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An act relating to controlled subst

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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 and the Department of Law Enforcement 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.; requiring a fine for certain violations involving excessive prescribing of controlled substances; 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 12 control of such forms; providing record-keeping requirements; providing other requirements for the use of such forms; creating s. 893.0655, F.S.; requiring certain practitioners to surrender such prescription forms; providing an effective date.

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

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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. Each board shall consult with the Florida College of Emergency Physicians in developing these guidelines.

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in prescribing and pharmacology. --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 continuing 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 13 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 16 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

Section 2. Instruction required for certain licensees

(2) Such licensees must submit confirmation of completion of such a course, on a form provided by the board, when submitting fees for the initial biennial license renewal after January 1, 2003.

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.

(3) 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 may include the

hours required to complete the course in the total required continuing educational requirements.

- (4) 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.
- (5) A licensee who fails to comply with this section is subject to disciplinary action under each respective practice act and s. 456.072(1)(k), Florida Statutes. In addition to discipline by the board, the licensee must complete the course.
- (6) 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 in the appropriate prescribing and pharmacology of controlled substances. An applicant who has not taken a course at the time of licensure shall, upon submitting an affidavit showing good cause, be allowed 6 months within which to complete this requirement.
- (7) The board may adopt rules necessary to administer this section.
- (8) Each board shall report to the President of the Senate, the Speaker of the House of Representatives, and the chairpersons of the appropriate substantive committees of the Legislature by March 1 of each year on the implementation of and compliance with 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 ss. 458.331(1)(q), 458.331(1)(r), 458.331(1)(aa), 459.015(1)(t), 459.015(1)(u), 459.015(1)(ee),

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461.013(1)(o), 461.013(1)(p), 461.013(1)(dd), 462.14(1)(q),
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   462.14(1)(r), 462.14(1)(aa), 464.018(1)(i), 465.016(1)(e),
   465.016(1)(i), 466.028(1)(p), 466.028(1)(q), 466.028(1)(r), or
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   466.028(1)(dd) or chapter 893, Florida Statutes, by a licensed
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   health care practitioner who is authorized to prescribe,
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   dispense, or administer controlled substances, the Department
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   of Health shall recommend the suspension or restriction of the
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   practitioner's license to the Secretary of Health within 10
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   working days after receiving such evidence. The Secretary of
   Health may suspend or restrict the license of the practitioner
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    in accordance with s. 120.60(6), Florida Statutes.
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- Section 4. Sharing of arrest and other information regarding certain health care practitioners.--
- (1) The Department of Health shall electronically submit to the Department of Law Enforcement a list of health care practitioners licensed in this state who are authorized to prescribe, dispense, or administer controlled substances. 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, the Department of Law Enforcement shall, when practicable, notify and provide investigative information to the Department of Health regarding the arrest of any such practitioner.
- (2) The Medical Examiner's Commission within the
 Department of Law Enforcement shall report quarterly to the
 Department of Health any deaths attributed to the abuse of
 controlled substances, based on autopsy reports completed
 within this state, 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 which

is subject to disciplinary action under s. 456.073, Florida 1 2 Statutes. The Department of Health or the board having 3 regulatory authority over the practitioner shall investigate any information received by the department or the board when 4 5 it has reasonable grounds to believe that the practitioner has violated any law relating to the practitioner's practice. 6 7 (3) To help the Department of Health and regulatory 8 boards control the diversion and resultant abuse of controlled 9 substances, the Department of Health and the Department of Law Enforcement shall study the feasibility of expanding the 10 11 electronic exchange of information to facilitate the transfer 12 to the Department of Health of criminal history information 13 involving licensed health care practitioners who are authorized to prescribe, administer, or dispense controlled 14 substances. The Department of Law Enforcement shall 15 16 investigate the feasibility of the electronic transmission of 17 information from medical examiners within this state to the Department of Health regarding autopsies and other public 18 19 reports that attribute death to controlled substance abuse. 20 The Department of Law Enforcement, in consultation with the Department of Health, must submit a report of its findings to 21 22 the Legislature by November 1, 2002. Section 5. Electronic monitoring system for 23 24 prescriptions.--25 (1) By July 1, 2003, the Department of Legal Affairs 26 shall design and establish an electronic system to monitor the 27 prescribing of Schedule II and Schedule III controlled 28 substances by health care practitioners within the state or 29 the dispensing of such controlled substances to an address within the state by a pharmacy permitted or registered by the 30 Board of Pharmacy.

1	(2) The Attorney General may, by rule, designate any
2	opiate listed as a Schedule IV controlled substance for
3	inclusion in such system.
4	(3) Each pharmacist or other person authorized by law
5	to dispense controlled substances within this state must
6	timely report to the Department of Legal Affairs the data
7	required by this section each time that:
8	(a) A Schedule II controlled substance is dispensed;
9	(b) A Schedule III controlled substance is dispensed;
10	<u>or</u>
11	(c) An opiate is dispensed which is listed in Schedule
12	IV as a controlled substance and is designated by the Attorney
13	General.
14	(4) The data required under this section includes:
15	(a) The patient's name.
16	(b) The patient's address.
17	(c) The national drug code number of the substance
18	dispensed.
19	(d) The date that the substance is dispensed.
20	(e) The quantity of substance dispensed.
21	(f) The dispenser's United States Drug Enforcement
22	Administration Number.
23	(g) The prescribing practitioner's United States Drug
24	Enforcement Administration Number.
25	(5) The information must be reported within 15 days
26	after the date the controlled substance is dispensed.
27	(6) A dispenser must transmit the information required
28	by this section in an electronic format specified by the
29	Department of Legal Affairs unless a specific waiver is
30	granted by the department to that dispenser.
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- (7) The Department of Legal Affairs shall establish a seven-member prescription monitoring program advisory council to assist it 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, 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 health care practitioner who is licensed in this state and authorized to prescribe controlled substances, a pharmacist who is licensed in this state, and a prosecutor who has expertise in the criminal prosecution of drug-diversion cases.
- (b) The advisory council members shall serve without compensation but may receive reimbursement, as provided in s. 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. The advisory council is abolished July 1, 2003.
- (8) The Department of Legal Affairs shall adopt rules pursuant to ss. 120.536(1) and 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.--

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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:

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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. If the violation is for inappropriate or excessive prescribing of any controlled substance, the board, or the department if there is no board, must impose a fine of \$25,000 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 .--

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 31 fellowship training in a teaching hospital in this state as

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30 31 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, a 2-hour educational course in the prescribing of controlled substances. The course shall consist of education in 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 a discussion of the risks and benefits of the use of 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 their medication or diversion of controlled substances, when appropriate. An applicant who has not taken a course at the time of registration shall, upon submitting an affidavit showing good cause, be allowed 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. Paragraph (h) is added to subsection (1) of section 893.04, Florida Statutes, and subsection (4) is added to said section, 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 controlled substance to any individual not known to the pharmacist without first obtaining proper 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 proper 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. For purposes of this section, identification is proper only if it contains the photograph, the printed name, and the signature of the individual obtaining the controlled substance.
- (4) Any prescribing practitioner who surrenders, by court order, or order of any state or governmental agency, or voluntarily, his or her controlled substance privileges may not possess, administer, dispense, or prescribe a controlled substance unless those privileges have been restored and the

practitioner has obtained current registration from the 1 2 appropriate federal agency as provided by law. 3 Section 11. Section 893.065, Florida Statutes, is 4 created to read: 5 893.065 Triplicate prescriptions required for certain 6 controlled substances .--7 (1) On or after July 1, 2002, a person may not issue a 8 prescription for a Schedule II or Schedule III controlled 9 substance, or an opiate listed in Schedule IV which has been designated by the Attorney General by rule, unless the 10 11 prescription meets the requirements of this section. 12 (2) The Department of Legal Affairs shall develop a 13 counterfeit-proof prescription blank for use by practitioners 14 who prescribe controlled substances classified in: 15 (a) Schedule II; 16 (b) Schedule III; or (c) Schedule IV, as an opiate that is designated by 17 the Attorney General by rule. 18 19 Prescription blanks shall be issued by the (3) 20 Department of Legal Affairs to such practitioners in serially numbered groups of not more than 100 forms each in triplicate, 21 unless a practitioner orally, electronically, or in writing 22 23 requests a larger quantity. The prescription blanks must be printed on distinctive paper; must contain the serial number 24 25 of the group; must be sequentially numbered; and must bear the 26 preprinted full name, address, and category of professional 27 licensure of the practitioner to whom they are issued and that 28 practitioner's federal registry number for controlled 29 substances. The prescription blanks may not be transferred. (4) The Department of Legal Affairs may charge a fee 30

for the prescription blanks in an amount sufficient to

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reimburse the department for its actual costs of preparing, issuing, and tracking such forms.

- (5) Notwithstanding s. 893.04(1)(a)-(d), a person may not prescribe a Schedule II or Schedule III controlled substance, or an opiate listed in Schedule IV which has been designated by the Attorney General by rule, nor may any person fill, compound, or dispense such a prescription, unless it complies with this section.
- 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 in triplicate, 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 and duplicate of the prescription must be delivered to the pharmacist filling the prescription.

The duplicate must be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years, and the original, 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, must be transmitted to the Department of Legal Affairs at the end of the month in which the prescription was filled. 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 or
 Schedule III controlled substance, or an opiate listed in
 Schedule IV 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.
- (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 or Schedule III controlled substance, or an opiate listed as a Schedule IV controlled substance which has been designated by the Attorney General by rule.
- (f) Any controlled substance listed in Schedule III, or any controlled substance that is an opiate listed as a controlled substance in Schedule IV and which has been designated by the Attorney General by rule, 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 1 2 an official form issued by the Department of Legal Affairs for 3 that purpose. Such prescriptions must be prepared in triplicate and must contain the date of the oral authorization 4 5 and the information required by paragraph (a). 6 Section 12. Section 893.0655, Florida Statutes, is 7 created to read: 8 893.0655 Surrender of prescription blanks.--9 (1) When a practitioner who is named in a warrant of 10 arrest for, or is charged in an accusatory pleading with, a 11 felony violation of chapter 499 or chapter 893, the court in 12 which the pleading is filed or the magistrate who issued the 13 warrant shall, upon the motion of a law enforcement agency, supported by probable cause, issue an order requiring the 14 practitioner to surrender to the clerk of the court all 15 16 triplicate prescription blanks in the practitioner's 17 possession at a specified time and shall direct the Department of Health to withhold prescription blanks from the 18 19 practitioner. The law enforcement agency obtaining the order 20 shall notify the Department of Health of this order. Except as provided in subsection (2), the order shall remain in effect 21 22 until further order of the court. Any practitioner possessing prescription blanks in violation of the order commits a 23 misdemeanor of the first degree, punishable as provided in s. 24 775.082, s. 775.083, or s. 775.084. 25 26 (2) Such order shall be vacated if the court or 27 magistrate finds that the underlying violation is not 28 supported by reasonable cause, at a hearing held within 2 29 court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency 30 that obtained the order a notice of motion to vacate the

order, with any affidavits on which the practitioner relies. 1 At the hearing, the burden of proof, by a preponderance of the 2 3 evidence, is on the prosecution. Evidence presented at the 4 hearing shall be limited to the warrant of arrest with 5 supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting 6 7 affidavits, the sworn complaint and any documents or reports 8 incorporated by reference thereto, which, if based on 9 information and belief, state the basis for the information, 10 or any other documents of similar reliability, as well as 11 affidavits submitted by the prosecution and defense. Granting 12 of the motion to vacate the order is no bar to prosecution of 13 the alleged violation. Section 13. This act shall take effect July 1, 2002. 14 15 16 17 LEGISLATIVE SUMMARY 18 Provides for the regulation of the prescribing of controlled substances. Requires education and continuing education in the prescribing of controlled substances by specified practitioners. Establishes penalties. Requires 19 20 certain state agencies to share information. Requires the creation of an electronic monitoring system. Creates an 21 advisory council. Prohibits presigning prescriptions.
Requires state issuance and regulation of prescription
forms for controlled substances. Prohibits certain
practitioners from prescribing. Establishes 22 23 record-keeping requirements. Requires certain practitioners to surrender their prescription forms. (See bill for details.) 24 25 26 27 2.8 29 30

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