By Senator Fasano

11-393-03 See HB 989

A bill to be entitled

An act relating to controlled substances; 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 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; providing rulemaking authority to the department; requiring the department to cover all costs for the system; providing a continuing appropriation; 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; providing effective dates.

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

Section 1. Section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.--

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

(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.

(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 <u>but shall be limited to a 48-hour supply</u>. No prescription for a controlled substance listed in Schedule II may be refilled.

(g) No prescription for a controlled substance listed in <u>Schedule</u> ~~Schedules~~ III, <u>Schedule</u> IV, or <u>Schedule</u> 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 individual without first obtaining suitable identification and documenting, in a log book kept by the pharmacist, the identity of the individual obtaining the controlled substance. The log book entry shall contain the printed name, address, phone number (if available), driver's license number or other suitable identification number, and signature of the person obtaining the controlled substance. If the individual does not have suitable identification or it is impracticable to obtain such 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. In such case, the pharmacist or his or her designee must obtain the other information required by this paragraph and must sign the log book to indicate that suitable identification was not available and that the pharmacist's professional judgment was exercised prior to dispensing the controlled substance. The Board of Pharmacy may adopt, by rule, procedures by which a pharmacist may verify the validity of a prescription for a controlled substance listed in Schedule II, Schedule III, or Schedule IV for circumstances when it is otherwise impracticable for the pharmacist to obtain suitable identification from the patient or the patient's agent. For purposes of this paragraph, identification is suitable only if it contains the photograph, printed name, and signature of the individual obtaining the controlled substance.

(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.

(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. Such prescriptions must contain the date of the oral authorization.

(d) All prescriptions issued for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the date and quantity on the face of the prescription.

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

(f) A pharmacist may not knowingly fill a prescription that has been mutilated or 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 2. 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 January 1, 2004, the Department of Health shall design and establish an electronic system to monitor the prescribing of controlled substances listed in Schedules II, III, and IV by health care practitioners within the state or the dispensing of such controlled substances to an 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 that is dispensed in this state must be reported to the Department of Health through the system, as soon thereafter as possible but not more than 30 days after the date the controlled substance is dispensed, each time the controlled substance is dispensed.

(3) This section does not apply to controlled substances that are:

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

(b) Dispensed by a health care practitioner to a patient and limited to an amount adequate to treat the patient for a period of no more than 48 hours.

(c) Dispensed by a health care practitioner to an in-patient of a facility with an institutional pharmacy permit.

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

(e) Ordered from an institutional pharmacy licensed under s. 465.019(2), Florida Statutes, in accordance with the institutional policy for such controlled substances or drugs.

(f) 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.

(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 and must include the category of professional licensure of the prescribing practitioner.

(5) A dispenser must transmit the information required by this section in an electronic format approved by rule of the Board of Pharmacy after consultation with the Department of Health, unless a specific waiver is granted to that dispenser by the Department of Health. The information transmitted to the Department of Health under this section may be transmitted to any agency authorized to receive it, and that agency may maintain the information received for up to 12 months before purging it from its records. Notwithstanding the foregoing, any authorized agency receiving such information may maintain it longer than 12 months if the information is pertinent to an ongoing investigation arising under this section.

(6) Any person who willfully 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 shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement and administer this section.

(8) The Department of Health must cover all costs for the prescription monitoring system, and there is appropriated annually out of the General Revenue Fund, to be paid to the Administrative Trust Fund of the department, an amount necessary to cover such costs.

Section 3. 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-proof 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 4. There is appropriated from the General Revenue Fund to the Administrative Trust Fund of the Department of Health an amount sufficient to cover the costs for fiscal year 2003-2004 of implementing the provisions of section 893.055, Florida Statutes, as created by this act. This section shall take effect July 1, 2003.

Section 5. This act shall take effect January 1, 2004, except that section 2 of this act shall take effect on the same date that SB ___ or similar legislation takes effect, if such legislation is enacted in the same legislative session or an extension thereof.