PREScribing LAWS AND RULES FOR FLORIDA LICENSED PHYSICIANS

EDWIN A. BAYÓ
GROSSMAN, FURLOW, AND BAYÓ, LLC
2022-2 RAYMOND DIEHL RD.
TALLAHASSEE, FL. 32308
(850) 385-1314
E.BAYO@GFBLAWFIRM.COM
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
A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient’s full name and address, and the practitioner’s full name, address, and DEA registration number. The prescription must also include:

- Drug name
- Strength
- Dosage form
- Quantity prescribed
- Directions for use
- Number of refills (if any) authorized

A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner’s signature.
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.
(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.
**Schedule II Prescriptions**

- **Cannot be Refilled**
- **Cannot be an Oral Prescription (except in an emergency situation and limited to a 72 hour supply)**
- **There is no specific Federal limit to the quantity that may be dispensed pursuant to one prescription, however…**
- **DEA has revised its regulations regarding the issuance of multiple prescriptions for a Schedule II. A practitioner may issue multiple prescriptions authorizing the patient to receive up to a 90 day supply. The prescriber must date all scripts on the same date signed and provide directions for filling (e.g. do not fill before August 1; September 1,…)**
DEA REGISTRATION

- In order for Florida licensed physicians to be able to prescribe, administer or dispense controlled substances, they must be registered with the U.S. Drug Enforcement Agency (DEA).

- DEA Form-224: New Application for Registration:
  - Available online and can be submitted electronically: [HTTP://WWW.DEADIVERSION.USDOJ.GOV/DRUGREG/INDEX.HTML#REGAPPS](HTTP://WWW.DEADIVERSION.USDOJ.GOV/DRUGREG/INDEX.HTML#REGAPPS)
  - Physical applications for registration may be obtained from a field office or by telephoning the Registration Section in the DEA Headquarters office at 1-800-882-9539.
DEA REGISTRATION

- The DEA Certificate of Registration (DEA Form 223) must be maintained at the registered location in a readily retrievable manner and kept available for official inspection.

- "A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported or dispensed by a person." C.F.R. 1301.12.

- DEA has historically provided an exception that a practitioner who is registered at one location, but also practices at other locations, is not required to register separately for any other location at which controlled substances are only prescribed.

- However, if the practitioner maintains supplies of controlled substances, administers, or directly dispenses controlled substances at the separate location the practitioner must obtain a separate DEA registration for that location. The exception applies only to a secondary location within the same state in which the practitioner maintains his/her registration.
DEA REGISTRATION MODIFICATION

- Practitioners who wish to modify their Drug Enforcement Administration Registration for a name change or change of address should let their local DEA office know ahead of time, so appropriate registration changes can be made.

- Information concerning the DEA registration process can also be obtained by contacting the Registration Call Center at (800) 882-9539.

- Registrations must renewed every three (3) years using DEA Form 224A.

- A renewal application is sent to the registrant approximately 45 days before the registration expiration date. The renewal application is sent to the address listed on the current registration certificate.

- If the renewal form is not received within 30 days before the expiration date of the current registration, the practitioner should contact the DEA registration office for their state, or DEA Headquarters at 1-800-882-9539, and request a renewal registration form.
Electronic Prescriptions for CS

- **Voluntary option**
- **Both the Practitioner and the Pharmacy must be enrolled and approved by the DEA**
- **Florida allows this option**
- **CSOS (Controlled Substance Ordering System)**
  - Electronic ordering system for C2 and C2N
  - Requires Digital Signature Certificate
  - Apply online at [WWW.DEADIVERSION.USDOJ.GOV](http://WWW.DEADIVERSION.USDOJ.GOV)
456.43  ELECTRONIC PRESCRIBING FOR MEDICINAL DRUGS.—

(1)  ELECTRONIC PRESCRIBING SHALL NOT INTERFERE WITH A PATIENT’S FREEDOM TO CHOOSE A PHARMACY.

(2)  ELECTRONIC PRESCRIBING SOFTWARE SHALL NOT USE ANY MEANS OR PERMIT ANY OTHER PERSON TO USE ANY MEANS, INCLUDING, BUT NOT LIMITED TO, ADVERTISING, INSTANT MESSAGING, AND POP-UP ADS, TO INFLUENCE OR ATTEMPT TO INFLUENCE, THROUGH ECONOMIC INCENTIVES OR OTHERWISE, THE PRESCRIBING DECISION OF A PRESCRIBING PRACTITIONER AT THE POINT OF CARE. SUCH MEANS SHALL NOT BE TRIGGERED OR IN SPECIFIC RESPONSE TO THE INPUT, SELECTION, OR ACT OF A PRESCRIBING PRACTITIONER OR HIS OR HER AGENT IN PRESCRIBING A CERTAIN PHARMACEUTICAL OR DIRECTING A PATIENT TO A CERTAIN PHARMACY. (A) THE TERM “PRESCRIBING DECISION” MEANS A PRESCRIBING PRACTITIONER’S DECISION TO PRESCRIBE A CERTAIN PHARMACEUTICAL.

(B) THE TERM “POINT OF CARE” MEANS THE TIME THAT A PRESCRIBING PRACTITIONER OR HIS OR HER AGENT IS IN THE ACT OF PRESCRIBING A CERTAIN PHARMACEUTICAL.

(3)  ELECTRONIC PRESCRIBING SOFTWARE MAY SHOW INFORMATION REGARDING A PAYOR’S FORMULARY AS LONG AS NOTHING IS DESIGNED TO PRECLUDE OR MAKE MORE DIFFICULT THE ACT OF A PRESCRIBING PRACTITIONER OR PATIENT SELECTING ANY PARTICULAR PHARMACY OR PHARMACEUTICAL.
§ 456.44, F.S. FLORIDA CONTROLLED SUBSTANCE PRESCRIBING:
ARE YOU TALKING TO ME?

This law is the source of some confusion. It provides definitions, exceptions, registration and standards of practice requirements, but it is only applicable to physicians who prescribe controlled substances for the treatment of “chronic nonmalignant pain.”

The first problem is that you have to refer to the pain-management clinic statutes (§458.3265 or 459.0137, F.S.) for the definition of “chronic nonmalignant pain.”

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.

What if you are not treating chronic nonmalignant pain?
§ 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.—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.

11. A PHOTOCOPY OF THE PATIENT’S GOVERNMENT-ISSUED PHOTO IDENTIFICATION.

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.
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:

(A) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall 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, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

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.
(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).
(D) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician’s evaluation of the patient’s progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(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.
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.
THE CLIFF NOTES VERSION:

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.
THE RULES ARE NOT IDENTICAL. THE BOM RULE STATES THAT TO JUSTIFY THE USE OF WEIGHT LOSS ENHANCERS THE PATIENT MUST HAVE A BODY MASS INDEX (BMI) OF 30 OR ABOVE, OR A BMI OF GREATER THAN 27 WITH AT LEAST ONE COMORBIDITY FACTOR, OR A MEASURABLE BODY FAT CONTENT EQUAL TO OR GREATER THAN 25% OF TOTAL BODY WEIGHT FOR MALE PATIENTS OR 30% OF TOTAL BODY WEIGHT FOR WOMEN. THE BOOM RULE STATES A BMI OF GREATER THAN 25.

THE BOM RULE STATES THAT PHYSICIANS IN FLORIDA ARE PROHIBITED FROM PRESCRIBING, ORDERING, DISPENSING, OR ADMINISTERING ANY WEIGHT LOSS ENHANCER THAT IS BOTH A SEROTONERGIC AND ANOREXIC AGENT UNLESS THE DRUG HAS BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION (FDA) SPECIFICALLY FOR USE IN WEIGHT LOSS MANAGEMENT. SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS (SSRIS) THAT HAVE NOT BEEN APPROVED BY THE FDA FOR WEIGHT LOSS MAY NOT BE PRESCRIBED, ORDERED, DISPENSED, OR ADMINISTERED FOR SUCH PURPOSES. THE BOOM RULE DOES NOT HAVE THIS PROVISION.
Standards for the Prescription of Obesity Drugs

An initial evaluation of the patient shall be conducted prior to the prescribing, ordering, dispensing, or administering of any drug, synthetic compound, nutritional supplement or herbal treatment and such evaluation shall include an appropriate physical and complete history; appropriate tests related to medical treatment for weight loss; and appropriate medical referrals as indicated by the physical, history, and testing; all in accordance with general medical standards of care.

(A) The initial evaluation may be delegated to an appropriately educated and trained physician’s assistant/osteopathic physician’s assistant licensed pursuant to Chapter 458 or 459, F.S., or an appropriately educated and trained advanced registered nurse practitioner licensed pursuant to Chapter 464, F.S.

(B) If the initial evaluation required above is delegated to a physician’s assistant or to an advanced registered nurse practitioner, then the delegating physician must personally review the resulting medical records prior to the issuance of an initial prescription, order, or dosage.
STANDARDS FOR THE PRESCRIPTION OF OBESITY DRUGS

Prescriptions or orders for any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of assisting in weight loss must be in writing and signed by the prescribing physician. Initial prescriptions or orders of this type shall not be called into a pharmacy by the physician or by an agent of the physician.

The Board of Medicine Rule provides: Even if the physician is registered as a dispensing physician, a hard copy of the written prescription must be maintained in the patient’s medical records for each time such weight loss enhancers are prescribed, ordered, dispensed, or administered.
STANDARDS FOR THE PRESCRIPTION OF OBESITY DRUGS

At the time of delivering the initial prescription or providing the initial supply of such drugs to a patient, the prescribing physician must personally meet with the patient and personally obtain an appropriate written informed consent from the patient. Such consent must state that there is a lack of scientific data regarding the potential danger of long term use of combination weight loss treatments, and shall discuss potential benefits versus potential risks of weight loss treatments. The written consent must also clearly state the need for dietary intervention and physical exercise as a part of any weight loss regimen. A copy of the signed informed consent shall be included in the patient’s permanent medical record.
STANDARDS FOR THE PRESCRIPTION OF OBESITY DRUGS

Each physician who is prescribing, ordering, or providing weight loss enhancers to patients must assure that such patients undergo an in-person re-evaluation within 2 to 4 weeks of receiving a prescription, order, or dosage. The re-evaluation shall include the elements of the initial evaluation and an assessment of the medical effects of the treatment being provided. Any patient that continues on a drug, synthetic compound, nutritional supplement or herbal treatment assisted weight loss program shall be re-evaluated at least once every 3 months.

Each physician who prescribes, orders, dispenses, or administers any drug, synthetic compound, nutritional supplement or herbal treatment for the purpose of assisting a patient in weight loss shall maintain medical records in compliance with the respective Board Rule, and must also reflect compliance with all requirements of this rule.

Each physician who prescribes, orders, dispenses, or administers weight loss enhancers for the purpose of providing medically assisted weight loss shall provide to each patient a legible copy of the Weight-Loss Consumer Bill of Rights as set forth in Sections 501.0575(1)(a) through (e)3., F.S. The physician shall also conspicuously post said document in those rooms wherein patients are evaluated for weight loss treatment.
STANDARDS FOR THE PRESCRIPTION OF OBESITY DRUGS

Any physician who advertises practice relating to weight loss or whose services are advertised by another person or entity shall be responsible for assuring that such advertising meets the requirements of Rule 64B8-11.001, F.A.C. In addition advertising of weight loss treatment shall be considered false, deceptive, or misleading if it contains representations that:

- (A) Promise specific results;
- (B) Raise unreasonable expectations;
- (C) Claim rapid, dramatic, incredible, or safe weight loss;
- (D) State or suggest that diets or exercise are not required; or
- (E) Suggest that weight loss is effortless or magical.
465.0276 Dispensing Practitioner.—

(2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

(A) Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed $100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.

(B) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.

(C) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner’s office or at any pharmacy.
A PRACTITIONER WHO CONFINES HER OR HIS ACTIVITIES TO THE DISPENSING OF COMPLIMENTARY PACKAGES OF MEDICINAL DRUGS TO THE PRACTITIONER’S OWN PATIENTS IN THE REGULAR COURSE OF HER OR HIS PRACTICE, WITHOUT THE PAYMENT OF FEE OR REMUNERATION OF ANY KIND, WHETHER DIRECT OR INDIRECT, AND WHO HERSELF OR HIMSELF DISPENSES SUCH DRUGS IS NOT REQUIRED TO REGISTER PURSUANT TO THIS SECTION. THE PRACTITIONER MUST DISPENSE SUCH DRUGS IN THE MANUFACTURER’S LABELED PACKAGE WITH THE PRACTITIONER’S NAME, PATIENT’S NAME, AND DATE DISPENSED, OR, IF SUCH DRUGS ARE NOT DISPENSED IN THE MANUFACTURER’S LABELED PACKAGE, THEY MUST BE DISPENSED IN A CONTAINER WHICH BEARS THE FOLLOWING INFORMATION:

- (A) PRACTITIONER’S NAME;
- (B) PATIENT’S NAME;
- (C) DATE DISPENSED;
- (D) NAME AND STRENGTH OF DRUG; AND
- (E) DIRECTIONS FOR USE.
465.0276 Dispensing Practitioner.—

465.0276 Dispensing Practitioner.—(1)(A) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(B) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to: 1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner’s own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (4).

2. The dispensing of controlled substances in the health care system of the Department of Corrections.

3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term “surgical procedure” means any procedure in any setting which involves, or reasonably should involve: A. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or B. The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term “approved clinical trial” means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under Part IV of chapter 400.
(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.
STANDARDS FOR TELEMEDICINE PRACTICE

(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.
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.

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
§ 465.0255, F.S.- Expiration Date of Medicinal Drugs; Display; Related Use and Storage Instructions:

The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser: the expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or an earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.
§ 465.0255, F.S.- EXPIRATION DATE OF MEDICINAL DRUGS; DISPLAY; RELATED USE AND STORAGE INSTRUCTIONS:

THE DISPENSING PHARMACIST OR PRACTITIONER MUST PROVIDE INFORMATION CONCERNING THE EXPIRATION DATE TO THE PURCHASER UPON REQUEST AND MUST PROVIDE APPROPRIATE INSTRUCTIONS REGARDING THE PROPER USE AND STORAGE OF THE DRUG.

THIS SECTION DOES NOT IMPOSE LIABILITY ON THE DISPENSING PHARMACIST OR PRACTITIONER FOR DAMAGES RELATED TO, OR CAUSED BY, A MEDICINAL DRUG THAT LOSES ITS EFFECTIVENESS PRIOR TO THE EXPIRATION DATE DISPLAYED BY THE DISPENSING PHARMACIST OR PRACTITIONER.

THE PROVISIONS OF THIS SECTION ARE INTENDED TO NOTIFY THE PATIENT RECEIVING A MEDICINAL DRUG OF THE INFORMATION REQUIRED BY THIS SECTION, AND THE DISPENSING PHARMACIST OR PRACTITIONER SHALL NOT BE LIABLE FOR THE PATIENT'S FAILURE TO HEED SUCH NOTICE OR TO FOLLOW THE INSTRUCTIONS FOR STORAGE.
§ 499.005 Prohibited acts.— It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(14) The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15) The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.
499.01 PERMITS.--

(1) PRIOR TO OPERATING, A PERMIT IS REQUIRED FOR EACH PERSON AND ESTABLISHMENT THAT INTENDS TO OPERATE AS:

(a) A PRESCRIPTION DRUG MANUFACTURER
(b) A PRESCRIPTION DRUG WHOLESALE DISTRIBUTOR
(c) A RETAIL PHARMACY DRUG WHOLESALE DISTRIBUTOR
(d) HEALTH CARE CLINIC ESTABLISHMENT.
HEALTH CARE CLINIC ESTABLISHMENT PERMIT: DO YOU NEED IT?

- Health care clinic establishment permit.—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number.

- For the purpose of this paragraph, the term “qualifying practitioner” means a licensed health care practitioner defined in S. 456.001, or a veterinarian licensed under Chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

- This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.
Other Chapter 893 Provisions

- §893.04: Pharmacist and Practitioner.
- §893.05: Practitioners and Persons Administering Controlled Substances in Their Absence.
- §893.055: Prescription Drug Monitoring Program.
- §893.06: Distribution of Controlled Substances; Order Forms; Labeling and Packaging Requirements.
- §893.065: Counterfeit-Resistant Prescription Blanks for Controlled Substances Listed in Schedule II, Schedule III, or Schedule IV.
CHAPTER 2017-169

Committee Substitute for Committee Substitute for House Bill No. 557

An act relating to controlled substance prescribing; amending s. 893.055, F.S.; revising requirements for reporting the dispensing of controlled substances; limiting an exception to reporting requirements for certain facilities that dispense controlled substances; authorizing certain employees of the United States Department of Veterans Affairs access to certain information in the prescription drug monitoring program database; specifying when a revised reporting requirement takes effect; providing effective dates.

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

    Section 1. Subsection (4), paragraph (g) of subsection (5), and paragraphs (a) and (b) of subsection (7) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but no later than the close of the next business day not more than 7 days after the day date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by submitting via the department-approved electronic system providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are

CODING: Words struck are deletions; words underlined are additions.
not limited to, regular postage, electronic media, regular electronic mail, and
facsimile charges.

(b) A pharmacy, prescriber, or dispenser, or the designee of a pharmacy,
prescriber, or dispenser, shall have access to information in the prescription
drug monitoring program's database which relates to a patient of that
pharmacy, prescriber, or dispenser in a manner established by the
department as needed for the purpose of reviewing the patient's controlled
substance prescription history. An employee of the United States Depart-
ment of Veterans Affairs who provides health care services pursuant to such
employment and who has the authority to prescribe controlled substances
shall have access to the information in the program's database in a manner
established by the department. Such access is limited to the information that
relates to a patient of such employee and may be accessed only for the
purpose of reviewing the patient's controlled substance prescription history.
Other access to the program's database shall be limited to the program's
manager and to the designated program and support staff, who may act only
at the direction of the program manager or, in the absence of the program
manager, as authorized. Access by the program manager or such designated
staff is for prescription drug program management only or for management
of the program's database and its system in support of the requirements of
this section and in furtherance of the prescription drug monitoring program.
Confidential and exempt information in the database shall be released only
as provided in paragraph (c) and s. 893.055(1). The program manager,
designated program and support staff who act at the direction of or in the
absence of the program manager, and any individual who has similar access
regarding the management of the database from the prescription drug
monitoring program shall submit fingerprints to the department for back-
ground screening. The department shall follow the procedure established by
the Department of Law Enforcement to request a statewide criminal history
record check and to request that the Department of Law Enforcement
forward the fingerprints to the Federal Bureau of Investigation for a
national criminal history record check.

Section 2. The requirement in s. 893.055(4), Florida Statutes, as
amended by this act, that the dispensing of a controlled substance be
reported to the Department of Health no later than the next business day
shall take effect January 1, 2018.

Section 3. Except as otherwise expressly provided in this act, this act
shall take effect July 1, 2017.

Approved by the Governor June 26, 2017.

Filed in Office Secretary of State June 26, 2017.
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
END OF PRESENTATION

EDWIN A. BAYÓ
GROSSMAN, FURLOW, AND BAYÓ, LLC
2022-2 RAYMOND DIEHL RD.
TALLAHASSEE, FL. 32308
(850) 385-1314
E.BAYO@GFBLAWFIRM.COM