CHAMBER ACTION

The Committee on Health Care recommends the following:

Committee Substitute

Remove the entire bill and insert:

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 Schedules II, III, and IV; requiring the dispensing of such controlled substances to be reported through the system; providing exceptions; providing restrictions on access; providing reporting requirements; providing penalties; limiting liability; requiring confidentiality of information to be maintained; requiring the department and regulatory boards to adopt rules; requiring the

department to cover all costs for the system, subject to availability of funds; providing a continuing appropriation; providing that a certain trust fund may not be used to fund the program; providing for future legislative review and repeal; 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; requiring reports of law enforcement agencies and medical examiners to include specified information if a person dies of an apparent overdose of a controlled substance listed in Schedule II, Schedule III, or Schedule IV; 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.

(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 must 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. 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 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. Effective July 1, 2004, subsection (1) of section 893.055, Florida Statutes, is created, and effective July 1, 2005, subsections (2) through (12) of said section are created, to read:

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

(1) By June 30, 2005, 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. The system shall be put into operation on July 1, 2005. The secretary of the department shall ensure that only those department employees who are authorized to investigate a specific violation of this section in response to a complaint

initiated by a patient, practitioner, or pharmacist pursuant to procedure adopted by rule by the department have access to the electronic monitoring system created by this section; however, nothing in this section shall preclude access to the system by employees or agents for purposes of creating, maintaining, or repairing the system.

(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 inpatient 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 younger 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 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 House Bill 399, 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 must

comply with relevant federal and state privacy and security laws. However, 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, subject to the availability of funds, and there is appropriated annually 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.

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

(10) A practitioner or pharmacist authorized to obtain information under this section is not liable for accessing or failing to access such information.

(11) A practitioner, pharmacist, or other person who obtains information from the electronic information system

authorized by this section shall maintain the confidentiality of such information pursuant to ss. 456.057 and 465.017, or as otherwise required by law.

(12) This section is repealed June 30, 2008, unless reviewed and saved from repeal through reenactment by the Legislature.

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. Effective July 1, 2004, 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 2004-2005, 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 be effective

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. If a person dies of an apparent drug overdose:

(1) A law enforcement agency shall prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV which is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. Thereafter, the law enforcement agency shall submit a copy of the report to the medical examiner.

(2) A medical examiner who is preparing his or her report pursuant to s. 406.11, Florida Statutes, shall include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV which is found in, on, or near the deceased or among the deceased's possessions.

Section 8. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2005, if House Bill 399 or similar legislation is adopted in the same legislative session or an extension thereof and becomes law.