By the Committee on Criminal Justice; and Senator Saunders

591-1751-06

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; providing rulemaking authority to the Board of Pharmacy; creating s. 893.055, F.S.; providing a definition; requiring the Department of Health to establish an electronic system to monitor the prescribing of controlled substances listed in Schedules II, III, and IV; requiring the dispensing of such controlled substances to be reported through the system; providing exceptions; providing reporting requirements; providing penalties; requiring that the department and regulatory boards adopt rules; requiring the department to cover all costs for the system; providing for annual appropriations, subject to availability of funds; prohibiting using funds from the Medical Quality Assurance Trust Fund to administer the program; 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 to prescribe 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 contingent effective dates.

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 listed in Schedules II, III, and IV.--

(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 or pharmacist's agent shall obtain a government-issued or other form of documentary identification substantiating the identity of a patient or patient's agent prior to dispensing any Schedule II, Schedule III, or Schedule IV controlled substance to such patient or patient's agent. The pharmacist or pharmacist's agent shall make a record of the type of documentary identification provided by the patient or patient's agent. If the patient or patient's agent does not have appropriate identification, the pharmacist may dispense the controlled substance only when the pharmacist determines, in the exercise of her or his professional judgment, that the order is valid and includes such information in the patient's record. The Board of Pharmacy may adopt, by rule, required patient-identification information for controlled substances and procedures for a pharmacist to verify the validity of a prescription for controlled substances for circumstances in which the pharmacist was not provided required identification information.

(b) 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.

(c) 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.

(d) 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.

(e) 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 Electronic-monitoring system for prescription of controlled substances listed in Schedules II, III, and IV.--

(1) As used in this section, the term "pharmacy" means any pharmacy subject to licensure or regulation by the Department of Health pursuant to chapter 465 which dispenses or delivers a controlled substance included on Schedule II, Schedule III, or Schedule IV to a patient in this state.

(2) By June 30, 2007, the Department of Health shall design and establish an electronic system consistent with standards of the American Society for Automation in Pharmacy to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV by health care practitioners within the state and the dispensing of such controlled substances to an individual at a specific address within the state by a pharmacy permitted or registered by the Board of Pharmacy.

(3) Any controlled substance listed in Schedule II, Schedule III, or Schedule IV which is dispensed to an individual in this state must be reported to the Department of Health through the system as soon thereafter as possible, but not more than 35 days after the date the controlled substance is dispensed, each time the controlled substance is dispensed. A pharmacy or dispensing practitioner may meet the reporting requirements of this section by providing to the Department of Health in written or any electronic or magnetic format, including, but not limited to, electronic submission via the Internet or magnetic disc or tape, each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses.

(4) This section does not apply to controlled substances:

(a) Administered by a health care practitioner directly to a patient.

(b) Dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of no more than 72 hours.

(c) Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit.

(d) Ordered from an institutional pharmacy permitted under s. 465.019 in accordance with the institutional policy for such controlled substances or drugs.

(e) Dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(f) Prescribed by a health care practitioner for a patient younger than 16 years of age.

(5) The data required to be reported under this section shall be determined by the Department of Health by rule but may include any data required under s. 893.04.

(6) A practitioner or pharmacist who dispenses a controlled substance under this section must submit the information required by this section in an electronic or other format approved by rule of the Department of Health. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, compact discs, zip-drive storage, regular electronic mail, magnetic tapes, diskettes, and facsimile charges. The information submitted to the Department of Health under this section may be transmitted to any person or agency authorized to receive it pursuant to section 1 of Senate Bill 176, or similar legislation, and that person or agency may maintain the information received for up to 24 months before purging the information from its records.

All transmissions required by this subsection must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain it for longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(7) Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8) The Department of Health and the regulatory boards for the health care practitioners subject to this section shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer this section.

(9) All costs incurred by the Department of Health in administering the prescription-monitoring system shall be borne by the department, and an amount necessary to cover such costs shall be appropriated annually, subject to the availability of funds, from the Grants and Donations Trust Fund. The Medical Quality Assurance Trust Fund may not be used to administer or otherwise fund this program.

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

893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedules II, III, and 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 to prescribe 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 $2,196,352 is appropriated from the Grants and Donations Trust Fund to the Department of Health, and three additional full-time equivalent positions are authorized for the 2006-2007 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(6), 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(7) 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, 2006, if Senate Bill 176, 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 178

- Provides that the pharmacist or pharmacist's agent shall obtain a government-issued or other form of documentary identification substantiating the identity of a patient or patient's agent prior to dispensing any Schedule II, Schedule III, or Schedule IV controlled substance to such patient or patient's agent. The pharmacist or pharmacist's agent shall make a record of the type of documentary identification provided by the patient or patient's agent.

- Provides a definition of "pharmacy" in s. 893.055, F.S., which is created by the bill and which creates an electronic monitoring system for prescription of controlled substances in Schedules II, III, and IV.

- Provides that a pharmacy or dispensing practitioner may meet the reporting requirements of the bill by providing to the Department of Health in written or any electronic or magnetic format, including but not limited to, electronic submission via the Internet or magnetic disc or tape of each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses.

- Inserts reference to SB 176, which is tied to SB 178 and which makes confidential and exempt from public disclosure identifying information of a patient, patient's agent, health care practitioner, pharmacist's agent, or pharmacy, which is contained in records held by the Department of Health or other specified agencies in an electronic-monitoring system for prescription of controlled substances.