

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

314-2255-04

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 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 affiliated groups must fulfill; amending
12 s. 895.02, F.S.; including violation of s.
13 465.0161, F.S., in the definition of the term
14 "racketeering activity" for prosecution under
15 ch. 895, F.S.; providing an appropriation and
16 authorizing positions; providing an effective
17 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 2. Each warehouse within the affiliated group must
7 comply with all applicable federal and state drug wholesale
8 permit requirements and must purchase, receive, hold, and
9 distribute prescription drugs only to a retail pharmacy or
10 warehouse within the affiliated group. Such a warehouse is
11 exempt from providing a pedigree paper in accordance with
12 paragraphs (d) and (e) to its affiliated group member
13 warehouse, provided that:

14 a. Any affiliated group member that purchases or
15 receives a prescription drug from outside the affiliated group
16 must receive a pedigree paper if the prescription drug is
17 distributed in or into this state and a pedigree paper is
18 required under this section and must authenticate the
19 documentation as required in subsection (4), regardless of
20 whether the affiliated group member is directly subject to
21 regulation under this chapter; and

22 b. The affiliated group makes available to the
23 department on request all records related to the purchase or
24 acquisition of prescription drugs by members of the affiliated
25 group, regardless of the location where the records are
26 stored, if the prescription drugs were distributed in or into
27 this state.

28 3. If a repackager repackages prescription drugs
29 solely for distribution to its affiliated group members for
30 the exclusive distribution to and among retail pharmacies that
31

1 are members of the affiliated group to which the repackager is
2 a member:

3 a. The repackager must:
4 (I) In lieu of the written statement required by
5 paragraph (d) or paragraph (e), for all repackaged
6 prescription drugs distributed in or into this state, issue
7 the following written statement under oath with each
8 distribution of a repackaged prescription drug to an
9 affiliated group member warehouse or repackager: "All
10 repackaged prescription drugs are purchased by the affiliated
11 group directly from the manufacturer or from a prescription
12 drug wholesaler that purchased the prescription drugs directly
13 from the manufacturer.";

14 (II) Purchase all prescription drugs it repackages:

15 (A) Directly from the manufacturer; or

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

18 (III) Maintain records in accordance with this section
19 to document that it purchased the prescription drugs directly
20 from the manufacturer or that its prescription drug wholesale
21 supplier purchased the prescription drugs directly from the
22 manufacturer.

23 b. In addition, all members of the affiliated group
24 must provide to agents of the department on request records of
25 purchases by all members of the affiliated group of
26 prescription drugs that have been repackaged, regardless of
27 the location where the records are stored or where the
28 repackager is located.

29 4. This paragraph expires July 1, 2006.

30 Section 11. Paragraph (a) of subsection (1) of section
31 895.02, Florida Statutes, is amended to read:

1 895.02 Definitions.--As used in ss. 895.01-895.08, the
2 term:
3 (1) "Racketeering activity" means to commit, to
4 attempt to commit, to conspire to commit, or to solicit,
5 coerce, or intimidate another person to commit:
6 (a) Any crime which is chargeable by indictment or
7 information under the following provisions of the Florida
8 Statutes:
9 1. Section 210.18, relating to evasion of payment of
10 cigarette taxes.
11 2. Section 403.727(3)(b), relating to environmental
12 control.
13 ~~3.4.~~ Section 409.920, relating to Medicaid provider
14 fraud.
15 ~~4.3.~~ Section 414.39, relating to public assistance
16 fraud.
17 5. Section 440.105 or s. 440.106, relating to workers'
18 compensation.
19 6. Section 465.0161, relating to distribution of
20 medicinal drugs without a permit as an Internet pharmacy.
21 ~~7.6.~~ Sections 499.0051, 499.0052, 499.0053, 499.0054,
22 and 499.0691, relating to crimes involving contraband and
23 adulterated drugs.
24 ~~8.7.~~ Part IV of chapter 501, relating to
25 telemarketing.
26 ~~9.8.~~ Chapter 517, relating to sale of securities and
27 investor protection.
28 ~~10.9.~~ Section 550.235, s. 550.3551, or s. 550.3605,
29 relating to dogracing and horseracing.
30 ~~11.10.~~ Chapter 550, relating to jai alai frontons.
31

1 ~~12.11.~~ Chapter 552, relating to the manufacture,
2 distribution, and use of explosives.
3 ~~13.12.~~ Chapter 560, relating to money transmitters, if
4 the violation is punishable as a felony.
5 ~~14.13.~~ Chapter 562, relating to beverage law
6 enforcement.
7 ~~15.14.~~ Section 624.401, relating to transacting
8 insurance without a certificate of authority, s.
9 624.437(4)(c)1., relating to operating an unauthorized
10 multiple-employer welfare arrangement, or s. 626.902(1)(b),
11 relating to representing or aiding an unauthorized insurer.
12 ~~16.15.~~ Section 655.50, relating to reports of currency
13 transactions, when such violation is punishable as a felony.
14 ~~17.16.~~ Chapter 687, relating to interest and usurious
15 practices.
16 ~~18.17.~~ Section 721.08, s. 721.09, or s. 721.13,
17 relating to real estate timeshare plans.
18 ~~19.18.~~ Chapter 782, relating to homicide.
19 ~~20.19.~~ Chapter 784, relating to assault and battery.
20 ~~21.20.~~ Chapter 787, relating to kidnapping.
21 ~~22.21.~~ Chapter 790, relating to weapons and firearms.
22 ~~23.22.~~ Section 796.03, s. 796.04, s. 796.05, or s.
23 796.07, relating to prostitution.
24 ~~24.23.~~ Chapter 806, relating to arson.
25 ~~25.24.~~ Section 810.02(2)(c), relating to specified
26 burglary of a dwelling or structure.
27 ~~26.25.~~ Chapter 812, relating to theft, robbery, and
28 related crimes.
29 ~~27.26.~~ Chapter 815, relating to computer-related
30 crimes.
31

1 ~~28.27.~~ Chapter 817, relating to fraudulent practices,
2 false pretenses, fraud generally, and credit card crimes.
3 ~~29.28.~~ Chapter 825, relating to abuse, neglect, or
4 exploitation of an elderly person or disabled adult.
5 ~~30.29.~~ Section 827.071, relating to commercial sexual
6 exploitation of children.
7 ~~31.30.~~ Chapter 831, relating to forgery and
8 counterfeiting.
9 ~~32.31.~~ Chapter 832, relating to issuance of worthless
10 checks and drafts.
11 ~~33.32.~~ Section 836.05, relating to extortion.
12 ~~34.33.~~ Chapter 837, relating to perjury.
13 ~~35.34.~~ Chapter 838, relating to bribery and misuse of
14 public office.
15 ~~36.35.~~ Chapter 843, relating to obstruction of
16 justice.
17 ~~37.36.~~ Section 847.011, s. 847.012, s. 847.013, s.
18 847.06, or s. 847.07, relating to obscene literature and
19 profanity.
20 ~~38.37.~~ Section 849.09, s. 849.14, s. 849.15, s.
21 849.23, or s. 849.25, relating to gambling.
22 ~~39.38.~~ Chapter 874, relating to criminal street gangs.
23 ~~40.39.~~ Chapter 893, relating to drug abuse prevention
24 and control.
25 ~~41.40.~~ Chapter 896, relating to offenses related to
26 financial transactions.
27 ~~42.41.~~ Sections 914.22 and 914.23, relating to
28 tampering with a witness, victim, or informant, and
29 retaliation against a witness, victim, or informant.
30 ~~43.42.~~ Sections 918.12 and 918.13, relating to
31 tampering with jurors and evidence.

1 Section 12. The sum of \$590,051 is appropriated from
2 the Medical Quality Assurance Trust Fund to the Department of
3 Health, and nine full-time equivalent positions are
4 authorized, for the 2004-2005 fiscal year for the purpose of
5 implementing this act.

6 Section 13. This act shall take effect July 1, 2004.

7
8 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
9 COMMITTEE SUBSTITUTE FOR
10 CS/CS/SB 1372

11 The Committee Substitute made the following substantive
12 changes to CS/CS/SB 1372:

- 13 1) Defined "Internet pharmacy" to include locations that are
14 not otherwise licensed or issued a permit under this
15 chapter, within or outside Florida, which uses the
16 Internet to communicate with or obtain information from
17 consumers in Florida and use such communication or
18 information to fill or refill prescriptions or to
19 dispense, distribute, or otherwise engage in the practice
20 of pharmacy in Florida
- 21 2) Provides that dispensing any medicinal drug based upon a
22 prescription that a pharmacist knows or has reason to
23 believe is not valid, is reason for the department or
24 board to revoke or suspend the pharmacy permit.
- 25 3) Further narrows the provision in the bill that allows a
26 pharmacy to use a common database for prescription
27 filling or dispensing in compliance with Federal law. The
28 pharmacy must comply with all state and federal
29 regulations governing the transfer of the prescription.
- 30 4) Appropriates \$590,051 from the Medical Quality Assurance
31 Trust Fund to the Department of Health and 9 FTE
positions for FY 2004-05 to implement the bill.