STORAGE NAME: h0701s1.sa.doc
DATE: February 12, 2002

HOUSE OF REPRESENTATIVES
COMMITTEE ON
STATE ADMINISTRATION
ANALYSIS

BILL #: CS/HB 701

RELATING TO: Controlled Substances

SPONSOR(S): Committee on State Administration and Representative(s) Crow

TIED BILL(S): HB 699

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) STATE ADMINISTRATION YEAS 5 NAYS 0
(2) HEALTH REGULATION
(3) COUNCIL FOR SMARTER GOVERNMENT
(4)
(5)

I. SUMMARY:

Current law provides for a schedule of controlled substances which are classified according to their potential for abuse and accepted medical use and permits practitioners and pharmacists to dispense controlled substances, with particular restrictions. The illegal dispensation of controlled substances is becoming more of a problem. As a result of growing abuse of controlled substances, many states have enacted electronic prescription monitoring systems. CS/HB 701 requires the Department of Legal Affairs to establish such an electronic monitoring system for certain controlled substances.

Also, this bill requires the Department of Legal Affairs to develop a counterfeit-proof prescription blank which must contain certain information. CS/HB 701 further requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules for prescribing controlled substances in emergency room settings; requires the completion of a one-hour educational course on controlled substances for all licensed physicians and fellows; requires the Department of Health (DOH) to recommend to the Secretary of the DOH the suspension of licenses for any practitioners who violate the controlled substance provisions; requires law enforcement agencies to notify the DOH regarding certain controlled substance violations; requires the Medical Examiners Commission to report any deaths involving lethal levels of controlled substances to the DOH; limits the dispensing of certain substances to a 30-day supply; and requires that certain identifying information be collected from those receiving prescriptions for controlled substances. This committee substitute provides rule-making authority to the Board of Medicine, the Board of Osteopathic Medicine, the Board of Pharmacy, certain professional licensing boards, and the Department of Legal Affairs.

CS/HB 701 may have a fiscal impact on local governments and has a negative fiscal impact on state government of approximately $2,958,337 for fiscal year 2002-03; $2,799,870 for fiscal year 2003-04; and $1,527,772 for fiscal year 2004-05. This is a total negative fiscal impact of approximately $7,284,979 on state government. Please see the "Fiscal Analysis and Economic Impact Statement" for further discussion.

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [X]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [X]
3.	Individual Freedom	Yes []	No [X]	N/A []
4.	Personal Responsibility	Yes []	No []	N/A [X]
5.	Family Empowerment	Yes []	No []	N/A [X]

For any principle that received a "no" above, please explain:

This committee substitute requires increased record keeping for pharmacists, the Florida Department of Law Enforcement, the Department of Legal Affairs, and law enforcement agencies. In addition, this committee substitute limits individual freedom by requiring the transmittance of certain information of individuals receiving certain controlled substances.

B. PRESENT SITUATION:

Chapter 893, F.S.

Chapter 893, F.S., is known as the "Florida Comprehensive Drug Abuse and Prevention Act." The act provides various definitions relating to the administration and distribution of certain substances. More particularly, the act defines a "controlled substance" to mean any substance that is named or described in Schedules I, II, III, IV, or V.[1] Any laws controlling the manufacture, distribution, preparation, dispensing, or administration of any such substances are drug abuse laws.[2]

This chapter 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.[3] The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner. This chapter also defines the term prescription, and specifies that a prescription order for a controlled substance may not be used on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule. In addition, a prescription order for a controlled substance may not be issued on the same prescription blank as a prescription order for a medicinal drug, which does not fall under the definition of a controlled substance.[4]

---

[1] 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 893.03, F.S.

[2] Section 893.02(4), F.S.

[3] Section 893.02(19), F.S.

[4] Section 893.02(20), F.S.

This chapter also provides that the Attorney General may by rule add a substance to a schedule described above, or transfer a substance between schedules, if he or she finds that it has a high potential of abuse. The Attorney General may also remove a substance previously added to a schedule if he or she find the substance does not meet the requirements for inclusion in that schedule. Additionally, the Attorney General can include designer drugs in the list of scheduled substances.[5]

This chapter authorizes a pharmacist, in good faith and only in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions.[6] The proprietor of the pharmacy in which a prescription for controlled substances is filled must retain the prescription on file for a period of two years. The chapter requires the original container in which a controlled substance is dispensed to bear a label with specified information.[7]

Upon the conviction in any court of any person holding a license, permit, or certificate issued by a state agency, for sale of, or trafficking in, a controlled substance or for conspiracy to sell, or traffic in, a controlled substance, if such offense is a felony, the clerk of the court must send a certified copy of the judgment of conviction with the person's license number to the agency head by which the convicted defendant has received a license, permit, or certificate.[8] The agency head must suspend or revoke the license, permit, or certificate of the convicted defendant to practice his or her profession or to carry on his or her business. The agency head may reinstate the license of the convicted defendant upon a showing that such person has had his or her civil rights restored or upon a showing that the defendant has met other criteria specified in s. 893.11, F.S.[9]

This chapter provides punishment for crimes involving the illegal selling, dispensing, manufacturing, delivery, or possessing of a controlled substance. Misdemeanors of the first degree are punishable by jail time up to one year and a fine of up to $1,000.[10] Chapter 893, F.S., also specifies various offenses as third degree felonies.[11] This chapter provides that these criminal provisions are not

---

[5] Section 893.035, F.S., refers to drugs which are sometimes called "designer drugs." Designer drugs can be designed to produce a desired pharmacological effect yet can avoid being classified as controlled substances and thereby avoid statutory regulation.

[6] 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; the name of the controlled substance prescribed and the strength, quantity, and directions for its use; 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. If the prescription is for an animal, the species of animal for which the controlled substance is prescribed must be provided. Section 893.04, F.S.

[7] Section 893.05, F.S., provides that a *practitioner*, in good faith and in the course of his or her professional practice only may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. The practitioner must follow similar guidelines as the pharmacist in the prescribing of the controlled substance.

[8] Section 893.11, F.S.

[9] Such criteria include seeking evaluation and enrollment in, and once enrolled maintaining enrollment in until completion, a drug treatment and rehabilitation program which is approved or regulation by the Department of Children and Family Services, or submitting to periodic urine drug testing pursuant to procedures prescribed by the Department of Corrections. Section 893.11(1), F.S.

[10] These crimes include: distributing or dispensing a controlled substances in violation of Chapter 893, F.S.; refusing or failing to make, keep, or furnish any record, notification, order form, statement, invoice, or information required by Chapter 893, F.S.; refusing entry into any premises for any inspection or refusing to allow an inspection authorized by Chapter 893, F.S.; and distributing a controlled substance named or described in Schedule I or II except pursuant to an order form. Any second or subsequent violation involving these crimes is currently punishable as a third degree felony. Section 893.13(7), F.S.

[11] These crimes include: acquiring or obtaining, or attempting to acquire or obtain, or possess a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge; affixing any false or forged label to a package or receptacle containing a controlled substance; and furnishing false or fraudulent material information in, or omit any material information from, any report or other document or record required to be kept or filed under Chapter 893, F.S. Section 893.13(7), F.S.

applicable to the delivery or actual possession of controlled substances for medical or scientific use for particular persons.[12]

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. Prescription monitoring systems may cover a specified number of controlled substances. Advantages of an electronic prescription data collection system include the following:

- Identifying "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies;
- Providing complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank and set priorities for cases;
- Maximizing investigators' effectiveness by providing prescription data in a convenient, comprehensive and timely method;
- Reducing intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns; and
- Reducing the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists' dispensing patterns.[13]

Chapter 456, F.S.

Chapter 456, F.S., pertains to health professional and occupations. This chapter provides the Department of Health (DOH) and the professional licensing boards under its jurisdiction with the authority to conduct disciplinary proceedings against practitioners for specific violations.[14] This chapter sets forth procedures that the DOH must follow in order to conduct disciplinary proceedings against practitioners under its jurisdiction.[15] The boards within the DOH have the status of an

---

[12] These persons include pharmacists, practitioners, person who procure controlled substances in good faith and in the course of professional practice, hospitals that procure controlled substances for lawful administration by practitioners, officers of employees of governments acting in their official capacity only, common carriers, manufacturers, wholesalers, distributors, and law enforcement officers. Section 893.13(8), F.S.

[13] *Id.*

[14] Section 456.072, F.S., provides for numerous violations including: intentionally violating any rule adopted by the board or the department; being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, a crime in any jurisdiction which relates to the practice of a licensee's profession; failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome; and having a license or the authority to practice any regulation profession revoked, suspended, or otherwise acted against by the licensing authority of any jurisdiction for a violation that would constitute a violation under Florida law.

[15] These practitioners include acupuncturists, any physician licensed to practice medicine, osteopathic physician, chiropractors, podiatric physician, those who practice naturopathy, optometrists, nurses, pharmacists, dentists, midwives, speech pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, pedorthists, those who practice electrolysis, massage therapists, clinical laboratory personnel, medical physicists, opticians, physical therapists, psychologists, and those who provide clinical, counseling, and psychotherapy services.

agency for certain administrative actions, including licensee discipline.[16] When the board, or the DOH in the absence of a board, finds any person guilty of the grounds set forth in this chapter, the board may impose various penalties.[17] These penalties include the imposition of a fine not to exceed $10,000 for each separate offense.[18]

Chapter 456, F.S., also provides for continuing education requirements on human immunodeficiency virus and acquired immune deficiency syndrome (AIDS/HIV) for certain health care professionals.[19] The appropriate board must require professionals under its jurisdiction to complete a one-hour continuing education course approved by the board on AIDS/HIV as a part of the professional's relicensure or recertification every two years.[20]

Medical Examiners Commission

Chapter 406, F.S., creates the Medical Examiners Commission (the Commission) within the Department of Law Enforcement. The Commission consists of nine persons, and must submit annual reports to the Governor and the Legislature; initiate cooperative policies with any agency of the state or political subdivision; remove or suspend district examiners pursuant to Chapter 406, F.S.; and oversee the distribution of state funds for the medical examiner districts. The Commission must establish medical examiner districts within the state. In particular 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 perform an investigation, examination, and autopsy as the medical examiner deems necessary.[21]

C. EFFECT OF PROPOSED CHANGES:

See "Section-by-Section Analysis."

D. SECTION-BY-SECTION ANALYSIS:

Sections 1 through 5 create new sections of law.

Section 1:

Requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules to establish guidelines for prescribing controlled substances to patients in emergency department settings. The guidelines must allow physicians to provide legitimate medical treatment of acute and chronic pain. The guidelines must also consider the requirements of state and federal law and of the Joint Commission on the Accreditation of Healthcare Organizations. Each board must consult with the Florida College of Emergency Physicians in developing these guidelines.

---

[16] For example, section 458.307, F.S., creates within the DOH the Board of Medicine, composed of 15 fifteen members appointed by the Governor. Additionally, s. 459.004, F.S., creates within the DOH the Board of Osteopathic Medicine, composed of seven members appointed by the Governor. Typically, boards are authorized to impose the following disciplinary penalties against licensees: refusal to certify, or to certify with restrictions, an application for a license; suspension or permanent revocation of a license; restriction of practice or license; imposition of an administrative fine for each count or separate offense; issuance of a reprimand or letter of concern; placement of the licensee on probation for a specified period of time and subject to specified conditions; or corrective action.

[17] Section 456.072(2), F.S.

[18] Section 456.072(2)(d), F.S.

[19] These health care professionals include acupuncturists, general practitioners, osteopathic physicians, nurses, pharmacists, dentists, nursing home administrators, occupational therapists, respiratory therapists, and dietitians.

[20] Section 456.033, F.S.

[21] Section 406.11, F.S.

Section 2:

Required Course: Prescribing of Controlled Substances

Requires each person licensed as a medical, osteopathic, podiatric, or naturopathic physician, physician assistant, or dentist to complete a one-hour education course, approved by the appropriate professional licensing board, on the prescribing and pharmacology of controlled substances, as part of the licensees' "initial license renewal" after January 1, 2003. *The committee substitute is unclear as to whether a licensed physician must complete the course each time his or her license is renewed, or whether the course is completed only when the license is renewed for the first time.* This act sets forth various requirements for the course. Exceptions for completing the course are provided for licensees who hold two or more licenses. Applicants who fail to complete the requirement are subject to disciplinary action. The appropriate licensing board may adopt rules needed to administer this section.

Section 3:

Enforcement

Requires the Department of Health (DOH) or its agents, within 10 working days of its receipt of sufficient evidence from any agency authorized to enforce the Florida Comprehensive Drug Abuse and Prevention Act, regarding a violation by a licensed health care practitioner who is authorized to prescribe, dispense, or administer controlled substances, to review the case. If the practitioner is a danger to the public health, safety, or welfare, the Secretary of the DOH may suspend or restrict that practitioner's license. Such violations include:

- Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug[22], including any controlled substance, other than in the course of the physician's or dentist's professional practice;
- Prescribing, dispensing, administering, or mixing a controlled substance to himself or herself unless such drug is prescribed, dispensed, or administered by another qualified practitioner;
- Engaging or attempting to engage in the possession, sale, or distribution of controlled substances for any other purpose than legitimate purposes authorized in statute;
- Pre-signing blank prescription forms;
- Violating Chapter 499, F.S., relating to drugs, devices and household products, the Federal Food, Drug, and Cosmetic Act, the Comprehensive Drug Abuse Prevention and Control Act (federal law relating to controlled substances), or Chapter 893, F.S., relating to controlled substances; and
- Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy.

The DOH must recommend the suspension or restriction of the practitioner's license to the Secretary of the DOH within 10 working days after receiving such evidence.

[22] A legend drug means any drug, including finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act of ss. 456.003(8), 499.007(12), or 499.0122(1)(b) or (c), F.S.

Section 4:

Exchange of Information Between Agencies

Requires law enforcement agencies to notify and provide investigative information to the DOH regarding the arrest of any practitioner to facilitate the efficiency of the DOH's investigation of violations involving the diversion of controlled substances by such practitioners. State attorneys and the Statewide Prosecutor are also required to provide the DOH with a copy of any indictment or information formally charging a health care practitioner. This section additionally requires the Medical Examiner's Commission within the Florida Department of Law Enforcement (FDLE) to report quarterly to the DOH any deaths involving lethal levels of controlled substances, based on autopsy reports completed within Florida, and any other relevant public information, to determine whether any of the deaths have involved conduct by a licensed health care practitioner. The DOH or the board having regulatory authority over the practitioner must then conduct an investigation. If the person arrested or charged is also licensed by the state in another field or profession, the DOH must forward the information to the appropriate licensing entity.

Report on the Possibility of Electronic Exchange

Requires the DOH and the FDLE to study the feasibility of expanding the electronic exchange of information to facilitate the transfer to the DOH of criminal history information involving licensed health care practitioners who are authorized to prescribe, administer, or dispense controlled substances. The study must address whether the collection and retention of fingerprint information of healthcare practitioners is advisable as a means of better regulating such practitioners. The FDLE must also investigate the feasibility of the electronic transmission of information from medical examiners within Florida to the DOH regarding autopsies and other public records that attribute death to controlled substance abuse. The FDLE, in consultation with the DOH, must submit a report of its findings to the Legislature by November 1, 2002.

Section 5:

Electronic Monitoring System

Requires, by July 1, 2003, the Department of Legal Affairs to design and establish an electronic monitoring system for prescriptions.[23] This system must monitor the prescribing of Schedule II controlled substances; other drugs designated by the Attorney General under this section[24]; and codeine, hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III, by health care practitioners within Florida. The system must also monitor the dispensing of such controlled substances to an address within Florida by a pharmacy permitted or registered by the Board of Pharmacy. Specified data regarding controlled substances or drugs subject to the requirements of the monitoring system must be timely reported, within 30 days after the date the controlled substance is dispensed, to the Department of Legal Affairs each time that such controlled substance or drug is dispensed. The specified data must include:

- The patient's name and address;

[23] The design of the electronic monitoring system must be consistent with the National Council of Prescription Drug Programs standards or the American Society for Automation in Pharmacy standards.

[24] The Attorney General may, by rule, designate any other drug for inclusion in the electronic monitoring system after making a determination that the drug is a drug of abuse. The Attorney General must consider the recommendations of the prescription-monitoring advisory council before designating a drug of abuse for inclusion in the monitoring system.

- The national drug code number of the substance dispensed;
- The date the substance is dispensed;
- Quantity dispensed;
- The dispenser's National Association of Board's of Pharmacy (NABP) number; and
- The prescriber's United States Drug Enforcement Administration Number.

A dispenser must transmit the required information in an electronic format approved by rule of the Board of Pharmacy after consultation with the advisory council for the prescription monitoring system and the Department of Legal Affairs, unless a waiver is granted. *The committee substitute does not specify how the information will be transmitted by those dispensers needing a waiver from the electronic requirement.* An exception to the reporting requirements under the electronic monitoring system is created for controlled substances or drugs that: (1) are ordered from an institutional pharmacy licensed under s. 465.019(2), F.S., in accordance with institutional policy for such controlled substances or drugs; or (2) are 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 Florida.

Prescription Monitoring Program Advisory Council

The Department of Legal Affairs must establish a 13-member prescription monitoring program advisory council to assist it in implementing the electronic monitoring system. [25] The advisory council members must meet no more often than quarterly at the call of the chairperson, and serve without compensation but may receive reimbursement for their per diem and travel expenses incurred in the performance of their official duties. The Department of Legal Affairs must provide staff and other administrative assistance that is reasonably necessary to assist the advisory council in carrying out its responsibilities, and the Department of Legal Affairs must adopt rules to administer both the electronic monitoring system for prescriptions and the advisory council.

Section 6:

Required Course: Prescribing of Controlled Substances

Requires resident physicians, interns, and fellows to complete a one-hour educational course in the prescribing of controlled substances upon initial registration. Elements of the course are specified and include education in certain areas.[26] A registration applicant who has not taken a course at the time of registration is allowed six months within which to complete the requirement.

---

[25] The Governor must appoint members to serve on the advisory council. The members shall include: the Attorney General or his or her designee to serve as the chairperson; the Secretary of Health or his or her designee; the executive director of the FDLE or his or her designee; the executive director of the Office of Drug Control or his or her designee; a Florida-licensed medical physician who is recommended by the Florida Medical Association; a Florida-licensed osteopathic physician who is recommended by the Florida Osteopathic Medical Association; a Florida-licensed podiatric physician who is recommended by the Florida Podiatric Medical Association; three Florida-licensed pharmacists recommended by specified organizations; a Florida-licensed dentist recommended by the Florida Dental Association; a Florida-licensed veterinarian recommended by the Florida Veterinary Medical Association; and a prosecutor who has expertise in criminal prosecution of drug-diversion cases.

[26] This areas include: the state and federal laws and rules governing the prescribing and dispensing of controlled substances; appropriate evaluation of patients for any risk of drug diversion and abuse of controlled substances; the use of informed consent and other protocols; the need to keep accurate and complete medical records to justify treatment with controlled substances; addiction and substance abuse issues with respect to patients; the appropriate use of recognized pain management guidelines; and the need for consultation and referral of patients who are at risk for misuse of medication or diversion of controlled substances, when appropriate.

Section 7:

Provides that a podiatric physician is subject to discipline for pre-signing blank prescription forms, a violation which is currently not provided for in statute.

Section 8:

Prescribing of Controlled Substances by Pharmacists

Prohibits a pharmacist from dispensing a Schedule II controlled substance; other drug of abuse designated by the Attorney General by rule; or codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III to any individual not personally known to the pharmacist. Before dispensing any drug of abuse, the pharmacist must without first obtain suitable identification and document the identity of the person receiving the controlled substance by signature on a log book kept by the pharmacist. Procedures are specified for the pharmacist to verify the validity of the prescription and identity of the patient, if the individual presenting the prescription does not have suitable identification[27] or it is *impracticable* to obtain such identification.[28] Pharmacists may dispense, in their professional judgment, controlled substances in the absence of proper identification.

Any pharmacist that dispenses a Schedule II controlled substance or drug subject to the requirements of this section when dispensed by mail is exempt from this requirement to obtain suitable identification.

All prescriptions issued for substances under this section must include both a written and numerical notation of quantity on the face of the prescription. *A pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance upon an oral prescription.* A pharmacist may not knowingly fill a prescription that has been mutilated or forged for any of these substances.

Section 9:

Counterfeit-Proof Prescription Blank

Requires the Department of Legal Affairs to develop and issue a counterfeit-proof prescription blank which must be used by practitioners for the filling, compounding, or dispensing of any prescription for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or other drug designated as a drug of abuse by the Attorney General, by rule, under the prescription monitoring system. The Department of Legal Affairs must issue these prescription blanks to prescribing practitioners and cover all costs

---

[27] Suitable identification is defined as identification that contains the photograph, the printed name, and the signature of the individual obtaining the controlled substance or drug of abuse.

[28] The pharmacist must verify the validity of a prescription and identity of the patient with the prescribing practitioner, or his or her agent before dispensing the drug as provided by rule of the Board of Pharmacy. *The Board of Pharmacy must adopt, by rule, procedures for a pharmacist to verify the validity of a prescription for a Schedule II controlled substance; other drug designated by the Attorney General under this section; or codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III for circumstances when it is otherwise impracticable for the pharmacist or dispensing practitioner to obtain suitable identification from the patient or the patient's agent.*

for both preparing and issuing such blanks and the implementation of the electronic prescription monitoring system.[29] *The prescription blanks may not be transferred.*

The prescription must conform to specified requirements. The signature on each prescription form must be wholly written in ink or indelible pencil in the handwriting of the prescribing practitioner. Each prescription must be prepared, dated, and signed by the prescribing practitioner on the day when issued, and must contain certain information already specified in Section 5 of this committee substitute.[30] The original copy of the prescription must be delivered to the pharmacist filling the prescription, must be retained on file by the proprietor of the pharmacy in which it was filled for a period of two years, and must be properly endorsed by the pharmacist.[31] A copy must be available for inspection-by the Department of Legal Affairs. *This committee substitute does not specify that the Department of Legal Affairs may obtain a copy of the prescription form; it only provides that a copy must be made available for inspection.*

Prescriptions may be dispensed by a pharmacist upon an oral prescription, if the pharmacist reduces it to writing in ink or indelible pencil in the handwriting of the pharmacist, upon an official form issued by the Department of Legal Affairs for that purpose. Such oral prescriptions must contain the date of the oral authorization and specified information.

Section 10:

Provides an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

The information on the fiscal impact on state government was provided by the Senate Analysis on CS/CS/SB 636 by the Committees on Judiciary and Health Aging and Long-Term Care. CS/CS/SB 636 contains substantially similar provisions as this committee substitute.

1. Revenues:

None.

2. Expenditures:

The Department of Legal Affairs

Electronic Prescription Monitoring System and Prescription Program: The Department of Legal Affairs indicates that its fiscal impact for this program is based upon the number of reporting entities to the system, and not the volume of information reported within the system. The

[29] The prescription blanks must be printed on distinctive paper and bear the preprinted full name, address, and category of professional licensure of the practitioner to whom they are issued and that practitioner's federal registry number for controlled substances.
[30] The prescriptions must be typewritten or handwritten by the physician or an employee of the physician and contain the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is prescribed; the name, quantity, and strength of the controlled substance; directions for use; and the address, category of professional licensure, and federal controlled substance registration number of the prescribing practitioner. The pharmacist must write or type such address on the prescription or maintain the information in a readily retrievable form in the pharmacy if the address is not provided by the practitioner.
[31] The pharmacist must include the name and address of the pharmacy, the pharmacy's state permit number, the date the prescription was filled, and the signature of the pharmacist.

Department of Legal Affairs estimates that it will incur the following costs to design and establish an electronic prescription monitoring system and counterfeit-proof prescription program in Florida for controlled substances in Schedules II and III, and any other drug of abuse as designated by the Attorney General, by rule:

Fiscal Year 2002-2003 - $1,591,588

Fiscal Year 2003-2004 - $1,526,772

Fiscal Year 2004-2005 - $1,526,772

The Department of Legal Affairs' estimate is based on an assumption that over 1 million prescriptions will be written for controlled substances in Florida annually which must be stored and gathered. The projected fiscal impact of $1,526,772 on an annualized basis included an estimated $600,000 to contract for the collection of the electronic prescription data. According to the Department of Legal Affairs, Florida has 19,594 registered pharmacists, with approximately 13,429 showing a Florida address; Florida has 6,283 pharmacies of which about 3,500 are community pharmacies.

The Department of Legal Affairs will incur costs to staff the *13-member prescription monitoring advisory council* which may be handled within existing resources of the Administrative Law Section of the department.

The Agency for Health Care Administration (AHCA)

AHCA reports that it will incur an additional workload to annually review an estimated 2,340 additional death reports from the Medical Examiner's Commission.

Fiscal Year 2002-2003 - $1,338,595 (includes a non-recurring impact of $87,890)

Fiscal Year 2003-2004 - $1,250,705

This includes the costs for 22 additional positions (investigators, clerical staff, and attorneys). Such costs will affect the current funding of the AHCA's contractual services covered by an interagency agreement between the AHCA and the Department of Health.

The Department of Health (DOH)

Prescribing and Pharmacology Continuing Education:

Fiscal Year 2002-2003 - $28,154

Fiscal Year 2003-2004 - $22,393

The DOH anticipates that it will need an additional 0.5 full time equivalent position to monitor compliance with the continuing education requirements.

The DOH indicated that there will be an indeterminate cost associated with the use of s*pecial controlled substance blanks* for health department pharmacies when taking an oral prescription order and an indeterminate increase in costs for special controlled substance or drug prescription blanks for health department dentists and physicians, although the Department of Health reports its pharmacies dispense very few controlled substances listed in Schedules II or lll.

Additional Entities Affected

Sharing of Criminal History Information on Practitioners authorized to Prescribe, Administer or Dispense Controlled Substances: Law enforcement entities and prosecuting entities are required to provide arrest and charging information to the Department of Health. The exact impact is indeterminate but is expected to be minimal.

Medical Examiner's Commission reports of Deaths attributed to Lethal Amounts of Controlled Substances based on Autopsy Reports to the Department of Heath for Review of Possible Conduct involving a Disciplinary Violation by a Licensed Health Care Practitioner: The FDLE notes that expenses of the Medical Examiners in each respective district should be minimal due to the bill's requirement to report suspected controlled substance-related deaths based on lethal amounts of controlled substances on a quarterly basis.

Total Fiscal Impact

Fiscal Year 2002-2003 -	$2,958,337 (plus any indeterminate costs mentioned above)
Fiscal Year 2003-2004 -	$2,799,870 (plus any indeterminate costs mentioned above)
Fiscal Year 2004-2005 -	$1,526,772 (plus any indeterminate costs mentioned above)

Total = $ 7,284,979

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

The Department of Law Enforcement believes that the fiscal impact on local governments is unknown, but could be substantial. "Expenses of the Medical Examiners in each of the respective districts could be significant due to requirement to report suspected controlled substance related deaths on a quarterly basis. It could also increase expenses depending on determination of what type of controlled substances are to be screened and how 'abuse' is to be determined, leading to greater expenses for payment of investigators. Mechanism/forms to be created by courts and law enforcement agencies to ensure court orders required are generated and provided to the Department of Health."[32]

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 this committee substitute. Consumers who currently may obtain such drugs

[32] Florida Department of Law Enforcement, Bill Information on HB 701, "Fiscal Impact on Local Governments as a whole," received by e-mail on January 28, 2002.

through an oral prescription may bear additional costs for medical visits to obtain prescriptions beyond a 30-day supply.[33]

D. FISCAL COMMENTS:

None.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This committee substitute does not require counties or municipalities to spend funds or to take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This committee substitute does not reduce the authority that counties or municipalities have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This committee substitute does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

Article III, Section 6 of the Florida Constitution provides that "[e]very law shall embrace but one subject and matter properly connected therewith, and the subject shall be briefly expressed in the title." Section 6 and Section 7 of the original proposed committee substitute contained provisions that did not fall under the subject matter provided for in the title of this legislation. Section 6 pertained to requirements for instruction for certain licensees on HIV and AIDS, and Section 7 pertained to general grounds for discipline and penalties assessed against practitioners. The title of this bill is: "An act relating to controlled substances." This is a possible violation of the "single-subject" clause of the Constitution. The Committee on State Administration adopted an amendment, however, that removed these sections from CS/HB 701.

B. RULE-MAKING AUTHORITY:

Several sections of this committee substitute provide for rule-making authority:

Section 1: Provides the Board of Medicine and the Board of Osteopathic Medicine with rule-making authority to establish guidelines for prescribing controlled substances to patients in emergency-department settings.

Section 2: Provides the appropriate professional licensing boards with rule-making authority to administer the requirement of the one-hour educational course on the prescribing and pharmacology of controlled substances.

[33] Senate Staff Analysis and Economic Impact Statement, CS/CS/SB 636, Committee on Judiciary and Health, Aging and Long-Term Care, February 5, 2002.

Section 5: Provides the Board of Pharmacy with rule-making authority to approve an electronic format through which a dispenser of controlled substances must transmit the required information. This section also provides the Department of Legal Affairs with rulemaking authority to administer the electronic monitoring system and to establish the 13-member prescription-monitoring program advisory council.

Section 10: Provides the Board of Pharmacy with rule-making authority to adopt procedures for a pharmacist to verify the validity of a prescription for a Schedule II controlled substance; other drug designated by the Attorney General; or codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, for circumstances when it is impracticable for the pharmacist to obtain suitable identification from the patient or the patient's agent.

C. OTHER COMMENTS:

This committee substitute contains substantially similar provisions as the Senate companion, CS/CS/SB 636.

An exemption to the Public Records Law for the identity of patients in the information and reports filed with the Department of Legal Affairs is being addressed in separate legislation (CS/SB 638).

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On February 12, 2002, the Committee on State Administration adopted two amendments to PCS/HB 701. Due to single subject concerns, the first amendment removed two sections from the proposed committee substitute relating to AIDS/HIV course requirements and the imposition of fines on health care practitioners. The second amendment permits pharmacists to dispense, in their professional judgment, controlled substances in the absence of proper identification. This provision was not included in the original proposed committee substitute. This proposed committee substitute, as amended, was reported favorably as a committee substitute.

VII. SIGNATURES:

COMMITTEE ON STATE ADMINISTRATION:

Prepared by:	Staff Director:
Lauren Cyran, M.S.	J. Marleen Ahearn, Ph.D., J.D.