

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill creates additional regulation regarding the dispensing of schedule II-IV prescription drugs; creates reporting requirements for law enforcement and medical examiners when a person dies of an apparent drug overdose; and creates a penalty for violations involving certain prescription blanks for controlled substances in schedules II-IV.

B. EFFECT OF PROPOSED CHANGES:

HB 913 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 by the Department of Health.

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

- The bill authorizes a pharmacist to record an oral prescription for controlled substances electronically.
- 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, oral prescriptions must be promptly reduced to writing by the pharmacist.
- 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, there is no specific limitation on the length of supply of a Schedule III drug 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. Currently, a Schedule II drug can only be dispensed upon a written prescription except in the case of an emergency which a Schedule II drug can be dispensed based on an oral prescription.
- 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 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.
- 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.

HB 913 also specifies that the Department of Health (DOH) will develop counterfeit-resistant blanks for controlled substances that may be used by practitioners to prescribe controlled substances 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.

If a person dies of an apparent drug overdose, the bill requires that a law enforcement agency shall prepare a report, which will be provided to the medical examiner, identifying each prescribed controlled substance that is found on or near the deceased or among the deceased's possession, and requires the law enforcement agency to identify the person who prescribed the drugs. The bill also requires that a medical examiner include in his or her report pursuant to s. 406.11, F.S., information identifying any Schedule II, Schedule III, or Schedule IV drug which is found in, on, or near the deceased or the deceased possessions.

CURRENT SITUATION

Florida Comprehensive Drug Abuse Prevention and Control Act

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. Controlled substances are classified 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.

Pharmaceutical Drug Dispensing

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 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, F.S., or to refuse or fail to make, keep, or furnish any record required under the chapter.⁴

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. 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 of 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.

Prescription Drug Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003. The National Institute on Drug abuse would like to reverse this trend by increasing awareness and promoting additional research on the topic.

Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system (CNS) depressants, and stimulants – when abused can alter the brain’s activity and lead to dependence and possible addiction.

BACKGROUND

Legislative History

Over the last several years similar legislation has been filed in the House of Representatives and Senate. However, in past years the bill has included the creation of an electronic monitoring system for the prescription of controlled substances listed in Schedules II, III, and IV. The electronic monitoring system must be consistent with the American Society for Automation in Pharmacy. The proposed monitoring system relies upon pharmacists reporting the dispensing of Schedule II, Schedule III, or Schedule IV drugs as soon as possible after dispensing (but not to exceed 35 days). Pharmacies may

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.

⁴ S. 893.03(7)(b), F.S.

report via electronic disk or tape. The database information is to be stored for up to 24 months before the information must be purged. The estimated fiscal impact for a statewide prescription monitoring database is approximately \$2 million dollars.

Prescription Monitoring Systems

In an effort to control the diversion of controlled substances, over fifteen states have established prescription monitoring systems. Prescription monitoring systems collect prescription data from pharmacies in either paper or electronic format. The data may be reviewed and analyzed for educational, public health, and investigational purposes. The goals of prescription monitoring systems are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription monitoring program has its own set of goals for its program.

Prescription monitoring systems may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II; while others cover a range of controlled substances listed in Schedules II through V.

Potential Advantages of an Electronic Prescription Data Collection System

Potential advantages of an electronic prescription data collection system include the following:

- Identifies “doctor shoppers” by tracking all their prescribing physicians and purchases from pharmacies. Doctor shopping is when a person continually switches physicians so that they can obtain enough of a drug to feed their addiction.
- Provides complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank, and set priorities for cases.
- Maximizes investigators’ effectiveness by providing prescription data in a convenient, comprehensive, and timely method.
- Reduces intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns.
- Reduces the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists’ dispensing patterns.

Potential Disadvantages of an Electronic Prescription Data Collection System

Some opponents of prescription monitoring systems dislike the concept of mandatory disclosure of protected health information and point to federal and state privacy laws as barriers to these monitoring systems.

There is a possibility that the tracking system could violate the Florida Constitution’s Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida’s Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides as follows:

Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person’s private life except as otherwise provided herein. This section shall not be construed to limit the public’s right of access to public records and meetings as provided by law.

This right to privacy protects Florida’s citizens from the government’s uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

Unlike the penumbra or “implicit” privacy right of the federal constitution, Florida’s privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal privacy provision, which contains a “penumbra” right of privacy created from the 1st, 3rd, 4th, 5th, and 9th amendments to the U.S. Constitution, extends only to such

fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and educating of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the federal constitution.⁵

Doctor Shoppers

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for non-medical use. People are obtaining these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it.

A data search indicated that no studies in the United States have specifically addressed the profile of a doctor shopper. A search of international data produced a report and findings from a study in Australia, which indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies.⁶

Frequent reasons used by doctor shoppers to obtain medicines are:

- Work hours interfere with sleep.
- Lost prescription.
- Relatives passed away.
- Migraine, cramp, toothache, or diarrhea.
- Just arrived in area.
- Handbag stolen.

Data shows that the age and gender of most doctor shoppers are as follows:

- 20% are aged between 15 and 29 years.
- 57% are aged between 30 and 49 years.
- 15% are aged between 50 and 64 years.
- 8% are 65 years and older.
- 58% are female.

C. SECTION DIRECTORY:

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

Section 2. – Amends s. 893.04, F.S., relating to pharmacist prescribing practices.

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

Section 4. – Provides that the penalties created in s. 831.311, F.S., are effective only upon adoption of certain rules.

Section 5. – Creates an unnumbered section of law relating to drug overdose.

⁵ See, *In re T.W.*, 551 So.2d 1186 (Fla. 1989).

⁶ www.hic.gov.au

Section 6. – Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

HB 913 makes it a third degree felony to sell, manufacture, alter, deliver 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.

The Department of Health has indicated that the fiscal impact of the bill is minimal.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

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 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:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule-making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill sponsor has indicated an amendment will be filed to create an electronic monitoring system for prescription of Schedule II, III, and IV controlled substance. **[See Background]**

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES