CHAMBER ACTION

The Health Care Regulation Committee recommends the following:

Council/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.; authorizing electronic recording of oral prescriptions for a controlled substance; providing additional requirements for the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV; creating s. 893.055, F.S.; providing a definition; requiring the Department of Health to establish an electronic system to monitor the prescribing and dispensing 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 liability for the improper release of any confidential information; precluding the use of a specified defense by specified defendants in certain

actions; 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 the use of funds from the Medical Quality Assurance Trust Fund to administer the program; providing for future repeal and review; creating s. 893.065, F.S.; requiring the department to develop and adopt by rule the form and content for a counterfeit-resistant prescription blank for voluntary use by practitioners to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV; 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 an 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 Violations involving certain prescription blanks for controlled substances in Schedules II-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 blank for controlled substances as provided in 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 or recorded electronically 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 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 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 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 the prescription to writing or records it

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

(d) Each written prescription from 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 Electronic monitoring system for prescription of controlled substances listed in Schedules II-IV.--

(1) As used in this section, the term "pharmacy" means any pharmacy subject to licensure or regulation by the department under chapter 465 that dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a patient in this state.

(2) By June 30, 2007, the department shall contract for the design, establishment, and maintenance of 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. The contracted vendor shall maintain the database within the United States.

(3) Any controlled substance listed in Schedule II, Schedule III, or Schedule IV that is dispensed to an individual in this state must be reported to the department's contract vendor through the system established under this section 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 to the department's contract vendor an exchangeable electronic disc, file, or tape

containing the required data concerning each controlled substance listed in Schedule II, Schedule III, or Schedule IV that the pharmacy 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 holding a permit 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 that 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 by rule and 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. 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's contract vendor under this section may be transmitted to any person or agency authorized to receive such information under s. 893.056 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 the information for longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

(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 or as a defense in tort, or any other application, for the maintenance of confidentiality of information and for any breach of contract.

(8) 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.

(9) The department and the regulatory boards for the health care practitioners subject to this section shall adopt rules under ss. 120.536(1) and 120.54 to administer this section.

(10) All costs incurred by the department 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 shall not be used to administer or otherwise fund this program.

(11) This section is repealed effective October 2, 2009, 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-IV.--The department shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank that may be used by practitioners to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV. The department 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 penalties created in s. 831.311(2), Florida Statutes, by this act shall be effective only upon the adoption of the rules required pursuant to s. 893.065, Florida Statutes, as created by this act.

Section 6. 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 of s. 893.03, Florida Statutes, that 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 a 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 of s. 893.03, Florida Statutes, that was found in, on, or near the deceased or among the deceased's possessions.

Section 7. This act shall take effect July 1, 2006.