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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 for a medicinal drug  
7 listed in Schedule II under ch. 893, F.S.;  
8 amending s. 499.0121, F.S.; providing  
9 recordkeeping requirements relating to the  
10 storage and handling of prescription drugs  
11 which certain affiliated groups must fulfill;  
12 amending s. 895.02, F.S.; including violation  
13 of s. 465.0161, F.S., in the definition of the  
14 term "racketeering activity" for prosecution  
15 under ch. 895, F.S.; providing an appropriation  
16 and authorizing positions; providing an  
17 effective date.

18

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

20

21 Section 1. Paragraph (a) of subsection (11) of section  
22 465.003, Florida Statutes, is amended to read:23 465.003 Definitions.--As used in this chapter, the  
24 term:25 (11)(a) "Pharmacy" includes a community pharmacy, an  
26 institutional pharmacy, a nuclear pharmacy, ~~and~~ a special  
27 pharmacy, and an Internet pharmacy.28 1. The term "community pharmacy" includes every  
29 location where medicinal drugs are compounded, dispensed,  
30 stored, or sold or where prescriptions are filled or dispensed  
31 on an outpatient basis.

1           2. The term "institutional pharmacy" includes every  
2 location in a hospital, clinic, nursing home, dispensary,  
3 sanitarium, extended care facility, or other facility,  
4 hereinafter referred to as "health care institutions," where  
5 medicinal drugs are compounded, dispensed, stored, or sold.

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

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

16           5. The term "Internet pharmacy" includes locations not  
17 otherwise licensed or issued a permit under this chapter,  
18 within or outside this state, which use the Internet to  
19 communicate with or obtain information from consumers in this  
20 state and use such communication or information to fill or  
21 refill prescriptions or to dispense, distribute, or otherwise  
22 engage in the practice of pharmacy in this state. Any act  
23 described in this definition constitutes the practice of  
24 pharmacy as defined in subsection (13).

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

27           465.0156 Registration of nonresident pharmacies.--

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

30           (8) Notwithstanding s. 465.003(10), for purposes of  
31 this section, the registered pharmacy and the pharmacist

1 designated by the registered pharmacy as the prescription  
2 department manager or the equivalent must be licensed in the  
3 state of location in order to dispense into this state.

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

6 465.016 Disciplinary actions.--

7 (1) The following acts constitute grounds for denial  
8 of a license or disciplinary action, as specified in s.  
9 456.072(2):

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

15 Section 4. Section 465.0161, Florida Statutes, is  
16 created to read:

17 465.0161 Distribution of medicinal drugs without a  
18 permit.--An Internet pharmacy that distributes a medicinal  
19 drug to any person in this state without being permitted as a  
20 pharmacy under this chapter commits a felony of the second  
21 degree, punishable as provided in s. 775.082, s. 775.083, or  
22 s. 775.084.

23 Section 5. Section 465.0196, Florida Statutes, is  
24 amended to read:

25 465.0196 Special pharmacy permits.--Any person  
26 desiring a permit to operate a special pharmacy ~~which does not~~  
27 ~~fall within the definitions set forth in s. 465.003(11)(a)1.,~~  
28 ~~2., and 3.~~ shall apply to the department for a special  
29 pharmacy permit. If the board certifies that the application  
30 complies with the applicable laws and rules of the board  
31 governing the practice of the profession of pharmacy, the

1 department shall issue the permit. No permit shall be issued  
2 unless a licensed pharmacist is designated to undertake the  
3 professional supervision of the compounding and dispensing of  
4 all drugs dispensed by the pharmacy. The licensed pharmacist  
5 shall be responsible for maintaining all drug records and for  
6 providing for the security of the area in the facility in  
7 which the compounding, storing, and dispensing of medicinal  
8 drugs occurs. The permittee shall notify the department within  
9 10 days of any change of the licensed pharmacist responsible  
10 for such duties. Every permittee that employs or otherwise  
11 utilizes pharmacy technicians shall have a written policy and  
12 procedures manual specifying those duties, tasks, and  
13 functions which a pharmacy technician is allowed to perform.

14 Section 6. Section 465.0197, Florida Statutes, is  
15 created to read:

16 465.0197 Internet pharmacy permits.--

17 (1) Any person desiring a permit to operate an  
18 Internet pharmacy shall apply to the department for an  
19 Internet pharmacy permit. If the board certifies that the  
20 application complies with the applicable laws and rules of the  
21 board governing the practice of the profession of pharmacy,  
22 the department shall issue the permit. No permit shall be  
23 issued unless a licensed pharmacist is designated as the  
24 prescription department manager for dispensing medicinal drugs  
25 to persons in this state. The licensed pharmacist shall be  
26 responsible for maintaining all drug records and for providing  
27 for the security of the area in the facility in which the  
28 compounding, storing, and dispensing of medicinal drugs to  
29 persons in this state occurs. The permittee shall notify the  
30 department within 30 days of any change of the licensed  
31 pharmacist responsible for such duties. Every permittee that

1 employs or otherwise utilizes pharmacy technicians shall have  
2 a written policy and procedures manual specifying those  
3 duties, tasks, and functions which a pharmacy technician is  
4 allowed to perform.

5 (2) An Internet pharmacy must obtain a permit under  
6 this section to sell medicinal drugs to persons in this state.

7 (3) An Internet pharmacy shall provide pharmacy  
8 services at a high level of protection and competence and  
9 shall disclose to the board the following specific  
10 information:

11 (a) That it maintains at all times a valid, unexpired  
12 license, permit, or registration to operate the pharmacy in  
13 compliance with the laws of the state in which the dispensing  
14 facility is located and from which the medicinal drugs shall  
15 be dispensed.

16 (b) The location, names, and titles of all principal  
17 corporate officers and the pharmacist who serves as the  
18 prescription department manager for dispensing medicinal drugs  
19 to persons in this state. This disclosure shall be made within  
20 30 days after any change of location, principal corporate  
21 officer, or pharmacist serving as the prescription department  
22 manager for dispensing medicinal drugs to persons in this  
23 state.

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

1           (d) That it maintains its records of medicinal drugs  
2 dispensed to patients in this state so that the records are  
3 readily retrievable from the other business records of the  
4 pharmacy and from the records of other medicinal drugs  
5 dispensed.

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

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

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

20           465.023 Pharmacy permittee; disciplinary action.--

21           (1) The department or the board may revoke or suspend  
22 the permit of any pharmacy permittee, and may fine, place on  
23 probation, or otherwise discipline any pharmacy permittee who  
24 has:

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

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

30           (c) Violated any of the requirements of this chapter  
31 or any of the rules of the Board of Pharmacy; of chapter 499,

1 known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss.  
2 301-392, known as the "Federal Food, Drug, and Cosmetic Act";  
3 of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug  
4 Abuse Prevention and Control Act; or of chapter 893; ~~or~~

5 (d) Been convicted or found guilty, regardless of  
6 adjudication, of a felony or any other crime involving moral  
7 turpitude in any of the courts of this state, of any other  
8 state, or of the United States; ~~or~~

9 (e) Dispensed any medicinal drug based upon a  
10 communication that purports to be a prescription as defined by  
11 s. 465.003(14) or s. 893.02(20) when the pharmacist knows or  
12 has reason to believe that the purported prescription is not  
13 based upon a valid practitioner-patient relationship that  
14 includes a documented patient evaluation, including history  
15 and a physical examination adequate to establish the diagnosis  
16 for which any drug is prescribed and any other requirement  
17 established by board rule under chapter 458, chapter 459,  
18 chapter 461, chapter 463, chapter 464, or chapter 466.

19 Section 8. Section 465.0255, Florida Statutes, is  
20 amended to read:

21 465.0255 Expiration date of medicinal drugs; display;  
22 related use and storage instructions.--

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

27 (2) Each pharmacist for a community pharmacy  
28 dispensing medicinal drugs and each practitioner dispensing  
29 medicinal drugs on an outpatient basis shall display on the  
30 outside of the container of each medicinal drug dispensed, or  
31 in other written form delivered to the purchaser: ~~7~~



1           (a) The expiration date when provided by the  
2 manufacturer, repackager, or other distributor of the drug; or  
3 ~~and~~

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

6  
7 The dispensing pharmacist or practitioner must provide  
8 information concerning the expiration date to the purchaser  
9 upon request and must provide appropriate instructions  
10 regarding the proper use and storage of the drug.

11           (3) Nothing in This section does not shall impose  
12 liability on the dispensing pharmacist or practitioner for  
13 damages related to, or caused by, a medicinal drug that loses  
14 its effectiveness prior to the expiration date displayed by  
15 the dispensing pharmacist or practitioner.

16           (4)(3) The provisions of this section are intended to  
17 notify the patient receiving a medicinal drug of the  
18 information required by this section, and the dispensing  
19 pharmacist or practitioner shall not be liable for the  
20 patient's failure to heed such notice or to follow the  
21 instructions for storage.

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

24           465.026 Filling of certain prescriptions.--Nothing  
25 contained in this chapter shall be construed to prohibit a  
26 pharmacist licensed in this state from filling or refilling a  
27 valid prescription which is on file in a pharmacy located in  
28 this state or in another state and has been transferred from  
29 one pharmacy to another by any means, including any electronic  
30 means, under the following conditions:

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1           (7) A community pharmacy licensed under this chapter  
2 which only receives and transfers prescriptions for dispensing  
3 by another pharmacy may transfer a prescription for a  
4 medicinal drug listed in Schedule II under chapter 893. The  
5 pharmacy receiving the prescription may ship, mail, or deliver  
6 into this state, in any manner, the dispensed Schedule II  
7 medicinal drug under the following conditions:

8           (a) The pharmacy receiving and dispensing the  
9 transferred prescription maintains at all times a valid,  
10 unexpired license, permit, or registration to operate the  
11 pharmacy in compliance with the laws of the state in which the  
12 pharmacy is located and from which the medicinal drugs are  
13 dispensed;

14           (b) The community pharmacy and the receiving pharmacy  
15 are owned and operated by the same person and share a  
16 centralized database; and

17           (c) The community pharmacy assures its compliance with  
18 federal laws and subsections (1)-(5).

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

21           499.0121 Storage and handling of prescription drugs;  
22 recordkeeping.--The department shall adopt rules to implement  
23 this section as necessary to protect the public health,  
24 safety, and welfare. Such rules shall include, but not be  
25 limited to, requirements for the storage and handling of  
26 prescription drugs and for the establishment and maintenance  
27 of prescription drug distribution records.

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

31

1       (h)1. This paragraph applies only to an affiliated  
2 group, as defined by s. 1504 of the Internal Revenue Code of  
3 1986, as amended, which is composed of chain drug entities,  
4 including at least 50 retail pharmacies, warehouses, or  
5 repackagers, which are members of the same affiliated group,  
6 if the affiliated group:

7           a. Discloses to the department the names of all its  
8 members; and

9           b. Agrees in writing to provide records on  
10 prescription drug purchases by members of the affiliated group  
11 not later than 48 hours after the department requests such  
12 records, regardless of the location where the records are  
13 stored.

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

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

30           b. The affiliated group makes available to the  
31 department on request all records related to the purchase or

1 acquisition of prescription drugs by members of the affiliated  
2 group, regardless of the location where the records are  
3 stored, if the prescription drugs were distributed in or into  
4 this state.

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

10 a. The repackager must:

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

20 (II) Purchase all prescription drugs it repackages:

21 (A) Directly from the manufacturer; or

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

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

29 b. All members of the affiliated group must provide to  
30 agents of the department on request records of purchases by  
31 all members of the affiliated group of prescription drugs that

1 have been repackaged, regardless of the location where the  
2 records are stored or where the repackager is located.

3 4. This paragraph expires July 1, 2006.

4 Section 11. Paragraph (a) of subsection (1) of section  
5 895.02, Florida Statutes, is amended to read:

6 895.02 Definitions.--As used in ss. 895.01-895.08, the  
7 term:

8 (1) "Racketeering activity" means to commit, to  
9 attempt to commit, to conspire to commit, or to solicit,  
10 coerce, or intimidate another person to commit:

11 (a) Any crime which is chargeable by indictment or  
12 information under the following provisions of the Florida  
13 Statutes:

14 1. Section 210.18, relating to evasion of payment of  
15 cigarette taxes.

16 2. Section 403.727(3)(b), relating to environmental  
17 control.

18 ~~3.4.~~ Section 409.920, relating to Medicaid provider  
19 fraud.

20 ~~4.3.~~ Section 414.39, relating to public assistance  
21 fraud.

22 5. Section 440.105 or s. 440.106, relating to workers'  
23 compensation.

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

26 ~~7.6.~~ Sections 499.0051, 499.0052, 499.0053, 499.0054,  
27 and 499.0691, relating to crimes involving contraband and  
28 adulterated drugs.

29 ~~8.7.~~ Part IV of chapter 501, relating to  
30 telemarketing.

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1           ~~9.8.~~ Chapter 517, relating to sale of securities and  
2 investor protection.

3           ~~10.9.~~ Section 550.235, s. 550.3551, or s. 550.3605,  
4 relating to dogracing and horseracing.

5           ~~11.10.~~ Chapter 550, relating to jai alai frontons.

6           ~~12.11.~~ Chapter 552, relating to the manufacture,  
7 distribution, and use of explosives.

8           ~~13.12.~~ Chapter 560, relating to money transmitters, if  
9 the violation is punishable as a felony.

10           ~~14.13.~~ Chapter 562, relating to beverage law  
11 enforcement.

12           ~~15.14.~~ Section 624.401, relating to transacting  
13 insurance without a certificate of authority, s.  
14 624.437(4)(c)1., relating to operating an unauthorized  
15 multiple-employer welfare arrangement, or s. 626.902(1)(b),  
16 relating to representing or aiding an unauthorized insurer.

17           ~~16.15.~~ Section 655.50, relating to reports of currency  
18 transactions, when such violation is punishable as a felony.

19           ~~17.16.~~ Chapter 687, relating to interest and usurious  
20 practices.

21           ~~18.17.~~ Section 721.08, s. 721.09, or s. 721.13,  
22 relating to real estate timeshare plans.

23           ~~19.18.~~ Chapter 782, relating to homicide.

24           ~~20.19.~~ Chapter 784, relating to assault and battery.

25           ~~21.20.~~ Chapter 787, relating to kidnapping.

26           ~~22.21.~~ Chapter 790, relating to weapons and firearms.

27           ~~23.22.~~ Section 796.03, s. 796.04, s. 796.05, or s.  
28 796.07, relating to prostitution.

29           ~~24.23.~~ Chapter 806, relating to arson.

30           ~~25.24.~~ Section 810.02(2)(c), relating to specified  
31 burglary of a dwelling or structure.

- 1        ~~26.25.~~ Chapter 812, relating to theft, robbery, and
- 2 related crimes.
- 3        ~~27.26.~~ Chapter 815, relating to computer-related
- 4 crimes.
- 5        ~~28.27.~~ Chapter 817, relating to fraudulent practices,
- 6 false pretenses, fraud generally, and credit card crimes.
- 7        ~~29.28.~~ Chapter 825, relating to abuse, neglect, or
- 8 exploitation of an elderly person or disabled adult.
- 9        ~~30.29.~~ Section 827.071, relating to commercial sexual
- 10 exploitation of children.
- 11        ~~31.30.~~ Chapter 831, relating to forgery and
- 12 counterfeiting.
- 13        ~~32.31.~~ Chapter 832, relating to issuance of worthless
- 14 checks and drafts.
- 15        ~~33.32.~~ Section 836.05, relating to extortion.
- 16        ~~34.33.~~ Chapter 837, relating to perjury.
- 17        ~~35.34.~~ Chapter 838, relating to bribery and misuse of
- 18 public office.
- 19        ~~36.35.~~ Chapter 843, relating to obstruction of
- 20 justice.
- 21        ~~37.36.~~ Section 847.011, s. 847.012, s. 847.013, s.
- 22 847.06, or s. 847.07, relating to obscene literature and
- 23 profanity.
- 24        ~~38.37.~~ Section 849.09, s. 849.14, s. 849.15, s.
- 25 849.23, or s. 849.25, relating to gambling.
- 26        ~~39.38.~~ Chapter 874, relating to criminal street gangs.
- 27        ~~40.39.~~ Chapter 893, relating to drug abuse prevention
- 28 and control.
- 29        ~~41.40.~~ Chapter 896, relating to offenses related to
- 30 financial transactions.
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1           ~~42.41.~~ Sections 914.22 and 914.23, relating to  
2 tampering with a witness, victim, or informant, and  
3 retaliation against a witness, victim, or informant.  
4           ~~43.42.~~ Sections 918.12 and 918.13, relating to  
5 tampering with jurors and evidence.  
6           Section 12. The sum of \$590,051 is appropriated from  
7 the Medical Quality Assurance Trust Fund to the Department of  
8 Health, and nine full-time equivalent positions are  
9 authorized, for the 2004-2005 fiscal year for the purpose of  
10 implementing this act.  
11           Section 13. This act shall take effect July 1, 2004.  
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