

By the Committees on Criminal Justice; Health, Aging, and Long-Term Care; and Senator Saunders

307-2130-04

1                                   A bill to be entitled  
2           An act relating to pharmacy; amending s.  
3           465.003, F.S.; defining the term "Internet  
4           pharmacy"; amending s. 465.0156, F.S.;  
5           exempting Internet pharmacies from registration  
6           requirements applicable to nonresident  
7           pharmacies; requiring the registered  
8           nonresident pharmacy and the pharmacist  
9           designated by that pharmacy to serve as the  
10          prescription department manager or its  
11          equivalent to be licensed in the state of  
12          location; amending s. 465.016, F.S.; providing  
13          for disciplinary action for dispensing a  
14          medicinal drug when the pharmacist knows or has  
15          reason to believe the prescription is not based  
16          on a valid practitioner-patient relationship;  
17          creating s. 465.0161, F.S.; prohibiting the  
18          distribution of medicinal drugs by an Internet  
19          pharmacy without a permit; providing penalties;  
20          amending s. 465.0196, F.S., relating to special  
21          pharmacy permits, to conform; creating s.  
22          465.0197, F.S.; requiring Internet pharmacies  
23          to be permitted and providing requirements  
24          therefor; requiring the Internet pharmacy and  
25          the pharmacist designated by that pharmacy to  
26          serve as the prescription department manager or  
27          its equivalent to be licensed in the state of  
28          location; amending s. 465.023, F.S.; providing  
29          an additional ground for which the Board of  
30          Pharmacy may take action against a permitted  
31          pharmacy; amending s. 465.0255, F.S.; revising

1 requirements for pharmacists to deliver  
2 specified disclosures to purchasers when  
3 dispensing a medicinal drug; amending s.  
4 465.026, F.S.; creating an exception to the  
5 requirements for filling or refilling a  
6 transferred prescription; amending s. 499.0121,  
7 F.S.; providing recordkeeping requirements  
8 relating to the storage and handling of  
9 prescription drugs which affiliated groups must  
10 fulfill; amending s. 895.02, F.S.; including  
11 violation of s. 465.0161, F.S., in the  
12 definition of the term "racketeering activity"  
13 for prosecution under ch. 895, F.S.; providing  
14 an effective date.

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

17  
18 Section 1. Paragraph (a) of subsection (11) of section  
19 465.003, Florida Statutes, is amended to read:

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

22 (11)(a) "Pharmacy" includes a community pharmacy, an  
23 institutional pharmacy, a nuclear pharmacy, ~~and~~ a special  
24 pharmacy, and an Internet pharmacy.

25 1. The term "community pharmacy" includes every  
26 location where medicinal drugs are compounded, dispensed,  
27 stored, or sold or where prescriptions are filled or dispensed  
28 on an outpatient basis.

29 2. The term "institutional pharmacy" includes every  
30 location in a hospital, clinic, nursing home, dispensary,  
31 sanitarium, extended care facility, or other facility,

1 hereinafter referred to as "health care institutions," where  
2 medicinal drugs are compounded, dispensed, stored, or sold.

3 3. The term "nuclear pharmacy" includes every location  
4 where radioactive drugs and chemicals within the  
5 classification of medicinal drugs are compounded, dispensed,  
6 stored, or sold. The term "nuclear pharmacy" does not include  
7 hospitals licensed under chapter 395 or the nuclear medicine  
8 facilities of such hospitals.

9 4. The term "special pharmacy" includes every location  
10 where medicinal drugs are compounded, dispensed, stored, or  
11 sold if such locations are not otherwise defined in this  
12 subsection.

13 5. The term "Internet pharmacy" includes locations  
14 that are not otherwise defined in this subsection where  
15 medicinal drugs are compounded, dispensed, or stored and  
16 subsequently sold primarily or exclusively to consumers over  
17 the Internet.

18 Section 2. Subsections (7) and (8) are added to  
19 section 465.0156, Florida Statutes, to read:

20 465.0156 Registration of nonresident pharmacies.--

21 (7) This section does not apply to Internet pharmacies  
22 required to be permitted under s. 465.0197.

23 (8) Notwithstanding s. 465.003(10), for purposes of  
24 this section, the registered pharmacy and the pharmacist  
25 designated by the registered pharmacy as the prescription  
26 department manager or the equivalent must be licensed in the  
27 state of location in order to dispense into this state.

28 Section 3. Paragraph (s) is added to subsection (1) of  
29 section 465.016, Florida Statutes, to read:

30 465.016 Disciplinary actions.--

31

1           (1) The following acts constitute grounds for denial  
2 of a license or disciplinary action, as specified in s.  
3 456.072(2):

4           (s) Dispensing any medicinal drug based upon a  
5 communication that purports to be a prescription as defined by  
6 s. 465.003(14) or s. 893.02(20) when the pharmacist knows or  
7 has reason to believe that the purported prescription is not  
8 based upon a valid practitioner-patient relationship.

9           Section 4. Section 465.0161, Florida Statutes, is  
10 created to read:

11           465.0161 Distribution of medicinal drugs without a  
12 permit.--An Internet pharmacy that distributes a medicinal  
13 drug to any person in this state without being permitted as a  
14 pharmacy under this chapter commits a felony of the second  
15 degree, punishable as provided in s. 775.082, s. 775.083, or  
16 s. 775.084.

17           Section 5. Section 465.0196, Florida Statutes, is  
18 amended to read:

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

1 which the compounding, storing, and dispensing of medicinal  
2 drugs occurs. The permittee shall notify the department within  
3 10 days of any change of the licensed pharmacist responsible  
4 for such duties. Every permittee that employs or otherwise  
5 utilizes pharmacy technicians shall have a written policy and  
6 procedures manual specifying those duties, tasks, and  
7 functions which a pharmacy technician is allowed to perform.

8 Section 6. Section 465.0197, Florida Statutes, is  
9 created to read:

10 465.0197 Internet pharmacy permits.--

11 (1) Any person desiring a permit to operate an  
12 Internet pharmacy shall apply to the department for an  
13 Internet pharmacy permit. If the board certifies that the  
14 application complies with the applicable laws and rules of the  
15 board governing the practice of the profession of pharmacy,  
16 the department shall issue the permit. No permit shall be  
17 issued unless a licensed pharmacist is designated as the  
18 prescription department manager for dispensing medicinal drugs  
19 to persons in this state. The licensed pharmacist shall be  
20 responsible for maintaining all drug records and for providing  
21 for the security of the area in the facility in which the  
22 compounding, storing, and dispensing of medicinal drugs to  
23 persons in this state occurs. The permittee shall notify the  
24 department within 30 days of any change of the licensed  
25 pharmacist responsible for such duties. Every permittee that  
26 employs or otherwise utilizes pharmacy technicians shall have  
27 a written policy and procedures manual specifying those  
28 duties, tasks, and functions which a pharmacy technician is  
29 allowed to perform.

30 (2) An Internet pharmacy must be permitted under this  
31 section to sell medicinal drugs to persons in this state.

1           (3) An Internet pharmacy shall provide pharmacy  
2 services at a high level of protection and competence and  
3 shall disclose to the board the following specific  
4 information:

5           (a) That it maintains at all times a valid, unexpired  
6 license, permit, or registration to operate the pharmacy in  
7 compliance with the laws of the state in which the dispensing  
8 facility is located and from which the medicinal drugs shall  
9 be dispensed.

10           (b) The location, names, and titles of all principal  
11 corporate officers and the pharmacist who serves as the  
12 prescription department manager for dispensing medicinal drugs  
13 to persons in this state. This disclosure shall be made within  
14 30 days after any change of location, principal corporate  
15 officer, or pharmacist serving as the prescription department  
16 manager for dispensing medicinal drugs to persons in this  
17 state.

18           (c) That it complies with all lawful directions and  
19 requests for information from the regulatory or licensing  
20 agency of all states in which it is licensed as well as with  
21 all requests for information made by the board pursuant to  
22 this section. It shall respond directly to all communications  
23 from the board concerning emergency circumstances arising from  
24 errors in the dispensing of medicinal drugs to persons in this  
25 state.

26           (d) That it maintains its records of medicinal drugs  
27 dispensed to patients in this state so that the records are  
28 readily retrievable from the other business records of the  
29 pharmacy and from the records of other medicinal drugs  
30 dispensed.

31

1           (e) That during its regular hours of operation but not  
2 less than 6 days per week, for a minimum of 40 hours per week,  
3 a toll-free telephone service shall be provided to facilitate  
4 communication between patients in this state and a pharmacist  
5 at the pharmacy who has access to the patient's records. This  
6 toll-free number must be disclosed on the label affixed to  
7 each container of dispensed medicinal drugs.

8           (4) Notwithstanding s. 465.003(10), for purposes of  
9 this section, the Internet pharmacy and the pharmacist  
10 designated by the Internet pharmacy as the prescription  
11 department manager or the equivalent must be licensed in the  
12 state of location in order to dispense into this state.

13           Section 7. Subsection (1) of section 465.023, Florida  
14 Statutes, is amended to read:

15           465.023 Pharmacy permittee; disciplinary action.--

16           (1) The department or the board may revoke or suspend  
17 the permit of any pharmacy permittee, and may fine, place on  
18 probation, or otherwise discipline any pharmacy permittee who  
19 has:

20           (a) Obtained a permit by misrepresentation or fraud or  
21 through an error of the department or the board;

22           (b) Attempted to procure, or has procured, a permit  
23 for any other person by making, or causing to be made, any  
24 false representation;

25           (c) Violated any of the requirements of this chapter  
26 or any of the rules of the Board of Pharmacy; of chapter 499,  
27 known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss.  
28 301-392, known as the "Federal Food, Drug, and Cosmetic Act";  
29 of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug  
30 Abuse Prevention and Control Act; or of chapter 893; ~~or~~

31

1 (d) Been convicted or found guilty, regardless of  
2 adjudication, of a felony or any other crime involving moral  
3 turpitude in any of the courts of this state, of any other  
4 state, or of the United States; or.

5 (e) Aided or abetted in dispensing any medicinal drug  
6 based upon a communication that purports to be a prescription  
7 as defined by s. 465.003(14) or s. 893.02(20) when the  
8 permittee knows or has reason to believe that the purported  
9 prescription is not based upon a valid practitioner-patient  
10 relationship.

11 Section 8. Section 465.0255, Florida Statutes, is  
12 amended to read:

13 465.0255 Expiration date of medicinal drugs; display;  
14 related use and storage instructions.--

15 (1) The manufacturer, repackager, or other distributor  
16 of any medicinal drug shall display the expiration date of  
17 each drug in a readable fashion on the container and on its  
18 packaging. The term "readable" means conspicuous and bold.

19 (2) Each pharmacist for a community pharmacy  
20 dispensing medicinal drugs and each practitioner dispensing  
21 medicinal drugs on an outpatient basis shall display on the  
22 outside of the container of each medicinal drug dispensed, or  
23 in other written form delivered to the purchaser:7

24 (a) The expiration date when provided by the  
25 manufacturer, repackager, or other distributor of the drug; or  
26 ~~and~~

27 (b) An earlier beyond-use date for expiration, which  
28 may be up to 1 year after the date of dispensing.

29  
30 The dispensing pharmacist or practitioner must provide  
31 information concerning the expiration date to the purchaser



1 upon request and must provide appropriate instructions  
2 regarding the proper use and storage of the drug.

3 (3) ~~Nothing in~~ This section does not ~~shall~~ impose  
4 liability on the dispensing pharmacist or practitioner for  
5 damages related to, or caused by, a medicinal drug that loses  
6 its effectiveness prior to the expiration date displayed by  
7 the dispensing pharmacist or practitioner.

8 (4)~~(3)~~ The provisions of this section are intended to  
9 notify the patient receiving a medicinal drug of the  
10 information required by this section, and the dispensing  
11 pharmacist or practitioner shall not be liable for the  
12 patient's failure to heed such notice or to follow the  
13 instructions for storage.

14 Section 9. Subsection (7) is added to section 465.026,  
15 Florida Statutes, to read:

16 465.026 Filling of certain prescriptions.--Nothing  
17 contained in this chapter shall be construed to prohibit a  
18 pharmacist licensed in this state from filling or refilling a  
19 valid prescription which is on file in a pharmacy located in  
20 this state or in another state and has been transferred from  
21 one pharmacy to another by any means, including any electronic  
22 means, under the following conditions:

23 (7) For purposes of this section, a mail order  
24 pharmacy that uses a common database to perform automated  
25 prescription filling or dispensing functions may process a  
26 prescription for a controlled substance using that common  
27 database to perform prescription filling or dispensing  
28 functions in compliance with federal law and regulation.

29 Section 10. Paragraph (h) is added to subsection (6)  
30 of section 499.0121, Florida Statutes, to read:

31

1           499.0121 Storage and handling of prescription drugs;  
2 recordkeeping.--The department shall adopt rules to implement  
3 this section as necessary to protect the public health,  
4 safety, and welfare. Such rules shall include, but not be  
5 limited to, requirements for the storage and handling of  
6 prescription drugs and for the establishment and maintenance  
7 of prescription drug distribution records.

8           (6) RECORDKEEPING.--The department shall adopt rules  
9 that require keeping such records of prescription drugs as are  
10 necessary for the protection of the public health.

11           (h)1. This paragraph applies only to an affiliated  
12 group, as defined by s. 1504 of the Internal Revenue Code of  
13 1986, as amended, which is composed of chain drug entities,  
14 including 50 retail pharmacies, warehouses, or repackagers,  
15 which are members of the same affiliated group.

16           2. Each warehouse within the affiliated group must  
17 comply with all applicable federal and state drug wholesale  
18 permit requirements and must purchase, receive, hold, and  
19 distribute prescription drugs only to a retail pharmacy or  
20 warehouse within the affiliated group. Such a warehouse is  
21 exempt from providing a pedigree paper in accordance with  
22 paragraphs (d) and (e) to its affiliated group member  
23 warehouse, provided that:

24           a. Any affiliated group member that purchases or  
25 receives a prescription drug from outside the affiliated group  
26 must receive a pedigree paper if the prescription drug is  
27 distributed in or into this state and a pedigree paper is  
28 required under this section and must authenticate the  
29 documentation as required in subsection (4), regardless of  
30 whether the affiliated group member is directly subject to  
31 regulation under this chapter; and

1           b. The affiliated group makes available to the  
2 department on request all records related to the purchase or  
3 acquisition of prescription drugs by members of the affiliated  
4 group, regardless of the location where the records are  
5 stored, if the prescription drugs were distributed in or into  
6 this state.

7           3. If a repackager repackages prescription drugs  
8 solely for distribution to its affiliated group members for  
9 the exclusive distribution to and among retail pharmacies that  
10 are members of the affiliated group to which the repackager is  
11 a member:

12           a. The repackager must:

13           (I) In lieu of the written statement required by  
14 paragraph (d) or paragraph (e), for all repackaged  
15 prescription drugs distributed in or into this state, issue  
16 the following written statement under oath with each  
17 distribution of a repackaged prescription drug to an  
18 affiliated group member warehouse or repackager: "All  
19 repackaged prescription drugs are purchased by the affiliated  
20 group directly from the manufacturer or from a prescription  
21 drug wholesaler that purchased the prescription drugs directly  
22 from the manufacturer.";

23           (II) Purchase all prescription drugs it repackages:

24           (A) Directly from the manufacturer; or

25           (B) From a prescription drug wholesaler that purchased  
26 the prescription drugs directly from the manufacturer; and

27           (III) Maintain records in accordance with this section  
28 to document that it purchased the prescription drugs directly  
29 from the manufacturer or that its prescription drug wholesale  
30 supplier purchased the prescription drugs directly from the  
31 manufacturer.

1           b. In addition, all members of the affiliated group  
2 must provide to agents of the department on request records of  
3 purchases by all members of the affiliated group of  
4 prescription drugs that have been repackaged, regardless of  
5 the location where the records are stored or where the  
6 repackager is located.

7           4. This paragraph expires July 1, 2006.

8           Section 11. Paragraph (a) of subsection (1) of section  
9 895.02, Florida Statutes, is amended to read:

10           895.02 Definitions.--As used in ss. 895.01-895.08, the  
11 term:

12           (1) "Racketeering activity" means to commit, to  
13 attempt to commit, to conspire to commit, or to solicit,  
14 coerce, or intimidate another person to commit:

15           (a) Any crime which is chargeable by indictment or  
16 information under the following provisions of the Florida  
17 Statutes:

18           1. Section 210.18, relating to evasion of payment of  
19 cigarette taxes.

20           2. Section 403.727(3)(b), relating to environmental  
21 control.

22           ~~3.4.~~ Section 409.920, relating to Medicaid provider  
23 fraud.

24           ~~4.3.~~ Section 414.39, relating to public assistance  
25 fraud.

26           5. Section 440.105 or s. 440.106, relating to workers'  
27 compensation.

28           6. Section 465.0161, relating to distribution of  
29 medicinal drugs without a permit as an Internet pharmacy.

1           ~~7.6.~~ Sections 499.0051, 499.0052, 499.0053, 499.0054,  
2 and 499.0691, relating to crimes involving contraband and  
3 adulterated drugs.

4           ~~8.7.~~ Part IV of chapter 501, relating to  
5 telemarketing.

6           ~~9.8.~~ Chapter 517, relating to sale of securities and  
7 investor protection.

8           ~~10.9.~~ Section 550.235, s. 550.3551, or s. 550.3605,  
9 relating to dogracing and horseracing.

10           ~~11.10.~~ Chapter 550, relating to jai alai frontons.

11           ~~12.11.~~ Chapter 552, relating to the manufacture,  
12 distribution, and use of explosives.

13           ~~13.12.~~ Chapter 560, relating to money transmitters, if  
14 the violation is punishable as a felony.

15           ~~14.13.~~ Chapter 562, relating to beverage law  
16 enforcement.

17           ~~15.14.~~ Section 624.401, relating to transacting  
18 insurance without a certificate of authority, s.  
19 624.437(4)(c)1., relating to operating an unauthorized  
20 multiple-employer welfare arrangement, or s. 626.902(1)(b),  
21 relating to representing or aiding an unauthorized insurer.

22           ~~16.15.~~ Section 655.50, relating to reports of currency  
23 transactions, when such violation is punishable as a felony.

24           ~~17.16.~~ Chapter 687, relating to interest and usurious  
25 practices.

26           ~~18.17.~~ Section 721.08, s. 721.09, or s. 721.13,  
27 relating to real estate timeshare plans.

28           ~~19.18.~~ Chapter 782, relating to homicide.

29           ~~20.19.~~ Chapter 784, relating to assault and battery.

30           ~~21.20.~~ Chapter 787, relating to kidnapping.

31           ~~22.21.~~ Chapter 790, relating to weapons and firearms.

1           ~~23.22.~~ Section 796.03, s. 796.04, s. 796.05, or s.  
2 796.07, relating to prostitution.  
3           ~~24.23.~~ Chapter 806, relating to arson.  
4           ~~25.24.~~ Section 810.02(2)(c), relating to specified  
5 burglary of a dwelling or structure.  
6           ~~26.25.~~ Chapter 812, relating to theft, robbery, and  
7 related crimes.  
8           ~~27.26.~~ Chapter 815, relating to computer-related  
9 crimes.  
10           ~~28.27.~~ Chapter 817, relating to fraudulent practices,  
11 false pretenses, fraud generally, and credit card crimes.  
12           ~~29.28.~~ Chapter 825, relating to abuse, neglect, or  
13 exploitation of an elderly person or disabled adult.  
14           ~~30.29.~~ Section 827.071, relating to commercial sexual  
15 exploitation of children.  
16           ~~31.30.~~ Chapter 831, relating to forgery and  
17 counterfeiting.  
18           ~~32.31.~~ Chapter 832, relating to issuance of worthless  
19 checks and drafts.  
20           ~~33.32.~~ Section 836.05, relating to extortion.  
21           ~~34.33.~~ Chapter 837, relating to perjury.  
22           ~~35.34.~~ Chapter 838, relating to bribery and misuse of  
23 public office.  
24           ~~36.35.~~ Chapter 843, relating to obstruction of  
25 justice.  
26           ~~37.36.~~ Section 847.011, s. 847.012, s. 847.013, s.  
27 847.06, or s. 847.07, relating to obscene literature and  
28 profanity.  
29           ~~38.37.~~ Section 849.09, s. 849.14, s. 849.15, s.  
30 849.23, or s. 849.25, relating to gambling.  
31           ~~39.38.~~ Chapter 874, relating to criminal street gangs.

1           ~~40.39.~~ Chapter 893, relating to drug abuse prevention  
2 and control.

3           ~~41.40.~~ Chapter 896, relating to offenses related to  
4 financial transactions.

5           ~~42.41.~~ Sections 914.22 and 914.23, relating to  
6 tampering with a witness, victim, or informant, and  
7 retaliation against a witness, victim, or informant.

8           ~~43.42.~~ Sections 918.12 and 918.13, relating to  
9 tampering with jurors and evidence.

10           Section 12. This act shall take effect July 1, 2004.

11  
12                           STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN  
13   COMMITTEE SUBSTITUTE FOR  
14   CS/SB 1372

15           Creates recordkeeping requirements in s. 499.0121, F.S., for  
16 affiliated groups as defined in the Internal Revenue Code.  
17 These groups include chain drug entities including 50 retail  
pharmacies, warehouses, or repackagers, which are members of  
the same affiliated group.