HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1449 CS Controlled Substances
SPONSOR(S): Harrell
TIED BILLS: **IDEN./SIM. BILLS:** SB 860

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Criminal Justice Committee	7 Y, 0 N, w/CS	Kramer	Kramer
2) Health Care Regulation Committee			
3) Justice Appropriations Committee			
4) Justice Council			
5)			

SUMMARY ANALYSIS

HB 1449 requires the development and adoption of a counterfeit-resistant prescription blank to be used voluntarily by physicians to prescribe Schedule II, Schedule III, or Schedule IV controlled substances. The bill prohibits the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks.

The bill provides additional requirements for the dispensing of a controlled substance. Most significantly, the bill:

- Provides that 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.

- Provides that a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription.

- Limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply.

- Provides that each written prescription 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.

Further, the bill provides that if a person dies of an apparent overdose, a law enforcement agency must prepare a report identifying each prescribed controlled substance listed in Schedule II, III or IV 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. The law enforcement agency must submit a copy of the report to the medical examiner. A medical examiner who is preparing a report pursuant to s. 406.11, F.S. must include in the report information identifying each prescribed controlled substance listed in Schedule II, III or IV that was found in, on or near the deceased or among the deceased possessions.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government: The bill creates reporting requirements for law enforcement and medical examiners when a person dies of an apparent drug overdose.

B. EFFECT OF PROPOSED CHANGES:

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.

Prescriptions: 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. 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.

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 section 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

[1] Section 893.04(1)(f), F.S.
[2] Section 893.04(1)(g), F.S.

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]

It is a first degree misdemeanor to distribute or dispense a controlled substance in violation of chapter 893 or to refuse or fail to make, keep, or furnish any record required under the chapter.[4]

The bill amends section 893.04, F.S. as follows:

- The bill authorizes a pharmacist to record an oral prescription for a controlled substances electronically.

- Currently, oral prescriptions must be promptly reduced to writing by the pharmacist. The bill provides that 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.

- Currently, there is no specific limitation on the length of supply of a Schedule III drug based on an oral prescription. Under the provisions of the bill, a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription.

- Currently, a Schedule II drug can only be dispensed upon a written prescription except in the case of an emergency in when a Schedule II drug can be dispensed based on an oral prescription. The bill limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply.

- Under the bill, 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 may dispense a controlled substance in the exercise or 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.

- The bill provides that each written prescription 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.

- The bill provides that 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.

Counterfeit-resistant prescription blanks: The bill creates section 893.065, F.S., to require the Department of Health 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.

[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.

[4] S. 893.03(7)(b), F.S.

HB 1449 creates s. 831.311, F.S., to make it a third degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of s. 893.13, F.S. sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blank. A third degree felony is punishable by imprisonment up to 5 years, and a fine up to $5,000 may also be imposed.

Drug overdose: Section 406.14, F.S. currently provides that any evidence material to the determination of the cause of death in possession of the law enforcement officers assigned to the investigation of the death must be made available to the medical examiner. Further the section provides that it is the duty of the law enforcement officer assigned to and investigating the death to immediately establish and maintain liaison with the medical examiner during the investigation into the cause of death. Section 406.11, F.S. provides that a district medical examiner must determine the cause of death of a human being in certain circumstances. The section does not require any particular information to be included in any report that the medical examiner creates.

The bill creates an unnumbered section of statute which provides that if a person dies of an apparent overdose, a law enforcement agency must prepare a report identifying each prescribed controlled substance listed in Schedule II, III or IV 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. The law enforcement agency must submit a copy of the report to the medical examiner. A medical examiner who is preparing a report pursuant to s. 406.11, F.S. must include in the report information identifying each prescribed controlled substance listed in Schedule II, III or IV that was found in, on or near the deceased or among the deceased possessions.

C. SECTION DIRECTORY:

Section 1. Creates s. 831.311, F.S. relating to violations involving certain prescription blanks.

Section 2. Creates s. 893.04, F.S. relating to pharmacist and practitioner prescribing.

Section 3. Creates s. 893.065, F.S. relating to counterfeit-resistant prescription blanks for controlled substances.

Section 4. Provides that penalties created in act shall be effective only upon the adoption of certain rules.

Section 5. Creates unnumbered section of statute relating to drug overdoses.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   HB 1449 makes it a third degree felony to sell, manufacture, alter, delivery or possess a counterfeit-resistant prescription blank for controlled substances under certain circumstances. The offense is not ranked in the offense severity ranking chart of the Criminal Punishment Code. The Criminal Justice Impact Conference has not met to consider the prison bed impact of this bill on the Department of Corrections. However, the conference generally determines that a bill which creates an unranked third degree felony will have an insignificant prison bed impact.

A fiscal analysis was requested from the Department of Health but due to the short amount of time between the request and the filing of this analysis, was not received before this analysis was published. Any information received from DOH will be included in an updated analysis.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

The bill requires a law enforcement agency to prepare a report identifying each prescribed controlled substance listed in Schedule II, III or IV that is found on or near the deceased or among the deceased possessions if a person dies of an apparent drug overdose. The report must identify the person who prescribed the controlled substance, if known or ascertainable. To the extent that this will require additional investigation or reporting on the part of law enforcement, there may be a fiscal impact on law enforcement.

Further, the bill requires a medical examiner who is preparing a report pursuant to s. 406.11, F.S. to include in the report information identifying each prescribed controlled substance listed in Schedule II, III or IV that was found in, on or near the deceased or among the deceased possessions. To the extent that this will require additional reporting on the part of the medical examiner, the bill may have a fiscal impact.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Schedule III controlled substance prescriptions intended to cover more than a 30-day supply must be in writing under the bill. Consumers who currently may obtain such drugs through an oral prescription may bear additional costs for medical visits to obtain prescriptions beyond a 30-day supply.

Practitioners opting to use the proposed counterfeit-proof prescription blank will likely pay a higher price than for customary prescription blanks.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because this bill does not appear to: require the counties or cities to spend funds or take an action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill requires the Department of Health to develop and adopt by rule the form and content for a counterfeit-resistant prescription blank.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

Under the original bill, a pharmacist or pharmacist's agent was required to obtain the patient or patient's agent identification information, in writing, electronic format or other approved manner prior to dispensing any controlled substance. The Criminal Justice Committee amended the bill to provide that a pharmacist may dispense a controlled substance in the exercise or 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.