

Bill No. CS for SB 2076

Amendment No.     

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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11 Senators Jones and Hargrett moved the following amendment:

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13 **Senate Amendment (with title amendment)**

14 On page 15, between lines 16 and 17,

15

16 insert:

17 Section 11. Effective July 1, 1998, subsection (12) of  
18 section 465.003, Florida Statutes, is amended, subsections (4)  
19 through (14) are renumbered as subsections (5) through (15),  
20 respectively, and a new subsection (4) is added to said  
21 section, to read:

22 465.003 Definitions.--As used in this chapter, the  
23 term:

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

28 (13)(12) "Practice of the profession of pharmacy"  
29 includes compounding, dispensing, and consulting concerning  
30 contents, therapeutic values, and uses of any medicinal drug;  
31 and consulting concerning therapeutic values and interactions

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1 of patent or proprietary preparations, whether pursuant to  
2 prescriptions or in the absence and entirely independent of  
3 such prescriptions or orders; and other pharmaceutical  
4 services. For purposes of this subsection, "other  
5 pharmaceutical services" means the evaluation and monitoring  
6 of the patient's health as it relates to drug therapy and  
7 assisting the patient in the management of his or her drug  
8 therapy, and includes the review of the patient's drug therapy  
9 and communication with the patient and the patient's  
10 prescribing health care provider as licensed under chapter  
11 458, chapter 459, chapter 461, or chapter 466, or similar  
12 statutory provision in another jurisdiction, or such  
13 provider's agent or such other persons as specifically  
14 authorized by the patient, regarding the drug therapy. Nothing  
15 herein shall be interpreted to permit an alteration of a  
16 prescriber's directions, unless otherwise permitted by law.  
17 "Practice of the profession of pharmacy"~~The phrase~~ also  
18 includes any other act, service, operation, research, or  
19 transaction incidental to, or forming a part of, any of the  
20 foregoing acts, requiring, involving, or employing the science  
21 or art of any branch of the pharmaceutical profession, study,  
22 or training, and shall expressly permit a pharmacist to  
23 transmit information from persons authorized to prescribe  
24 medicinal drugs to their patients. A pharmacist may also  
25 administer immunizations within the framework of an  
26 established protocol under a supervisory practitioner who is a  
27 physician licensed under chapter 458 or chapter 459 or by  
28 written agreement with a county health department. Each  
29 protocol must contain specific procedures to address any  
30 unforeseen allergic reaction to an immunization. A pharmacist  
31 may not enter into a protocol unless he or she maintains at

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1 least \$200,000 of professional liability insurance, and not  
2 until the pharmacist has completed training in immunizations  
3 as may be required by the board. The decision by a supervisory  
4 practitioner to enter into such a protocol is a professional  
5 decision of the practitioner, and no person may interfere with  
6 a supervisory practitioner's decision as to whether to enter  
7 into such a protocol. A pharmacist may not enter into a  
8 protocol that is to be performed while acting as an employee  
9 without the written approval of the owner of the pharmacy.

10 Section 12. Paragraph (1) of subsection (1) of section  
11 465.016, Florida Statutes, is amended to read:

12 465.016 Disciplinary actions.--

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

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

27 Section 13. Effective July 1, 1998, a new paragraph  
28 (q) is added to subsection (1) of section 465.016, Florida  
29 Statutes, to read:

30 465.016 Disciplinary actions.--

31 (1) The following acts shall be grounds for

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1 disciplinary action set forth in this section:

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

4 Section 14. Effective July 1, 1998, subsection (2) of  
5 section 465.017, Florida Statutes, is amended to read:

6 465.017 Authority to inspect.--

7 (2) Except as permitted by this chapter, and chapters  
8 406, 409, 455, 499, and 893, records maintained by in a  
9 pharmacy relating to the filling of prescriptions and the  
10 dispensing of medicinal drugs shall not be furnished, except  
11 upon the written authorization of the patient, to any person  
12 other than to the patient for whom the drugs were dispensed,  
13 ~~or her or his legal representative, or to the department~~  
14 ~~pursuant to existing law,~~ or, in the event that the patient is  
15 incapacitated or unable to request said records, her or his  
16 spouse; or to the department pursuant to existing law; or to  
17 health care practitioners and pharmacists consulting or  
18 dispensing to the patient; or to insurance carriers or other  
19 payors authorized by the patient to receive such records. For  
20 purposes of this section, records held in a pharmacy shall be  
21 considered owned by the owner of the pharmacy. The pharmacy  
22 owner may use such records in the aggregate without patient  
23 identification data, regardless of where such records are  
24 held, for purposes reasonably related to the business and  
25 practice of pharmacy ~~except upon the written authorization of~~  
26 ~~such patient.~~ Such records may be furnished in any civil or  
27 criminal proceeding, upon the issuance of a subpoena from a  
28 court of competent jurisdiction and proper notice to the  
29 patient or her or his legal representative by the party  
30 seeking such records. Such records or any part thereof, if  
31 transmitted through a data communication device not under the

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1 control or ownership of a pharmacy or affiliated company or  
2 not directly between a pharmacy and a treating practitioner,  
3 may not be accessed, used, or maintained by the operator or  
4 owner of the data communication device unless specifically  
5 authorized by this section. It is the intent of this  
6 subsection to allow the use and sharing of such records to  
7 improve patient care, provided the pharmacist acts in the best  
8 interests of their patient. Nothing herein shall be construed  
9 to authorize or expand solicitation or marketing to patients  
10 or potential patients in any manner not otherwise specifically  
11 authorized by law.

12 Section 15. Effective July 1, 1998, subsection (4) of  
13 section 465.019, Florida Statutes, is amended to read:

14 465.019 Institutional pharmacies; permits.--

15 (4) Medicinal drugs shall be dispensed in an  
16 institutional pharmacy to outpatients only when that  
17 institution has secured a community pharmacy permit from the  
18 department. However, an individual licensed to prescribe  
19 medicinal drugs in this state may dispense up to a 24-hour  
20 supply of a medicinal drug to any patient of an emergency  
21 department of a hospital that operates a Class II  
22 institutional pharmacy, provided the physician treating the  
23 patient in such hospital's emergency department determines  
24 that the medicinal drug is warranted and that community  
25 pharmacy services are not readily accessible, geographically  
26 or otherwise, to the patient. Such dispensing from the  
27 emergency department shall be in accordance with the  
28 procedures of the hospital. For any such patient for whom a  
29 medicinal drug is warranted for a period to exceed 24 hours,  
30 an individual licensed to prescribe such drug shall dispense a  
31 24-hour supply of such drug to the patient and shall provide

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1 the patient a prescription for such drug for use after the  
2 initial 24-hour period. The board may adopt rules necessary to  
3 carry out the provisions of this subsection.

4 Section 16. Effective July 1, 1998, section 465.014,  
5 Florida Statutes, is amended to read:

6 465.014 Pharmacy technician.--No person other than a  
7 licensed pharmacist or pharmacy intern may engage in the  
8 practice of the profession of pharmacy, except that a licensed  
9 pharmacist may delegate to nonlicensed pharmacy technicians  
10 those duties, tasks, and functions which do not fall within  
11 the purview of s. 465.003(13)(12). All such delegated acts  
12 shall be performed under the direct supervision of a licensed  
13 pharmacist who shall be responsible for all such acts  
14 performed by persons under his or her supervision. A pharmacy  
15 technician, under the supervision of a pharmacist, may  
16 initiate or receive communications with a practitioner or his  
17 or her agent, on behalf of a patient, regarding refill  
18 authorization requests. No licensed pharmacist shall supervise  
19 more than one pharmacy technician unless otherwise permitted  
20 by the guidelines adopted by the board. The board shall  
21 establish guidelines to be followed by licensees or permittees  
22 in determining the circumstances under which a licensed  
23 pharmacist may supervise more than one but not more than three  
24 pharmacy technicians.

25 Section 17. Effective July 1, 1998, paragraph (c) of  
26 subsection (2) of section 465.015, Florida Statutes, is  
27 amended to read:

28 465.015 Violations and penalties.--

29 (2) It is unlawful for any person:

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

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

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1 prescription.

2 Section 18. Effective July 1, 1998, section 465.0196,  
3 Florida Statutes, is amended to read:

4 465.0196 Special pharmacy permits.--Any person  
5 desiring a permit to operate a pharmacy which does not fall  
6 within the definitions set forth in s. 465.003(11)(~~10~~)(a)1.,  
7 2., and 3. shall apply to the department for a special  
8 pharmacy permit. If the board certifies that the application  
9 complies with the applicable laws and rules of the board  
10 governing the practice of the profession of pharmacy, the  
11 department shall issue the permit. No permit shall be issued  
12 unless a licensed pharmacist is designated to undertake the  
13 professional supervision of the compounding and dispensing of  
14 all drugs dispensed by the pharmacy. The licensed pharmacist  
15 shall be responsible for maintaining all drug records and for  
16 providing for the security of the area in the facility in  
17 which the compounding, storing, and dispensing of medicinal  
18 drugs occurs. The permittee shall notify the department  
19 within 10 days of any change of the licensed pharmacist  
20 responsible for such duties.

21 Section 19. Effective July 1, 1998, subsection (3) of  
22 section 468.812, Florida Statutes, is amended to read:

23 468.812 Exemptions from licensure.--

24 (3) The provisions of this act relating to orthotics  
25 or pedorthics do not apply to any licensed pharmacist or to  
26 any person acting under the supervision of a licensed  
27 pharmacist. The practice of orthotics or pedorthics by a  
28 pharmacist or any of the pharmacist's employees acting under  
29 the supervision of a pharmacist shall be construed to be  
30 within the meaning of the term "practice of the profession of  
31 pharmacy" as set forth in s. 465.003(13)(~~12~~), and shall be

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1 subject to regulation in the same manner as any other pharmacy  
 2 practice. The Board of Pharmacy shall develop rules regarding  
 3 the practice of orthotics and pedorthics by a pharmacist. Any  
 4 pharmacist or person under the supervision of a pharmacist  
 5 engaged in the practice of orthotics or pedorthics shall not  
 6 be precluded from continuing that practice pending adoption of  
 7 these rules.

8 Section 20. Effective July 1, 1998, subsection (19) of  
 9 section 499.003, Florida Statutes, is amended to read:

10 499.003 Definitions of terms used in ss.

11 499.001-499.081.--As used in ss. 499.001-499.081, the term:

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

18 Section 21. Effective July 1, 1998, paragraph (a) of  
 19 subsection (1) of section 499.012, Florida Statutes, is  
 20 amended to read:

21 499.012 Wholesale distribution; definitions; permits;  
 22 general requirements.--

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

24 (a) "Wholesale distribution" means distribution of  
 25 prescription drugs to persons other than a consumer or  
 26 patient, but does not include lawful dispensing of a  
 27 prescription drug in accordance with chapter 465; however:

28 1. As used in s. 499.005(21), the term "wholesale  
 29 distribution" does not include any of the following activities  
 30 if the activity is conducted in accordance with s. 499.014:

31 a.1. The purchase or other acquisition by a hospital



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1 or other health care entity that is a member of a group  
2 purchasing organization of a prescription drug for its own use  
3 from the group purchasing organization or from other hospitals  
4 or health care entities that are members of that organization;

5 ~~b.2.~~ The sale, purchase, or trade of a prescription  
6 drug or an offer to sell, purchase, or trade a prescription  
7 drug by a charitable organization described in s. 501(c)(3) of  
8 the Internal Revenue Code of 1986, as amended and revised, to  
9 a nonprofit affiliate of the organization to the extent  
10 otherwise permitted by law;

11 ~~c.3.~~ The sale, purchase, or trade of a prescription  
12 drug or an offer to sell, purchase, or trade a prescription  
13 drug among hospitals or other health care entities that are  
14 under common control. For purposes of this section, "common  
15 control" means the power to direct or cause the direction of  
16 the management and policies of a person or an organization,  
17 whether by ownership of stock, by voting rights, by contract,  
18 or otherwise.

19 2. As used in s. 499.005(21), the term "wholesale  
20 distribution" also does not include any of the following  
21 activities if the activity is done in accordance with rules  
22 established by the department:

23 ~~a.4.~~ The sale, purchase, or trade of a prescription  
24 drug among federal, state, or local government health care  
25 entities that are under common control and are authorized to  
26 purchase such prescription drug.

27 b. The sale, purchase, trade, or other transfer of a  
28 prescription drug from or for any of the following entities: a  
29 federal, state, or local government agency or any entity  
30 eligible to purchase prescription drugs at public health  
31 services prices pursuant to s. 602 of Pub. L. No. 102-585 to a

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1 contract provider or its subcontractor for eligible patients  
2 of the entity if:

3 (I) The entity obtains written authorization for the  
4 sale, purchase, trade, or other transfer of a prescription  
5 drug under this paragraph from the Secretary of Health. This  
6 written authorization must be based on a favorable  
7 recommendation by the Drug Regulation Advisory Group after the  
8 group has reviewed the entity's submission to the department  
9 of a detailed plan and justification for the sale, purchase,  
10 trade, or other transfer of a prescription drug under this  
11 paragraph and must enhance the public's health by improving  
12 needed access, quality, or safety because current patient drug  
13 delivery systems are inadequate;

14 (II) The contract provider or subcontractor is  
15 authorized by law to administer or dispense prescription  
16 drugs;

17 (III) In the case of a subcontractor, the entity is a  
18 party to and executes the subcontract;

19 (IV) A contract provider or subcontractor maintains  
20 separate and apart any prescription drugs of the entity in its  
21 possession from other prescription drug inventory;

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

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1 number or administered by patient identifier, which must be  
 2 submitted to the entity monthly;

3 (VI) The contract provider or subcontractor either  
 4 administers or dispenses the prescription drugs only to the  
 5 eligible patients of the entity or returns the prescription  
 6 drug for or to the entity. The contract provider or  
 7 subcontractor must require proof from each person seeking to  
 8 fill a prescription or obtain treatment that the person is an  
 9 eligible patient of the entity and must, at a minimum,  
 10 maintain a copy of this proof as part of the records of the  
 11 contractor or subcontractor required under  
 12 sub-sub-subparagraph (V);

13 (VII) The prescription drugs transferred pursuant to  
 14 this paragraph may not be billed to Medicaid; and

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

24 c.5. The sale, purchase, or trade of a prescription  
 25 drug or an offer to sell, purchase, or trade a prescription  
 26 drug for emergency medical reasons; for purposes of this  
 27 sub-subparagraph ~~subparagraph~~, the term "emergency medical  
 28 reasons" includes transfers of prescription drugs by a retail  
 29 pharmacy to another retail pharmacy to alleviate a temporary  
 30 shortage.

31 d.6. The ~~transfer purchase or acquisition~~ of a

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

7 ~~7. The dispensing of a prescription drug pursuant to a~~  
 8 ~~prescription~~

9 ~~e.8.~~ The distribution of prescription drug samples by  
 10 manufacturers' representatives or distributors'  
 11 representatives conducted in accordance with s. 499.028. ~~or~~

12 ~~f.9.~~ The sale, purchase, or trade of blood and blood  
 13 components intended for transfusion. As used in this section,  
 14 the term "blood" means whole blood collected from a single  
 15 donor and processed either for transfusion or further  
 16 manufacturing, and the term "blood components" means that part  
 17 of the blood separated by physical or mechanical means.

18 Section 22. Effective July 1, 1998, section 499.0722,  
 19 Florida Statutes, is created to read:

20 499.0722 Drug Regulation Advisory Group; exemptions.--

21 (1) There is created the Drug Regulation Advisory  
 22 Group, which is an independent advisory group composed of at  
 23 least 11 members appointed by the Secretary of Health and  
 24 including:

25 (a) One member representing the prescription drug  
 26 wholesale industry in this state;

27 (b) One member representing pharmaceutical  
 28 manufacturers, who may represent pharmaceutical manufacturers  
 29 nationwide;

30 (c) One member who is a practicing pharmacist;

31 (d) One member representing the Agency for Health Care

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1 Administration;

2 (e) One member who is a physician licensed under  
3 chapter 458 or chapter 459;

4 (f) One consumer representative;

5 (g) One member representing the cosmetic industry;

6 (h) One member representing the compressed medical gas  
7 industry;

8 (i) One member representing the medical device  
9 manufacturing industry;

10 (j) The Executive Director of the Board of Pharmacy,  
11 who shall be an ex officio member; and

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

14 (l) One member representing hospitals.

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

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

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

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

30 (a) Making recommendations to the Secretary of Health  
31 regarding authorizations for the sale, purchase, trade, or

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1 other transfer of a prescription drug under s. 499.012(1)(b)2.

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

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

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

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

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

15  
16

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

18 And the title is amended as follows:

19 On page 1, line 25, after the semicolon

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21 insert:

22 amending s. 465.003, F.S.; defining the term  
23 "data communication device"; revising the  
24 definition of the term "practice of the  
25 profession of pharmacy"; amending s. 465.016,  
26 F.S.; authorizing the redispensing of unused or  
27 returned unit-dose medication by correctional  
28 facilities under certain conditions; amending  
29 s. 465.016, F.S.; providing a ground for which  
30 a pharmacist may be subject to discipline by  
31 the Board of Pharmacy; amending s. 465.017,

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1 F.S.; providing additional persons and entities  
2 to whom records relating to the filling of  
3 prescriptions and the dispensing of medicinal  
4 drugs that are maintained by a pharmacy may be  
5 furnished; specifying authorized uses of  
6 patient records by pharmacy owners; providing  
7 restrictions on such records when transmitted  
8 through a data communication device; amending  
9 s. 465.019, F.S.; providing for certain  
10 dispensing of medicinal drugs to patients in  
11 emergency departments of certain hospitals;  
12 amending ss. 465.014, 465.015, 465.0196,  
13 468.812, and 499.003, F.S.; correcting cross  
14 references, to conform; amending s. 499.012,  
15 F.S.; redefining the term "wholesale  
16 distribution," relating to the distribution of  
17 prescription drugs, by providing for the  
18 exclusion of certain activities; creating s.  
19 499.0722, F.S.; creating the Drug Regulation  
20 Advisory Group; providing membership; providing  
21 terms of office; providing for meetings, for  
22 reimbursement of expenses, and for purposes and  
23 duties of the group; allowing the Department of  
24 Health to publish compliance policy guidelines  
25 that include recommendations of the group;

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