

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: SB 860

SPONSOR: Senator Fasano

SUBJECT: Controlled Substances

DATE: April 22, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Favorable
2.	_____	_____	CJ	_____
3.	_____	_____	HA	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill creates a third-degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts under the Florida Comprehensive Drug Abuse Prevention and Control Act, sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances adopted by rule of the Department of Health (DOH).

The bill authorizes a pharmacist to record an oral prescription for a controlled substance electronically. The dispensing of Schedule II drugs in an emergency situation based upon an oral prescription is limited to a 72-hour supply. The dispensing of Schedule III controlled substances based upon an oral prescription is limited to a 30-day supply. Procedures are specified for a pharmacist to verify the validity of the prescription for controlled substances listed in Schedule II, Schedule III, or Schedule IV, and the identity of the individual obtaining any controlled substance.

Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon 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. All written prescriptions for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of the prescription. 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.

The Department of Health must 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. DOH 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 bill requires a law enforcement agency to prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV that is found on or near the deceased or among the deceased's possessions, when a person dies of an apparent drug overdose. Medical examiners must include certain information regarding prescribed controlled substances in their reports for deceased individuals.

This bill amends section 893.04, F.S., and creates sections 831.311, and 893.065, F.S., and two undesignated sections of law.

II. Present Situation:

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds. Section 893.02, F.S., defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing

practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The chapter requires the original container in which a controlled substance is dispensed to bear a label with specified information.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by regulation of DOH, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.¹ No prescription for a controlled substance listed in Schedules III, IV, or 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 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.³

Medical Examiners

Chapter 406, F.S., provides requirements for medical examiners. Under section 406.11, F.S., in any of the following circumstances involving the death of a human being, the medical examiner of the district in which the death occurred or the body was found must determine the cause of death and must, for that purpose, make or have performed such examinations, investigations, and autopsies as he or she shall deem necessary or as may be requested by the state attorney. When any person dies in the state:

- Of criminal violence;
- By accident;
- By suicide;
- Suddenly, when in apparent good health;
- Unattended by a practicing physician or other recognized practitioner;
- In any prison or penal institution;
- In police custody;
- In any suspicious or unusual circumstance;

¹ Section 893.04(1)(f), F.S.

² Section 893.04(1)(g), F.S.

³ See 21 CFR 1306.11(d)(1) which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

- By criminal abortion;
- By poison;
- By disease constituting a threat to public health; or
- By disease, injury, or toxic agent resulting from employment.

Autopsies are also required when a dead body is brought into Florida without proper medical certification or when a body is to be cremated, dissected, or buried at sea.

Department of Health

As a part of its mission, DOH must promote and protect the health of Florida's residents. DOH and various boards within the department regulate health care practitioners.

III. Effect of Proposed Changes:

Section 1. Creates s. 831.311, F.S., to create a third-degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts (section 893.13, F.S.) under the Florida Comprehensive Drug Abuse Prevention and Control Act, sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances the form and content of which are adopted by rule of DOH pursuant to s. 893.065, F.S. A third-degree felony is punishable by imprisonment of up to 5 years and a fine of up to \$5,000.

Section 2. Amends section 893.04, F.S., to authorize a pharmacist to record an oral prescription for controlled substances electronically. The bill limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply. A pharmacist is prohibited from dispensing a controlled substance in Schedule II, Schedule III, or Schedule IV to any patient or the 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 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, using his or her professional judgment, that the order is valid and includes such information in the patient's record. The Board of Pharmacy may adopt by administrative rule, required patient or patient agent 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 is not provided required identification information.

Any pharmacist that dispenses a controlled substance listed in Schedule II, Schedule III, or Schedule IV by mail is exempt from the requirement to obtain suitable identification.

Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon oral prescription if, before filling the prescription the pharmacist reduces the prescription to writing or records the prescription electronically. Such prescriptions must contain the date of the oral authorization.

All written prescriptions prescribed by a practitioner in Florida for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of the prescription. A pharmacist is permitted, upon verification by the prescriber, to document any information required on the prescription.

A pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription issued in Florida. 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.

Section 3. Creates section 893.065, F.S., to require DOH to 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. DOH 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. Creates an undesignated section of law, to provide that the penalties created in section 831.311(2), F.S., by the bill are effective only upon the adoption of the rules required by section 893.065, F.S., as created by the bill.

Section 5. Creates an undesignated section of law, to require a law enforcement agency to prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV that is found on or near the deceased or among the deceased's possessions, when a person dies of an apparent drug overdose. The report must identify the person who prescribed the controlled substance, if known or ascertainable. Thereafter, the law enforcement agency must submit a copy of the report to the medical examiner.

A medical examiner who is preparing a report under section 406.11, F.S., must include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV that was found in, on, or near the deceased or among the deceased's possessions.

Section 6. Provides an effective date of July 1, 2005.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health reports that the fiscal impact of the bill is indeterminate because the impact is primarily associated with the department's requirements to adopt rules and administer discipline against licensed health care practitioners. The department notes that an additional workload on inspectors, investigators and prosecutors is expected to be minimal.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
