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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 requirements for the design, issuance, and prescription forms developed by the Department of Legal Affairs for certain controlled substances and drugs; granting rulemaking authority to the Department of Legal Affairs; providing inspection of such forms by the Department of Legal Affairs; 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.

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Section 2. <u>Instruction required for certain licensees</u> 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 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

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by taking only one such board-approved course for relicensure
   of all such licenses.
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          (4) A licensee who fails to comply with this section
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    is subject to disciplinary action under each respective
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    practice act and section 456.072(1)(k), Florida Statutes. In
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    addition to discipline by the board, the licensee must
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    complete the course.
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          (5) The board shall require, as a condition of
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    granting a license under the chapter specified in subsection
   (1), that an applicant for initial licensure complete an
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    educational course set forth in subsection (1). An applicant
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    who has not taken a course at the time of licensure shall be
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    allowed 6 months within which to complete this requirement.
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          (6) The board may adopt rules necessary to administer
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    this section.
           Section 3. Emergency suspension orders; controlled
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    substances. -- Upon receipt of sufficient evidence from any
    agency authorized to enforce chapter 893, Florida Statutes,
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    regarding a violation of section 458.331(1)(q), section
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    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
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    461.013(1)(o), section 461.013(1)(p), section 461.013(1)(dd),
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    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),
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    section 465.016(1)(i), section 466.028(1)(p), section
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    466.028(1)(q), section 466.028(1)(r), or section
    466.028(1)(dd) or of chapter 893, Florida Statutes, by a
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    licensed health care practitioner who is authorized to
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    prescribe, dispense, or administer controlled substances, the
    Department of Health shall review the case and if the
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    practitioner is a danger to the public health, safety, or
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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

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;
  - (f) The agency case number assigned to the arrest; and
- (g) The arrest report, investigative report, or statement of the allegations supporting 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.
- enforcement agency or notice of formal charging by a prosecuting entity, 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 that the person arrested or charged 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 1 2 substances. The study must address whether the collection and 3 retention of fingerprint information concerning licensed 4 health care practitioners subject to the profiling provisions 5 of sections 456.039 and 456.0391, Florida Statutes, is 6 advisable as a means of better regulating such practitioners 7 and guarding against abuse of the privileges of such licensure 8 with respect to controlling the diversion and resultant abuse 9 of controlled substances. The Department of Law Enforcement shall investigate the feasibility of the electronic 10 transmission of information from medical examiners within this 11 12 state to the Department of Health regarding autopsies and 13 other public reports that attribute death to 14 controlled-substance abuse. The Department of Law Enforcement, in consultation with the Department of Health, must submit a 15 16 report of its findings to the Legislature by November 1, 2002. 17 Section 5. Electronic monitoring system for 18 prescriptions.--19 (1) By July 1, 2003, the Department of Legal Affairs 20 shall design and establish an electronic system consistent 21 with the National Council of Prescription Drug Programs (NCPDP) standards or the American Society for Automation in 22 23 Pharmacy (ASAP) standards to monitor the prescribing of Schedule II controlled substances, other drugs designated by 24 rule by the Attorney General under this section, and codeine, 25 26 hydrocodone, dihydrocodeine, ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III, by health care 27 practitioners within the state or the dispensing of such 28 29 controlled substances to an address within the state by a 30 pharmacy permitted or registered by the Board of Pharmacy. 31

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- (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.
- $\underline{\text{(c)} \ \ \text{The national drug code number of the substance}} \\ \text{dispensed.}$ 
  - (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.
- 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. The information transmitted may be maintained by any department receiving it for up to 12 months before purging it from its records. Notwithstanding the foregoing, any department receiving such information may maintain it longer than 12 months if the information is pertinent to an ongoing investigation arising under this act.

The Department of Legal Affairs shall establish a 1 2 14-member prescription-monitoring program advisory council to 3 assist it in identifying drugs of abuse for inclusion in the monitoring system and in implementing the system. 4 5 The Governor shall appoint members to serve on the (a) 6 advisory council. The members of the council shall include the 7 Attorney General or his or her designee who shall serve as the 8 chairperson; the Secretary of Health or his or her designee; 9 the executive director of the Department of Law Enforcement or his or her designee; the director of the Office of Drug 10 Control within the Executive Office of Governor or his or her 11 12 designee; a physician who is licensed in this state under 13 chapter 458, Florida Statutes, who is recommended by the 14 Florida Medical Association; a physician who is licensed in 15 this state under chapter 458 or chapter 459, Florida Statutes, 16 who is recommended by the Florida Academy of Pain Medicine; a 17 physician who is licensed in this state under chapter 459, Florida Statutes, who is recommended by the Florida 18 19 Osteopathic Medical Association; a podiatric physician who is 20 licensed in this state under chapter 461, Florida Statutes, who is recommended by the Florida Podiatric Medical 21 Association; a pharmacist who is licensed in this state under 22 23 chapter 465, Florida Statutes, who is recommended by the 24 Florida Pharmacy Association; a pharmacist who is licensed in this state under chapter 465, Florida Statutes, who is 25 26 recommended by the Florida Retail Federation; a pharmacist who is licensed in this state under chapter 465, Florida Statutes, 27 who is recommended by the National Community Pharmacy 28 29 Association; a dentist who is licensed in this state under chapter 466, Florida Statutes, who is recommended by the 30 31 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:

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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 a 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, in a log book kept by the pharmacist, the identity of the individual obtaining the controlled substance. The log book entry must contain the printed name, address, telephone number if available, and driver's license number or other suitable identification number, and signature of the person obtaining the controlled substance or drug. If the individual does not have suitable identification or it is impracticable to obtain such identification, the pharmacist may dispense the controlled substance or drug only when the pharmacist determines, in the exercise of her or his professional

judgment, that the order is valid and necessary for treatment. 2 In such a case, the pharmacist or his or her designee must 3 obtain the other information required under this paragraph, 4 and the pharmacist or pharmacist's designee must sign the log 5 to indicate that suitable identification was not available and 6 that the pharmacist's professional judgment was exercised 7 prior to dispensing the controlled substance or drug. The Board of Pharmacy may adopt, by rule, procedures for a 8 9 pharmacist to verify the validity of a prescription for a 10 Schedule II controlled substance; other drug designated by the Attorney General under this section; or codeine, hydrocodone, 11 12 dihydrocodeine, ethylmorphine, or morphine, as scheduled in Schedule II and Schedule III, for circumstances when it is 13 14 otherwise impracticable for the pharmacist or dispensing 15 practitioner to obtain suitable identification from the 16 patient or the patient's agent. For purposes of this section, 17 identification is suitable only if it contains the photograph, the printed name, and the signature of the individual 18 19 obtaining the Schedule II controlled substance or drug of 20 abuse under the prescription-monitoring system. 21

- (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

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numerical notation of quantity on the face of the 1 2 prescription. 3 (k) A pharmacist may not dispense more than a 30-day 4 supply of a controlled substance listed in Schedule III upon 5 an oral prescription. 6 (1) A pharmacist may not knowingly fill a prescription 7 that has been mutilated or forged for a Schedule II controlled substance; codeine, hydrocodone, dihydrocodeine, 8 9 ethylmorphine, and morphine, as scheduled in Schedule II and Schedule III; or a drug of abuse under the 10 prescription-monitoring system which has been designated by 11 12 the Attorney General by rule. Section 11. Section 893.065, Florida Statutes, is 13 14 created to read: 893.065 Voluntary program for counterfeit-resistant 15 prescription blanks. -- The Department of Legal Affairs, may, by 16 17 rule, after consultation with the prescription monitoring program advisory council established under this act, develop a 18 19 voluntary program for counterfeit-resistant prescription 20 blanks to be used by practitioners who prescribe controlled substances or any drug of abuse under the electronic 21 prescription-monitoring system which has been designated by 22 23 the Attorney General. The Department of Legal Affairs may develop, by rule, a counterfeit-resistant prescription blank 24 for voluntary use by practitioners who prescribe controlled 25 26 substances or any drug of abuse under the electronic prescription monitoring system. The Department of Legal 27 Affairs may, by rule, require the blanks to be printed on 28 29 distinctive paper, serially numbered, and to bear the preprinted name, address, and category of professional 30 31 licensure of the practitioner to whom they are issued and that

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   practitioner's federal registry number for controlled
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    substances. The prescription blanks may be issued by the
    Department of Legal Affairs in serially numbered groups to
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    prescribing practitioners. If such blanks are issued by the
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    Department of Legal Affairs to implement a voluntary program
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    for counterfeit-resistant prescription blanks, a copy must be
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    available for inspection by the Department of Legal Affairs,
    and all costs of preparing, issuing, and tracking prescription
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    blanks may be covered by the Department of Legal Affairs.
           Section 12. This act shall take effect July 1, 2002.
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CODING: Words stricken are deletions; words underlined are additions.