By the Committee on Criminal Justice; and Senators Saunders, Bennett and Deutch

591-2354-07

A bill to be entitled

An act relating to controlled substances; creating s. 831.311, F.S.; prohibiting the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances; providing penalties; amending s. 893.04, F.S.; providing additional requirements for the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV; specifying circumstances under which a pharmacist who dispenses controlled substances by mail is exempt from certain requirements governing patient identification; providing requirements and limitations for dispensing controlled substances upon an oral prescription; creating s. 893.055, F.S.; defining terms; requiring the Agency for Health Care Administration to contract for the creation of a website to provide private-sector medication history to certain pharmacies and health care practitioners; providing limitations on use; providing for liability for the improper release of any confidential information; precluding the use of specified legal defenses by defendants in certain actions; providing penalties; creating s. 893.065, F.S.; requiring the department to develop and adopt by rule the form and content for a counterfeit-proof prescription blank for voluntary use by physicians in prescribing a

controlled substance listed in Schedule II, Schedule III, or Schedule IV; providing an appropriation and authorizing additional positions; providing for the contingent applicability of penalties; providing a contingent effective date.

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

Section 1. Section 831.311, Florida Statutes, is created to read:

831.311 Unlawful sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances.--

(1) It is unlawful for any person having the intent to injure or defraud any person or to facilitate any violation of s. 893.13 to sell, manufacture, alter, deliver, utter, or possess any counterfeit-resistant prescription blanks for controlled substances, the form and content of which are adopted by rule of the Department of Health pursuant to s. 893.065.

(2) Any person who violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 2. Section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.--

(1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(a) Oral prescriptions must be promptly reduced to writing by the pharmacist or recorded electronically if permitted by federal law.

(b) The written prescription must be dated and signed by the prescribing practitioner on the day when issued.

(c) There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:

1. The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed.

2. The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.

3. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.

4. The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.

5. The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6. The initials of the pharmacist filling the prescription and the date filled.

(d) The prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.

(e) Affixed to the original container in which a controlled substance is delivered upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:

1. The name and address of the pharmacy from which such controlled substance was dispensed.

2. The date on which the prescription for such controlled substance was filled.

3. The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.

4. The name of the prescribing practitioner.

5. The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.

6. The directions for the use of the controlled substance prescribed in the prescription.

7. A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

(f) A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A ~~No~~ prescription for a controlled substance listed in Schedule II may not be refilled.

(g) A ~~No~~ prescription for a controlled substance listed in Schedule ~~Schedules~~ III, Schedule IV, or Schedule V may not be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.

(2)(a) A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the

order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

(b) Any pharmacist who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan.

(c) Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically if permitted by federal law. Such prescriptions must contain the date of the oral authorization.

(d) Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity on the face of the prescription and a notation of the date, with the abbreviated month written out on the face of the prescription. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph.

(e) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.

(f) A pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

(3)~~(2)~~ Notwithstanding ~~the provisions of~~ subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, in compliance with the provisions of s. 465.0275.

(4)~~(3)~~ The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, or pharmacy. Such controlled substances may be sold only upon an order form, when such an order form is required for sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.

Section 3. Section 893.055, Florida Statutes, is created to read:

893.055 Prescription drug history.--

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Department" means the Department of Health.

(c) "Federal privacy laws" means the provisions relating to the disclosure of patient privacy information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-91, and its implementing regulations, the Federal Privacy Act, 5 U.S.C. s. 552(a), and its implementing regulations, and any other federal law, including, but not limited to, federal common law and decisional law that would prohibit the disclosure of patient privacy information.

(d) "Health care practitioner" means, with the exception of a pharmacist, a practitioner licensed under chapter 456 and authorized by law to prescribe drugs.

(e) "Pharmacy" means a pharmacy subject to licensure or regulation by the department under chapter 465 which dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a patient in this state.

(2)(a) By June 30, 2008, the agency shall contract with a vendor for the design and operation of a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to comprehensive patient medication history. In order to provide comprehensive patient medication history, the agency shall require the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication history.

(b) The contracted vendor shall comply with all applicable state and federal privacy laws and maintain the website within the United States.

(c) The contracted vendor must create a system to verify with the department that each health care practitioner, pharmacy, or pharmacist requesting access to the website holds a valid, active license.

(3) A health care practitioner authorized to access the website may use only the website to obtain medication history for a current patient for prescribing purposes with the written permission of the patient.

(4) A pharmacy or pharmacist authorized to access the website may use only the website to obtain medication history in dispensing a current prescription for Schedule II, Schedule III, or Schedule IV medicinal drugs with the written permission of the patient. The pharmacy or pharmacist may not

have access to pharmacy-identifying information within a patient's medication history.

(5) Recovery is not allowed in any court in this state against a health care practitioner, pharmacy, or pharmacist authorized to obtain information under this section for accessing or failing to access such information.

(6) A violation of this section by a health care practitioner, pharmacy, or pharmacist constitutes grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(k).

(7) Any contractor entering into a contract under this section is liable in tort for the improper release of any confidential information received, in addition to any breach of contract liability. Sovereign immunity may not be raised by the contractor, or the insurer of that contractor on the contractor's behalf, as a defense in any action arising out of the performance of any contract entered into under this section, as a defense in tort, in any other application regarding the maintenance of confidentiality of information, or for any breach of contract.

Section 4. Section 893.065, Florida Statutes, is created to read:

893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV.--The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which may be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, or Schedule IV. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted

name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Section 5. The sum of $2,564,670 in recurring general revenue funds and $1,837,677 in nonrecurring general revenue funds are appropriated to the Department of Health to implement the provisions of this bill. Three additional full-time equivalent positions are authorized for the 2007-2008 fiscal year to implement the provisions of ss. 893.055 and 893.065, Florida Statutes, as created by this act.

Section 6. The penalties created in ss. 831.311(2) and 893.055(7), Florida Statutes, by this act shall take effect only upon the adoption by the Department of Health and each applicable professional regulatory board of the rules required pursuant to ss. 893.055(8) and 893.065, Florida Statutes, as created by this act.

Section 7. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2007, if Senate Bill 520, or similar legislation, is adopted in the same legislative session or an extension thereof and becomes law.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
Senate Bill 518

- Precludes a pharmacist from dispensing a controlled substance listed in Schedule II, III, or IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid, but authorizes a pharmacist to dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

- Provides that, by June 30, 2008, the Agency for Health Care Administration (AHCA) must contract with a vendor for the design and operation of a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to comprehensive patient medication history, which is provided by the AHCA requiring the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication history.

- Requires the contracted vendor to comply with all applicable state and federal privacy laws and maintain the website within the United States, and create a system to verify with the Department of Health that each health care practitioner, pharmacy, or pharmacist requesting access to the website holds a valid, active license.

- Provides that a health care practitioner authorized to access the website may use only the website to obtain medication history for a current patient for prescribing purposes with the written permission of the patient, and a pharmacy or pharmacist with this authorization may use only the website to obtain medication history in dispensing a current prescription for Schedule II, III, or IV medicinal drugs with the written permission of the patient.

- Precludes the pharmacy or pharmacist from access to pharmacy-identifying information within a patient's medication history.

- Disallows recovery in any Florida court against a health care practitioner, pharmacy, or pharmacist authorized to obtain information for accessing or failing to access such information.

- Provides that a health care practitioner, pharmacy, or pharmacist who violates requirements pertaining to the website constitutes grounds for disciplinary action.

- Provides that any contractor entering into a contract is liable in tort for the improper release of any confidential information received, in addition to any breach of contract liability.

- Provides that sovereign immunity may not be raised by the contractor or the insurer of that contractor on the contractor's behalf as a defense in any action arising out of the performance of any contract, as a defense in tort, in any other application regarding the maintenance of confidentiality of information, or for any breach of contract.