

By the Committee on Health, Aging and Long-Term Care; and  
 Senator Lee

317-2054-99

1                                   A bill to be entitled  
 2           An act relating to pharmacy practice; amending  
 3           s. 465.003, F.S.; revising the definition of  
 4           the term "practice of the profession of  
 5           pharmacy"; amending s. 465.016, F.S.;  
 6           authorizing the redispensing of unused or  
 7           returned unit-dose medication by correctional  
 8           facilities under certain conditions; amending  
 9           s. 499.012, F.S.; redefining the term  
 10          "wholesale distribution," relating to the  
 11          distribution of prescription drugs, to provide  
 12          for the exclusion of certain activities;  
 13          providing effective dates.

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

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 17           Section 1. Subsection (12) of section 465.003, Florida  
 18 Statutes, is amended to read:

19           465.003 Definitions.--As used in this chapter, the  
 20 term:

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

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

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

23 465.016 Disciplinary actions.--

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

26 (1) Placing in the stock of any pharmacy any part of  
27 any prescription compounded or dispensed which is returned by  
28 a patient; however, in a hospital, nursing home, correctional  
29 facility, or extended care facility in which unit-dose  
30 medication is dispensed to inpatients, each dose being  
31 individually sealed and the individual unit dose or unit-dose

1 system labeled with the name of the drug, dosage strength,  
2 manufacturer's control number, and expiration date, if any,  
3 the unused unit dose of medication may be returned to the  
4 pharmacy for redispensing. Each pharmacist shall maintain  
5 appropriate records for any unused or returned medicinal  
6 drugs.

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

10 499.012 Wholesale distribution; definitions; permits;  
11 general requirements.--

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

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

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

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

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

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

1 among hospitals or other health care entities that are under  
2 common control. For purposes of this section, "common control"  
3 means the power to direct or cause the direction of the  
4 management and policies of a person or an organization,  
5 whether by ownership of stock, by voting rights, by contract,  
6 or otherwise.

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

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

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

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

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

27 (V) The contract provider and subcontractor must  
28 maintain and produce immediately for inspection all records of  
29 movement or transfer of all the prescription drugs belonging  
30 to the agency or entity, including, but not limited to, the  
31 records of receipt and disposition of prescription drugs.

1 Each contractor and subcontractor dispensing or administering  
2 these drugs must maintain and produce records documenting the  
3 dispensing or administration. Records that are required to be  
4 maintained include, but are not limited to, a perpetual  
5 inventory itemizing drugs received and drugs dispensed by  
6 prescription number or administered by patient identifier,  
7 which must be submitted to the agency or entity quarterly.

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

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

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

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

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

5           b. The sale, purchase, or trade of a prescription drug  
6 or an offer to sell, purchase, or trade a prescription drug  
7 for emergency medical reasons. ~~For purposes of this~~  
8 ~~sub-subparagraph~~ subparagraph, the term "emergency medical  
9 reasons" includes transfers of prescription drugs by a retail  
10 pharmacy to another retail pharmacy to alleviate a temporary  
11 shortage.

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

19           d. The revocation of a sale or the return of a  
20 prescription drug to the person's prescription drug wholesale  
21 supplier.

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

27           f. The transfer of a prescription drug by a person  
28 authorized to purchase or receive prescription drugs to a  
29 person licensed or permitted to handle reverse distributions  
30 or destruction under the laws of the jurisdiction in which the  
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1 person handling the reverse distribution or destruction  
2 receives the drug.

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

5 3.4. The distribution of prescription drug samples by  
6 manufacturers' representatives or distributors'  
7 representatives conducted in accordance with s. 499.028. ~~or~~

8 4.5. The sale, purchase, or trade of blood and blood  
9 components intended for transfusion. As used in this  
10 subparagraph section, the term "blood" means whole blood  
11 collected from a single donor and processed either for  
12 transfusion or further manufacturing, and the term "blood  
13 components" means that part of the blood separated by physical  
14 or mechanical means.

15 5. The lawful dispensing of a prescription drug in  
16 accordance with chapter 465.

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

21 Section 4. Except as otherwise provided in this act,  
22 this act shall take effect July 1, 1999.

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1                   STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN  
2                   COMMITTEE SUBSTITUTE FOR  
3                   Senate Bill 812

4   The Committee Substitute for SB 812 no longer authorizes  
5   pharmacists to administer immunizations under a protocol;  
6   deletes provisions expanding the parties to whom  
7   pharmaceutical records may be released; revises the definition  
8   of "other pharmaceutical services" to mean the monitoring of  
9   the patient's drug therapy and assisting the patient in the  
10  management of his or her drug therapy, and includes review of  
11  the patient's drug therapy and communication with the  
12  patient's prescribing health care provider as licensed under  
13  the medical practice act, the osteopathic practice act, the  
14  podiatric practice act, or the dental practice act, or similar  
15  law in another jurisdiction, or such provider's agent or other  
16  persons specifically authorized by the patient, regarding the  
17  drug therapy. The committee substitute provides that a  
18  pharmacist may not alter a prescriber's directions, the  
19  diagnosis or treatment of any disease, the initiation of any  
20  drug therapy, the practice of medicine, or the practice of  
21  osteopathic medicine, unless otherwise permitted by law.  
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