${\bf By}$ the Committee on Health, Aging, and Long-Term Care; and Senator Saunders

317-1737-04

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A bill to be entitled An act relating to pharmacy; amending s. 465.003, F.S.; defining the term "Internet pharmacy"; amending s. 465.0156, F.S.; exempting Internet pharmacies from registration requirements applicable to nonresident pharmacies; requiring the registered nonresident pharmacy and the pharmacist designated by that pharmacy to serve as the prescription department manager or its equivalent to be licensed in the state of location; amending s. 465.016, F.S.; providing for disciplinary action for dispensing a medicinal drug when the pharmacist knows or has reason to believe the prescription is not based on a valid practitioner-patient relationship; creating s. 465.0161, F.S.; prohibiting the distribution of medicinal drugs by an Internet pharmacy without a permit; providing penalties; amending s. 465.0196, F.S., relating to special pharmacy permits, to conform; creating s. 465.0197, F.S.; requiring Internet pharmacies to be permitted and providing requirements therefor; requiring the Internet pharmacy and the pharmacist designated by that pharmacy to serve as the prescription department manager or its equivalent to be licensed in the state of location; amending s. 465.023, F.S.; providing an additional ground for which the Board of Pharmacy may take action against a permitted pharmacy; amending s. 465.0255, F.S.; revising

requirements for pharmacists to deliver specified disclosures to purchasers when dispensing a medicinal drug; amending s. 465.026, F.S.; creating an exception to the requirements for filling or refilling a transferred prescription; amending s. 895.02, F.S.; including violation of s. 465.0161, F.S., in the definition of the term "racketeering activity" for prosecution under ch. 895, F.S.; providing an effective date.

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

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

16 17 term:

465.003 Definitions.--As used in this chapter, the

- "Pharmacy" includes a community pharmacy, an (11)(a) institutional pharmacy, a nuclear pharmacy, and a special pharmacy, and an Internet pharmacy.
- The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- The term "institutional pharmacy" includes every 2. location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
- The term "nuclear pharmacy" includes every location 31 where radioactive drugs and chemicals within the

classification of medicinal drugs are compounded, dispensed,
stored, or sold. The term "nuclear pharmacy" does not include
hospitals licensed under chapter 395 or the nuclear medicine
facilities of such hospitals.

4. The term "special pharmacy" includes every location

- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
- 5. The term "Internet pharmacy" includes locations
 that are not otherwise defined in this subsection where
 medicinal drugs are compounded, dispensed, or stored and
 subsequently sold primarily or exclusively to consumers over
 the Internet.

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

465.0156 Registration of nonresident pharmacies.--

- (7) This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.
- (8) Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

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

465.016 Disciplinary actions.--

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by

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s. 465.003(14) or s. 893.02(20) when the pharmacist knows or has reason to believe that the purported prescription is not 2 3 based upon a valid practitioner-patient relationship. 4

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

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

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

465.0196 Special pharmacy permits. -- Any person desiring a permit to operate a special pharmacy which does not fall within the definitions set forth in s. 465.003(11)(a)1., 2., and 3.shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise 31 utilizes pharmacy technicians shall have a written policy and

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procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.

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

465.0197 Internet pharmacy permits.--

- (1) Any person desiring a permit to operate an Internet pharmacy shall apply to the department for an Internet pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in this state. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in this state occurs. The permittee shall notify the department within 30 days of any change of the licensed pharmacist responsible for such duties. Every permittee that employs or otherwise utilizes pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions which a pharmacy technician is allowed to perform.
- (2) An Internet pharmacy must be permitted under this section to sell medicinal drugs to persons in this state.
- (3) An Internet pharmacy shall provide pharmacy services at a high level of protection and competence and shall disclose to the board the following specific information:

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- CODING: Words stricken are deletions; words underlined are additions.

- (a) That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.
- (b) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to persons in this state. This disclosure shall be made within 30 days after any change of location, principal corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to persons in this state.
- (c) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to persons in this state.
- (d) That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed.
- (e) That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This

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toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs. 2 3

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

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

465.023 Pharmacy permittee; disciplinary action. --

- The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee who has:
- (a) Obtained a permit by misrepresentation or fraud or through an error of the department or the board;
- (b) Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;
- (c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893; or
- (d) Been convicted or found guilty, regardless of adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States; or-
- (e) Aided or abetted in dispensing any medicinal drug 31 based upon a communication that purports to be a prescription

 as defined by s. 465.003(14) or s. 893.02(20) when the permittee knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

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

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

- (1) The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.
- (2) Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:
- $\underline{\text{(a)}}$ The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or $\underline{\text{and}}$
- (b) An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

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

(3) Nothing in This section does not shall impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses

 its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

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

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

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

pharmacy that uses a common database to perform automated prescription fulfillment functions may process a prescription for a controlled substance using that common database to perform prescription fulfillment functions in compliance with federal law and regulation.

Section 10. Paragraph (a) of subsection (1) of section 895.02, Florida Statutes, is amended to read:

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

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

31 enforcement.

1 (a) Any crime which is chargeable by indictment or 2 information under the following provisions of the Florida 3 Statutes: Section 210.18, relating to evasion of payment of 4 5 cigarette taxes. 6 Section 403.727(3)(b), relating to environmental 7 control. 3.4. Section 409.920, relating to Medicaid provider 8 9 fraud. 10 4.3. Section 414.39, relating to public assistance 11 fraud. Section 440.105 or s. 440.106, relating to workers' 12 5. 13 compensation. 6. Section 465.0161, relating to distribution of 14 15 medicinal drugs without a permit as an Internet pharmacy. 7.6. Sections 499.0051, 499.0052, 499.0053, 499.0054, 16 and 499.0691, relating to crimes involving contraband and 17 adulterated drugs. 18 19 8.7. Part IV of chapter 501, relating to 20 telemarketing. 9.8. Chapter 517, relating to sale of securities and 21 22 investor protection. 10.9. Section 550.235, s. 550.3551, or s. 550.3605, 23 24 relating to dogracing and horseracing. 25 11.10. Chapter 550, relating to jai alai frontons. 12.11. Chapter 552, relating to the manufacture, 26 27 distribution, and use of explosives. 28 13.12. Chapter 560, relating to money transmitters, if 29 the violation is punishable as a felony. 14.13. Chapter 562, relating to beverage law 30

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            15.14. Section 624.401, relating to transacting
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    insurance without a certificate of authority, s.
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    624.437(4)(c)1., relating to operating an unauthorized
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    multiple-employer welfare arrangement, or s. 626.902(1)(b),
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    relating to representing or aiding an unauthorized insurer.
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            16.<del>15.</del> Section 655.50, relating to reports of currency
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    transactions, when such violation is punishable as a felony.
            17.<del>16.</del> Chapter 687, relating to interest and usurious
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    practices.
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            18.<del>17.</del> Section 721.08, s. 721.09, or s. 721.13,
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    relating to real estate timeshare plans.
            19.<del>18.</del> Chapter 782, relating to homicide.
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            20.<del>19.</del> Chapter 784, relating to assault and battery.
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            21.20. Chapter 787, relating to kidnapping.
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            22.<del>21.</del> Chapter 790, relating to weapons and firearms.
            23.<del>22.</del> Section 796.03, s. 796.04, s. 796.05, or s.
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    796.07, relating to prostitution.
            24.<del>23.</del> Chapter 806, relating to arson.
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            25.24. Section 810.02(2)(c), relating to specified
    burglary of a dwelling or structure.
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            26.25. Chapter 812, relating to theft, robbery, and
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    related crimes.
            27.<del>26.</del> Chapter 815, relating to computer-related
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    crimes.
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            28.<del>27.</del> Chapter 817, relating to fraudulent practices,
    false pretenses, fraud generally, and credit card crimes.
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            29.28. Chapter 825, relating to abuse, neglect, or
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    exploitation of an elderly person or disabled adult.
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            30.<del>29.</del> Section 827.071, relating to commercial sexual
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    exploitation of children.
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           31.30. Chapter 831, relating to forgery and
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    counterfeiting.
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           32.<del>31.</del> Chapter 832, relating to issuance of worthless
    checks and drafts.
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           33.32. Section 836.05, relating to extortion.
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           34.33. Chapter 837, relating to perjury.
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           35.34. Chapter 838, relating to bribery and misuse of
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    public office.
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           36.35. Chapter 843, relating to obstruction of
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    justice.
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           37.<del>36.</del> Section 847.011, s. 847.012, s. 847.013, s.
    847.06, or s. 847.07, relating to obscene literature and
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    profanity.
           38.<del>37.</del> Section 849.09, s. 849.14, s. 849.15, s.
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    849.23, or s. 849.25, relating to gambling.
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           39.38. Chapter 874, relating to criminal street gangs.
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           40.<del>39.</del> Chapter 893, relating to drug abuse prevention
    and control.
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           41.40. Chapter 896, relating to offenses related to
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    financial transactions.
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           42.41. Sections 914.22 and 914.23, relating to
    tampering with a witness, victim, or informant, and
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    retaliation against a witness, victim, or informant.
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           43.<del>42.</del> Sections 918.12 and 918.13, relating to
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    tampering with jurors and evidence.
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           Section 11. This act shall take effect July 1, 2004.
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STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR Senate Bill 1372 The Committee Substitute revises grounds for which a pharmacy or pharmacist may be subject to discipline for dispensing a medication when there is reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship. Internet pharmacies and nonresident pharmacies and the pharmacist designated by that pharmacy as the prescription department manager are required to be licensed in the state of location in order to dispense drugs in Florida. The Committee Substitute revises requirements for pharmacists to display the expiration date on the outside of the container of each medicinal drug dispensed. The Committee Substitute provides an additional condition under which a pharmacist is not prohibited from filling or refilling a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, including electronic means. to another by any means, including electronic means.