eligible patient of the agency or entity  
30 \_\_\_\_\_  
31 of the records of the contractor or subcontractor required

1 under sub-sub-subparagraph (V).

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

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

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

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

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

27 c. The transfer ~~purchase or acquisition~~ of a  
28 prescription drug acquired by a medical director on behalf of  
29 a licensed ~~an~~ emergency medical services provider to that  
30 ~~medical director for use by~~ emergency medical services  
31 provider and its transport vehicles for use in accordance with

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1 the provider's license under ~~providers acting within the scope~~  
2 ~~of their professional practice pursuant to~~ chapter 401.

3 d. The revocation of a sale or the return of a  
4 prescription drug to the person's prescription drug wholesale  
5 supplier.

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

11 f. The transfer of a prescription drug by a person  
12 authorized to purchase or receive prescription drugs to a  
13 person licensed or permitted to handle reverse distributions  
14 or destruction under the laws of the jurisdiction in which the  
15 person handling the reverse distribution or destruction  
16 receives the drug.

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

19 ~~3.4.~~ The distribution of prescription drug samples by  
20 manufacturers' representatives or distributors'  
21 representatives conducted in accordance with s. 499.028. ~~or~~

22 ~~4.5.~~ The sale, purchase, or trade of blood and blood  
23 components intended for transfusion. As used in this  
24 subparagraph ~~section~~, the term "blood" means whole blood  
25 collected from a single donor and processed either for  
26 transfusion or further manufacturing, and the term "blood  
27 components" means that part of the blood separated by physical  
28 or mechanical means.

29 5. The lawful dispensing of a prescription drug in  
30 accordance with chapter 465.

31 (5) The department may adopt rules governing the

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1 recordkeeping, storage, and handling with respect to each of  
2 the distributions of prescription drugs specified in  
3 subparagraphs (1)(a)~~1.-4.1., 2., 4., and 5.~~

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

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

9 And the title is amended as follows:

10 remove from the title of the bill: everything before the  
11 enacting clause

12

13 and insert in lieu thereof:

14

A bill to be entitled

15

An act relating to pharmacy practice; providing

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

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defining the term "data communication device";

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revising the definition of the term "practice

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of the profession of pharmacy"; amending s.

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465.016, F.S.; authorizing the redispensing of

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unused or returned unit-dose medication by

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correctional facilities under certain

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conditions; providing that using or releasing a

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patient's records except as authorized by

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chapter 455 or chapter 465, F.S., constitutes a

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ground for disciplinary action against a

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pharmacist, for which there are penalties;

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amending s. 465.017, F.S.; providing additional

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persons to whom and entities to which records

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relating to the filling of prescriptions and

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the dispensing of medicinal drugs that are

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2 specifying authorized uses of patient records  
3 by pharmacy owners; providing restrictions on  
  
5 communication device; amending ss. 465.014,  
6 465.015, 465.0196, 468.812, and 499.003, F.S.;  
  
8 amending s. 499.012, F.S.; redefining the term  
9 "wholesale distribution," relating to the  
  
11 for the exclusion of certain activities;  
12 providing effective dates.

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