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HOUSE OF REPRESENTATIVES
AS REVISED BY THE COMMITTEE ON
HEALTH & HUMAN SERVICES APPROPRIATIONS
ANALYSIS

BILL #: HB 15-E

RELATING TO: Controlled Substances (Health Care Practitioner Regulation)

SPONSOR(S): Representatives Crow, Fasano and others

TIED BILL(S): HB35-B

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

(1) COUNCIL FOR HEALTHY COMMUNITIES YEAS 12 NAYS 2
(2) HEALTH & HUMAN SERVICES APPROPRIATIONS
(3)
(4)
(5)

I. SUMMARY:

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.

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 nationwide. As a result of growing abuse of controlled substances, approximately 15 states have enacted some form of electronic prescription monitoring. This bill requires the Department of Health to establish such an electronic monitoring system for certain controlled substances.

Also, this bill requires the Department of Health to develop a counterfeit-proof prescription blank which must contain certain information to be used voluntarily; 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. The bill 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.

This bill may have a fiscal impact on local governments and has a fiscal impact on state government of approximately $1,399,735 for fiscal year 2002-03 and $1,427,452 for fiscal year 2003-04. Please see the "Fiscal Analysis and Economic Impact Statement" for further discussion.

On May 1, 2002, the Council for Healthy Communities adopted 8 amendments which are traveling with the bill. Please see the Amendments section for explanation.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1. Less Government Yes [] No [x] N/A []

This bill creates a new government program, increases government regulation, requires additional rules, and creates a new advisory council. This bill requires increased record keeping for pharmacists, the Florida Department of Health, and law enforcement agencies.

2. Lower Taxes Yes [] No [x] N/A []

The three-year fiscal impact is estimated at approximately $7 million to develop and operate the electronic prescription monitoring system. Health care practitioners will have to complete a mandated continuing education program at their own cost.

3. Individual Freedom Yes [] No [x] N/A []

This bill limits individual freedom by requiring the transmittal of certain personal information of individuals receiving certain controlled substances. Personal medical information about patients will be collected and reviewed by the government. The bill enables government review of patient choices about who, what, when, where, why, and how a prescription is filled and could invite scrutiny of the decision-making by health care practitioners prescribing controlled substances.

4. Personal Responsibility Yes [x] No [x] N/A []

The criminal justice system will be more involved in prosecuting persons with an addiction to pain-relieving medications who otherwise have no criminal history. However, this bill may encourage responsible behavior by prescribers and patients.

5. Family Empowerment Yes [] No [x] N/A []

The bill may result in more frequent initiation of substance abuse treatment as a result of government action rather than family intervention.

B. PRESENT SITUATION:

Regulation of Legend Drugs in Florida, Including Controlled Substances

Florida's Bureau of Pharmacy Services within the Department of Health administers and enforces the provisions of ss. 499.001-499.081, F.S., which is known as the Florida Drug and Cosmetic Act pursuant to s. 499.001, F.S. The duties set forth in statute require the Department of Health to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

The Florida Drug and Cosmetic Act applies to all legend drugs, otherwise known as prescription drugs or medicinal drugs pursuant to s. 499.003(19), F.S. Controlled Substances are legend drugs and are subject to the provisions of the Act.

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.

The 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. 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 the Department of Health, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled. 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. 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.

Section 893.11, F.S., provides that 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 said 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. Such 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.

Section 893.13(7)(a)1.-8., F.S., provides that each of the following acts constitutes a misdemeanor of the first degree, punishable by jail time of up to 1 year and a fine of up to $1,000 and any second or subsequent violation is currently punishable as a third degree felony:

- distributing or dispensing a controlled substance in violation of ch. 893, F.S.; refusing or failing to make, keep, or furnish any record, notification, order form, statement, invoice, or information required by ch. 893, F.S.;
- refusing entry into any premises for any inspection or refusing to allow an inspection authorized by ch. 893, F.S.;
- distributing a controlled substance named or described in Schedule I or Schedule II except pursuant to an order form; keeping or maintaining any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, other structure or place which is resorted to by persons using controlled substances in violation of ch. 893, F.S., for the purpose of using these substances, or which is used for keeping or selling them in violation of ch. 893, F.S.;
- using to his or her personal advantage, or to reveal, any information obtained in a prosecution or administrative hearing for a violation of ch. 893, F.S.;
- withholding information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person has received a controlled substance or a prescription for a controlled substance from another practitioner within the last 30 days; and
- possessing a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is a pharmacist, or is a supplier of prescription forms who is authorized by that practitioner to possess those forms.

Section 893.13(7)(a) 9.-11., F.S., specifies that the following offenses are punishable as a third degree felony: 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 required to be kept or filed under ch. 893, F.S., or any record required to be kept by ch. 893, F.S.

Section 893.13(8), F.S., provides that the criminal provisions in s. 893.13(1)-(7), F.S., are not applicable to the delivery to, or actual constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties which include: pharmacists; practitioners; persons who

procure controlled substances in good faith and in the course of professional practice only , by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale; hospitals that procure controlled substances for lawful administration by practitioners, but only for use by or in the particular hospital; officers or employees of state, federal, or local governments acting in their official capacity only, or informers acting under their jurisdiction; common carriers; manufacturers, wholesalers, and distributors; or law enforcement officers for bona fide law enforcement purposes in the course of an active criminal investigation.

In addition to the Florida Comprehensive Drug Abuse Prevention and Control Act, other Florida laws govern the practice of health care professionals. The practice acts that govern the health care professionals who may prescribe, dispense, or administer controlled substances specify regulations that set practice standards these professionals must meet. Health care professionals are subject to disciplinary action by their regulatory boards for violating their practice standards. For instance, the Medical Practice Act (chapter 458, F.S.) specifies several grounds for which a physician may be subject to discipline by the board for acts relating to the prescribing of drugs. Such violations include: prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician'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; and presigning blank prescription forms. Other health care practitioner practice acts for those practitioners who may prescribe controlled substances contain similar provisions.

Pharmacists are subject to discipline for violations relating to dispensing which include violating: ch. 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 ch. 893, F.S., relating to controlled substances; and for compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. Nurses are prohibited from engaging or attempting to engage in the possession, sale, or distribution of controlled substances for any other than legitimate purposes authorized by part I, ch. 464, F.S.

Physicians, dentists, and pharmacists are regulated by their peers appointed by the Governor to a regulatory board. The Board of Medicine regulates allopathic physicians, the Board of Osteopathic Medicine regulates osteopathic physicians, the Board of Podiatric Medicine regulates podiatric physicians, the Board of Dentistry regulates dentists, and the Board of Pharmacy regulates pharmacists. These regulatory boards are usually considered to be the experts in the standard of care of their profession in the state of Florida. The regulatory boards are under the jurisdiction of the Department of Health.

OxyContin®

The diversion of controlled substances from legitimate sources into illicit street drug traffic is a major problem that confronts the nation. Recent reports on the abuse of OxyContin® have initiated a number of responses from the states. Diversion of OxyContin appears to be concentrated in rural areas and eastern states but is quickly spreading according to the United States Drug Enforcement Administration. According to the Office of Diversion Control within the United States Drug Enforcement Administration in a recent report, concern has been growing among federal, state, and local officials about the dramatic increase in the illicit availability and abuse of the prescription drug OxyContin®. OxyContin® is a controlled release form of Schedule II oxycodone which is legitimately used as a medication to treat moderate to severe pain. Abusers can easily compromise the controlled release formulation for a powerful morphine-like high which has resulted in:

fraudulent prescriptions; “doctor shopping;” over-prescribing; pharmacy theft; organized rings of individuals diverting and selling the drug; and foreign smuggling into the United States. Please see the Comments Section of this analysis.

Prescription Monitoring Systems

In an effort to control the diversion of controlled substances, over 15 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. Prescription monitoring systems may combine the use of serialized prescription forms by prescribing practitioners that is tracked by state officials and an electronic data system that tracks the prescriptions. California and Texas are the only states to require the use of a serialized triplicate form. New York recently moved from the use of a triplicate prescription form to a serialized single copy, effective June 1, 2001. Each program achieves different objectives and offers advantages for drug diversion control efforts that cannot be achieved through either program acting alone. A multiple-copy prescription or single-copy prescription serialized form program provides the opportunity, through analysis of the data, to identify the prescribers who may be involved in inappropriate prescribing and patients who may be “doctor shopping” for prescription drugs. A multiple-copy prescription or single-copy serialized form program discourages “doctor shopping” by persons who visit several unsuspecting physicians during a short period of time and obtain prescriptions for controlled substances by feigning illness and other illegal behavior.

Disciplinary Procedures

Section 456.073, F.S., sets forth procedures the Department of Health and the regulatory boards must follow in order to conduct disciplinary proceedings against practitioners under its jurisdiction. The department, for the boards under its jurisdiction, must investigate all written complaints filed with it that are legally sufficient. The department may investigate anonymous, written complaints or complaints filed by confidential informants, and if the department has reasonable cause to believe that a licensee has violated any applicable regulations, the department may initiate an investigation on its own.

Emergency Suspension of License

Section 120.60(6), F.S., authorizes an agency to take emergency action against a licensee if the agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license. The agency may take such action by any procedure that is fair under the circumstances if: the procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the United States Constitution; the agency takes only that action necessary to protect the public interest under the emergency procedure; and the agency states in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency’s findings of immediate danger, necessity, and procedural fairness are judicially reviewable.

Summary suspension, restriction, or limitation may be ordered, but a suspension or revocation proceeding under ss. 120.569 and 120.57, F.S., must also be promptly instituted and acted upon.

Section 456.073, F.S., empowers the Secretary of the Department of Health to summarily suspend a health care practitioner's license to practice his or her profession, in accordance with s. 120.60(6), F.S.

AIDS/HIV Continuing Education

Section 456.033, F.S., provides continuing education requirements on human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) for health care professionals licensed or certified under chapter 457, F.S. (acupuncture), chapter 458, F.S. (medical practice), chapter 459, F.S. (osteopathic medicine), chapter 464, F.S. (nursing), chapter 465, F.S., (pharmacy), chapter 466, F.S. (dentistry and dental hygiene), parts II, III, V, and X of chapter 468, F.S. (nursing home administration, occupational therapy, respiratory therapy, and dietetics and nutrition practice), and chapter 486, F.S. (physical therapy). The appropriate board must require professionals under its jurisdiction to complete a 1-hour continuing education course approved by the board on AIDS/HIV as a part of the professional's relicensure or recertification every 2 years. The course must consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of AIDS/ HIV. Such course must include information on current Florida law on AIDS and its impact on testing, confidentiality of testing results, treatment of patients, and any protocols and procedures applicable to HIV counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification.

Each licensee or certificate holder must submit confirmation of having completed such course, on a form provided by the board when submitting fees for each renewal. A professional is subject to discipline for failure to comply with the requirements to complete the required AIDS/HIV course. As a condition of granting a license, applicants for initial licensure must complete a course on AIDS/HIV or show good cause for not completing the requirement and then be allowed 6 months to do so. The board may approve additional equivalent courses that may be used to satisfy the AIDS/HIV course requirements. Any person holding two or more licenses must be permitted to show proof of having taken one board-approved course on AIDS/HIV.

The AIDS/HIV continuing education requirement in s. 456.033, F.S., was amended to provide a health care professional the option of completing an end-of-life care and palliative health care course in lieu of an AIDS/HIV course for licensure and licensure renewal, if the health care professional has completed an AIDS/HIV course in the immediately preceding 2 years.

The AIDS/HIV continuing education requirement in s. 456.033, F.S., was amended last year to provide a licensed dentist or dental hygienist the option of completing a course approved by the Board of Dentistry in lieu of an AIDS/HIV course for licensure renewal, if the licensed dentist or dental hygienist has completed an AIDS/HIV course in the immediately preceding 2 years.

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.

C. EFFECT OF PROPOSED CHANGES:

Please see Section-by-Section Analysis.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates an undesignated section of law to require 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 and require them to recognize and prevent abuse of pain medications prescribed in emergency department settings. 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.

Section 2. Creates an undesignated section of law to require each person licensed as a medical, osteopathic, podiatric, or naturopathic physician, physician assistant, or dentist to complete a 1-hour education course, approved by the board, on appropriate prescribing and pharmacology of controlled substances, as part of the licensees' initial license renewal after January 1, 2003, in lieu of current HIV/AIDS continuing education requirements. Elements of the course are specified and include education in: 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.

Exceptions are provided for licensees who hold two or more licenses. Applicants who fail to complete the requirement are subject to disciplinary action and in addition to any discipline must complete the course. An applicant for initial licensure must complete an educational course in the appropriate prescribing and pharmacology of controlled substances and shall be allowed 6 months within which to complete this requirement. The board may adopt rules needed to administer this section.

Section 3. Creates an undesignated section of law to require the Department of Health or its agents, within 10 working days of its receipt of sufficient evidence from any agency authorized to enforce ch. 893, F.S., relating to controlled substances, regarding a violation by a licensed health care practitioner who is authorized to prescribe, dispense, or administer controlled substances, to review the case and if the practitioner is a danger to the public health, safety, or welfare as set forth in s. 120.60(6), F.S., to recommend to the Secretary of the Department of Health, the suspension or restriction of the license of a health care practitioner who is authorized to prescribe, dispense, or administer controlled substances for specified disciplinary violations. Such violations include:

- prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, 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 than legitimate purposes authorized by part I, ch. 464, F.S.;
- presigning blank prescription forms; violating ch. 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 ch. 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 Department of Health must recommend the suspension or restriction of the practitioner's license to the Secretary of the Department of Health within 10 working days after receiving such evidence. The Secretary of Health may suspend or restrict the license of the practitioner in accordance with section 120.60(6), F.S.

Section 4. Creates an undesignated section of law to require law enforcement agencies to notify and provide investigative information to the Department of Health regarding the arrest of any practitioner to facilitate the efficiency of the Department of Health's investigation of applicable violations involving the diversion of controlled substances by such practitioners. State attorneys and the Statewide Prosecutor are also required to provide the Department of Health with a copy of any indictment or information formally charging a health care practitioner

The Medical Examiner's Commission within FDLE must report quarterly to the Department of Health any deaths involving lethal levels of controlled substances, based on autopsy reports completed within Florida. Under current law, the Department of Health or the board having regulatory authority over the practitioner may initiate an investigation when it has reasonable grounds to believe that the practitioner has violated any applicable law related to the practitioner's practice (see s. 456.073(1), F.S.). If the person arrested or charged is also licensed by the state in another field or profession, the Department of Health must forward the information to the appropriate licensing entity.

The Department of Health and FDLE must study the feasibility of expanding the electronic exchange of information to facilitate the transfer to the Department of Health 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 doctors and nurses is advisable as a means of better regulating such practitioners. The Department of Law Enforcement must investigate the feasibility of the electronic transmission of information from medical examiners within Florida to the Department of Health regarding autopsies and other public records that attribute death to controlled substance abuse. The Department of Law Enforcement in consultation with the Department of Health must submit a report of its findings to the Legislature by November 1, 2002.

Section 5. Creates an undesignated section of law to require, by July 1, 2003, the Department of Health, Bureau of Pharmacy Services, to design and establish an electronic system to monitor the prescribing of Schedule II controlled substances; other drugs designated by the Department of Health under this section; and codeine, hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III, by health care practitioners within Florida or the dispensing of such controlled substances to an address within Florida by a pharmacy permitted or registered by the Board of Pharmacy. Based upon recommendations of the Attorney General, the Department of Health, may, by rule, designate any other drug for inclusion in such system after a determination is made that the drug is a drug of abuse. The design of the electronic system to monitor the prescribing of these controlled substances and drugs must be consistent with the National Council of Prescription Drug Programs standards or the American Society for

Automation in Pharmacy standards. The Department of Health 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 department must consider the recommendations of the prescription-monitoring advisory council before designating a drug of abuse for inclusion in the monitoring system and only after he or she determines that the current level of regulation over the prescribing and dispensing of such drug is inadequate and that the drug has a high potential for abuse or is being excessively misused, abused, or diverted into illicit drug trafficking.

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 Health each time that such controlled substance or drug (Schedule II controlled substance; other drug designated by the department under this section; or codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III) is dispensed. The specified data must include:

- the patient's name and address;
- 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 unless a waiver is granted. 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. 465.19(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.

The Department of Health must establish a 14-member prescription monitoring program advisory council to assist it in implementing the system. The Governor must appoint members to serve on the advisory council. The members shall include:

- the Attorney General or his or her designee who shall serve as the chairperson;
- the Secretary of Health or his or her designee;
- the executive director of the Department of Law Enforcement or his or her designee;
- the director of the Office of Drug Control within the Executive Office of the Governor or his or her designee;
- a Florida-licensed medical physician who is recommended by the Florida Medical Association;
- a Florida-licensed allopathic or osteopathic physician who is recommended by the Florida Academy of Pain Medicine;
- 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.

The advisory council members shall 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 as provided for in s. 112.061, F.S. The Department of Health must provide staff and other administrative assistance that is reasonably necessary to assist the advisory council in carrying out its responsibilities.

The Department of Health must adopt rules to administer the electronic monitoring system for prescriptions and the advisory council.

Section 6. Amends s. 456.033, F.S., relating to HIV/AIDS continuing education requirements for specified licensed health care professionals, to delete the requirement for medical physicians, osteopathic physicians, podiatric physicians, and dentists to complete an AIDS/HIV course as a condition of licensure and license renewal.

Section 7. Repeals ss. 458.319(4) and 459.008(5), F.S., relating to alternative continuing education courses for allopathic and osteopathic physicians.

Section 8. Amends s. 456.072, F.S., relating to grounds for which a licensed health care practitioner may be subject to discipline, to increase the maximum administrative fine that a board or the Department of Health may impose on a disciplined licensee from $10,000 to $25,000 for each count or separate offense.

Sections 9-37. Reenacts provisions which cross-reference s. 456.072, F.S.

Section 38. Amends s. 458.345, F.S., relating to the registration of resident physicians, interns and fellows, to require upon initial registration, a 1-hour educational course in the prescribing of controlled substances. Elements of the course are specified in the bill.

A registration applicant who has not taken a course at the time of registration shall be allowed 6 months within which to complete the requirement.

Section 39. Amends s. 461.013, F.S., relating to grounds for which a podiatric physician may be disciplined for unprofessional conduct, to make a podiatric physician subject to discipline for presigning blank prescription forms.

Section 40. Amends s. 893.04, F.S., relating to requirements for the dispensing of controlled substances by a pharmacist, to prohibit a pharmacist from dispensing a Schedule II controlled substance; a drug of abuse designated by the Department of Health, Bureau of Pharmacy Services, 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, without first obtaining suitable identification and documenting the identity of the person obtaining 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 or it is impracticable to obtain such identification. In cases where the individual does not have suitable identification or it is impracticable to obtain that information, a pharmacist may dispense the substance if, in his or her professional judgment, it is necessary for treatment. The Board of Pharmacy may adopt, by rule, procedures for a pharmacist to verify the validity of a prescription for a Schedule II controlled

substance; a drug designated by the Department of Health, Bureau of Pharmacy Services 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. 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.

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

All prescriptions issued for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or a drug designated as a drug of abuse by the Department of Health, Bureau of Pharmacy Services, by rule, under the prescription monitoring system, 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 a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or a drug designated as a drug of abuse by the Department of Health, Bureau of Pharmacy Services, by rule, under the prescription monitoring system.

Section 41. Creates s. 893.065, F.S., relating to a voluntary program for counterfeit-resistant prescription documents; provides rulemaking authority to the Department of Health, Bureau of Pharmacy Services.

Section 42. Provides that any law amended during both special session and regular session shall be construed to have been enacted during the same session and full effect shall be given to each if possible.

Section 43. Provides an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

N/A

2. Expenditures:

The DOH provided the following information regarding the fiscal impact on their agency.

	FY 02-03	FY 03-04
Electronic Prescription Monitoring System	$ 600,000	$ 600,000
Management of Monitoring System (5 FTE)	$ 290,384	$ 310,311
Monitoring Prescription Practices (1 FTE)	$ 385,146	$ 381,582
Advisory Council (1 FTE)	$ 98,258	$ 109,612
Prescribing and Pharmacology Continuing Education (.5 FTE)	$ 25,947	$ 25,947
Total Cost	$1,399,735	$1,427,452

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

Please see Fiscal Comments. 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."

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Practitioners will incur the cost of completing the required continuing education courses. Pharmacies, dispensing practitioners, and prescribers may incur costs relating to reporting of the required data.

Schedule III controlled substance prescriptions intended to cover more than a 30-day supply must be in writing. 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.

D. FISCAL COMMENTS:

In addition to the figures reported by the Department of Health, the follow items may have a fiscal impact which is either indeterminate at this time or minimal.

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.

Sharing of **Arrest and Formal Charging Information**: The Agency for Health Care Administration reports that there could be an increase in investigative workload from the requirement that law enforcement agencies and prosecutors provide the Department of Health with arrest and charging information. The fiscal impact of any workload increase is indeterminate.

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.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill 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 bill 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 bill 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." This is a possible violation of the "single-subject" clause of the Constitution.

B. RULE-MAKING AUTHORITY:

The bill provides rulemaking authority to the following entities:

- the Board of Medicine and the Board of Osteopathic Medicine to establish guidelines for prescribing controlled substances to patients in emergency-department settings;
- the appropriate professional licensing boards to administer the requirement of the one-hour educational course on the prescribing and pharmacology of controlled substances;
- the Board of Pharmacy to approve an electronic format through which a dispenser of controlled substances must transmit the required information;
- the Department of Health to administer the electronic monitoring system;
- the Department of Health Legal Affairs to establish the 14-member prescription-monitoring program advisory council; and
- the Board of Pharmacy to adopt procedures for a pharmacist to verify the validity of a prescription for a Schedule II controlled substance; a drug designated by the Department of Health, Bureau of Pharmacy Services; 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:

The Bureau of Pharmacy Services within the Department of Health does not have any current jurisdiction to determine the appropriateness of prescriptions and the standard of care of physicians and dentists who prescribe controlled substances to patients. The Board of Medicine, the Board of Osteopathic Medicine, the Board of Dentistry, and the Board of Podiatry have the expertise and statutory authority to make these judgment calls. These regulatory boards are under the umbrella of the Department of Health, Division of Medical Quality Assurance. Therefore, it might be appropriate to provide this new statutory authority to the Department of Health and require the staff of the Bureau of Pharmacy Services and the Division of Medical Quality Assurance to work together to implement and enforce the provisions of this bill.

An exemption to the Public Records Law for the identity of patients in the information and reports filed with the Department of Health is being addressed in HB 35-E.

Information from the Florida Department of Law Enforcement:

On February 9, 2001, the Florida Department of Law Enforcement and the Florida Office of Drug Control issued a safety alert. The alert was also posted on the Department of Health's website. The purpose of the alert was to warn Floridians and the law enforcement community "about the abuse of two dangerous prescription drugs." The alert discussed the deaths which had been associated with the abuse of hydrocodone and oxycodone and the brand-name pharmaceutical drugs containing these substances. The alert provided preliminary statistics from the state medical examiners and urged law enforcement, hospitals, poison control centers, and emergency medical technicians to better educate themselves about the symptoms and effects associated with the drugs.

The Florida Department of Law Enforcement published an *Overview of Prescription Drug Abuse & The Oxycodone Problem in Florida.* This overview was also posted on the Department of Health's website. In the background section, the department provided information concerning a 2001 National Drug Threat Assessment by law enforcement agencies. Those law enforcement agencies reported that prescription fraud, the sale of prescriptions by medical professionals, theft, and "doctor shopping" were the most frequent means of obtaining pharmaceutical drugs for illegal use. Among the conclusions reached in that overview, the department recommended that "increases in prescription drug fraud and pharmacy robberies/burglaries should be closely monitored." The department also recommended that "Florida law enforcement should work closely with DEA (United States Drug Enforcement Administration) Diversion agents and the Office of the Attorney General, Medicaid Fraud Unit, in the investigation of OxyContin diversion." That report did not recommend that a prescription monitoring database be created.

Comments from the Department of Health: Section 5 of the bill, subsection (7), limits the ability of the Bureau of Pharmacy Services to maintain the data submitted beyond 12 months of the date of the prosecution unless the information is part of an ongoing investigation. This limitation impacts on the usefulness of the monitoring system to identify anything other than a short-term abuse trend and may negatively impact on legal proceeding.

Section 5 of the bill, subsection (9), limits the ability of the DOH to act on the data gathered without having consultations with experts and a joint finding of probable cause by the expert and a DOH attorney. This provision may hinder the efficient use of the data and increase costs.

The Department of Health recommends the following changes:

On page 12, lines 1, 2, and 4, substitute "24 months" for "12 months."

On page 15, between lines 13 and 14, insert: (12) Funds from the Medical Quality Assurance Trust Fund may not be used to establish, use, or maintain the electronic monitoring system.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On May 1, 2002, the Council for Healthy Communities adopted 8 amendments which are traveling with the bill.

Amendment 1: Clarifies that the name and place of business of the manufacturer or distributor of the finished dosage form of the drug shall be identified on the package label. If it is not listed, the drug will be considered misbranded. This amendment is intended to ensure that the Department of Health Bureau of Pharmacy Services consistently enforces the misbranding provisions of both state and federal law. This language conforms Florida law to federal law.

Amendment 2: Clarifies that no Medical Quality Assurance Trust Fund money will be used to create and implement the electronic prescription-monitoring system. Because the MQATF is facing a deficit during 2003, this amendment will make sure that this bill doesn't harm the financial stability of the MQATF by using practitioner licensing fees to fund this new program.

Amendment 3: Removes section 41 of the bill relating to counterfeit-resistant prescription documents. This provision was confusing and was not supported by the medical community affected by this bill. This section was not included in the Senate companion.

Amendment 4: Clarifies the purpose of the electronic prescription-monitoring system by removing superfluous wording.

Amendment 5: Provides protection to patients who have legitimate prescriptions from having such prescriptions unnecessarily reviewed by law enforcement by requiring law enforcement to articulate in writing reasonable cause to believe that a criminal violation has occurred prior to gaining access to the Department of Health's electronic prescription-monitoring system.

Amendment 6: Removes from the database the name and driver's license number or other identification of the person picking up the prescription. This section was also amended in the Senate companion.

Amendment 7 & 8: Adds one more member to the advisory council by adding a Florida licensed pharmacist recommended by the Florida Society of Health System Pharmacists.

VII. SIGNATURES:

COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by:	Council Director:
Wendy Smith Hansen/ Lucretia Shaw Collins	David De la Paz

AS REVISED BY THE COMMITTEE ON HEALTH & HUMAN SERVICES APPROPRIATIONS:

Prepared by:	Council Director:
Tom Weaver	Cynthia Kelly