PREScribing LAWS AND RULES FOR FLORIDA LICENSED HEALTHCARE PROFESSIONALS

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DISCLOSURES

- I HAVE NO RELEVANT DISCLOSURES AT THIS TIME.
Section 1

Federal and State Controlled Substance Prescribing Laws and Rules
FEDERAL & FLORIDA REGULATORY SOURCES

- FEDERAL
  - Drug Enforcement Administration
  - U.S. Food and Drug Administration
- FLORIDA
  - Chapter 456, Florida Statutes
  - Chapter 458/459, Florida Statutes (Practice Acts)
  - Chapter 499, Florida Statutes
  - Chapter 893, Florida Statutes
  - Rule Chapters 64B8 and 64B15, Florida Administrative Code
§1306.04 Purpose of issue of prescription.
(A) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

§1306.05 Manner of issuance of prescriptions.
(A) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

D) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

(F) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.
CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

§1306.11 Requirement of prescription.

(A) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (D) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner’s agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (E), (F), or (G) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

§1306.21 Requirement of prescription.

(A) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner’s agent to the pharmacy, an electronic prescription that meets the requirements of this part and Part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Sec. 1306.05, except for the signature of the practitioner.
CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

§1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(A) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(B)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (B) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.
456.42 Written Prescriptions for Medicinal Drugs.—(1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.
§893.049(1)(d), (e), F.S.

(d) Each prescription written by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include a written and a numerical notation of the quantity of the controlled substance prescribed and a notation of the date in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance, but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

(e) A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.
**§456.44, F.S. Florida Controlled Substance Prescribing**

This law was created in 2011. It provides definitions, exceptions, registration and standards of practice requirements, which are applicable to physicians who prescribe controlled substances for the treatment of “chronic nonmalignant pain,” which is defined as “pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.”

If you prescribe any controlled substance for the treatment of chronic nonmalignant pain, you must:

(A) Designate yourself as a controlled substance prescribing practitioner on his or her practitioner profile.

(B) Comply with the requirements of this law and applicable board rules.
§456.44, F.S. FLORIDA CONTROLLED SUBSTANCE PRESCRIBING

DOES NOT APPLY TO:

BOARD-ELIGIBLE OR BOARD-CERTIFIED ANESTHESIOLOGIST, PHYSIATRIST, RHEUMATOLOGIST, OR NEUROLOGIST, OR TO A BOARD-CERTIFIED PHYSICIAN WHO HAS SURGICAL PRIVILEGES AT A HOSPITAL OR AMBULATORY SURGERY CENTER AND PRIMARILY PROVIDES SURGICAL SERVICES.

BOARD-ELIGIBLE OR BOARD-CERTIFIED MEDICAL SPECIALIST WHO HAS ALSO COMPLETED A FELLOWSHIP IN PAIN MEDICINE APPROVED BY THE ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION OR THE AMERICAN OSTEOPATHIC ASSOCIATION, OR WHO IS BOARD ELIGIBLE OR BOARD CERTIFIED IN PAIN MEDICINE BY THE AMERICAN BOARD OF PAIN MEDICINE, THE AMERICAN BOARD OF INTERVENTIONAL PAIN PHYSICIANS, THE AMERICAN ASSOCIATION OF PHYSICIAN SPECIALISTS, OR A BOARD APPROVED BY THE AMERICAN BOARD OF MEDICAL SPECIALTIES OR THE AMERICAN OSTEOPATHIC ASSOCIATION AND PERFORMS INTERVENTIONAL PAIN PROCEDURES OF THE TYPE ROUTINELY BILLED USING SURGICAL CODES.

A REGISTRANT WHO PRESCRIBES MEDICALLY NECESSARY CONTROLLED SUBSTANCES FOR A PATIENT DURING AN INPATIENT STAY IN A HOSPITAL LICENSED UNDER CHAPTER 395.
§456.44, F.S.  Controlled substance prescribing.—

(3) Standards of Practice for Treatment of Chronic Nonmalignant Pain.—The Standards of Practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(A) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient’s risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient’s risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(B) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.
§456.44, F.S.  **CONTROLLED SUBSTANCE PRESCRIBING.**—

(c) The registrant shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient’s surrogate or guardian if the patient is incompetent. The registrant shall use a written controlled substance agreement between the registrant and the patient outlining the patient’s responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.
2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant unless otherwise authorized by the treating registrant and documented in the medical record.
§456.44, F.S.  CONTROLLED SUBSTANCE PRESCRIBING.—

(D)  The patient shall be seen by the registrant at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient’s progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant’s evaluation of the patient’s progress. If treatment goals are not being achieved, despite medication adjustments, the registrant shall reevaluate the appropriateness of continued treatment. The registrant shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(E)  The registrant shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or a psychiatrist.
§456.44. F.S. CONTROLLED SUBSTANCE PRESCRIBING.—

(F) A registrant must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.
9. Periodic reviews.
10. Results of any drug testing.
12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
13. The registrant’s full name presented in a legible manner.
§456.44, F.S. CONTROLLED SUBSTANCE PRESCRIBING.—

(g) A registrant shall immediately refer patients with signs or symptoms of substance abuse to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant’s report, a prescribing registrant shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant’s written report, the prescribing registrant shall incorporate the consultant’s recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient’s medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the registrant shall be documented in the patient’s medical record.
THE VERY LATEST! CS/CS/HB 21

THE 2018 LEGISLATURE AMENDED §456.44 TO ADDRESS OPIOID ABUSE BY EXPANDING THE USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM (PDMP), INCREASING REGULATION OF PRESCRIBERS AND DISPENSERS, AMENDING CRIMINAL LAWS, AND MAKING APPROPRIATIONS.

THE BILL LIMITS THE PRESCRIPTION FOR A SCHEDULE II OPIOID FOR ACUTE PAIN TO A 3-DAY SUPPLY, OR A 7-DAY SUPPLY IF DEEMED MEDICALLY NECESSARY BY THE PRESCRIBER. THE BILL EXCLUDES PAIN RELATED TO CANCER, TERMINAL ILLNESS, PALLIATIVE CARE, AND SERIOUS TRAUMATIC INJURY FROM THESE PRESCRIBING LIMITS. THE BILL REQUIRES REGULATORY BOARDS WITHIN THE DEPARTMENT OF HEALTH (DOH) TO ADOPT RULES ESTABLISHING GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR ACUTE PAIN. THE BILL ALSO REQUIRES A HEALTH CARE PRACTITIONER TO REVIEW A PATIENT’S PDMP HISTORY BEFORE PRESCRIBING OR DISPENSING A CONTROLLED SUBSTANCE, WITH EXEMPTIONS. THE BILL AUTHORIZES A DISPENSING PRACTITIONER WHO IS APPROVED TO PROVIDE MEDICATION-ASSISTED TREATMENT FOR SUBSTANCE ABUSE DISORDERS TO DISPENSE SCHEDULE II AND III SUBSTANCES FOR SUCH PURPOSE.
(A) "Acute pain" means the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

2. A terminal condition. For purposes of this subparagraph, the term "terminal condition" means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.
3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.
4. A traumatic injury with an Injury Severity Score of 9 or greater.
STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN

(4) STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN.—The applicable boards shall adopt rules establishing guidelines for prescribing controlled substances for acute pain, including evaluation of the patient, creation and maintenance of a treatment plan, obtaining informed consent and agreement for treatment, periodic review of the treatment plan, consultation, medical record review, and compliance with controlled substance laws and regulations. Failure of a prescriber to follow such guidelines constitutes grounds for disciplinary action pursuant to s. 456.072(1)(g), punishable as provided in s. 456.072(2).

(5) PRESCRIPTION SUPPLY.—

(a) For the treatment of acute pain, a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812 may not exceed a 3-day supply, except that up to a 7-day supply may be prescribed if:

1. The prescriber, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient’s pain as an acute medical condition;
2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the prescription; and
3. The prescriber adequately documents in the patient’s medical records the acute medical condition and lack of alternative treatment options that justify deviation from the 3-day supply limit established in this subsection.

(b) For the treatment of pain other than acute pain, a prescriber must indicate "NONACUTE PAIN" on a prescription for an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

(6) EMERGENCY OPIOID ANTAGONIST.—For the treatment of pain related to a traumatic injury with an Injury Severity Score of 9 or greater, a prescriber who prescribes a Schedule II controlled substance listed in s. 893.03 or 21 U.S.C. s. 812 must concurrently prescribe an emergency opioid antagonist, as defined in s. 381.887(1).
MANDATORY C.E. ON CONTROLLED SUBSTANCE PRESCRIBING

Section 456.0301, F.S., was enacted by CS/CS/HB 21. It requires each appropriate board to require any licensee who has a DEA registration to complete a 2 hour C.E. course on prescribing controlled substances. The course must address:

Current standards on prescribing controlled substances, particularly opiates;

Alternatives to the current standards on controlled substance prescribing;

Nonpharmacological therapies;

Prescribing emergency opioid antagonists; and

Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

The course must be offered by a statewide association of physicians in this state that is accredited to provide AMA category 1 or AOA category 1-A continuing education (i.e. the FMA or FOMA).

This course must be completed by January 31, 2019 and DOH may not renew the license of any prescriber who fails to complete this CE requirement.
§893.055: PRESCRIPTION DRUG MONITORING PROGRAM (SUBSTANTIALLY RE-WRITTEN BY CS/CS/HB 21)

893.055 PRESCRIPTION DRUG MONITORING PROGRAM.—

(2)(A) THE DEPARTMENT SHALL MAINTAIN AN ELECTRONIC SYSTEM TO COLLECT AND STORE CONTROLLED SUBSTANCE DISPENSING INFORMATION AND SHALL RELEASE THE INFORMATION AS AUTHORIZED IN THIS SECTION AND S. 893.0551. THE ELECTRONIC SYSTEM MUST:

1. NOT INFRINGE UPON THE LEGITIMATE PRESCRIBING OR DISPENSING OF A CONTROLLED SUBSTANCE BY A PRESCRIBER OR DISPENSER ACTING IN GOOD FAITH AND IN THE COURSE OF PROFESSIONAL PRACTICE.

2. BE CONSISTENT WITH STANDARDS OF THE AMERICAN SOCIETY FOR AUTOMATION IN PHARMACY.

3. COMPLY WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT AS IT PERTAINS TO PROTECTED HEALTH INFORMATION, ELECTRONIC PROTECTED HEALTH INFORMATION, AND ALL OTHER RELEVANT STATE AND FEDERAL PRIVACY AND SECURITY LAWS AND REGULATIONS.

4. PURGE OR CAUSE TO BE PURGED INFORMATION IN THE DATABASE THAT IS MORE THAN 4 YEARS OLD.

(B) THE DEPARTMENT MAY COLLABORATE WITH PROFESSIONAL HEALTH CARE REGULATORY BOARDS, APPROPRIATE ORGANIZATIONS, AND OTHER STATE AGENCIES TO IDENTIFY INDICATORS OF CONTROLLED SUBSTANCE ABUSE.
§893.055: Prescription Drug Monitoring Program (Substantially Re-written by CS/CS/HB 21)

(3)(A) For each controlled substance dispensed to a patient in this state, the following information must be reported by the dispenser to the system as soon thereafter as possible but no later than the close of the next business day after the day the controlled substance is dispensed unless an extension or exemption is approved by the Department:

1. The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification or other appropriate identifier, and the date of the prescription.

2. The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the system.

3. The full name, address, telephone number, and date of birth of the person for whom the prescription was written.

4. The name, national drug code, quantity, and strength of the controlled substance dispensed.

5. The full name, federal Drug Enforcement Administration registration number, State of Florida Department of Health issued pharmacy permit number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, address, federal Drug Enforcement Administration registration number, State of Florida Department of Health issued license number, and National Provider Identification.

6. Whether the drug was dispensed as an initial prescription or a refill, and the number of refills ordered.

7. The name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.

8. Other appropriate identifying information as determined by department rule.
§893.055: PRESCRIPTION DRUG MONITORING PROGRAM (SUBSTANTIALLY RE-WRITTEN BY CS/CS/HB 21)

(4) The following persons must be provided direct access to information in the system:

(A) A prescriber or dispenser or his or her designee.
(B) An employee of the United States Department of Veterans Affairs, the United States Department of Defense, or the Indian Health Service who provides health care services pursuant to such employment and who has the authority to prescribe or dispense controlled substances shall have access to the information in the program's system upon verification of employment.
(C) The program manager or designated program and support staff to administer the system.

1. In order to calculate performance measures pursuant to subsection (14), the program manager or program and support staff members who have been directed by the program manager to calculate performance measures may have direct access to information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser.

2. The program manager or designated program and support staff must provide the department, upon request, data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information for public health care and safety initiatives purposes.

3. The program manager, upon determining a pattern consistent with the department's rules established under subsection (16), may provide relevant information to the prescriber and dispenser.

4. The program manager, upon determining a pattern consistent with the rules established under subsection (16) and having cause to believe a violation of s. 893.13(7)(A)8., (8)(A), or (8)(B) has occurred, may provide relevant information to the applicable law enforcement agency.
§893.055: PRESCRIPTION DRUG MONITORING PROGRAM
(SUBSTANTIALLY RE-WRITTEN BY CS/CS/HB 21)

(5) THE FOLLOWING ENTITIES MAY NOT DIRECTLY ACCESS INFORMATION IN THE SYSTEM, BUT MAY REQUEST INFORMATION FROM THE PROGRAM MANAGER OR DESIGNATED PROGRAM AND SUPPORT STAFF:

(A) THE DEPARTMENT AND ITS HEALTH CARE REGULATORY BOARDS, AS APPROPRIATE, FOR INVESTIGATIONS INVOLVING LICENSEES AUTHORIZED TO PRESCRIBE OR DISPENSE CONTROLLED SUBSTANCES.

(B) THE ATTORNEY GENERAL FOR MEDICAID FRAUD CASES INVOLVING PRESCRIBED CONTROLLED SUBSTANCES.

(C) A LAW ENFORCEMENT AGENCY DURING ACTIVE INVESTIGATIONS OF POTENTIAL CRIMINAL ACTIVITY, FRAUD, OR THEFT REGARDING PRESCRIBED CONTROLLED SUBSTANCES.

(D) A MEDICAL EXAMINER WHEN CONDUCTING AN AUTHORIZED INVESTIGATION UNDER S. 406.11, TO DETERMINE THE CAUSE OF DEATH OF AN INDIVIDUAL.

(E) AN IMPAIRED PRACTITIONER CONSULTANT WHO IS RETAINED BY THE DEPARTMENT UNDER S. 456.076 TO REVIEW THE SYSTEM INFORMATION OF AN IMPAIRED PRACTITIONER PROGRAM PARTICIPANT OR A REFERRAL WHO HAS AGREED TO BE EVALUATED OR MONITORED THROUGH THE PROGRAM AND WHO HAS SEPARATELY AGREED IN WRITING TO THE CONSULTANT’S ACCESS TO AND REVIEW OF SUCH INFORMATION.

(F) A PATIENT OR THE LEGAL GUARDIAN OR DESIGNATED HEALTH CARE SURROGATE OF AN INCAPACITATED PATIENT WHO SUBMITS A WRITTEN AND NOTARIZED REQUEST THAT INCLUDES THE PATIENT’S FULL NAME, ADDRESS, PHONE NUMBER, DATE OF BIRTH, AND A COPY OF A GOVERNMENT-ISSUED PHOTO IDENTIFICATION.
§893.055: PRESCRIPTION DRUG MONITORING PROGRAM (SUBSTANTIALLY RE-WRITTEN BY CS/CS/HB 21)

(8) A prescriber or dispensing or a designee of a prescriber or dispensing must consult the system to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient age 16 or older. This requirement does not apply when prescribing or dispensing a nonopioid controlled substance listed in Schedule V of s. 893.03 or 21 U.S.C. 812. For purposes of this subsection, a "nonopioid controlled substance" is a controlled substance that does not contain any amount of a substance listed as an opioid in s. 893.03 or 21 U.S.C. 812.

(a) The duty to consult the system does not apply when the system:

1. Is determined by the department to be nonoperational; or
2. Cannot be accessed by the prescriber or dispensing or a designee of the prescriber or dispensing because of a temporary technological or electrical failure.

(b) A prescriber or dispensing or designee of a prescriber or dispensing who does not consult the system under this subsection shall document the reason he or she did not consult the system in the patient’s medical record or prescription record and shall not prescribe or dispense greater than a 3-day supply of a controlled substance to the patient.

(c) The department shall issue a nondisciplinary citation to any prescriber or dispensing who fails to consult the system as required by this subsection for an initial offense. Each subsequent offense is subject to disciplinary action pursuant to s. 456.073.

(9) A person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
(10) Information in the Prescription Drug Monitoring Program’s System may be released only as provided in this section and s. 893.0551. The content of the System is intended to be informational only. Information in the System is not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of information in the System. The Program Manager and authorized persons who participate in preparing, reviewing, issuing, or any other activity related to management of the System may not be permitted or required to testify in any such civil or administrative action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with management of the System.

(11) A prescriber or dispenser, or his or her designee, may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient’s controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the Prescription Drug Monitoring Program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.
64K-1.003 Accessing Database.

(1) Definitions:

(A) “Designee” means a person, preferably a licensed or certified health care professional, appointed to act as an agent of a prescriber or dispenser for the purposes of requesting or receiving information from the Prescription Drug Monitoring Program database, E-FORCSE®.

(B) A registered designee will not have access to the database until the designating prescriber or dispenser affirmatively accepts responsibility for the designee and links the designee to a pharmacy, prescriber or dispenser E-FORCSE® account as described in the “Training Guide for Florida Practitioners and Pharmacists.” The linking process will require the prescriber or dispenser to certify that the designee has reviewed the “Training Guide for Florida Practitioners and Pharmacists” and the “Information Security and Privacy Training Course for Designees.” The designating prescriber or dispenser shall maintain printed copies of the certification of these reviews and make them available to the program manager upon request.

(C) Registered designees who do not access the E-FORCSE® database for a period in excess of six months will be deactivated. Deactivated designees may reapply for access.
RULES 64B8-9.012 AND 64B15-14.005: STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

These rules and §456.44. F.S are very similar. That is because the legislature basically copied these rules, which were promulgated in 1999-2000, into this statute passed in 2011.

The rules contain the following definitions:

(A) Acute Pain. For the purpose of this rule, “Acute pain” is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(D) Chronic Pain. For the purpose of this rule, “Chronic pain” is defined as a pain state which is persistent.

(E) Pain. For the purpose of this rule, “Pain” is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.
RULES 64B8-9.012 AND 64B15-14.005: STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

(3) STANDARDS. THE BOARD HAS ADOPTED THE FOLLOWING STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR PAIN CONTROL:


(B) TREATMENT PLAN. THE WRITTEN TREATMENT PLAN SHALL STATE OBJECTIVES THAT WILL BE USED TO DETERMINE TREATMENT SUCCESS, SUCH AS PAIN RELIEF AND IMPROVED PHYSICAL AND PSYCHOSOCIAL FUNCTION, AND SHALL INDICATE IF ANY FURTHER DIAGNOSTIC EVALUATIONS OR OTHER TREATMENTS ARE PLANNED. AFTER TREATMENT BEGINS, THE PHYSICIAN SHALL ADJUST DRUG THERAPY, IF NECESSARY, TO THE INDIVIDUAL MEDICAL NEEDS OF EACH PATIENT. OTHER TREATMENT MODALITIES OR A REHABILITATION PROGRAM MAY BE NECESSARY DEPENDING ON THE ETIOLOGY OF THE PAIN AND THE EXTENT TO WHICH THE PAIN IS ASSOCIATED WITH PHYSICAL AND PSYCHOSOCIAL IMPAIRMENT.
RULES 64B8-9.012 AND 64B15-14.005: STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

(C) INFORMED CONSENT AND AGREEMENT FOR TREATMENT. THE PHYSICIAN SHALL DISCUSS THE RISKS AND BENEFITS OF THE USE OF CONTROLLED SUBSTANCES WITH THE PATIENT, PERSONS DESIGNATED BY THE PATIENT, OR WITH THE PATIENT’S SURROGATE OR GUARDIAN IF THE PATIENT IS INCOMPETENT. THE PATIENT SHALL RECEIVE PRESCRIPTIONS FROM ONE PHYSICIAN AND ONE PHARMACY WHERE POSSIBLE. IF THE PATIENT IS DETERMINED TO BE AT HIGH RISK FOR MEDICATION ABUSE OR HAVE A HISTORY OF SUBSTANCE ABUSE, THE PHYSICIAN SHALL EMPLOY THE USE OF A WRITTEN AGREEMENT BETWEEN PHYSICIAN AND PATIENT OUTLINING PATIENT RESPONSIBILITIES, INCLUDING, BUT NOT LIMITED TO:

1. URINE/SERUM MEDICATION LEVELS SCREENING WHEN REQUESTED;
2. NUMBER AND FREQUENCY OF ALL PRESCRIPTION REFILLS; AND
3. REASONS FOR WHICH DRUG THERAPY MAY BE DISCONTINUED (I.E., VIOLATION OF AGREEMENT).
RULES 64B8-9.012 AND 64B15-14.005: STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN


(E) CONSULTATION. THE PHYSICIAN SHALL BE WILLING TO REFER THE PATIENT AS NECESSARY FOR ADDITIONAL EVALUATION AND TREATMENT IN ORDER TO ACHIEVE TREATMENT OBJECTIVES. SPECIAL ATTENTION MUST BE GIVEN TO THOSE PAIN PATIENTS WHO ARE AT RISK FOR MISUSING THEIR MEDICATIONS AND THOSE WHOSE LIVING ARRANGEMENTS POSE A RISK FOR MEDICATION MISUSE OR DIVERSION. THE MANAGEMENT OF PAIN IN PATIENTS WITH A HISTORY OF SUBSTANCE ABUSE OR WITH A COMORBID PSYCHIATRIC DISORDER REQUIRES EXTRA CARE, MONITORING, AND DOCUMENTATION, AND MAY REQUIRE CONSULTATION WITH OR REFERRAL TO AN EXPERT IN THE MANAGEMENT OF SUCH PATIENTS.
RULES 64B8-9.012 AND 64B15-14.005: STANDARDS FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

(F) MEDICAL RECORDS. THE PHYSICIAN IS REQUIRED TO KEEP ACCURATE AND COMPLETE RECORDS TO INCLUDE, BUT NOT BE LIMITED TO:

1. THE COMPLETE MEDICAL HISTORY AND A PHYSICAL EXAMINATION, INCLUDING HISTORY OF DRUG ABUSE OR DEPENDENCE, AS APPROPRIATE;

2. DIAGNOSTIC, THERAPEUTIC, AND LABORATORY RESULTS;

3. EVALUATIONS AND CONSULTATIONS;

4. TREATMENT OBJECTIVES;

5. DISCUSSION OF RISKS AND BENEFITS;

6. TREATMENTS;

7. MEDICATIONS (INCLUDING DATE, TYPE, DOSAGE, AND QUANTITY PRESCRIBED);

8. INSTRUCTIONS AND AGREEMENTS;

9. DRUG TESTING RESULTS; AND

10. PERIODIC REVIEWS. RECORDS MUST REMAIN CURRENT, MAINTAINED IN AN ACCESSIBLE MANNER, READILY AVAILABLE FOR REVIEW, AND MUST BE IN FULL COMPLIANCE WITH RULE 64B8-9.003, F.A.C, AND SECTION 458.331(1)(M), F.S.
(1) “TELEMEDICINE” means the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.

(2) The standard of care, as defined in Section 456.50(1)(e), F.S., shall remain the same regardless of whether a Florida licensed physician or physician assistant provides health care services in person or by telemedicine.

(3) Florida licensed physicians and physician assistants providing health care services by telemedicine are responsible for the quality of the equipment and technology employed and are responsible for their safe use. Telemedicine equipment and technology must be able to provide, at a minimum, the same information to the physician and physician assistant which will enable them to meet or exceed the prevailing standard of care for the practice of medicine.
(4) Controlled substances shall not be prescribed through the use of telemedicine except for the treatment of psychiatric disorders. This provision does not preclude physicians or physician assistants from ordering controlled substances through the use of telemedicine for patients hospitalized in a facility licensed pursuant to Chapter 395, F.S.

(5) Prescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances, as well as prescribing legend drugs other than in the course of a physician’s professional practice.

(6) Physicians and physician assistants shall not provide treatment recommendations, including issuing a prescription, via electronic or other means, unless the following elements have been met:

(A) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.

(B) Discussion between the physician or the physician assistant and the patient regarding treatment options and the risks and benefits of treatment.

(C) Maintenance of contemporaneous medical records meeting the requirements of Rule 64B8-9.003, F.A.C.
(7) The practice of medicine by telemedicine does not alter any obligation of the physician or the physician assistant regarding patient confidentiality or recordkeeping.

(8) A physician-patient relationship may be established through telemedicine.

(9)(A) Nothing contained in this rule shall prohibit consultations between physicians or the transmission and review of digital images, pathology specimens, test results, or other medical data by physicians or other qualified providers related to the care of Florida patients.

(B) This rule does not apply to emergency medical services provided by emergency physicians, emergency medical technicians (EMTs), paramedics, and emergency dispatchers. Emergency medical services are those activities or services to prevent or treat a sudden critical illness or injury and to provide emergency medical care and prehospital emergency medical transportation to sick, injured, or otherwise incapacitated persons in this state.

(C) The provisions of this rule shall not apply where a physician or physician assistant is treating a patient with an emergency medical condition that requires immediate medical care. An emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.

(D) The provisions of this rule shall not be construed to prohibit patient care in consultation with another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient’s treatment, including the use of any prescribed medications, nor on-call or cross-coverage situations in which the physician has access to patient records.
Section 2
Current Florida Statistics Regarding Morbidity and Mortality of Controlled Substance Related Deaths
FLORIDA’S OPIOID CRISIS DEATH MAP 2015

2,538
Total Direct Cause Deaths from Opioids

3,896
Deaths with Opioids Present

FLORIDA’S OPIOID CRISIS - HOSPITAL COSTS 2015

Source: Compiled in affiliation with the Palm Beach Post and the Agency for Health Care Administration

Some general statewide trends for the first half of 2016 (January – June) are listed below. **Please note: comparisons to 2015 are based on data for January through June.**

- Total drug-related deaths increased by 13.9 percent (658 more) when compared with the first half of 2015.
- 3,044 individuals (466 more deaths than the first half of 2015) died with one or more prescription drugs in their system. The drugs were identified as both the cause of death and present in the decedent. These drugs may have also been mixed with illicit drugs and/or alcohol.
- 1,616 individuals (440 more deaths than the first half of 2015) died with at least one prescription drug in their system that was identified as the cause of death. These drugs may have been mixed with other prescription drugs, illicit drugs, and/or alcohol.
- Occurrences of fentanyl and fentanyl analog caused deaths significantly increased in the first half of 2016. In addition to illicit (non-prescription) fentanyl, the following analogs were noted – Acetyl Fentanyl, Butyryl Fentanyl, Carfentanil, Despropionyl Fentanyl (4-ANPP), Fluoroisobutyryl Fentanyl, Para-fluorobutyryl Fentanyl, and Furanyl Fentanyl. 4-ANPP is a precursor chemical used in the manufacture of fentanyl and is also a metabolite of fentanyl.
- The six most frequently occurring drugs found in individuals were ethyl alcohol (2,466), benzodiazepines (2,344, including 850 alprazolam deaths), cocaine (1,144), cannabinoids (1,071), morphine (878), and fentanyl (805). The increase in positive cannabinoid findings is due to the increased surveillance by medical examiner offices and not a direct reflection of the increased use of cannabis by decedents.
- The drugs that caused the most deaths were fentanyl (704), cocaine (643), benzodiazepines (632, including 355 alprazolam deaths), morphine (559), heroin (406), ethyl alcohol (405), oxycodone (324), methadone (156), and fentanyl analogs (149). Of these drugs, heroin (93.5 percent), fentanyl (87.5 percent), fentanyl analogs (81.4 percent), methadone (65.0 percent), morphine (63.7 percent), cocaine (56.2 percent), and oxycodone (51.3 percent) were listed as causing death in more than 50 percent of the deaths in which these drugs were found.
- Occurrences of heroin increased by 25.1 percent (87 more) and deaths caused by heroin increased by 25.3 percent (82 more) compared with the first half of 2015; 96 percent of all heroin occurrences were in accidental deaths.
- Occurrences of fentanyl increased by 98.8 percent (400 more) and deaths caused by fentanyl increased by 139.5 percent (410 more) compared with the first half of 2015.
- Occurrences of methadone remained the same and hydrocodone decreased by 9.0 percent (32 less) compared with the first half of 2015. Deaths caused by methadone decreased by 1.3 percent (2 less) and hydrocodone increased by 2.7 percent (3 more) during the same period.
## Comparison of Drug Occurrences in Decedents

<table>
<thead>
<tr>
<th>DRUG PRESENT IN BODY</th>
<th>JANUARY-JUNE 2015</th>
<th>JANUARY-JUNE 2016</th>
<th>PERCENTAGE CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amphetamines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphetamine</td>
<td>182</td>
<td>266</td>
<td>46.2</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>132</td>
<td>237</td>
<td>79.5</td>
</tr>
<tr>
<td><strong>Benzodiazepines</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alprazolam</td>
<td>674</td>
<td>850</td>
<td>26.1</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>52</td>
<td>48</td>
<td>-7.7</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>224</td>
<td>238</td>
<td>6.3</td>
</tr>
<tr>
<td>Diazepam</td>
<td>274</td>
<td>300</td>
<td>9.5</td>
</tr>
<tr>
<td>Estazolam</td>
<td>2</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>Flunitrazepam</td>
<td>1</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>4</td>
<td>2</td>
<td>*</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>114</td>
<td>109</td>
<td>-4.4</td>
</tr>
<tr>
<td>Midazolam</td>
<td>95</td>
<td>78</td>
<td>-17.9</td>
</tr>
<tr>
<td>Nordiazepam</td>
<td>322</td>
<td>331</td>
<td>2.8</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>196</td>
<td>164</td>
<td>-16.3</td>
</tr>
<tr>
<td>Temazepam</td>
<td>253</td>
<td>219</td>
<td>-13.4</td>
</tr>
<tr>
<td>Triazolam</td>
<td>2</td>
<td>5</td>
<td>*</td>
</tr>
<tr>
<td><strong>Ethanol</strong></td>
<td>2,308</td>
<td>2,466</td>
<td>6.8</td>
</tr>
<tr>
<td><strong>Hallucinogens</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>0</td>
<td>0</td>
<td>*</td>
</tr>
<tr>
<td>PCP Analogs</td>
<td>N/A</td>
<td>2</td>
<td>N/A</td>
</tr>
<tr>
<td>Phenethylamines/Piperazines</td>
<td>11</td>
<td>17</td>
<td>*</td>
</tr>
<tr>
<td>Tryptamines</td>
<td>1</td>
<td>1</td>
<td>*</td>
</tr>
</tbody>
</table>

*Due to the small number of occurrences, percent changes were not calculated.

N/A – Drug was not tracked during the previous reporting year, therefore a comparison could not be calculated.

Note: Many deaths were found to have several drugs contributing to the death, and therefore, the count of specific drugs listed is greater than the number of deaths.
## Comparison of Drug Occurrences in Decedents (continued)

<table>
<thead>
<tr>
<th>Drug Present in Body</th>
<th>January-June 2015</th>
<th>January-June 2016</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inhalants</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halogenated</td>
<td>25</td>
<td>24</td>
<td>*</td>
</tr>
<tr>
<td>Helium</td>
<td>13</td>
<td>4</td>
<td>*</td>
</tr>
<tr>
<td>Hydrocarbon</td>
<td>2</td>
<td>6</td>
<td>*</td>
</tr>
<tr>
<td>Nitrous Oxide</td>
<td>1</td>
<td>1</td>
<td>*</td>
</tr>
<tr>
<td><strong>Opioids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>29</td>
<td>55</td>
<td>89.7</td>
</tr>
<tr>
<td>Codeine</td>
<td>211</td>
<td>236</td>
<td>11.8</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>405</td>
<td>805</td>
<td>98.8</td>
</tr>
<tr>
<td>Fentanyl Analogs</td>
<td>N/A</td>
<td>183</td>
<td>N/A</td>
</tr>
<tr>
<td>Heroin</td>
<td>347</td>
<td>434</td>
<td>25.1</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>357</td>
<td>325</td>
<td>-9.0</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>239</td>
<td>273</td>
<td>14.2</td>
</tr>
<tr>
<td>Meperidine</td>
<td>5</td>
<td>4</td>
<td>*</td>
</tr>
<tr>
<td>Methadone</td>
<td>240</td>
<td>240</td>
<td>0.0</td>
</tr>
<tr>
<td>Morphine</td>
<td>683</td>
<td>878</td>
<td>28.6</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>528</td>
<td>632</td>
<td>19.7</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>174</td>
<td>240</td>
<td>37.9</td>
</tr>
<tr>
<td>Tramadol</td>
<td>239</td>
<td>210</td>
<td>-12.1</td>
</tr>
<tr>
<td><strong>Cannabinoids</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cannabinoids</td>
<td>804</td>
<td>1,071</td>
<td>33.2</td>
</tr>
<tr>
<td>Carisoprodol/Meprobamate</td>
<td>64</td>
<td>68</td>
<td>6.3</td>
</tr>
<tr>
<td>Cathinones</td>
<td>88</td>
<td>41</td>
<td>-53.4</td>
</tr>
<tr>
<td>Cocaine</td>
<td>853</td>
<td>1,144</td>
<td>34.1</td>
</tr>
<tr>
<td>GHB</td>
<td>1</td>
<td>1</td>
<td>*</td>
</tr>
<tr>
<td>Ketamine</td>
<td>12</td>
<td>36</td>
<td>200.0\textsuperscript{1}</td>
</tr>
<tr>
<td>Sympathomimetic Amines</td>
<td>15</td>
<td>14</td>
<td>*</td>
</tr>
<tr>
<td>Synthetic Cannabinoids</td>
<td>10</td>
<td>10</td>
<td>*</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>104</td>
<td>128</td>
<td>23.1</td>
</tr>
</tbody>
</table>

*Due to the small number of occurrences, percent changes were not calculated.

N/A – Drug was not tracked during the previous reporting year, therefore a comparison could not be calculated.

\textsuperscript{1}The increase in ketamine occurrences is largely due to the clinical use of ketamine as a sedative and anesthetic in the hospital.

Note: Many deaths were found to have several drugs contributing to the death, and therefore, the count of specific drugs listed is greater than the number of deaths.
Section 3
Pharmacology of Opiates
Opioids are a group of analgesic agents commonly used in clinical practice. There are three classical opioid receptors (DOP, KOP and MOP), while the novel NOP receptor is considered to be a non-opioid branch of the opioid receptor family.

Opioids can act at these receptors as agonists, antagonists or partial agonists. Opioid agonists bind to G-protein coupled receptors to cause cellular hyperpolarization. Most clinically relevant opioid analgesics bind to MOP receptors in the central and peripheral nervous system in an agonist manner to elicit analgesia.

Opioids may also be classified according to their mode of synthesis into alkaloids, semi-synthetic and synthetic compounds.
Basic Opioid Pharmacology

- Opioids can also be classified according to their effect at opioid receptors. In this manner opioids can be considered as agonists, partial agonists and antagonists.
- Agonists interact with a receptor to produce a maximal response from that receptor (analgesia following morphine administration is an example).
- Conversely, antagonists bind to receptors but produce no functional response, while at the same time preventing an agonist from binding to that receptor (naloxone).
- Partial agonists bind to receptors but elicit only a partial functional response no matter the amount of drug administered (buprenorphine).
Basic Opioid Pharmacology

- In clinical practice the stimulation of the differing opioid receptors produces a range of effects, which are often dependent upon the location of the receptor, along with analgesia.
- Agonists binding to MOP receptors may cause analgesia, but also sedation, respiratory depression, bradycardia, nausea and vomiting and a reduction in gastric motility.
- Activation of DOP receptors can cause spinal and supraspinal analgesia and reduce gastric motility, while KOP receptor stimulation may produce spinal analgesia, diuresis and dysphoria.
- Spinally, N/OFQ has been shown to produce analgesia and hyperalgesia, dependent upon the administered concentration, and allodynia. Supraspinally, when administered intracerebrovascularly it is thought to produce a pro-nociceptive anti-analgesic effect, owing to an inhibition of endogenous opioid tone.
Basic Opioid Pharmacology

- Opioids may cause a reduction in conscious level and euphoria, making them drugs of abuse. They also exert effects on the respiratory system, reducing respiratory rate and obtunding airway reflexes, an effect which is considered advantageous during anesthesia.

- Amongst many other side-effects, opioids can also cause constipation, nausea, vomiting, urinary retention, pruritus, muscular rigidity, miosis and dysphoria in certain individuals.

- This list is by no means comprehensive, but, despite their numerous drawbacks to this day, opioids remain the yardstick against which all other clinically effective analgesics are measured.

Section 4

Proper Prescribing of Opiate Drugs
Pain Management Balancing Act
CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

The guideline is intended for primary care clinicians (e.g., family physicians, internists, nurse practitioners, and physician assistants) who are treating patients with chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings. The guideline is intended to apply to patients 18 years and older with chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of the guideline. The guideline addresses: 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use.

The guideline provides 12 specific recommendations:
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/d), or concurrent benzodiazepine use are present.
9. Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.
9. Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.
Opioids pose a risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing.

**Use nonopioid therapies**

Use nonpharmacologic therapies (such as exercise and cognitive behavioral therapy) and nonopioid pharmacologic therapies (such as anti-inflammatories) for chronic pain. Don’t use opioids routinely for chronic pain. When opioids are used, combine them with nonpharmacologic or nonopioid pharmacologic therapy, as appropriate, to provide greater benefits.

**Start low and go slow**

When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

**Follow-up**

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or reduce dosage and discontinue, if needed.
Section 5

Physician Liability for Overprescribing Controlled Substances
PHYSICIAN LIABILITY FOR OVERPREScribing CONTROLLED SUBSTANCES

458.331 GROUNDS FOR DISCIPLINARY ACTION; ACTION BY THE BOARD AND DEPARTMENT.—

(1) THE FOLLOWING ACTS CONSTITUTE GROUNDS FOR DENIAL OF A LICENSE OR DISCIPLINARY ACTION, AS SPECIFIED IN S. 456.072(2):

(q) 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. FOR THE PURPOSES OF THIS PARAGRAPH, IT SHALL BE LEGALLY PRESUMED THAT PRESCRIBING, DISPENSING, ADMINISTERING, MIXING, OR OTHERWISE PREPARING LEGEND DRUGS, INCLUDING ALL CONTROLLED SUBSTANCES, INAPPROPRIATELY OR IN EXCESSIVE OR INAPPROPRIATE QUANTITIES IS NOT IN THE BEST INTEREST OF THE PATIENT AND IS NOT IN THE COURSE OF THE PHYSICIAN’S PROFESSIONAL PRACTICE, WITHOUT REGARD TO HIS OR HER INTENT.
459.015 Grounds for disciplinary action; action by the board and department.—

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

(T) Prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing a legend drug, including all controlled substances, other than in the course of the osteopathic physician’s professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the osteopathic physician’s professional practice, without regard to his or her intent.
PHYSICIAN LIABILITY FOR OVERPRESCRIBING CONTROLLED SUBSTANCES

893.13 PROHIBITED ACTS; PENALTIES.—

(8)(b) If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (A)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (A)1.
Section 6

Diagnosis of Opioid Addiction and Treatment Options
On October 17, 2000, Congress passed the Drug Addiction Treatment Act (DATA) which permits qualified physicians to treat narcotic dependence with schedules III-V narcotic controlled substances that have been approved by the Food and Drug Administration (FDA) for that indication.

The legislation waives the requirement for obtaining a separate Drug Enforcement Administration (DEA) registration as a Narcotic Treatment Program (NTP) for qualified physicians administering, dispensing, and prescribing these specific FDA approved controlled substances. Physicians registered with the DEA as practitioners who apply and are qualified pursuant to DATA are issued a waiver (DWP) and will be authorized to conduct maintenance and detoxification treatment using specifically approved schedule III, IV, or V narcotic medications. DATA waivers are only granted to qualified physicians. Hospitals and mid-level practitioners do not qualify under the DATA.

http://buprenorphine.samhsa.gov/faq.html#A10
DATA waived physicians may treat 30 or 100 patients at any one time, dependent on individual authorization from the Center for Substance Abuse Treatment (CSAT). Physicians who submitted the notification for initial authorization at least one year prior may submit a second notification of the need and intent to increase the patient limit from 30 patients up to 100 patients. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration with a business activity code to identify whether the physician is authorized to treat 30 or 100 patients.

Under the authority of the Controlled Substances Act (21 U.S.C. 822 (f)), DEA is authorized to conduct periodic on-site inspections of all registrants. DWPs are also subject to on-site inspections to ensure compliance with the DATA and its implementing regulations.

HTTP://BUPRENORPHINE.SAMHSA.GOV/FAQ.HTML#A10
Rule 64B15-14.009, F.A.C.: Standards of Practice for Office Based Opioid Addiction Treatment

There is no similar rule in the Board of Medicine’s rules. Incorporates many of the requirements contained in the Drug Abuse Treatment Act.
U.C.S.D. PHYSICIAN PRESCRIBING COURSE

- The Physician Prescribing Course is a two and one-half day small group CME program designed to improve the participant's prescribing behavior by providing education on the legal, biomedical and clinical aspects of prescribing drugs, especially controlled drugs. Topics in this course include:
  - State Laws and Medical Board Guidelines for the Prescription of Controlled Drugs
  - Pharmacokinetics and Drug Metabolism
  - Pharmacology of Sedatives, Narcotics, and Amphetamines
  - Drug Interactions
  - Patient Compliance
  - Charting Drug Prescriptions
  - Managing the "Difficult" Patient
  - Critical Review of the Medical Literature
  - Management of Chronic Pain
  - Special Issues in Chronic Pain: Headache and Back Pain
COMING ATTRACTIONS

U.S. CONGRESS H.R. 4482 THE OPIOID ABUSE DETERRENCE, RESEARCH, AND RECOVERY ACT OF 2017

PRESCRIBERS MUST SUBMIT A “CERTIFICATION” TO DEA THAT THEY WILL NOT PRESCRIBE MORE THAN A 7 DAY SUPPLY (OR LESS IF WITHIN A STATE ESTABLISHED PRESCRIPTION LIMIT) OF A SCH. II OR III FOR THE INITIAL TREATMENT OF ACUTE PAIN.
END OF PRESENTATION

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