By the Committees on Judiciary; Health, Aging and Long-Term Care; and Senator Burt

308-1850-02

A bill to be entitled

An act relating to controlled substances; providing for specified licensing boards to adopt rules governing the prescribing of controlled substances; requiring certain health care providers to complete education courses relating to the prescription of controlled substances; providing penalties and requiring a report; providing for the emergency suspension of certain licenses for prescribing violations; requiring the Department of Health, the Department of Law Enforcement, the Statewide Prosecutor, and State Attorneys to share certain information regarding health care practitioners; requiring a report; requiring the Department of Legal Affairs to establish an electronic system to monitor the prescribing of certain controlled substances; establishing an advisory council and providing for its membership, duties, staff, and compensation; amending s. 456.033, F.S.; eliminating certain requirements for HIV and AIDS education courses; amending s. 456.072, F.S., revising penalties; amending s. 458.345, F.S.; requiring certain resident physicians, interns, and fellows to complete an educational course in prescribing controlled substances; amending s. 461.013, F.S.; prohibiting the presigning of blank prescription forms and providing penalties; amending s. 893.04, F.S.; providing additional requirements for pharmacists

regarding the identification of persons to whom controlled substances are dispensed; prohibiting certain prescribing practitioners from possessing, administering, dispensing, or prescribing controlled substances; creating s. 893.065, F.S.; establishing protocols requiring prescriptions for certain controlled substances to be issued on special forms developed by the Department of Legal Affairs; establishing requirements for the design, issuance, and control of such forms; providing record-keeping requirements; providing other requirements for the use of such forms; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Physicians; rules establishing prescribing guidelines.--To minimize the diversion and resultant abuse of controlled substances, the Board of Medicine and the Board of Osteopathic Medicine shall adopt rules to establish guidelines for prescribing controlled substances to patients in emergency-department settings. Such 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 requirements of state and federal law and of the Joint Commission on the Accreditation of Healthcare Organizations. Each board shall consult with the Florida College of Emergency Physicians in developing these guidelines.

Section 2. Instruction required for certain licensees in prescribing and pharmacology.--

(1) The appropriate professional licensing board shall require each person licensed under chapter 458, chapter 459, chapter 461, chapter 462, or chapter 466, Florida Statutes, to complete a 1-hour educational course, approved by the board, on appropriate prescribing and pharmacology of controlled substances, as part of the licensee's initial license renewal after January 1, 2003. The course shall provide education in the state and federal laws and rules governing the prescribing and dispensing of controlled substances; in appropriate evaluation of patients for any risk of drug diversion and the resulting abuse of controlled substances; in the use of informed consent and other protocols, such as discussing the risks and benefits of using controlled substances, with patients to prevent drug diversion; in the need to keep accurate and complete medical records to justify treatment with controlled substances; in addiction and substance-abuse issues with respect to patients; in the appropriate use of recognized pain-management guidelines; and in the need for consultation and referral of patients who are at risk for misuse of medication or diversion of controlled substances, when appropriate.

(2) The board may approve additional equivalent courses that satisfy the requirements of subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section shall include the hours required to complete the course in the total required continuing educational requirements.

(3) Any person who holds two or more licenses subject to this section may satisfy the requirements of this section

by taking only one such board-approved course for relicensure of all such licenses.

(4) A licensee who fails to comply with this section is subject to disciplinary action under each respective practice act and section 456.072(1)(k), Florida Statutes. In addition to discipline by the board, the licensee must complete the course.

(5) The board shall require, as a condition of granting a license under the chapter specified in subsection (1), that an applicant for initial licensure complete an educational course set forth in subsection (1). An applicant who has not taken a course at the time of licensure shall be allowed 6 months within which to complete this requirement.

(6) The board may adopt rules necessary to administer this section.

Section 3. Emergency suspension orders; controlled substances.--Upon receipt of sufficient evidence from any agency authorized to enforce chapter 893, Florida Statutes, regarding a violation of section 458.331(1)(q), section 458.331(1)(r), section 458.331(1)(aa), section 459.015(1)(t), section 459.015(1)(u), section 459.015(1)(ee), section 461.013(1)(o), section 461.013(1)(p), section 461.013(1)(dd), section 462.14(1)(q), section 462.14(1)(r), section 462.14(1)(aa), section 464.018(1)(i), section 465.016(1)(e), section 465.016(1)(i), section 466.028(1)(p), section 466.028(1)(q), section 466.028(1)(r), or section 466.028(1)(dd) or of chapter 893, Florida Statutes, by a licensed health care practitioner who is authorized to prescribe, dispense, or administer controlled substances, the Department of Health shall review the case and if the practitioner is a danger to the public health, safety, or

welfare of the public as set forth in section 120.60(6), Florida Statutes, recommend the suspension or restriction of the practitioner's license to the Secretary 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), Florida Statutes.

Section 4. Sharing of arrest, formal-charging, and other information regarding health care practitioners.--

(1) In order to facilitate the efficiency of the Department of Health's investigation of applicable violations involving the diversion of controlled substances by such practitioners, or other violations of criminal law that may adversely affect a practitioner's licensed practice, any law enforcement agency that arrests a person known or suspected to be a health care practitioner licensed by the state shall promptly notify the Department of Health and provide it with:

(a) Notice of the arrest, including the name of the arresting agency and lead investigator, detective, or officer in the case;

(b) The name of the person charged;

(c) All known personal identifying information related to the person arrested;

(d) The date of the arrest;

(e) The charges for which the person is arrested; and

(f) The agency case number assigned to the arrest.

(2) A state attorney or the Statewide Prosecutor, upon the filing of an indictment or information against a person known or suspected to be a health care practitioner licensed by the state, shall forward a copy of the indictment or information to the Department of Health.

(3) The Medical Examiners Commission within the Department of Law Enforcement shall report to the Department of Health quarterly any information in its possession regarding the deaths of persons who had lethal levels of controlled substances in their bodies as such information has been reported to the commission by the medical examiners within the state.

(4) Upon receipt of arrest information from a law enforcement agency, notice of formal charging by a prosecuting entity, or information from the Medical Examiners Commission, as provided in this section, the Department of Health or the board having regulatory authority over the practitioner shall investigate any information received and determine whether it has reasonable grounds to believe that the practitioner has violated any law relating to the practitioner's practice and shall take appropriate licensure action as provided by law or rule. If the Department of Health receives information pursuant to this section which suggests the person arrested, charged, or otherwise identified is also licensed by the state in another field or profession, the Department of Health shall forward such information to the appropriate licensing entity for review and appropriate licensure action as provided by law or rule.

(5) To help the Department of Health and regulatory boards control the diversion and resultant abuse of controlled substances, the Department of Health and the Department of Law Enforcement shall 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 shall address whether collection and retention of fingerprint information concerning licensed health care practitioners is advisable as a means of better regulating such practitioners and guarding against abuse of the privileges of such licensure. The Department of Law Enforcement shall investigate the feasibility of the electronic transmission of information from medical examiners within this state to the Department of Health regarding autopsies and other public reports 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. Electronic monitoring system for prescriptions.--

(1) By July 1, 2003, the Department of Legal Affairs shall design and establish an electronic system consistent with the National Council of Prescription Drug Programs (NCPDP) standards or the American Society for Automation in Pharmacy (ASAP) standards to monitor the prescribing of Schedule II controlled substances, other drugs designated by rule 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 the state or the dispensing of such controlled substances to an address within the state by a pharmacy permitted or registered by the Board of Pharmacy.

(2) All Schedule II controlled substances, and codeine hydrocodone, dihydrocodeine, ethylmorphine, and morphine as scheduled in Schedule II and Schedule III, and any other drug designated by the Attorney General under this section shall be included in the electronic monitoring system. The Attorney

General may, by rule, designate any other drug for inclusion in such 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 created by this section before designating a drug of abuse for inclusion in the electronic 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.

(3) Each controlled substance or drug subject to this section which is dispensed in this state must be timely reported to the Department of Legal Affairs. Such data must be reported each time that:

(a) A Schedule II controlled substance is dispensed;

(b) A drug that is designated by the Attorney General under subsection (2) is dispensed; or

(c) Codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine as scheduled in Schedule II and Schedule III is dispensed.

(4) This section does not apply to controlled substances or drugs:

(a) Ordered from an institutional pharmacy licensed under section 465.019(2), Florida Statutes, in accordance with the institutional policy for such controlled substances or drugs; or

(b) 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 this state.

(5) The data required under this section includes:

(a) The patient's name.

(b) The patient's address.

(c) The national drug code number of the substance dispensed.

(d) The date that the substance is dispensed.

(e) The quantity of substance dispensed.

(f) The dispenser's National Association of Board's of Pharmacy (NABP) number.

(g) The prescribing practitioner's United States Drug Enforcement Administration Number.

(6) The information must be reported within 30 days after the date the controlled substance or drug is dispensed.

(7) A dispenser must transmit the information required by this section in an electronic format approved by rule of the Board of Pharmacy after consultation with the advisory council and the Department of Legal Affairs unless a specific waiver is granted to that dispenser by the Department of Legal Affairs.

(8) The Department of Legal Affairs shall establish a 13-member prescription-monitoring program advisory council to assist it in identifying drugs of abuse for inclusion in the monitoring system and in implementing the system.

(a) The Governor shall appoint members to serve on the advisory council. The members of the council 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 Governor or his or her designee; a physician who is licensed in this state under chapter 458, Florida Statutes, who is recommended by the Florida Medical Association; a physician who is licensed in this state under chapter 459, Florida Statutes, who is recommended by the Florida Osteopathic Medical Association; a podiatric physician who is licensed in this state under chapter 461, Florida Statutes, who is recommended by the Florida Podiatric Medical Association; a pharmacist who is licensed in this state under chapter 465, Florida Statutes, who is recommended by the Florida Pharmacy Association; a pharmacist who is licensed in this state under chapter 465, Florida Statutes, who is recommended by the Florida Retail Federation; a pharmacist who is licensed in this state under chapter 465, Florida Statutes, who is recommended by the National Community Pharmacy Association; a dentist who is licensed in this state under chapter 466, Florida Statutes, who is recommended by the Florida Dental Association; a veterinarian who is licensed in this state under chapter 474, Florida Statutes, who is recommended by the Florida Veterinary Medical Association; and a prosecutor who has expertise in the criminal prosecution of drug-diversion cases.

(b) The advisory council members shall meet no more often than quarterly at the call of the chairperson, and serve without compensation. However, such members may receive reimbursement, as provided in section 112.061, Florida Statutes, for per diem and travel expenses incurred in the performance of their official duties.

(c) The Department of Legal Affairs shall provide staff and other administrative assistance that is reasonably

necessary to assist the advisory council in carrying out its responsibilities.

(9) The Department of Legal Affairs shall adopt rules pursuant to section 120.536(1) and section 120.574, Florida Statutes, necessary to administer this section.

Section 6. Subsections (1) and (9) of section 456.033, Florida Statutes, are amended to read:

456.033 Requirement for instruction for certain licensees on HIV and AIDS.--

(1) The appropriate board shall require each person licensed or certified under chapter 457; ~~chapter 458; chapter 459;~~chapter 460; ~~chapter 461;~~chapter 463; part I of chapter 464; chapter 465; ~~chapter 466;~~part II, part III, part V, or part X of chapter 468; or chapter 486 to complete a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(9)~~(a)~~ In lieu of completing a course as required in subsection (1), the licensee may complete a course in end-of-life care and palliative health care, so long as the

licensee completed an approved AIDS/HIV course in the immediately preceding biennium.

~~(b) In lieu of completing a course as required by subsection (1), a person licensed under chapter 466 who has completed an approved AIDS/HIV course in the immediately preceding 2 years may complete a course approved by the Board of Dentistry.~~

Section 7. Paragraph (d) of subsection (2) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.--

(2) When the board, or the department when there is no board, finds any person guilty of the grounds set forth in subsection (1) or of any grounds set forth in the applicable practice act, including conduct constituting a substantial violation of subsection (1) or a violation of the applicable practice act which occurred prior to obtaining a license, it may enter an order imposing one or more of the following penalties:

(d) Imposition of an administrative fine not to exceed $25,000~~$10,000~~ for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

Section 8. Paragraph (d) is added to subsection (1) of section 458.345, Florida Statutes, to read:

458.345 Registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.--

(1) Any person desiring to practice as a resident physician, assistant resident physician, house physician,

intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07(44) or s. 395.805(2), who does not hold a valid, active license issued under this chapter shall apply to the department to be registered and shall remit a fee not to exceed $300 as set by the board. The department shall register any applicant the board certifies has met the following requirements:

(d) Has completed, upon initial registration, the 1-hour educational course in the prescribing of controlled substances as set forth in section 2 of this act. An applicant who has not taken a course at the time of registration shall be allowed up to 6 months within which to complete this requirement.

Section 9. Paragraph (dd) is added to subsection (1) of section 461.013, Florida Statutes, to read:

461.013 Grounds for disciplinary action; action by the board; investigations by department.--

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(dd) Presigning blank prescription forms.

Section 10. Paragraphs (h), (i), (j), (k), and (l) are added to subsection (1) of section 893.04, Florida Statutes, to read:

893.04 Pharmacist and practitioner.--

(1) A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances

upon a written or oral prescription of a practitioner, under the following conditions:

(h) A pharmacist may not dispense a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or drug of abuse designated by the Attorney General by rule under the prescription-monitoring system to any individual not personally known to the pharmacist, without first obtaining suitable identification and documenting, by signature on a log book kept by the pharmacist, the identity of the individual obtaining the controlled substance. If the individual does not have suitable identification or it is impracticable to obtain such identification, the pharmacist must verify the validity of the prescription and identity of the patient with the prescribing practitioner, or the prescribing practitioner's authorized agent, before dispensing the controlled substance or drug as provided by rule of the Board of Pharmacy. The Board of Pharmacy must adopt, by rule, procedures for a pharmacist to verify the validity of a prescription for a Schedule II controlled substance; other drug designated by the Attorney General under this section; or codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III, for circumstances when it is otherwise impracticable for the pharmacist or dispensing practitioner to obtain suitable identification from the patient or the patient's agent. For purposes of this section, identification is suitable only if it contains the photograph, the printed name, and the signature of the individual obtaining the Schedule II controlled substance or drug of abuse under the prescription-monitoring system.

(i) 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 requirements to obtain suitable identification.

(j) 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 of abuse under the prescription-monitoring system which has been designated by the Attorney General by rule, must include both a written and numerical notation of quantity on the face of the prescription.

(k) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription.

(l) A pharmacist may not knowingly fill a prescription that has been mutilated or forged for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III; or a drug of abuse under the prescription-monitoring system which has been designated by the Attorney General by rule.

Section 11. Section 893.065, Florida Statutes, is created to read:

893.065 Prescriptions required for certain controlled substances.--

(1) On or after July 1, 2002, a person may not issue a prescription for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or any drug included as a drug of abuse under the prescription-monitoring

system which has been designated by the Attorney General by rule, unless the prescription meets the requirements of this section.

(2) The Department of Legal Affairs shall develop a counterfeit-proof prescription blank for use by practitioners who prescribe controlled substances classified in:

(a) Schedule II;

(b) Any drug that is designated by the Attorney General by rule under subsection (1).

(c) Schedule II or Schedule III as codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine.

(3) Prescription blanks shall be issued by the Department of Legal Affairs to such practitioners. The prescription blanks must be printed on distinctive paper and must 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.

(4) 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.

(5) Notwithstanding s. 893.04(1)(a)-(d), a person may not prescribe a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or any drug which has been designated by the Attorney General by rule under subsection (1), nor may any person fill, compound, or dispense such a prescription, unless it complies with this section.

(a) The signature on each such 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. If the prescription is for an animal, the prescription must state the species of animal for which it is prescribed. If the prescribing practitioner does not specify the address of the person for whom, or animal for which, the prescription is prescribed, 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.

(b) 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 is filled for a period of 2 years, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state permit number, the date that the prescription was filled, and the signature of the pharmacist, and a copy must be available for inspection by the Department of Legal Affairs. Notwithstanding any provision of this section, the prescribing practitioner's address, category of professional licensure, or federal controlled substances registration

number need not appear on the prescription if that information is readily retrievable in the pharmacy.

(c) All prescriptions issued for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or any drug which has been designated by the Attorney General by rule under subsection (1), must include both a written and numerical notation of quantity on the face of the prescription.

(d) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription.

(e) 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 any drug which has been designated by the Attorney General by rule under subsection (1).

(f) Any controlled substance listed in Schedule III; codeine, hydrocodone, dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III; or any drug which has been designated by the Attorney General by rule under subsection (1), may be dispensed by a pharmacist upon an oral prescription, if before filling the prescription, 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 prescriptions must contain the date of the oral authorization and the information required by paragraph (a).

(6) 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 requirements to use the required prescription blanks.

Section 12. This act shall take effect July 1, 2002.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR CS for Senate Bill 636

Clarifies the bill's provisions regarding the sharing of information regarding health care practitioners to specify the following:

-- Any law enforcement agency that arrests a health care practitioner must notify the Department of Health of the arrest and provide the department with specified information pertaining to the arrest.

-- A State Attorney or the Statewide Prosecutor must provide the Department of Health with a copy of any indictment or information filed against a health care practitioner.

-- The Medical Examiners Commission must provide the Department of Health with quarterly reports reflecting any information in its possession regarding the deaths of persons who had lethal levels of controlled substances in their bodies.

-- The Department of Health must investigate any information received from law enforcement authorities, prosecutors, or the Medical Examiners Commission to determine whether the practitioner has violated any law relating to the practitioner's practice that requires licensure action. If the practitioner 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 Law Enforcement and the Department of Health, in addition to studying the feasibility of expanding the electronic exchange of information between the two departments, are also required to study the advisability of the collection and retention of fingerprint information of licensed health care practitioners.

Allows the Department of Legal Affairs to design and establish an electronic monitoring system for prescriptions that is consistent with the National Council of Prescription Drug Programs standards or the American Society for Automation in Pharmacy standards.