By the Committees on Appropriations; Health, Aging, and Long-Term Care; and Senators Fasano and Aronberg

309-2441-03

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.; requiring the Department of Health to establish an electronic system to monitor the prescribing of controlled substances listed in Schedule II, Schedule III, and Schedule IV; requiring the dispensing of such controlled substances to be reported through the system; providing exceptions; providing reporting requirements; providing penalties; providing rulemaking authority to the department; requiring the department to cover all costs for the system; providing for an appropriation, subject to availability of funds; providing that a certain trust fund may not be used to fund 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 positions; providing 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 with 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 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. No prescription for a controlled substance listed in Schedule II may be refilled.

(g) No prescription for a controlled substance listed in Schedule ~~Schedules~~ III, Schedule IV, or Schedule V may 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

also obtain the patient or patient's agent identification information, in writing, electronic format or other approved manner prior to dispensing any controlled substance. 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 pharmacist that dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV shall be exempt from the requirement to obtain suitable identification for the prescription dispensed by mail.

(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) All written prescriptions 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 shall be permitted, upon verification by the

prescriber, to 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 Electronic monitoring system for prescription of controlled substances listed in Schedules II, III, and IV.--

(1) By June 30, 2004, the Department of Health shall design and establish an electronic system consistent with the American Society for Automation in Pharmacy (ASAP) standards 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.

(2) 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 may meet the reporting requirements of this section by providing the Department of Health an exchangeable electronic disc or tape of each controlled substance listed in Schedules II, III, and IV which it dispenses.

(3) 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 in-patient of a facility with 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) Either 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 less than 16 years of age.

(4) 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.

(5) 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 subsection shall not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, compact disks, 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 2 of Senate Bill 1784 or similar legislation, and that person or agency may maintain the information received for up to 24 months before purging it from its records. All transmissions required by this paragraph shall comply with relevant federal and state privacy and security laws. Notwithstanding the foregoing, any authorized agency receiving such information may maintain it longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(6) 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.

(7) 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 necessary to implement and administer this section.

(8) All costs incurred by the Department of Health in implementing the prescription monitoring system shall be borne by the department, and there is appropriated annually, subject to the availability of funds, from the Grants and Donations Trust Fund an amount necessary to cover such costs. The Medical Quality Assurance Trust Fund may not be used to implement 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. There is appropriated $2,196,352 from the Grants and Donations Trust Fund to the Department of Health, and three full-time equivalent positions are authorized, for

fiscal year 2003-2004 to implement the provisions of sections 893.055 and 893.065, Florida Statutes, as created by this act.

Section 6. The penalties created in sections 831.311(2) and 893.055(6), Florida Statutes, by this act shall be effective only upon the adoption by the Department of Health and each applicable professional regulatory board of the rules required pursuant to sections 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, 2004, if Senate Bill 1784 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
CS for Senate Bill 2390

The Committee Substitute allows a controlled substance dispensed by a pharmacist upon an oral prescription to be recorded electronically if permitted by federal law.

Allows a controlled substance, listed in Schedules III or IV, dispensed by a pharmacist upon an oral prescription to be recorded electronically if permitted by federal law.

Requires all written prescriptions prescribed by a practitioner for a controlled substance listed in Schedules II, III or IV, to include the "abbreviated" month written on the face of the prescription.

Appropriates, subject to the availability of funds, $2,196,352 from the Grants and Donations Trust Fund and authorizes three positions to the Department of Health for fiscal year 2003-04.

Changes the date that the Department of Health is required to design and establish a prescription electronic monitoring system from January 1, 2004 to June 30, 2004.

Requires manufacturers to file a written list of all authorized distributors with the Department of Health and to notify the Department of changes to the list no later than 10 days after the change. The Department is required to publish the list of all authorized distributors on its website.

Limits the definition of an authorized distributor to those wholesalers who have a verified account with a manufacturer if the manufacturer fails to provide the Department with a list of authorized distributors.