SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/CS/SB 636

SPONSOR: Committees on Judiciary and Health, Aging and Long-Term Care and Senator Burt

SUBJECT: Controlled Substances

DATE: February 5, 2002 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	Forgas	Johnson	JU	Favorable/CS
3.			APJ	
4.			AP	
5.				
6.				

I. Summary:

The Committee Substitute for CS/SB 636 requires the Department of Legal Affairs, by July 1, 2003, to design and establish an electronic prescription monitoring system in Florida for Schedule II controlled substances; other drugs designated by the Attorney General by rule; and codeine, hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III. The Attorney General may, by rule, designate any other drug for inclusion in the system after making a determination that the drug is a drug of abuse and after the consideration of specified criteria. A 13-member advisory council is created to assist the Attorney General with the prescription monitoring system.

Certain data must be reported to the Department of Legal Affairs each time the designated drugs are dispensed. 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 committee substitute establishes a prescription program for controlled substances in Schedule II; codeine, hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III; and other drugs included in the electronic prescription monitoring system as designated by the Attorney General, by rule. The Department of Legal Affairs must develop a counterfeit-proof prescription blank that is to be issued to prescribing practitioners for prescribing the specified controlled substances or drugs. Requirements for the

prescription of such controlled substances are specified, including a written and numerical notation of quantity on the face of the prescription.

The committee substitute requires the Board of Medicine and the Board of Osteopathic Medicine to adopt rules to establish guidelines for physicians to prescribe controlled substances to patients in emergency department settings. Each person licensed as a medical physician, osteopathic physician, podiatric physician, naturopathic physician, physician assistant or dentist is required to complete a 1-hour educational course on appropriate prescribing and pharmacology of controlled substances as part of the initial renewal of the licensee's license after January 1, 2003, in lieu of current HIV/AIDS continuing education requirements. Resident physicians or fellows are required to complete a 1-hour educational course on the prescribing of controlled substances as a condition of initial registration to practice in Florida.

The Department of Health or its agents, within 10 working days of its receipt of sufficient evidence, must review and if appropriate, 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 violations relating to the prescribing, dispensing or administering of controlled substances. Law enforcement agencies and prosecutors must notify and provide investigative and charging information to the Florida Department of Health regarding the arrest and formal charging of any licensed health care practitioner who is authorized to prescribe, administer or dispense controlled substances. The Florida Department of Law Enforcement and the Department of Health must study the feasibility of expanding the electronic exchange of information to facilitate the transfer of criminal history information involving licensed health care practitioners. The Medical Examiner's Commission must report any deaths involving lethal levels 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 dispensing of Schedule III controlled substances is limited to a thirty day supply based upon an oral prescription. Any person who is dispensed controlled substances must show suitable identification to the dispensing pharmacist. If the person does not have suitable identification or if it is impracticable to obtain identification, the pharmacist must verify the validity of the prescription and identity of the patient with the prescribing practitioner as provided by rule of the Board of Pharmacy. Exceptions are specified to the requirements for dispensing pharmacists to obtain suitable identification. Pharmacists must maintain a record of identity verification. The maximum fine for disciplinary violations for all licensed health care practitioners is increased from $10,000 to $25,000.

This committee substitute creates five undesignated sections of law and section 893.065, Florida Statutes.

This committee substitute amends ss. 456.033, 456.072, 458.345, 461.013, and 893.04, F.S.

II. Present Situation:

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[1], 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.

Prescription Monitoring Systems

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

Prescription monitoring systems may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II, while others cover a range of controlled substances listed in Schedules II through V. 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. The use of a serialized form, be it single, duplicate, or triplicate, may provide the following advantages:

[1] "Working to Prevent the Diversion and Abuse of OxyContin®," United States Drug Enforcement Administration, June 12, 2001.

- Eliminates as a deterrent almost all forgeries and counterfeit prescriptions.
- Prevents unlicensed persons or practitioners who have been disciplined from writing prescriptions for heavily abused drugs without affecting prescriptions for non-abused drugs.
- Significantly reduces emergency room visits involving drugs requiring the form as reported by the Drug Abuse Warning Network program of the United States Drug Enforcement Administration.
- Increases pharmacists' ability to determine whether the prescriptions are valid and written for the patient submitting the form.
- Provides strong evidence in diversion cases because each serialized form is assigned to a specific, individual practitioner.
- Provides an evidence trail beginning with the practitioner's signature on the form for the prescription blanks and, later in the process, additional information is added including the patient's name, the drug, the dispensing pharmacy and the dispensing pharmacist, thereby providing an audit trail for the prescribing and dispensing of controlled substances for state regulatory and law enforcement officials.
- Provides physicians with the convenience of a permanent record for their patient files of each prescription written.

Advantages of an electronic prescription data collection system include the following:

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

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds. 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. [2] 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.[3] 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

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

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; 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. 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 professional practice acts for those practitioners who may prescribe controlled substances contain similar provisions.[4]

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.

Disciplinary Procedures

Section 456.073, F.S., sets forth procedures the Department of Health 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. Complaints are legally sufficient if they contain facts, which, if true, show that a licensee has violated any applicable regulations governing the licensee's profession or occupation. Even if the original complainant withdraws or otherwise indicates a desire that the complaint not be investigated or prosecuted to its completion, the department at its discretion may continue its investigation of the complaint. The department may investigate anonymous, written complaints or complaints filed by confidential informants if the complaints are legally sufficient and the department has reason to believe after a preliminary inquiry that the alleged violations are true. If the department has reasonable cause to believe that a licensee has violated any applicable regulations governing the licensee's profession, the department may initiate an investigation on its own.

When investigations of licensees within the department's jurisdiction are determined to be complete and legally sufficient, the department is required to prepare, and submit to a probable cause panel of the appropriate board, if there is a board, an investigative report along with a recommendation of the department regarding the existence of probable cause. A board has discretion over whether to delegate the responsibility of determining probable cause to the

[4] See s. 459.015, F.S. (osteopathic physicians); s. 461.013, F.S. (podiatric physicians); s. 462.14, F.S. (naturopathic physicians); and s. 466.028, F.S. (dentists).

department or to retain the responsibility to do so by appointing a probable cause panel for the board. The determination as to whether probable cause exists must be made by majority vote of a probable cause panel of the appropriate board, or by the department if there is no board or if the board has delegated the probable cause determination to the department.

The subject of the complaint must be notified regarding the department's investigation of alleged violations that may subject the licensee to disciplinary action. When the department investigates a complaint, it must provide the subject of the complaint or her or his attorney a copy of the complaint or document that resulted in the initiation of the investigation. Within 20 days after the service of the complaint, the subject of the complaint may submit a written response to the information contained in the complaint. The department may conduct an investigation without notification to the subject if the act under investigation is a criminal offense. If the department's secretary or her or his designee and the chair of its probable cause panel agree, in writing, that notification to the subject of the investigation would be detrimental to the investigation, then the department may withhold notification of the subject.

If the subject of the complaint makes a written request and agrees to maintain the confidentiality of the information, the subject may review the department's complete investigative file. The licensee may respond within 20 days of the licensee's review of the investigative file to information in the file before it is considered by the probable cause panel. Complaints and information obtained by the department during its investigations are exempt from the public records law until 10 days after probable cause has been found to exist by the probable cause panel or the department, or until the subject of the investigation waives confidentiality. If no probable cause is found to exist, the complaints and information remain confidential in perpetuity.

When the department presents its recommendations regarding the existence of probable cause to the probable cause panel of the appropriate board, the panel may find that probable cause exists or does not exist, or it may find that additional investigative information is necessary in order to make its findings regarding probable cause. Probable cause proceedings are exempt from the noticing requirements of ch. 120, F.S. After the panel convenes and receives the department's final investigative report, the panel may make additional requests for investigative information. Section 456.073(4), F.S., specifies time limits within which the probable cause panel may request additional investigative information from the department and within which the probable cause panel must make a determination regarding the existence of probable cause. Within 30 days of receiving the final investigative report, the department or the appropriate probable cause panel must make a determination regarding the existence of probable cause. The secretary of the department may grant an extension of the 15-day and 30-day time limits outlined in s. 456.073(4), F.S. If the panel does not issue a letter of guidance or find probable cause within the 30-day time limit as extended, the department must make a determination regarding the existence of probable cause within 10 days after the time limit has elapsed.

Instead of making a finding of probable cause, the probable cause panel may issue a letter of guidance to the subject of a disciplinary complaint. Letters of guidance do not constitute discipline. If the panel finds that probable cause exists, it must direct the department to file a formal administrative complaint against the licensee under the provisions of ch. 120, F.S. The department has the option of not prosecuting the complaint if it finds that probable cause has

been improvidently found by the probable cause panel. In the event the department does not prosecute the complaint on the grounds that probable cause was improvidently found, it must refer the complaint back to the board that then may independently prosecute the complaint. The department must report to the appropriate board any investigation or disciplinary proceeding not before the Division of Administrative Hearings under ch. 120, F.S., or otherwise not completed within 1 year of the filing of the complaint. The appropriate probable cause panel then has the option to retain independent legal counsel, employ investigators, and continue the investigation, as it deems necessary.

When an administrative complaint is filed against a subject based on an alleged disciplinary violation, the subject of the complaint is informed of her or his right to request an informal hearing if there are no disputed issues of material fact, or a formal hearing if there are disputed issues of material fact or the subject disputes the allegations of the complaint. The subject may waive her or his rights to object to the allegations of the complaint, which allows the department to proceed with the prosecution of the case without the licensee's involvement. Once the administrative complaint has been filed, the licensee has 21 days to respond to the department. If the subject of the complaint and the department do not agree in writing that there are no disputed issues of material fact, s. 456.073(5), F.S., requires a formal hearing before a hearing officer of the Division of Administrative Hearings under ch. 120, F.S. The hearing provides a forum for the licensee to dispute the allegations of the administrative complaint. At any point before an administrative hearing is held the licensee and the department may reach a settlement. The settlement is prepared by the prosecuting attorney and sent to the appropriate board. The board may accept, reject, or modify the settlement offer. If accepted, the board may issue a final order to dispose of the complaint. If rejected or modified by the board, the licensee and department may renegotiate a settlement or the licensee may request a formal hearing. If a hearing is held, the hearing officer makes findings of fact and conclusions of law that are placed in a recommended order. The licensee and the department's prosecuting attorney may file exceptions to the hearing officer's findings of facts. The boards resolve the exceptions to the hearing officer's findings of facts when they issue a final order for the disciplinary action.

The boards within the Department of Health have the status of an agency for certain administrative actions, including licensee discipline. A board may issue an order imposing discipline on any licensee under its jurisdiction as authorized by the profession's practice act and the provisions of ch. 456, F.S. 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. The department contracts with the Agency for Health Care Administration to investigate and prosecute disciplinary complaints.

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.[5] 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.[6] 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.

[5] Similar procedures are required for emergency rulemaking under the Administrative Procedure Act (s. 120.54(4)(a), F.S.)
[6] See also, s. 120.68, F.S., which provides for immediate judicial review of final agency action.

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.

III. Effect of Proposed Changes:

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, and any other public information that may facilitate that department's expeditious investigation of the information to determine whether any of the deaths have involved conduct by a licensed health care practitioner. The Department of Health or the board having regulatory authority over the practitioner must investigate such information when it has reasonable grounds to believe that the practitioner has violated any applicable law related to the practitioner's practice. 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 healthcare practitioners 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 Legal Affairs to design and establish an electronic system to monitor the prescribing of Schedule II controlled substances; other drugs designated by the Attorney General 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. 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 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 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 Legal Affairs each time that such controlled substance or drug (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) 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 of Legal Affairs 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 Legal Affairs must establish a 13-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 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. 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 Legal Affairs must provide staff and other administrative assistance that is reasonably necessary to assist the advisory council in carrying out its responsibilities.

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

Section 6. Amends s. 456.033, 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. 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.

Section 8. 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 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. 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 9. 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 10. 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; 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, 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. 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. 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 other drug designated as a drug of abuse by the Attorney General, 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 other drug designated as a drug of abuse by the Attorney General, by rule, under the prescription monitoring system.

Section 11. Creates s. 893.065, F.S., to prohibit a person from issuing any prescription or a person from filling, compounding, or dispensing 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, unless the prescription conforms to specified requirements. The Department of Legal Affairs must develop a counterfeit-proof prescription blank for use by practitioners who prescribe controlled substances classified in Schedule II; any drug that is designated by the Attorney General by rule, as a drug of abuse; and in Schedule II or Schedule III as codeine, hydrocodone, dihydrocodone, ethylmorphine, or morphine.

The Department of Legal Affairs must issue prescription blanks to prescribing practitioners. 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. The prescription blanks may not be transferred. The Department of Legal Affairs must cover all costs for the electronic prescription monitoring program, including the department's actual costs of preparing, issuing, and tracking prescription blanks.

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, typewritten or handwritten by the physician or an employee of the physician, 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 filling the prescription or an employee acting under the direction of the pharmacist must write or type the address on the prescription or maintain the information in a readily retrievable form in the pharmacy, if the prescribing practitioner fails to specify the address of the patient for whom, or animal for which, the prescription is prescribed.

The original of the prescription must be delivered to the pharmacist filling the prescription. The original must be retained on file by the proprietor of the pharmacy in which it was filled for a period of 2 years, and must be properly endorsed by the pharmacist with 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. A copy must be available for inspection by the Department of Legal Affairs. If the prescribing practitioner's address, category of professional licensure, or federal controlled substances registration number is readily retrievable in the pharmacy, this information does not need to appear on the prescription.

All prescriptions 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, must include both a written and numerical notation of quantity on the face of the prescription and a pharmacist may not knowingly fill a prescription that has been mutilated or forged. Such 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. A pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance upon an oral prescription.

An exemption from the use of the required prescription blanks for a Schedule II controlled substance or drug subject to the requirements of this section, is provided for a pharmacist that dispenses these drugs by mail.

Section 12. Provides an effective date of July 1, 2002.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

B. Public Records/Open Meetings Issues:

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).

C. Trust Funds Restrictions:

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

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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

C. Government Sector Impact:

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 Department of Legal Affairs estimates that it will incur the following costs for fiscal year 2002-2003, $1,591,588; for fiscal year 2003-2004, $1,526,772; and for fiscal year 2004-2005, $1,526,772 to implement the bill's provisions 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. 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 Department of Health indicated that there will be an indeterminate cost associated with the use of special 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 III.

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.

The Agency for Health Care Administration reports that it will incur an additional workload to annually review an estimated 2,340 additional death reports from the Medical Examiner's Commission. This additional workload would have a fiscal impact of $1,250,705 and a non-recurring impact of $87,890 which will result in a total impact of $1,338,595 in fiscal year 2002-2003 and $1,250,705 in fiscal year 2003-2004. This includes the costs for 22 additional positions (investigators, clerical staff, and attorneys). Such costs will affect the current funding of the Agency for Health Care Administration's contractual services covered by an interagency agreement between the Agency for Health Care Administration and the Department of Health.

Prescribing and Pharmacology Continuing Education: The Department of Health anticipates that it will incur costs of $28,154, for fiscal year 2002-2003 and $22,393, for fiscal year 2003-2004 and need an additional 0.5 full time equivalent position to monitor compliance with the continuing education requirements

Administrative Fines on Disciplined Practitioners: The Department of Health reports approximately $420,000 in anticipated revenue from increasing the maximum fine from $10,000 to $25,000. During fiscal year 2000-2001 the Board of Medicine took action on 28 cases involving violations relating to controlled substances.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.