

The Florida

# Board of Nursing

## Agenda Controlled Substances Formulary Committee

Florida Hospital Association  
307 Park Lake Circle  
Orlando, FL  
**June 29, 2016 @ 9:00 a.m.**



Doreen Cassarino, DNP,  
ARNP, FNP-BC, BC-  
ADM, FAANP - Chair

Joe Baker, Jr.  
Executive Director

Controlled Substances Formulary Committee  
Agenda

June 29, 2016 @ 9:00 a.m.

**Committee Members:**

Doreen Cassarino, DNP, FNP-BC, BC-ADM, FAANP (Chair)  
Vicky Stone-Gale, DNP, FNP-C, MSN  
Jim Quinlan, DNP, ARNP  
Bernardo B. Fernandez, Jr., MD, MBA, FACP  
Joshua D. Lenchus, DO, RPh, FACP, SFHM  
Eduardo C. Oliveira, MD, MBA, FCCP  
Jeffrey Mesaros, PharmD, JD

**Attorney:**

Lee Ann Gustafson, Senior Assistant Attorney General

**Board Staff:**

Joe Baker, Jr., Executive Director  
Jessica Hollingsworth, Program Operations Administrator

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Call to Order

Roll Call

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- I. Welcome – Chair Cassarino
- II. Introductions
- III. Comments by Counsel
  - A. Overview of Section 464.012(6), FS
    - 1. Reference S. 893.03, FS
    - 2. Reference S. 394.455, FS
  - B. Overview of Sunshine Law
- IV. Comments by Rebecca R. Poston, BPharm, MHL 1 E-FORCSE  
Florida's Prescription Drug Monitoring Program 1 Program Director
- V. Examples of Formularies and Correspondence from the AANP
  - A. State Formulary Laws Updated 5.2.16
  - B. FL Formulary BOD Statute Share 5.2.16 signed
- VI. Pending State and/or Federal Rules Related to the Prescribing of Opiates (Medicaid)
  - A. <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>
  - B. CDC Guidelines
  - C. Board of Pharmacy Rule 64B16-27.831
  - D. Board of Medicine Rule 64B8-9.012; Standards for the Prescription of Obesity Drugs
  - E. Board of Medicine Rule 64B8-9.013; Standards for the Use of Controlled Substances for the Treatment of Pain
  - F. Board of Medicine Rule 64B8-9.0141; Standards for Telemedicine Prescribing Practice
  - G. Board of Medicine Rule 64B8-30.008; PA Formulary Rule
- VII. Public Comment
- VIII. Next Meeting Date
- IX. Adjournment

## CHAPTER 2016-224

### House Bill No. 423

An act relating to access to health care services; amending s. 110.12315, F.S.; expanding the categories of persons who may prescribe brand name drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; exempting controlled substances prescribed by an advanced registered nurse practitioner or a physician assistant from the disqualifications for certification or licensure, and for continued certification or licensure, as a deputy pilot or state pilot; amending s. 456.072, F.S.; applying existing penalties for violations relating to the prescribing or dispensing of controlled substances by an advanced registered nurse practitioner; amending s. 456.44, F.S.; defining the term “registrant”; deleting an obsolete date; requiring advanced registered nurse practitioners and physician assistants who prescribe controlled substances for the treatment of certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; providing applicability; amending ss. 458.3265 and 459.0137, F.S.; limiting the authority to prescribe a controlled substance in a pain-management clinic only to a physician licensed under ch. 458 or ch. 459, F.S.; amending s. 458.347, F.S.; revising the required continuing education requirements for a physician assistant; requiring that a specified formulary limit the prescription of certain controlled substances by physician assistants as of a specified date; amending s. 464.003, F.S.; revising the term “advanced or specialized nursing practice”; deleting the joint committee established in the definition; amending s. 464.012, F.S.; requiring the Board of Nursing to establish a committee to recommend a formulary of controlled substances that may not be prescribed, or may be prescribed only on a limited basis, by an advanced registered nurse practitioner; specifying the membership of the committee; providing parameters for the formulary; requiring that the formulary be adopted by board rule; specifying the process for amending the formulary and imposing a burden of proof; limiting the formulary’s application in certain instances; requiring the board to adopt the committee’s initial recommendations by a specified date; providing a short title; authorizing an advanced registered nurse practitioner to prescribe, dispense, administer, or order drugs, including certain controlled substances under certain circumstances, as of a specified date; amending s. 464.013, F.S.; revising continuing education requirements for renewal of a license or certificate; amending s. 464.018, F.S.; specifying acts that constitute grounds for denial of a license or for disciplinary action against an advanced registered nurse practitioner; creating s. 627.42392, F.S.; defining the term “health insurer”; requiring that certain health insurers that do not already use a certain form use only a prior authorization form approved by the Financial Services Commission in consultation with the Agency for Health Care Administration; requiring the commission in consultation with the agency to adopt by rule guidelines for such forms; providing that prior-

authorization approvals do not preclude certain benefit verifications or medical reviews; amending s. 766.1115, F.S.; revising the definition of the term “contract”; amending s. 893.02, F.S.; revising the term “practitioner” to include advanced registered nurse practitioners and physician assistants under the Florida Comprehensive Drug Abuse Prevention and Control Act if a certain requirement is met; amending s. 948.03, F.S.; providing that possession of drugs or narcotics prescribed by an advanced registered nurse practitioner or a physician assistant does not violate a prohibition relating to the possession of drugs or narcotics during probation; amending ss. 458.348 and 459.025, F.S.; conforming provisions to changes made by the act; reenacting ss. 458.331(10), 458.347(7)(g), 459.015(10), 459.022(7)(f), and 465.0158(5)(b), F.S., to incorporate the amendment made to s. 456.072, F.S., in references thereto; reenacting ss. 456.072(1)(mm) and 466.02751, F.S., to incorporate the amendment made to s. 456.44, F.S., in references thereto; reenacting ss. 458.303, 458.3475(7)(b), 459.022(4)(e) and (9)(c), and 459.023(7)(b), F.S., to incorporate the amendment made to s. 458.347, F.S., in references thereto; reenacting s. 464.012(3)(c), F.S., to incorporate the amendment made to s. 464.003, F.S., in a reference thereto; reenacting ss. 456.041(1)(a), 458.348(1) and (2), and 459.025(1), F.S., to incorporate the amendment made to s. 464.012, F.S., in references thereto; reenacting s. 464.0205(7), F.S., to incorporate the amendment made to s. 464.013, F.S., in a reference thereto; reenacting ss. 320.0848(11), 464.008(2), 464.009(5), and 464.0205(1)(b), (3), and (4)(b), F.S., to incorporate the amendment made to s. 464.018, F.S., in references thereto; reenacting s. 775.051, F.S., to incorporate the amendment made to s. 893.02, F.S., in a reference thereto; reenacting ss. 944.17(3)(a), 948.001(8), and 948.101(1)(e), F.S., to incorporate the amendment made to s. 948.03, F.S., in references thereto; providing effective dates.

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

Section 1. Subsection (7) of section 110.12315, Florida Statutes, is amended to read:

110.12315 Prescription drug program.—The state employees’ prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(7) The department shall establish the reimbursement schedule for prescription pharmaceuticals dispensed under the program. Reimbursement rates for a prescription pharmaceutical must be based on the cost of the generic equivalent drug if a generic equivalent exists, unless the physician, advanced registered nurse practitioner, or physician assistant prescribing the pharmaceutical clearly states on the prescription that the brand name drug is medically necessary or that the drug product is included on the

formulary of drug products that may not be interchanged as provided in chapter 465, in which case reimbursement must be based on the cost of the brand name drug as specified in the reimbursement schedule adopted by the department.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended, and subsection (3) of that section is republished, to read:

310.071 Deputy pilot certification.—

(1) In addition to meeting other requirements specified in this chapter, each applicant for certification as a deputy pilot must:

(c) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, an advanced registered nurse practitioner, or a physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot, each certificated deputy pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder satisfactorily meets the standards. The standards for certificateholders shall include a drug test.

(3) The initial certificate issued to a deputy pilot shall be valid for a period of 12 months, and at the end of this period, the certificate shall automatically expire and shall not be renewed. During this period, the board shall thoroughly evaluate the deputy pilot's performance for suitability to continue training and shall make appropriate recommendations to the department. Upon receipt of a favorable recommendation by the board, the department shall issue a certificate to the deputy pilot, which shall be valid for a period of 2 years. The certificate may be renewed only two times, except in the case of a fully licensed pilot who is cross-licensed as a deputy pilot in another port, and provided the deputy pilot meets the requirements specified for pilots in paragraph (1)(c).

Section 3. Subsection (3) of section 310.073, Florida Statutes, is amended to read:

310.073 State pilot licensing.—In addition to meeting other requirements specified in this chapter, each applicant for license as a state pilot must:

(3) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, an advanced registered nurse practitioner, or a physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a licensed state pilot, each licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the licensee satisfactorily meets the standards. The standards for licensees shall include a drug test.

Section 4. Paragraph (b) of subsection (3) of section 310.081, Florida Statutes, is amended to read:

310.081 Department to examine and license state pilots and certificate deputy pilots; vacancies.—

(3) Pilots shall hold their licenses or certificates pursuant to the requirements of this chapter so long as they:

(b) Are in good physical and mental health as evidenced by documentary proof of having satisfactorily passed a physical examination administered by a licensed physician or physician assistant within each calendar year. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot or a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, an advanced registered nurse practitioner, or a physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot or licensed state pilot, each certificated deputy pilot or licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder or licensee satisfactorily meets the standards. The standards for certificateholders and for licensees shall include a drug test.

Upon resignation or in the case of disability permanently affecting a pilot's ability to serve, the state license or certificate issued under this chapter shall be revoked by the department.

Section 5. Subsection (7) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), or that an advanced registered nurse practitioner has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 464.018(1)(n) or (p)~~6.~~ the physician or advanced registered nurse practitioner shall be suspended for a period of not less than 6 months and pay a fine of not less than \$10,000 per count. Repeated violations shall result in increased penalties.

Section 6. Section 456.44, Florida Statutes, is amended to read:

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.—As used in this section, the term:

(a) “Addiction medicine specialist” means a board-certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b) “Adverse incident” means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c) “Board-certified pain management physician” means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d) “Board eligible” means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e) “Chronic nonmalignant pain” means 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.

(f) “Mental health addiction facility” means a facility licensed under chapter 394 or chapter 397.

(g) “Registrant” means a physician, a physician assistant, or an advanced registered nurse practitioner who meets the requirements of subsection (2).

(2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced registered nurse practitioner certified under part I of chapter 464 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on his or her ~~the physician’s~~ practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(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 clinician~~ 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 physician~~ 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.

(c) The ~~registrant physician~~ 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 physician~~ shall use a written controlled substance agreement between the ~~registrant physician~~ 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 physician~~ unless otherwise authorized by the treating ~~registrant physician~~ and documented in the medical record.

(d) The patient shall be seen by the ~~registrant physician~~ 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 physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the ~~registrant physician~~ shall reevaluate the appropriateness of continued treatment. The ~~registrant physician~~ 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 physician~~ 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.

(f) A registrant ~~physician registered under this section~~ 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 ~~physician's~~ full name presented in a legible manner.

(g) A registrant shall immediately refer patients with signs or symptoms of substance abuse ~~shall be immediately referred~~ 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 ~~physician~~ 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 ~~physician~~ 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 ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a 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. This subsection does not apply to a 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. This subsection does not apply to a registrant physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 7. Paragraph (b) of subsection (2) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) ~~Only a person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459 may dispense medication or prescribe a controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic.~~

Section 8. Paragraph (b) of subsection (2) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) ~~Only a person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 458 may dispense medication or prescribe a controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic.~~

Section 9. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended, and paragraph (c) of subsection (9) of that section is republished, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or designated by the American Academy of Physician Assistants as a Category 1 credit.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(c) The council shall:

1. Recommend to the department the licensure of physician assistants.

2. Develop all rules regulating the use of physician assistants by physicians under this chapter and chapter 459, except for rules relating to the formulary developed under paragraph (4)(f). The council shall also develop rules to ensure that the continuity of supervision is maintained in each practice setting. The boards shall consider adopting a proposed rule developed by the council at the regularly scheduled meeting immediately following the submission of the proposed rule by the council. A proposed rule submitted by the council may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The language of all proposed rules submitted by the council must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules. If either board rejects the council's proposed rule, that board must specify its objection to the council with particularity and include any recommendations it may have for the modification of the proposed rule.

3. Make recommendations to the boards regarding all matters relating to physician assistants.

4. Address concerns and problems of practicing physician assistants in order to improve safety in the clinical practices of licensed physician assistants.

Section 10. Effective January 1, 2017, paragraph (f) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include ~~controlled substances as defined in chapter 893~~; general anesthetics; and radiographic contrast materials, and must limit the prescription of Schedule II controlled substances as listed in s. 893.03 to a 7-day supply. The formulary must also restrict the prescribing of psychiatric mental health controlled substances for children younger than 18 years of age.

2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, a deletion, or a modification of a medicinal drug listed on such formulary has the burden of proof to show cause why such addition, deletion, or modification should be made.

4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed \$200 to fund the provisions of this paragraph and paragraph (e).

Section 11. Subsection (2) of section 464.003, Florida Statutes, is amended to read:

464.003 Definitions.—As used in this part, the term:

(2) “Advanced or specialized nursing practice” means, in addition to the practice of professional nursing, the performance of advanced-level nursing acts approved by the board which, by virtue of postbasic specialized education, training, and experience, are appropriately performed by an advanced registered nurse practitioner. Within the context of advanced or specialized nursing practice, the advanced registered nurse practitioner may perform acts of nursing diagnosis and nursing treatment of alterations of the health status. The advanced registered nurse practitioner may also perform acts of medical diagnosis and treatment, prescription, and operation as authorized within the framework of an established supervisory protocol which are identified and approved by a joint committee composed of three members appointed by the Board of Nursing, two of whom must be advanced registered nurse practitioners; three members appointed by the Board of Medicine, two of whom must have had work experience with advanced registered nurse practitioners; and the State Surgeon General or the State Surgeon General’s designee. Each committee member appointed by a board shall be appointed to a term of 4 years unless a shorter term is required to establish or maintain staggered terms. The Board of Nursing shall adopt rules authorizing the performance of any such acts approved by the joint committee. Unless otherwise specified by the joint committee, such acts must be performed under the general supervision of a practitioner licensed under chapter 458, chapter 459, or chapter 466 within the framework of standing protocols which identify the medical acts to be performed and the conditions for their performance. The department may, by rule, require that a copy of the protocol be filed with the department along with the notice required by s. 458.348.

Section 12. Section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.

(b) Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(c) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

(2) The board shall provide by rule the appropriate requirements for advanced registered nurse practitioners in the categories of certified registered nurse anesthetist, certified nurse midwife, and nurse practitioner.

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Monitor and alter drug therapies.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(4) In addition to the general functions specified in subsection (3), an advanced registered nurse practitioner may perform the following acts within his or her specialty:

(a) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

(b) The certified nurse midwife may, to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse midwife's physician backup when the delivery is performed in a patient's home, perform any or all of the following:

1. Perform superficial minor surgical procedures.
2. Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.
3. Order, initiate, and perform appropriate anesthetic procedures.
4. Perform postpartum examination.
5. Order appropriate medications.
6. Provide family-planning services and well-woman care.
7. Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

(c) The nurse practitioner may perform any or all of the following acts within the framework of established protocol:

1. Manage selected medical problems.
2. Order physical and occupational therapy.
3. Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.
4. Monitor and manage patients with stable chronic diseases.
5. Establish behavioral problems and diagnosis and make treatment recommendations.

(5) The board shall certify, and the department shall issue a certificate to, any nurse meeting the qualifications in this section. The board shall establish an application fee not to exceed \$100 and a biennial renewal fee not to exceed \$50. The board is authorized to adopt such other rules as are necessary to implement the provisions of this section.

(6)(a) The board shall establish a committee to recommend a formulary of controlled substances that an advanced registered nurse practitioner may not prescribe or may prescribe only for specific uses or in limited quantities. The committee must consist of three advanced registered nurse practitioners licensed under this section, recommended by the board; three physicians licensed under chapter 458 or chapter 459 who have work experience with advanced registered nurse practitioners, recommended by the Board of Medicine; and a pharmacist licensed under chapter 465 who is a doctor of pharmacy, recommended by the Board of Pharmacy. The committee may

recommend an evidence-based formulary applicable to all advanced registered nurse practitioners which is limited by specialty certification, is limited to approved uses of controlled substances, or is subject to other similar restrictions the committee finds are necessary to protect the health, safety, and welfare of the public. The formulary must restrict the prescribing of psychiatric mental health controlled substances for children younger than 18 years of age to advanced registered nurse practitioners who also are psychiatric nurses as defined in s. 394.455. The formulary must also limit the prescribing of Schedule II controlled substances as listed in s. 893.03 to a 7-day supply, except that such restriction does not apply to controlled substances that are psychiatric medications prescribed by psychiatric nurses as defined in s. 394.455.

(b) The board shall adopt by rule the recommended formulary and any revision to the formulary which it finds is supported by evidence-based clinical findings presented by the Board of Medicine, the Board of Osteopathic Medicine, or the Board of Dentistry.

(c) The formulary required under this subsection does not apply to a controlled substance that is dispensed for administration pursuant to an order, including an order for medication authorized by subparagraph (4)(a) 3., subparagraph (4)(a)4., or subparagraph (4)(a)9.

(d) The board shall adopt the committee's initial recommendation no later than October 31, 2016.

(7) This section shall be known as "The Barbara Lumpkin Prescribing Act."

Section 13. Effective January 1, 2017, subsection (3) of section 464.012, Florida Statutes, as amended by this act, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any drug; however, an advanced registered nurse practitioner may prescribe or dispense a

controlled substance as defined in s. 893.03 only if the advanced registered nurse practitioner has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills ~~Monitor and alter drug therapies.~~

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

Section 14. Subsection (3) of section 464.013, Florida Statutes, is amended to read:

464.013 Renewal of license or certificate.—

(3) The board shall by rule prescribe up to 30 hours of continuing education biennially as a condition for renewal of a license or certificate.

(a) A nurse who is certified by a health care specialty program accredited by the National Commission for Certifying Agencies or the Accreditation Board for Specialty Nursing Certification is exempt from continuing education requirements. The criteria for programs must ~~shall~~ be approved by the board.

(b) Notwithstanding the exemption in paragraph (a), as part of the maximum 30 hours of continuing education hours required under this subsection, advanced registered nurse practitioners certified under s. 464.012 must complete at least 3 hours of continuing education on the safe and effective prescription of controlled substances. Such continuing education courses must be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, the American Nurses Credentialing Center, the American Association of Nurse Anesthetists, or the American Association of Nurse Practitioners and may be offered in a distance learning format.

Section 15. Paragraph (p) is added to subsection (1) of section 464.018, Florida Statutes, and subsection (2) of that section is republished, to read:

464.018 Disciplinary actions.—

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

(p) For an advanced registered nurse practitioner:

1. Presigning blank prescription forms.

2. Prescribing for office use any medicinal drug appearing on Schedule II in chapter 893.

3. Prescribing, ordering, dispensing, administering, supplying, selling, or giving a drug that is an amphetamine, a sympathomimetic amine drug, or a compound designated in s. 893.03(2) as a Schedule II controlled substance, to or for any person except for:

a. The treatment of narcolepsy; hyperkinesia; behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity; or drug-induced brain dysfunction.

b. The differential diagnostic psychiatric evaluation of depression or the treatment of depression shown to be refractory to other therapeutic modalities.

c. The clinical investigation of the effects of such drugs or compounds when an investigative protocol is submitted to, reviewed by, and approved by the department before such investigation is begun.

4. Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of muscle building or to enhance athletic performance. As used in this subparagraph, the term “muscle building” does not include the treatment of injured muscle. A prescription written for the drug products identified in this subparagraph may be dispensed by a pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form a community pharmacy unless the form also states: “This prescription may be filled at any pharmacy of your choice.”

6. Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of his or her professional practice. For the purposes of this subparagraph, it is 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 advanced registered nurse practitioner’s professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on any schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced registered nurse practitioner by another practitioner authorized to prescribe, dispense, or administer medicinal drugs.

8. Prescribing, ordering, dispensing, administering, supplying, selling, or giving amygdalin (laetrile) to any person.

9. Dispensing a substance designated in s. 893.03(2) or (3) as a substance controlled in Schedule II or Schedule III, respectively, in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a substance designated in s. 893.03 as a controlled substance.

(2) The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

Section 16. Section 627.42392, Florida Statutes, is created to read:

627.42392 Prior authorization.—

(1) As used in this section, the term “health insurer” means an authorized insurer offering health insurance as defined in s. 624.603, a managed care plan as defined in s. 409.962(9), or a health maintenance organization as defined in s. 641.19(12).

(2) Notwithstanding any other provision of law, in order to establish uniformity in the submission of prior authorization forms on or after January 1, 2017, a health insurer, or a pharmacy benefits manager on behalf of the health insurer, which does not use an electronic prior authorization form for its contracted providers shall use only the prior authorization form that has been approved by the Financial Services Commission in consultation with the Agency for Health Care Administration to obtain a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form may not exceed two pages in length, excluding any instructions or guiding documentation.

(3) The Financial Services Commission in consultation with the Agency for Health Care Administration shall adopt by rule guidelines for all prior authorization forms which ensure the general uniformity of such forms.

(4) Electronic prior-authorization approvals do not preclude benefit verification or medical review by the insurer under either the medical or pharmacy benefits.

Section 17. Paragraph (a) of subsection (3) of section 766.1115, Florida Statutes, is amended to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

(3) DEFINITIONS.—As used in this section, the term:

(a) “Contract” means an agreement executed in compliance with this section between a health care provider and a governmental contractor for

volunteer, uncompensated services which allows the health care provider to deliver health care services to low-income recipients as an agent of the governmental contractor. ~~The contract must be for volunteer, uncompensated services, except as provided in paragraph (4)(g).~~ For services to qualify as volunteer, uncompensated services under this section, the health care provider, or any employee or agent of the health care provider, must receive no compensation from the governmental contractor for any services provided under the contract and must not bill or accept compensation from the recipient, or a public or private third-party payor, for the specific services provided to the low-income recipients covered by the contract, except as provided in paragraph (4)(g). A free clinic as described in subparagraph (d) 14. may receive a legislative appropriation, a grant through a legislative appropriation, or a grant from a governmental entity or nonprofit corporation to support the delivery of contracted services by volunteer health care providers, including the employment of health care providers to supplement, coordinate, or support the delivery of such services. The appropriation or grant for the free clinic does not constitute compensation under this paragraph from the governmental contractor for services provided under the contract, nor does receipt or use of the appropriation or grant constitute the acceptance of compensation under this paragraph for the specific services provided to the low-income recipients covered by the contract.

Section 18. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) “Practitioner” means a physician licensed under pursuant to chapter 458, a dentist licensed under pursuant to chapter 466, a veterinarian licensed under pursuant to chapter 474, an osteopathic physician licensed under pursuant to chapter 459, an advanced registered nurse practitioner certified under chapter 464, a naturopath licensed under pursuant to chapter 462, a certified optometrist licensed under pursuant to chapter 463, or a podiatric physician licensed under pursuant to chapter 461, or a physician assistant licensed under chapter 458 or chapter 459, provided such practitioner holds a valid federal controlled substance registry number.

Section 19. Paragraph (n) of subsection (1) of section 948.03, Florida Statutes, is amended to read:

948.03 Terms and conditions of probation.—

(1) The court shall determine the terms and conditions of probation. Conditions specified in this section do not require oral pronouncement at the time of sentencing and may be considered standard conditions of probation. These conditions may include among them the following, that the probationer or offender in community control shall:

(n) Be prohibited from using intoxicants to excess or possessing any drugs or narcotics unless prescribed by a physician, an advanced registered nurse practitioner, or a physician assistant. The probationer or community controllee may shall not knowingly visit places where intoxicants, drugs, or other dangerous substances are unlawfully sold, dispensed, or used.

Section 20. Paragraph (a) of subsection (1) and subsection (2) of section 458.348, Florida Statutes, are amended to read:

458.348 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(1) NOTICE.—

(a) When a physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. 401.27, which relationship or orders contemplate the performance of medical acts, or when a physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts ~~identified and approved by the joint committee pursuant to s. 464.003(2)~~ or acts set forth in s. 464.012(3) and (4), the physician shall submit notice to the board. The notice shall contain a statement in substantially the following form:

I, ...(name and professional license number of physician)..., of ...(address of physician)... have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with ...(number of persons)... emergency medical technician(s), ...(number of persons)... paramedic(s), or ...(number of persons)... advanced registered nurse practitioner(s).

(2) ESTABLISHMENT OF STANDARDS BY JOINT COMMITTEE.—

The joint committee ~~created under s. 464.003(2)~~ shall determine minimum standards for the content of established protocols pursuant to which an advanced registered nurse practitioner may perform medical acts identified and approved by the joint committee pursuant to s. 464.003(2) or acts set forth in s. 464.012(3) and (4) and shall determine minimum standards for supervision of such acts by the physician, unless the joint committee determines that any act set forth in s. 464.012(3) or (4) is not a medical act. Such standards shall be based on risk to the patient and acceptable standards of medical care and shall take into account the special problems of medically underserved areas. The standards developed by the joint committee shall be adopted as rules by the Board of Nursing and the Board of Medicine for purposes of carrying out their responsibilities pursuant to part I of chapter 464 and this chapter, respectively, but neither board shall have disciplinary powers over the licensees of the other board.

Section 21. Paragraph (a) of subsection (1) of section 459.025, Florida Statutes, is amended to read:

459.025 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(1) NOTICE.—

(a) When an osteopathic physician enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic licensed pursuant to s. 401.27, which relationship or orders contemplate the performance of medical acts, or when an osteopathic physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts ~~identified and approved by the joint committee pursuant to s. 464.003(2)~~ or acts set forth in s. 464.012(3) and (4), the osteopathic physician shall submit notice to the board. The notice must contain a statement in substantially the following form:

I, ...(name and professional license number of osteopathic physician)..., of ...(address of osteopathic physician)... have hereby entered into a formal supervisory relationship, standing orders, or an established protocol with ... (number of persons)... emergency medical technician(s), ...(number of persons)... paramedic(s), or ...(number of persons)... advanced registered nurse practitioner(s).

Section 22. Subsection (10) of s. 458.331, paragraph (g) of subsection (7) of s. 458.347, subsection (10) of s. 459.015, paragraph (f) of subsection (7) of s. 459.022, and paragraph (b) of subsection (5) of s. 465.0158, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.072, Florida Statutes, in references thereto.

Section 23. Paragraph (mm) of subsection (1) of s. 456.072 and s. 466.02751, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.44, Florida Statutes, in references thereto.

Section 24. Section 458.303, paragraph (b) of subsection (7) of s. 458.3475, paragraph (e) of subsection (4) and paragraph (c) of subsection (9) of s. 459.022, and paragraph (b) of subsection (7) of s. 459.023, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 458.347, Florida Statutes, in references thereto.

Section 25. Paragraph (c) of subsection (3) of s. 464.012, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 464.003, Florida Statutes, in a reference thereto.

Section 26. Paragraph (a) of subsection (1) of s. 456.041, subsections (1) and (2) of s. 458.348, and subsection (1) of s. 459.025, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.012, Florida Statutes, in references thereto.

Section 27. Subsection (7) of s. 464.0205, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 464.013, Florida Statutes, in a reference thereto.

Section 28. Subsection (11) of s. 320.0848, subsection (2) of s. 464.008, subsection (5) of s. 464.009, and paragraph (b) of subsection (1), subsection (3), and paragraph (b) of subsection (4) of s. 464.0205, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.018, Florida Statutes, in references thereto.

Section 29. Section 775.051, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 893.02, Florida Statutes, in a reference thereto.

Section 30. Paragraph (a) of subsection (3) of s. 944.17, subsection (8) of s. 948.001, and paragraph (e) of subsection (1) of s. 948.101, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 948.03, Florida Statutes, in references thereto.

Section 31. Except as otherwise expressly provided in this act, this act shall take effect upon becoming a law.

Approved by the Governor April 14, 2016.

Filed in Office Secretary of State April 14, 2016.

**893.03 Standards and schedules.**—The substances enumerated in this section are controlled by this chapter. The controlled substances listed or to be listed in Schedules I, II, III, IV, and V are included by whatever official, common, usual, chemical, trade name, or class designated. The provisions of this section shall not be construed to include within any of the schedules contained in this section any excluded drugs listed within the purview of 21 C.F.R. s. 1308.22, styled “Excluded Substances”; 21 C.F.R. s. 1308.24, styled “Exempt Chemical Preparations”; 21 C.F.R. s. 1308.32, styled “Exempted Prescription Products”; or 21 C.F.R. s. 1308.34, styled “Exempt Anabolic Steroid Products.”

(1) SCHEDULE I.—A substance in Schedule I has a high potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. The following substances are controlled in Schedule I:

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1. Acetyl-alpha-methylfentanyl.
2. Acetylmethadol.
3. Allylprodine.
4. Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).
5. Alphamethadol.
6. Alpha-methylfentanyl (N-[1-(alpha-methyl-betaphenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine).
7. Alpha-methylthiofentanyl.
8. Alphameprodine.
9. Benzethidine.
10. Benzylfentanyl.
11. Betacetylmethadol.
12. Beta-hydroxyfentanyl.
13. Beta-hydroxy-3-methylfentanyl.
14. Betameprodine.
15. Betamethadol.
16. Betaprodine.
17. Clonitazene.

18. Dextromoramide.
19. Diampromide.
20. Diethylthiambutene.
21. Difenoxin.
22. Dimenoxadol.
23. Dimepheptanol.
24. Dimethylthiambutene.
25. Dioxaphetyl butyrate.
26. Dipipanone.
27. Ethylmethylthiambutene.
28. Etonitazene.
29. Etoxidine.
30. Flunitrazepam.
31. Furethidine.
32. Hydroxypethidine.
33. Ketobemidone.
34. Levomoramide.
35. Levophenacymorphan.
36. Desmethylprodine (1-Methyl-4-Phenyl-4-Propionoxypiperidine).
37. 3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide).
38. 3-Methylthiofentanyl.
39. Morpheridine.
40. Noracymethadol.
41. Norlevorphanol.
42. Normethadone.
43. Norpipanone.
44. Para-Fluorofentanyl.
45. Phenadoxone.
46. Phenampromide.
47. Phenomorphan.
48. Phenoperidine.
49. PEPAP (1-(2-Phenylethyl)-4-Phenyl-4-Acetyloxypiperidine).
50. Piritramide.
51. Proheptazine.
52. Properidine.
53. Propiram.

54. Racemoramide.
55. Thenylfentanyl.
56. Thiofentanyl.
57. Tilidine.
58. Trimeperidine.
59. Acetylfentanyl.
60. Butyrylfentanyl.
61. Beta-Hydroxythiofentanyl.

(b) Unless specifically excepted or unless listed in another schedule, any of the following substances, their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1. Acetorphine.
2. Acetyldihydrocodeine.
3. Benzylmorphine.
4. Codeine methylbromide.
5. Codeine-N-Oxide.
6. Cyprenorphine.
7. Desomorphine.
8. Dihydromorphine.
9. Drotebanol.
10. Etorphine (except hydrochloride salt).
11. Heroin.
12. Hydromorphenol.
13. Methyldesorphine.
14. Methyldihydromorphine.
15. Monoacetylmorphine.
16. Morphine methylbromide.
17. Morphine methylsulfonate.
18. Morphine-N-Oxide.
19. Myrophine.
20. Nicocodine.
21. Nicomorphine.
22. Normorphine.
23. Pholcodine.
24. Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances or that contains any of their salts, isomers, including optical, positional, or geometric isomers, homologues, nitrogen-heterocyclic analogs, esters, ethers, and salts of isomers, homologues, nitrogen-heterocyclic analogs, esters, or ethers, if the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation or class description:

1. Alpha-Ethyltryptamine.
2. 4-Methylaminorex (2-Amino-4-methyl-5-phenyl-2-oxazoline).
3. Aminorex (2-Amino-5-phenyl-2-oxazoline).
4. DOB (4-Bromo-2,5-dimethoxyamphetamine).
5. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).
6. Bufotenine.
7. Cannabis.
8. Cathinone.
9. DET (Diethyltryptamine).
10. 2,5-Dimethoxyamphetamine.
11. DOET (4-Ethyl-2,5-Dimethoxyamphetamine).
12. DMT (Dimethyltryptamine).
13. PCE (N-Ethyl-1-phenylcyclohexylamine)(Ethylamine analog of phencyclidine).
14. JB-318 (N-Ethyl-3-piperidyl benzilate).
15. N-Ethylamphetamine.
16. Fenethylamine.
17. 3,4-Methylenedioxy-N-hydroxyamphetamine.
18. Ibogaine.
19. LSD (Lysergic acid diethylamide).
20. Mescaline.
21. Methcathinone.
22. 5-Methoxy-3,4-methylenedioxyamphetamine.
23. PMA (4-Methoxyamphetamine).
24. PMMA (4-Methoxymethamphetamine).
25. DOM (4-Methyl-2,5-dimethoxyamphetamine).
26. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).
27. MDA (3,4-Methylenedioxyamphetamine).
28. JB-336 (N-Methyl-3-piperidyl benzilate).
29. N,N-Dimethylamphetamine.
30. Parahexyl.

31. Peyote.
32. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine) (Pyrrolidine analog of phencyclidine).
33. Psilocybin.
34. Psilocyn.
35. *Salvia divinorum*, except for any drug product approved by the United States Food and Drug Administration which contains *Salvia divinorum* or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.
36. Salvinorin A, except for any drug product approved by the United States Food and Drug Administration which contains Salvinorin A or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.
37. Xylazine.
38. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine) (Thiophene analog of phencyclidine).
39. 3,4,5-Trimethoxyamphetamine.
40. Methyldone (3,4-Methylenedioxy-methcathinone).
41. MDPV (3,4-Methylenedioxy-pyrovalerone).
42. Methylmethcathinone.
43. Methoxymethcathinone.
44. Fluoromethcathinone.
45. Methylethcathinone.
46. CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-yl)phenol) and its dimethyloctyl (C8) homologue.
47. HU-210 [(6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol].
48. JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).
49. JWH-073 (1-Butyl-3-(1-naphthoyl)indole).
50. JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole).
51. BZP (Benzylpiperazine).
52. Fluorophenylpiperazine.
53. Methylphenylpiperazine.
54. Chlorophenylpiperazine.
55. Methoxyphenylpiperazine.
56. DBZP (1,4-Dibenzylpiperazine).
57. TFMPP (Trifluoromethylphenylpiperazine).
58. MBDB (Methylbenzodioxolylbutanamine) or (3,4-Methylenedioxy-N-methylbutanamine).

59. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).
60. 5-Hydroxy-N-methyltryptamine.
61. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).
62. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).
63. Methyltryptamine.
64. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).
65. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).
66. Tyramine (4-Hydroxyphenethylamine).
67. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).
68. DiPT (N,N-Diisopropyltryptamine).
69. DPT (N,N-Dipropyltryptamine).
70. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).
71. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).
72. DOI (4-Iodo-2,5-dimethoxyamphetamine).
73. DOC (4-Chloro-2,5-dimethoxyamphetamine).
74. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).
75. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).
76. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).
77. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).
78. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).
79. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).
80. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).
81. Butylone (3,4-Methylenedioxy-alpha-methylaminobutyrophenone).
82. Ethcathinone.
83. Ethylone (3,4-Methylenedioxy-N-ethylcathinone).
84. Naphyrone (Naphthylpyrovalerone).
85. Dimethylone (3,4-Methylenedioxy-N,N-dimethylcathinone).
86. 3,4-Methylenedioxy-N,N-diethylcathinone.
87. 3,4-Methylenedioxy-propiofenone.
88. 3,4-Methylenedioxy-alpha-bromopropiofenone.
89. 3,4-Methylenedioxy-propiofenone-2-oxime.
90. 3,4-Methylenedioxy-N-acetylcathinone.
91. 3,4-Methylenedioxy-N-acetylmethcathinone.
92. 3,4-Methylenedioxy-N-acetylethcathinone.
93. Bromomethcathinone.
94. Buphedrone (alpha-Methylamino-butyrophenone).

95. Eutylone (3,4-Methylenedioxy-alpha-ethylaminobutyrophenone).
96. Dimethylcathinone.
97. Dimethylmethcathinone.
98. Pentylone (3,4-Methylenedioxy-alpha-methylaminovalerophenone).
99. MDPPP (3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone).
100. MDPBP (3,4-Methylenedioxy-alpha-pyrrolidinobutyrophenone).
101. MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).
102. MPHP (Methyl-alpha-pyrrolidinohexanophenone).
103. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP (Benocyclidine).
104. F-MABP (Fluoromethylaminobutyrophenone).
105. MeO-PBP (Methoxypyrrolidinobutyrophenone).
106. Et-PBP (Ethylpyrrolidinobutyrophenone).
107. 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).
108. Me-EABP (Methylethylaminobutyrophenone).
109. Etizolam.
110. PPP (Pyrrolidinopropiophenone).
111. PBP (Pyrrolidinobutyrophenone).
112. PVP (Pyrrolidinovalerophenone) or (Pyrrolidinopentiophenone).
113. MPPP (Methyl-alpha-pyrrolidinopropiophenone).
114. JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).
115. JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).
116. JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).
117. JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).
118. JWH-072 (1-Propyl-3-(1-naphthoyl)indole).
119. JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).
120. JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).
121. JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).
122. JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).
123. JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).
124. JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).
125. JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).
126. JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).
127. JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).
128. JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).
129. JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole).

130. HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).
131. HU-308 ([1R,2R,5R)-2-[2,6-Dimethoxy-4-(2-methyloctan-2-yl)phenyl]-7,7-dimethyl-4-bicyclo[3.1.1]hept-3-enyl] methanol).
132. HU-331 (3-Hydroxy-2-[(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-2,5-cyclohexadiene-1,4-dione).
133. CB-13 (4-Pentyloxy-1-(1-naphthoyl)naphthalene).
134. CB-25 (N-Cyclopropyl-11-(3-hydroxy-5-pentylphenoxy)-undecanamide).
135. CB-52 (N-Cyclopropyl-11-(2-hexyl-5-hydroxyphenoxy)-undecanamide).
136. CP 55,940 (2-[3-Hydroxy-6-propanol-cyclohexyl]-5-(2-methyloctan-2-yl)phenol).
137. AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).
138. AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole).
139. RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).
140. RCS-8 (1-(2-Cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole).
141. WIN55,212-2 ((R)-(+)-[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).
142. WIN55,212-3 ([3S]-2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).
143. Pentedrone (alpha-Methylaminovalerophenone).
144. Fluoroamphetamine.
145. Fluoromethamphetamine.
146. Methoxetamine.
147. Methiopropamine.
148. Methylbuphedrone (Methyl-alpha-methylaminobutyrophenone).
149. APB ((2-Aminopropyl)benzofuran).
150. APDB ((2-Aminopropyl)-2,3-dihydrobenzofuran).
151. UR-144 (1-Pentyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
152. XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
153. Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
154. AKB48 (N-Adamant-1-yl 1-pentylindazole-3-carboxamide).
155. AM-2233(1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodobenzoyl)indole).
156. STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-carboxamide).
157. URB-597 ((3'-(Aminocarbonyl)[1,1'-biphenyl]-3-yl)-cyclohexylcarbamate).
158. URB-602 ([1,1'-Biphenyl]-3-yl-carbamic acid, cyclohexyl ester).
159. URB-754 (6-Methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one).
160. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).

161. 2C-H (2,5-Dimethoxyphenethylamine).
162. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).
163. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).
164. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
165. MDMA (3,4-Methylenedioxyamphetamine).
166. PB-22 (8-Quinoliny 1-pentylindole-3-carboxylate).
167. Fluoro PB-22 (8-Quinoliny 1-(fluoropentyl)indole-3-carboxylate).
168. BB-22 (8-Quinoliny 1-(cyclohexylmethyl)indole-3-carboxylate).
169. Fluoro AKB48 (N-Adamant-1-yl 1-(fluoropentyl)indazole-3-carboxamide).
170. AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).
171. AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).
172. ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).
173. Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).
174. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
175. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
176. AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).
177. FUB-PB-22 (8-Quinoliny 1-(4-fluorobenzyl)indole-3-carboxylate).
178. Fluoro-NNEI (N-Naphthalen-1-yl 1-(fluoropentyl)indole-3-carboxamide).
179. Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).
180. THJ-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indazole).
181. AM-855 ((4aR,12bR)-8-Hexyl-2,5,5-trimethyl-1,4,4a,8,9,10,11,12b-octahydronaphtho[3,2-c]isochromen-12-ol).
182. AM-905 ((6aR,9R,10aR)-3-[(E)-Hept-1-enyl]-9-(hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-hexahydrobenzo[c]chromen-1-ol).
183. AM-906 ((6aR,9R,10aR)-3-[(Z)-Hept-1-enyl]-9-(hydroxymethyl)-6,6-dimethyl-6a,7,8,9,10,10a-hexahydrobenzo[c]chromen-1-ol).
184. AM-2389 ((6aR,9R,10aR)-3-(1-Hexyl-cyclobut-1-yl)-6a,7,8,9,10,10a-hexahydro-6,6-dimethyl-6H-dibenzo[b,d]pyran-1,9 diol).
185. HU-243 ((6aR,8S,9S,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-8,9-ditritio-7,8,10,10a-tetrahydro-6aH-benzo[c]chromen-1-ol).
186. HU-336 ((6aR,10aR)-6,6,9-Trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-1H-benzo[c]chromene-1,4(6H)-dione).

187. MAPB ((2-Methylaminopropyl)benzofuran).

188. 5-IT (2-(1H-Indol-5-yl)-1-methyl-ethylamine).

189. 6-IT (2-(1H-Indol-6-yl)-1-methyl-ethylamine).

190. Synthetic Cannabinoids.—Unless specifically excepted or unless listed in another schedule or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation that contains any quantity of a synthetic cannabinoid found to be in any of the following chemical class descriptions, or homologues, nitrogen-heterocyclic analogs, isomers (including optical, positional, or geometric), esters, ethers, salts, and salts of homologues, nitrogen-heterocyclic analogs, isomers, esters, or ethers, whenever the existence of such homologues, nitrogen-heterocyclic analogs, isomers, esters, ethers, salts, and salts of isomers, esters, or ethers is possible within the specific chemical class or designation. Since nomenclature of these synthetically produced cannabinoids is not internationally standardized and may continually evolve, these structures or the compounds of these structures shall be included under this subparagraph, regardless of their specific numerical designation of atomic positions covered, if it can be determined through a recognized method of scientific testing or analysis that the substance contains properties that fit within one or more of the following categories:

a. Tetrahydrocannabinols.—Any tetrahydrocannabinols naturally contained in a plant of the genus *Cannabis*, the synthetic equivalents of the substances contained in the plant or in the resinous extracts of the genus *Cannabis*, or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity, including, but not limited to, Delta 9 tetrahydrocannabinols and their optical isomers, Delta 8 tetrahydrocannabinols and their optical isomers, Delta 6a,10a tetrahydrocannabinols and their optical isomers, or any compound containing a tetrahydrobenzo[c]chromene structure with substitution at either or both the 3-position or 9-position, with or without substitution at the 1-position with hydroxyl or alkoxy groups, including, but not limited to:

(I) Tetrahydrocannabinol.

(II) HU-210 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(III) HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(IV) JWH-051 ((6aR,10aR)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(V) JWH-133 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VI) JWH-057 ((6aR,10aR)-6,6,9-Trimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VII) JWH-359 ((6aR,10aR)-1-Methoxy-6,6,9-trimethyl-3-(2,3-dimethylpentan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromene).

(VIII) AM-087 ((6aR,10aR)-3-(2-Methyl-6-bromohex-2-yl)-6,6,9-trimethyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(IX) AM-411 ((6aR,10aR)-3-(1-Adamantyl)-6,6,9-trimethyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

(X) Parahexyl.

b. Naphthoylindoles, Naphthoylindazoles, Naphthoylcarbazoles, Naphthylmethylindoles, Naphthylmethylindazoles, and Naphthylmethylcarbazoles.—Any compound containing a naphthoylindole, naphthoylindazole, naphthoylcarbazole, naphthylmethylindole, naphthylmethylindazole, or naphthylmethylcarbazole structure, with or without substitution on the indole, indazole, or carbazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) JWH-007 (1-Pentyl-2-methyl-3-(1-naphthoyl)indole).

(II) JWH-011 (1-(1-Methylhexyl)-2-methyl-3-(1-naphthoyl)indole).

(III) JWH-015 (1-Propyl-2-methyl-3-(1-naphthoyl)indole).

(IV) JWH-016 (1-Butyl-2-methyl-3-(1-naphthoyl)indole).

(V) JWH-018 (1-Pentyl-3-(1-naphthoyl)indole).

(VI) JWH-019 (1-Hexyl-3-(1-naphthoyl)indole).

(VII) JWH-020 (1-Heptyl-3-(1-naphthoyl)indole).

(VIII) JWH-022 (1-(4-Pentenyl)-3-(1-naphthoyl)indole).

(IX) JWH-071 (1-Ethyl-3-(1-naphthoyl)indole).

(X) JWH-072 (1-Propyl-3-(1-naphthoyl)indole).

(XI) JWH-073 (1-Butyl-3-(1-naphthoyl)indole).

(XII) JWH-080 (1-Butyl-3-(4-methoxy-1-naphthoyl)indole).

(XIII) JWH-081 (1-Pentyl-3-(4-methoxy-1-naphthoyl)indole).

(XIV) JWH-098 (1-Pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole).

(XV) JWH-116 (1-Pentyl-2-ethyl-3-(1-naphthoyl)indole).

(XVI) JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).

(XVII) JWH-149 (1-Pentyl-2-methyl-3-(4-methyl-1-naphthoyl)indole).

(XVIII) JWH-164 (1-Pentyl-3-(7-methoxy-1-naphthoyl)indole).

(XIX) JWH-175 (1-Pentyl-3-(1-naphthylmethyl)indole).

(XX) JWH-180 (1-Propyl-3-(4-propyl-1-naphthoyl)indole).

(XXI) JWH-182 (1-Pentyl-3-(4-propyl-1-naphthoyl)indole).

- (XXII) JWH-184 (1-Pentyl-3-[(4-methyl)-1-naphthylmethyl]indole).
- (XXIII) JWH-193 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methyl-1-naphthoyl)indole).
- (XXIV) JWH-198 (1-[2-(4-Morpholinyl)ethyl]-3-(4-methoxy-1-naphthoyl)indole).
- (XXV) JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole).
- (XXVI) JWH-210 (1-Pentyl-3-(4-ethyl-1-naphthoyl)indole).
- (XXVII) JWH-387 (1-Pentyl-3-(4-bromo-1-naphthoyl)indole).
- (XXVIII) JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole).
- (XXIX) JWH-412 (1-Pentyl-3-(4-fluoro-1-naphthoyl)indole).
- (XXX) JWH-424 (1-Pentyl-3-(8-bromo-1-naphthoyl)indole).
- (XXXI) AM-1220 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(1-naphthoyl)indole).
- (XXXII) AM-1235 (1-(5-Fluoropentyl)-6-nitro-3-(1-naphthoyl)indole).
- (XXXIII) AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole).
- (XXXIV) Chloro JWH-018 (1-(Chloropentyl)-3-(1-naphthoyl)indole).
- (XXXV) Bromo JWH-018 (1-(Bromopentyl)-3-(1-naphthoyl)indole).
- (XXXVI) AM-2232 (1-(4-Cyanobutyl)-3-(1-naphthoyl)indole).
- (XXXVII) THJ-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indazole).
- (XXXVIII) MAM-2201 (1-(5-Fluoropentyl)-3-(4-methyl-1-naphthoyl)indole).
- (XXXIX) EAM-2201 (1-(5-Fluoropentyl)-3-(4-ethyl-1-naphthoyl)indole).
- (XL) EG-018 (9-Pentyl-3-(1-naphthoyl)carbazole).
- (XLI) EG-2201 (9-(5-Fluoropentyl)-3-(1-naphthoyl)carbazole).

c. Naphthoylpyrroles.—Any compound containing a naphthoylpyrrole structure, with or without substitution on the pyrrole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

- (I) JWH-030 (1-Pentyl-3-(1-naphthoyl)pyrrole).
- (II) JWH-031 (1-Hexyl-3-(1-naphthoyl)pyrrole).
- (III) JWH-145 (1-Pentyl-5-phenyl-3-(1-naphthoyl)pyrrole).
- (IV) JWH-146 (1-Heptyl-5-phenyl-3-(1-naphthoyl)pyrrole).
- (V) JWH-147 (1-Hexyl-5-phenyl-3-(1-naphthoyl)pyrrole).
- (VI) JWH-307 (1-Pentyl-5-(2-fluorophenyl)-3-(1-naphthoyl)pyrrole).
- (VII) JWH-309 (1-Pentyl-5-(1-naphthalenyl)-3-(1-naphthoyl)pyrrole).
- (VIII) JWH-368 (1-Pentyl-5-(3-fluorophenyl)-3-(1-naphthoyl)pyrrole).
- (IX) JWH-369 (1-Pentyl-5-(2-chlorophenyl)-3-(1-naphthoyl)pyrrole).
- (X) JWH-370 (1-Pentyl-5-(2-methylphenyl)-3-(1-naphthoyl)pyrrole).

d. Naphthylmethylenindenes.—Any compound containing a naphthylmethylenindene structure, with or without substitution at the 3-position of the indene ring to any extent, whether or not

substituted on the naphthyl ring to any extent, including, but not limited to, JWH-176 (3-Pentyl-1-(naphthylmethylene)indene).

e. Phenylacetylindoles and Phenylacetylindazoles.—Any compound containing a phenylacetylindole or phenylacetylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring to any extent, including, but not limited to:

- (I) JWH-167 (1-Pentyl-3-(phenylacetyl)indole).
- (II) JWH-201 (1-Pentyl-3-(4-methoxyphenylacetyl)indole).
- (III) JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole).
- (IV) JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole).
- (V) JWH-251 (1-Pentyl-3-(2-methylphenylacetyl)indole).
- (VI) JWH-302 (1-Pentyl-3-(3-methoxyphenylacetyl)indole).
- (VII) Cannabipiperidiethanone.
- (VIII) RCS-8 (1-(2-Cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole).

f. Cyclohexylphenols.—Any compound containing a cyclohexylphenol structure, with or without substitution at the 5-position of the phenolic ring to any extent, whether or not substituted on the cyclohexyl ring to any extent, including, but not limited to:

- (I) CP 47,497 (2-(3-Hydroxycyclohexyl)-5-(2-methyloctan-2-yl)phenol).
- (II) Cannabicyclohexanol (CP 47,497 dimethyloctyl (C8) homologue).
- (III) CP-55,940 (2-(3-Hydroxy-6-propanol-cyclohexyl)-5-(2-methyloctan-2-yl)phenol).

g. Benzoylindoles and Benzoylindazoles.—Any compound containing a benzoylindole or benzoylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring to any extent, including, but not limited to:

- (I) AM-679 (1-Pentyl-3-(2-iodobenzoyl)indole).
- (II) AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole).
- (III) AM-1241 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodo-5-nitrobenzoyl)indole).
- (IV) Pravadoline (1-[2-(4-Morpholinyl)ethyl]-2-methyl-3-(4-methoxybenzoyl)indole).
- (V) AM-2233 (1-[(N-Methyl-2-piperidinyl)methyl]-3-(2-iodobenzoyl)indole).
- (VI) RCS-4 (1-Pentyl-3-(4-methoxybenzoyl)indole).
- (VII) RCS-4 C4 homologue (1-Butyl-3-(4-methoxybenzoyl)indole).
- (VIII) AM-630 (1-[2-(4-Morpholinyl)ethyl]-2-methyl-6-iodo-3-(4-methoxybenzoyl)indole).

h. Tetramethylcyclopropanoylindoles and Tetramethylcyclopropanoylindazoles.—Any compound containing a tetramethylcyclopropanoylindole or tetramethylcyclopropanoylindazole structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the tetramethylcyclopropyl group to any extent, including, but not limited to:

- (I) UR-144 (1-Pentyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

- (II) XLR11 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (III) Chloro UR-144 (1-(Chloropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (IV) A-796,260 (1-[2-(4-Morpholinyl)ethyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (V) A-834,735 (1-[4-(Tetrahydropyranyl)methyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (VI) M-144 (1-(5-Fluoropentyl)-2-methyl-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (VII) FUB-144 (1-(4-Fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (VIII) FAB-144 (1-(5-Fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indazole).
- (IX) XLR12 (1-(4,4,4-Trifluorobutyl)-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).
- (X) AB-005 (1-[(1-Methyl-2-piperidinyl)methyl]-3-(2,2,3,3-tetramethylcyclopropanoyl)indole).

i. Adamantoylindoles, Adamantoylindazoles, Adamantylindole carboxamides, and Adamantylindazole carboxamides.—Any compound containing an adamantoyl indole, adamantoyl indazole, adamantyl indole carboxamide, or adamantyl indazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent, including, but not limited to:

- (I) AKB48 (N-Adamant-1-yl 1-pentylindazole-3-carboxamide).
- (II) Fluoro AKB48 (N-Adamant-1-yl 1-(fluoropentyl)indazole-3-carboxamide).
- (III) STS-135 (N-Adamant-1-yl 1-(5-fluoropentyl)indole-3-carboxamide).
- (IV) AM-1248 (1-(1-Methylpiperidine)methyl-3-(1-adamantoyl)indole).
- (V) AB-001 (1-Pentyl-3-(1-adamantoyl)indole).
- (VI) APICA (N-Adamant-1-yl 1-pentylindole-3-carboxamide).
- (VII) Fluoro AB-001 (1-(Fluoropentyl)-3-(1-adamantoyl)indole).

j. Quinolinyndolecarboxylates, Quinolinyndazolecarboxylates, Quinolinyndolecarboxamides, and Quinolinyndazolecarboxamides.—Any compound containing a quinolinyndole carboxylate, quinolinyndazole carboxylate, isoquinolinyndole carboxylate, isoquinolinyndazole carboxylate, quinolinyndole carboxamide, quinolinyndazole carboxamide, isoquinolinyndole carboxamide, or isoquinolinyndazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the quinoline or isoquinoline ring to any extent, including, but not limited to:

- (I) PB-22 (8-Quinolinyndole 1-pentylindole-3-carboxylate).
- (II) Fluoro PB-22 (8-Quinolinyndole 1-(fluoropentyl)indole-3-carboxylate).
- (III) BB-22 (8-Quinolinyndole 1-(cyclohexylmethyl)indole-3-carboxylate).
- (IV) FUB-PB-22 (8-Quinolinyndole 1-(4-fluorobenzyl)indole-3-carboxylate).
- (V) NPB-22 (8-Quinolinyndole 1-pentylindazole-3-carboxylate).
- (VI) Fluoro NPB-22 (8-Quinolinyndole 1-(fluoropentyl)indazole-3-carboxylate).
- (VII) FUB-NPB-22 (8-Quinolinyndole 1-(4-fluorobenzyl)indazole-3-carboxylate).
- (VIII) THJ (8-Quinolinyndole 1-pentylindazole-3-carboxamide).

(IX) Fluoro THJ (8-Quinoliny 1-(fluoropentyl)indazole-3-carboxamide).

k. Naphthylindolecarboxylates and Naphthylindazolecarboxylates.—Any compound containing a naphthylindole carboxylate or naphthylindazole carboxylate structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) NM-2201 (1-Naphthalenyl 1-(5-fluoropentyl)indole-3-carboxylate).

(II) SDB-005 (1-Naphthalenyl 1-pentylindazole-3-carboxylate).

(III) Fluoro SDB-005 (1-Naphthalenyl 1-(fluoropentyl)indazole-3-carboxylate).

(IV) FDU-PB-22 (1-Naphthalenyl 1-(4-fluorobenzyl)indole-3-carboxylate).

(V) 3-CAF (2-Naphthalenyl 1-(2-fluorophenyl)indazole-3-carboxylate).

l. Naphthylindole carboxamides and Naphthylindazole carboxamides.—Any compound containing a naphthylindole carboxamide or naphthylindazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the naphthyl ring to any extent, including, but not limited to:

(I) NNEI (N-Naphthalen-1-yl 1-pentylindole-3-carboxamide).

(II) Fluoro-NNEI (N-Naphthalen-1-yl 1-(fluoropentyl)indole-3-carboxamide).

(III) Chloro-NNEI (N-Naphthalen-1-yl 1-(chloropentyl)indole-3-carboxamide).

(IV) MN-18 (N-Naphthalen-1-yl 1-pentylindazole-3-carboxamide).

(V) Fluoro MN-18 (N-Naphthalen-1-yl 1-(fluoropentyl)indazole-3-carboxamide).

m. Alkylcarbonyl indole carboxamides, Alkylcarbonyl indazole carboxamides, Alkylcarbonyl indole carboxylates, and Alkylcarbonyl indazole carboxylates.—Any compound containing an alkylcarbonyl group, including 1-amino-3-methyl-1-oxobutan-2-yl, 1-methoxy-3-methyl-1-oxobutan-2-yl, 1-amino-1-oxo-3-phenylpropan-2-yl, 1-methoxy-1-oxo-3-phenylpropan-2-yl, with an indole carboxamide, indazole carboxamide, indole carboxylate, or indazole carboxylate, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the alkylcarbonyl group to any extent, including, but not limited to:

(I) ADBICA, (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindole-3-carboxamide).

(II) Fluoro ADBICA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

(III) Fluoro ABICA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

(IV) AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(V) Fluoro AB-PINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(VI) ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(VII) Fluoro ADB-PINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(VIII) AB-FUBINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(IX) ADB-FUBINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(X) AB-CHMINACA (N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XI) MA-CHMINACA (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XII) MAB-CHMINACA (N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XIII) AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide).

(XIV) Fluoro-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(fluoropentyl)indazole-3-carboxamide).

(XV) FUB-AMB (N-(1-Methoxy-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XVI) MDMB-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XVII) MDMB-FUBINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XVIII) MDMB-CHMICA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide).

(XIX) PX-1 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-fluoropentyl)indole-3-carboxamide).

(XX) PX-2 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide).

(XXI) PX-3 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide).

(XXII) PX-4 (N-(1-Amino-1-oxo-3-phenylpropan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide).

(XXIII) MO-CHMINACA (N-(1-Methoxy-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxylate).

n. Cumylindolecarboxamides and Cumylindazolecarboxamides.—Any compound containing a N-(2-phenylpropan-2-yl) indole carboxamide or N-(2-phenylpropan-2-yl) indazole carboxamide structure, with or without substitution on the indole or indazole ring to any extent, whether or not substituted on the phenyl ring of the cumyl group to any extent, including, but not limited to:

(I) CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-pentylindole-3-carboxamide).

(II) Fluoro CUMYL-PICA (N-(2-Phenylpropan-2-yl)-1-(fluoropentyl)indole-3-carboxamide).

o. Other Synthetic Cannabinoids.—Any material, compound, mixture, or preparation that contains any quantity of a Synthetic Cannabinoid, as described in sub-subparagraphs a.-n.:

(I) With or without modification or replacement of a carbonyl, carboxamide, alkylene, alkyl, or carboxylate linkage between either two core rings, or linkage between a core ring and group structure, with or without the addition of a carbon or replacement of a carbon;

(II) With or without replacement of a core ring or group structure, whether or not substituted on the ring or group structures to any extent; and

(III) Is a cannabinoid receptor agonist, unless specifically excepted or unless listed in another schedule or contained within a pharmaceutical product approved by the United States Food and Drug Administration.

191. Substituted Cathinones.—Unless specifically excepted, listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations:

- a. Any compound containing a 2-amino-1-phenyl-1-propanone structure;
- b. Any compound containing a 2-amino-1-naphthyl-1-propanone structure; or
- c. Any compound containing a 2-amino-1-thiophenyl-1-propanone structure,

whether or not the compound is further modified:

(I) With or without substitution on the ring system to any extent with alkyl, alkylthio, thio, fused alkylendioxy, alkoxy, haloalkyl, hydroxyl, nitro, fused furan, fused benzofuran, fused dihydrofuran, fused tetrahydropyran, fused alkyl ring, or halide substituents;

(II) With or without substitution at the 3-propanone position with an alkyl substituent or removal of the methyl group at the 3-propanone position;

(III) With or without substitution at the 2-amino nitrogen atom with alkyl, dialkyl, acetyl, or benzyl groups, whether or not further substituted in the ring system; or

(IV) With or without inclusion of the 2-amino nitrogen atom in a cyclic structure, including, but not limited to:

- (A) Methcathinone.
- (B) Ethcathinone.
- (C) Methylone (3,4-Methylenedioxy-methcathinone).
- (D) 2,3-Methylenedioxy-methcathinone.
- (E) MDPV (3,4-Methylenedioxy-pyrovalerone).
- (F) Methylmethcathinone.
- (G) Methoxymethcathinone.

- (H) Fluoromethcathinone.
- (I) Methylethcathinone.
- (J) Butylone (3,4-Methylenedioxy-alpha-methylaminobutyrophenone).
- (K) Ethylone (3,4-Methylenedioxy-N-ethylcathinone).
- (L) BMDP (3,4-Methylenedioxy-N-benzylcathinone).
- (M) Naphyrone (Naphthylpyrovalerone).
- (N) Bromomethcathinone.
- (O) Buphedrone (alpha-Methylaminobutyrophenone).
- (P) Eutylone (3,4-Methylenedioxy-alpha-ethylaminobutyrophenone).
- (Q) Dimethylcathinone.
- (R) Dimethylmethcathinone.
- (S) Pentylone (3,4-Methylenedioxy-alpha-methylaminovalerophenone).
- (T) Pentedrone (alpha-Methylaminovalerophenone).
- (U) MDPPP (3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone).
- (V) MDPBP (3,4-Methylenedioxy-alpha-pyrrolidinobutyrophenone).
- (W) MPPP (Methyl-alpha-pyrrolidinopropiophenone).
- (X) PPP (Pyrrolidinopropiophenone).
- (Y) PVP (Pyrrolidinovalerophenone) or (Pyrrolidinopentiophenone).
- (Z) MOPPP (Methoxy-alpha-pyrrolidinopropiophenone).
- (AA) MPHP (Methyl-alpha-pyrrolidinohexanophenone).
- (BB) F-MABP (Fluoromethylaminobutyrophenone).
- (CC) Me-EABP (Methylethylaminobutyrophenone).
- (DD) PBP (Pyrrolidinobutyrophenone).
- (EE) MeO-PBP (Methoxypyrrolidinobutyrophenone).
- (FF) Et-PBP (Ethylpyrrolidinobutyrophenone).
- (GG) 3-Me-4-MeO-MCAT (3-Methyl-4-Methoxymethcathinone).
- (HH) Dimethylone (3,4-Methylenedioxy-N,N-dimethylcathinone).
- (II) 3,4-Methylenedioxy-N,N-diethylcathinone.
- (JJ) 3,4-Methylenedioxy-N-acetylcathinone.
- (KK) 3,4-Methylenedioxy-N-acetylmethcathinone.
- (LL) 3,4-Methylenedioxy-N-acetylethcathinone.
- (MM) Methylbuphedrone (Methyl-alpha-methylaminobutyrophenone).
- (NN) Methyl-alpha-methylaminohexanophenone.
- (OO) N-Ethyl-N-methylcathinone.
- (PP) PHP (Pyrrolidinohexanophenone).
- (QQ) PV8 (Pyrrolidinoheptanophenone).

(RR) Chloromethcathinone.

(SS) 4-Bromo-2,5-dimethoxy-alpha-aminoacetophenone.

192. Substituted Phenethylamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations, any compound containing a phenethylamine structure, without a beta-keto group, and without a benzyl group attached to the amine group, whether or not the compound is further modified with or without substitution on the phenyl ring to any extent with alkyl, alkylthio, nitro, alkoxy, thio, halide, fused alkylendioxy, fused furan, fused benzofuran, fused dihydrofuran, or fused tetrahydropyran substituents, whether or not further substituted on a ring to any extent, with or without substitution at the alpha or beta position by any alkyl substituent, with or without substitution at the nitrogen atom, and with or without inclusion of the 2-amino nitrogen atom in a cyclic structure, including, but not limited to:

- a. 2C-B (4-Bromo-2,5-dimethoxyphenethylamine).
- b. 2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).
- c. 2C-T-4 (4-Isopropylthio-2,5-dimethoxyphenethylamine).
- d. 2C-C (4-Chloro-2,5-dimethoxyphenethylamine).
- e. 2C-T (4-Methylthio-2,5-dimethoxyphenethylamine).
- f. 2C-T-2 (4-Ethylthio-2,5-dimethoxyphenethylamine).
- g. 2C-T-7 (4-(n)-Propylthio-2,5-dimethoxyphenethylamine).
- h. 2C-I (4-Iodo-2,5-dimethoxyphenethylamine).
- i. 2C-D (4-Methyl-2,5-dimethoxyphenethylamine).
- j. 2C-H (2,5-Dimethoxyphenethylamine).
- k. 2C-N (4-Nitro-2,5-dimethoxyphenethylamine).
- l. 2C-P (4-(n)-Propyl-2,5-dimethoxyphenethylamine).
- m. MDMA (3,4-Methylenedioxyamphetamine).
- n. MBDB (Methylbenzodioxolylbutanamine) or (3,4-Methylenedioxy-N-methylbutanamine).
- o. MDA (3,4-Methylenedioxyamphetamine).
- p. 2,5-Dimethoxyamphetamine.
- q. Fluoroamphetamine.
- r. Fluoromethamphetamine.
- s. MDEA (3,4-Methylenedioxy-N-ethylamphetamine).
- t. DOB (4-Bromo-2,5-dimethoxyamphetamine).
- u. DOC (4-Chloro-2,5-dimethoxyamphetamine).
- v. DOET (4-Ethyl-2,5-dimethoxyamphetamine).

- w. DOI (4-Iodo-2,5-dimethoxyamphetamine).
- x. DOM (4-Methyl-2,5-dimethoxyamphetamine).
- y. PMA (4-Methoxyamphetamine).
- z. N-Ethylamphetamine.
- aa. 3,4-Methylenedioxy-N-hydroxyamphetamine.
- bb. 5-Methoxy-3,4-methylenedioxyamphetamine.
- cc. PMMA (4-Methoxymethamphetamine).
- dd. N,N-Dimethylamphetamine.
- ee. 3,4,5-Trimethoxyamphetamine.
- ff. 4-APB (4-(2-Aminopropyl)benzofuran).
- gg. 5-APB (5-(2-Aminopropyl)benzofuran).
- hh. 6-APB (6-(2-Aminopropyl)benzofuran).
- ii. 7-APB (7-(2-Aminopropyl)benzofuran).
- jj. 4-APDB (4-(2-Aminopropyl)-2,3-dihydrobenzofuran).
- kk. 5-APDB (5-(2-Aminopropyl)-2,3-dihydrobenzofuran).
- ll. 6-APDB (6-(2-Aminopropyl)-2,3-dihydrobenzofuran).
- mm. 7-APDB (7-(2-Aminopropyl)-2,3-dihydrobenzofuran).
- nn. 4-MAPB (4-(2-Methylaminopropyl)benzofuran).
- oo. 5-MAPB (5-(2-Methylaminopropyl)benzofuran).
- pp. 6-MAPB (6-(2-Methylaminopropyl)benzofuran).
- qq. 7-MAPB (7-(2-Methylaminopropyl)benzofuran).
- rr. 5-EAPB (5-(2-Ethylaminopropyl)benzofuran).
- ss. 5-MAPDB (5-(2-Methylaminopropyl)-2,3-dihydrobenzofuran),

which does not include phenethylamine, mescaline as described in subparagraph 20., substituted cathinones as described in subparagraph 191., N-Benzyl phenethylamine compounds as described in subparagraph 193., or methamphetamine as described in subparagraph (2)(c)4.

193. N-Benzyl Phenethylamine Compounds.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation, including its salts, isomers, esters, or ethers, and salts of isomers, esters, or ethers, whenever the existence of such salts is possible within any of the following specific chemical designations, any compound containing a phenethylamine structure without a beta-keto group, with substitution on the nitrogen atom of the amino group with a benzyl substituent, with or without substitution on the phenyl or benzyl ring to any extent with alkyl, alkoxy, thio, alkylthio, halide, fused alkylendioxy, fused furan, fused benzofuran, or fused tetrahydropyran substituents, whether or not further substituted

on a ring to any extent, with or without substitution at the alpha position by any alkyl substituent, including, but not limited to:

- a. 25B-NBOMe (4-Bromo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- b. 25B-NBOH (4-Bromo-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).
- c. 25B-NBF (4-Bromo-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).
- d. 25B-NBMD (4-Bromo-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).
- e. 25I-NBOMe (4-Iodo-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- f. 25I-NBOH (4-Iodo-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).
- g. 25I-NBF (4-Iodo-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).
- h. 25I-NBMD (4-Iodo-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).
- i. 25T2-NBOMe (4-Methylthio-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- j. 25T4-NBOMe (4-Isopropylthio-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- k. 25T7-NBOMe (4-(n)-Propylthio-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- l. 25C-NBOMe (4-Chloro-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- m. 25C-NBOH (4-Chloro-2,5-dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).
- n. 25C-NBF (4-Chloro-2,5-dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).
- o. 25C-NBMD (4-Chloro-2,5-dimethoxy-[N-(2,3-methylenedioxybenzyl)]phenethylamine).
- p. 25H-NBOMe (2,5-Dimethoxy-[N-(2-methoxybenzyl)]phenethylamine).
- q. 25H-NBOH (2,5-Dimethoxy-[N-(2-hydroxybenzyl)]phenethylamine).
- r. 25H-NBF (2,5-Dimethoxy-[N-(2-fluorobenzyl)]phenethylamine).
- s. 25D-NBOMe (4-Methyl-2,5-dimethoxy-[N-(2-methoxybenzyl)]phenethylamine),

which does not include substituted cathinones as described in subparagraph 191.

194. Substituted Tryptamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation containing a 2-(1H-indol-3-yl)ethanamine, for example tryptamine, structure with or without mono- or di-substitution of the amine nitrogen with alkyl or alkenyl groups, or by inclusion of the amino nitrogen atom in a cyclic structure, whether or not substituted at the alpha position with an alkyl group, whether or not substituted on the indole ring to any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy groups, including, but not limited to:

- a. Alpha-Ethyltryptamine.
- b. Bufotenine.
- c. DET (Diethyltryptamine).
- d. DMT (Dimethyltryptamine).
- e. MET (N-Methyl-N-ethyltryptamine).

- f. DALT (N,N-Diallyltryptamine).
- g. EiPT (N-Ethyl-N-isopropyltryptamine).
- h. MiPT (N-Methyl-N-isopropyltryptamine).
- i. 5-Hydroxy-AMT (5-Hydroxy-alpha-methyltryptamine).
- j. 5-Hydroxy-N-methyltryptamine.
- k. 5-MeO-MiPT (5-Methoxy-N-methyl-N-isopropyltryptamine).
- l. 5-MeO-AMT (5-Methoxy-alpha-methyltryptamine).
- m. Methyltryptamine.
- n. 5-MeO-DMT (5-Methoxy-N,N-dimethyltryptamine).
- o. 5-Me-DMT (5-Methyl-N,N-dimethyltryptamine).
- p. 5-MeO-DiPT (5-Methoxy-N,N-Diisopropyltryptamine).
- q. DiPT (N,N-Diisopropyltryptamine).
- r. DPT (N,N-Dipropyltryptamine).
- s. 4-Hydroxy-DiPT (4-Hydroxy-N,N-diisopropyltryptamine).
- t. 5-MeO-DALT (5-Methoxy-N,N-Diallyltryptamine).
- u. 4-AcO-DMT (4-Acetoxy-N,N-dimethyltryptamine).
- v. 4-AcO-DiPT (4-Acetoxy-N,N-diisopropyltryptamine).
- w. 4-Hydroxy-DET (4-Hydroxy-N,N-diethyltryptamine).
- x. 4-Hydroxy-MET (4-Hydroxy-N-methyl-N-ethyltryptamine).
- y. 4-Hydroxy-MiPT (4-Hydroxy-N-methyl-N-isopropyltryptamine).
- z. Methyl-alpha-ethyltryptamine.
- aa. Bromo-DALT (Bromo-N,N-diallyltryptamine),

which does not include tryptamine, psilocyn as described in subparagraph 34., or psilocybin as described in subparagraph 33.

195. Substituted Phenylcyclohexylamines.—Unless specifically excepted or unless listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, any material, compound, mixture, or preparation containing a phenylcyclohexylamine structure, with or without any substitution on the phenyl ring, any substitution on the cyclohexyl ring, any replacement of the phenyl ring with a thiophenyl or benzothiophenyl ring, with or without substitution on the amine with alkyl, dialkyl, or alkoxy substituents, inclusion of the nitrogen in a cyclic structure, or any combination of the above, including, but not limited to:

- a. BTCP (Benzothiophenylcyclohexylpiperidine) or BCP (Benocyclidine).
- b. PCE (N-Ethyl-1-phenylcyclohexylamine)(Ethylamine analog of phencyclidine).
- c. PCPY (N-(1-Phenylcyclohexyl)-pyrrolidine)(Pyrrolidine analog of phencyclidine).

- d. PCPr (Phenylcyclohexylpropylamine).
- e. TCP (1-[1-(2-Thienyl)-cyclohexyl]-piperidine)(Thiophene analog of phencyclidine).
- f. PCEEA (Phenylcyclohexyl(ethoxyethylamine)).
- g. PCMPA (Phenylcyclohexyl(methoxypropylamine)).
- h. Methoxetamine.
- i. 3-Methoxy-PCE ((3-Methoxyphenyl)cyclohexylethylamine).
- j. Bromo-PCP ((Bromophenyl)cyclohexylpiperidine).
- k. Chloro-PCP ((Chlorophenyl)cyclohexylpiperidine).
- l. Fluoro-PCP ((Fluorophenyl)cyclohexylpiperidine).
- m. Hydroxy-PCP ((Hydroxyphenyl)cyclohexylpiperidine).
- n. Methoxy-PCP ((Methoxyphenyl)cyclohexylpiperidine).
- o. Methyl-PCP ((Methylphenyl)cyclohexylpiperidine).
- p. Nitro-PCP ((Nitrophenyl)cyclohexylpiperidine).
- q. Oxo-PCP ((Oxophenyl)cyclohexylpiperidine).
- r. Amino-PCP ((Aminophenyl)cyclohexylpiperidine).

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances, including any of its salts, isomers, optical isomers, salts of their isomers, and salts of these optical isomers whenever the existence of such isomers and salts is possible within the specific chemical designation:

- 1. 1,4-Butanediol.
- 2. Gamma-butyrolactone (GBL).
- 3. Gamma-hydroxybutyric acid (GHB).
- 4. Methaqualone.
- 5. Mecloqualone.

(2) SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. The following substances are controlled in Schedule II:

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis:

1. Opium and any salt, compound, derivative, or preparation of opium, except nalmefene or isoquinoline alkaloids of opium, including, but not limited to the following:

- a. Raw opium.
- b. Opium extracts.
- c. Opium fluid extracts.

- d. Powdered opium.
  - e. Granulated opium.
  - f. Tincture of opium.
  - g. Codeine.
  - h. Ethylmorphine.
  - i. Etorphine hydrochloride.
  - j. Hydrocodone.
  - k. Hydromorphone.
  - l. Levo-alpha-acetylmethadol (also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).
  - m. Metopon (methyldihydromorphinone).
  - n. Morphine.
  - o. Oxycodone.
  - p. Oxymorphone.
  - q. Thebaine.
2. Any salt, compound, derivative, or preparation of a substance which is chemically equivalent to or identical with any of the substances referred to in subparagraph 1., except that these substances shall not include the isoquinoline alkaloids of opium.
3. Any part of the plant of the species *Papaver somniferum*, L.
4. Cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine.
- (b) Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:
1. Alfentanil.
  2. Alphaprodine.
  3. Anileridine.
  4. Bezitramide.
  5. Bulk propoxyphene (nondosage forms).
  6. Carfentanil.
  7. Dihydrocodeine.
  8. Diphenoxylate.
  9. Fentanyl.
  10. Isomethadone.
  11. Levomethorphan.

12. Levorphanol.
13. Metazocine.
14. Methadone.
15. Methadone-Intermediate,4-cyano-2-dimethylamino-4,4-diphenylbutane.
16. Moramide-Intermediate,2-methyl-3-morpholino-1,1-diphenylpropane-carboxylic acid.
17. Nabilone.
18. Pethidine (meperidine).
19. Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine.
20. Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate.
21. Pethidine-Intermediate-C,1-methyl-4-phenylpiperidine-4-carboxylic acid.
22. Phenazocine.
23. Phencyclidine.
24. 1-Phenylcyclohexylamine.
25. Piminodine.
26. 1-Piperidinocyclohexanecarbonitrile.
27. Racemethorphan.
28. Racemorphan.
29. Sufentanil.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts, isomers, optical isomers, salts of their isomers, and salts of their optical isomers:

1. Amobarbital.
2. Amphetamine.
3. Glutethimide.
4. Methamphetamine.
5. Methylphenidate.
6. Pentobarbital.
7. Phenmetrazine.
8. Phenylacetone.
9. Secobarbital.

(3) SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United

States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. The following substances are controlled in Schedule III:

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant or stimulant effect on the nervous system:

1. Any substance which contains any quantity of a derivative of barbituric acid, including thiobarbituric acid, or any salt of a derivative of barbituric acid or thiobarbituric acid, including, but not limited to, butabarbital and butalbital.

2. Benzphetamine.
3. Chlorhexadol.
4. Chlorphentermine.
5. Clortermine.
6. Lysergic acid.
7. Lysergic acid amide.
8. Methyprylon.
9. Phendimetrazine.
10. Sulfondiethylmethane.
11. Sulfonethylmethane.
12. Sulfonmethane.
13. Tiletamine and zolazepam or any salt thereof.

(b) Nalorphine.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following controlled substances or any salts thereof:

1. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

3. Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4. Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients that are not controlled substances.

5. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

7. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

For purposes of charging a person with a violation of s. 893.135 involving any controlled substance described in subparagraph 3. or subparagraph 4., the controlled substance is a Schedule III controlled substance pursuant to this paragraph but the weight of the controlled substance per milliliters or per dosage unit is not relevant to the charging of a violation of s. 893.135. The weight of the controlled substance shall be determined pursuant to s. 893.135(6).

(d) Anabolic steroids.

1. The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth and includes:

- a. Androsterone.
- b. Androsterone acetate.
- c. Boldenone.
- d. Boldenone acetate.
- e. Boldenone benzoate.
- f. Boldenone undecylenate.
- g. Chlorotestosterone (Clostebol).
- h. Dehydrochlormethyltestosterone.
- i. Dihydrotestosterone (Stanolone).
- j. Drostanolone.
- k. Ethylestrenol.
- l. Fluoxymesterone.
- m. Formebolone (Formebolone).
- n. Mesterolone.
- o. Methandrostenolone (Methandienone).
- p. Methandranone.
- q. Methandriol.

- r. Methenolone.
- s. Methyltestosterone.
- t. Mibolerone.
- u. Nortestosterone (Nandrolone).
- v. Norethandrolone.
- w. Nortestosterone decanoate.
- x. Nortestosterone phenylpropionate.
- y. Nortestosterone propionate.
- z. Oxandrolone.
- aa. Oxymesterone.
- bb. Oxymetholone.
- cc. Stanozolol.
- dd. Testolactone.
- ee. Testosterone.
- ff. Testosterone acetate.
- gg. Testosterone benzoate.
- hh. Testosterone cypionate.
- ii. Testosterone decanoate.
- jj. Testosterone enanthate.
- kk. Testosterone isocaproate.
- ll. Testosterone oleate.
- mm. Testosterone phenylpropionate.
- nn. Testosterone propionate.
- oo. Testosterone undecanoate.
- pp. Trenbolone.
- qq. Trenbolone acetate.
- rr. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph if that salt, ester, or isomer promotes muscle growth.

2. The term does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the United States Secretary of Health and Human Services for such administration. However, any person who prescribes, dispenses, or distributes such a steroid for human use is considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(e) Ketamine, including any isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

(f) Dronabinol (synthetic THC) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration.

(g) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under s. 505 of the Federal Food, Drug, and Cosmetic Act.

(4) SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are controlled in Schedule IV:

- (a) Alprazolam.
- (b) Barbitol.
- (c) Bromazepam.
- (d) Camazepam.
- (e) Cathine.
- (f) Chloral betaine.
- (g) Chloral hydrate.
- (h) Chlordiazepoxide.
- (i) Clobazam.
- (j) Clonazepam.
- (k) Clorazepate.
- (l) Clotiazepam.
- (m) Cloxazolam.
- (n) Delorazepam.
- (o) Propoxyphene (dosage forms).
- (p) Diazepam.
- (q) Diethylpropion.
- (r) Estazolam.
- (s) Ethchlorvynol.
- (t) Ethinamate.
- (u) Ethyl loflazepate.
- (v) Fencamfamin.
- <sup>1</sup>(w) Fenfluramine.

- (x) Fenproporex.
- (y) Fludiazepam.
- (z) Flurazepam.
- (aa) Halazepam.
- (bb) Haloxazolam.
- (cc) Ketazolam.
- (dd) Loprazolam.
- (ee) Lorazepam.
- (ff) Lormetazepam.
- (gg) Mazindol.
- (hh) Mebutamate.
- (ii) Medazepam.
- (jj) Mefenorex.
- (kk) Meprobamate.
- (ll) Methohexital.
- (mm) Methylphenobarbital.
- (nn) Midazolam.
- (oo) Nimetazepam.
- (pp) Nitrazepam.
- (qq) Nordiazepam.
- (rr) Oxazepam.
- (ss) Oxazolam.
- (tt) Paraldehyde.
- (uu) Pemoline.
- (vv) Pentazocine.
- (ww) Phenobarbital.
- (xx) Phentermine.
- (yy) Pinazepam.
- (zz) Pipradrol.
- (aaa) Prazepam.
- (bbb) Propylhexedrine, excluding any patent or proprietary preparation containing propylhexedrine, unless otherwise provided by federal law.
- (ccc) Quazepam.
- (ddd) Tetrazepam.
- (eee) SPA[(-)-1 dimethylamino-1, 2 diphenylethane].

(fff) Temazepam.

(ggg) Triazolam.

(hhh) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(iii) Butorphanol tartrate.

(jjj) Carisoprodol.

(5) SCHEDULE V.—A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

(a) Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:

1. Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

2. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

3. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts: Buprenorphine.

(c) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone.

**History.**—s. 3, ch. 73-331; s. 247, ch. 77-104; s. 1, ch. 77-174; ss. 1, 2, ch. 78-195; s. 2, ch. 79-325; s. 1, ch. 80-353; s. 1, ch. 82-16; s. 1, ch. 84-89; s. 2, ch. 85-242; s. 1, ch. 86-147; s. 2, ch. 87-243; s. 1, ch. 87-299; s. 1, ch. 88-59; s. 3, ch. 89-281; s. 54, ch. 92-69; s. 1, ch. 93-92; s. 4, ch. 95-415; s. 1, ch. 96-360; ss. 1, 5, ch. 97-1; s. 96, ch. 97-264; s. 1, ch. 99-186; s. 2, ch. 2000-320; s. 1, ch. 2001-55; s. 5, ch. 2001-57; s. 1, ch. 2002-78; s. 2, ch. 2003-10; s. 1, ch. 2008-88; s. 2, ch. 2011-73; s. 1, ch. 2011-90; s. 1, ch. 2012-23; s. 1, ch. 2013-29; s. 1, ch. 2014-159; s. 1, ch. 2015-34; s. 2, ch. 2016-105.

<sup>1</sup>**Note.**—Section 1, ch. 97-1, added paragraph (4)(w) listing fenfluramine. Section 5, ch. 97-1, repealed paragraph (4)(w) effective upon the removal of fenfluramine from the schedules of controlled substances in 21 C.F.R. s. 1308. The Drug Enforcement Administration of the United States Department of Justice filed a proposed final rule removing fenfluramine from the schedules, *see* 62 F.R. 24620, May 6, 1997.

**394.455 Definitions.**—As used in this part, the term:

- (1) “Access center” means a facility that has medical, mental health, and substance abuse professionals to provide emergency screening and evaluation for mental health or substance abuse disorders and may provide transportation to an appropriate facility if an individual is in need of more intensive services.
- (2) “Addictions receiving facility” is a secure, acute care facility that, at a minimum, provides emergency screening, evaluation, detoxification, and stabilization services; is operated 24 hours per day, 7 days per week; and is designated by the department to serve individuals found to have substance abuse impairment who qualify for services under this part.
- (3) “Administrator” means the chief administrative officer of a receiving or treatment facility or his or her designee.
- (4) “Adult” means an individual who is 18 years of age or older or who has had the disability of nonage removed under chapter 743.
- (5) “Clinical psychologist” means a psychologist as defined in s. [490.003\(7\)](#) with 3 years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure, or a psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility under this part.
- (6) “Clinical record” means all parts of the record required to be maintained and includes all medical records, progress notes, charts, and admission and discharge data, and all other information recorded by facility staff which pertains to the patient’s hospitalization or treatment.
- (7) “Clinical social worker” means a person licensed as a clinical social worker under s. [491.005](#) or s. [491.006](#).
- (8) “Community facility” means a community service provider that contracts with the department to furnish substance abuse or mental health services under part IV of this chapter.
- (9) “Community mental health center or clinic” means a publicly funded, not-for-profit center that contracts with the department for the provision of inpatient, outpatient, day treatment, or emergency services.
- (10) “Court,” unless otherwise specified, means the circuit court.
- (11) “Department” means the Department of Children and Families.
- (12) “Designated receiving facility” means a facility approved by the department which may be a public or private hospital, crisis stabilization unit, or addictions receiving facility; which provides, at a minimum, emergency screening, evaluation, and short-term stabilization for mental health or substance abuse disorders; and which may have an agreement with a corresponding facility for transportation and services.

(13) “Detoxification facility” means a facility licensed to provide detoxification services under chapter 397.

(14) “Electronic means” means a form of telecommunication which requires all parties to maintain visual as well as audio communication when being used to conduct an examination by a qualified professional.

(15) “Express and informed consent” means consent voluntarily given in writing, by a competent person, after sufficient explanation and disclosure of the subject matter involved to enable the person to make a knowing and willful decision without any element of force, fraud, deceit, duress, or other form of constraint or coercion.

(16) “Facility” means any hospital, community facility, public or private facility, or receiving or treatment facility providing for the evaluation, diagnosis, care, treatment, training, or hospitalization of persons who appear to have or who have been diagnosed as having a mental illness or substance abuse impairment. The term does not include a program or an entity licensed under chapter 400 or chapter 429.

(17) “Guardian” means the natural guardian of a minor, or a person appointed by a court to act on behalf of a ward’s person if the ward is a minor or has been adjudicated incapacitated.

(18) “Guardian advocate” means a person appointed by a court to make decisions regarding mental health treatment on behalf of a patient who has been found incompetent to consent to treatment pursuant to this part.

(19) “Hospital” means a hospital licensed under chapter 395 and part II of chapter 408.

(20) “Incapacitated” means that a person has been adjudicated incapacitated pursuant to part V of chapter 744 and a guardian of the person has been appointed.

(21) “Incompetent to consent to treatment” means a state in which a person’s judgment is so affected by a mental illness or a substance abuse impairment that he or she lacks the capacity to make a well-reasoned, willful, and knowing decision concerning his or her medical, mental health, or substance abuse treatment.

(22) “Involuntary examination” means an examination performed under s. [394.463](#), s. [397.6772](#), s. [397.679](#), s. [397.6798](#), or s. [397.6811](#) to determine whether a person qualifies for involuntary services.

(23) “Involuntary services” means court-ordered outpatient services or inpatient placement for mental health treatment pursuant to s. [394.4655](#) or s. [394.467](#).

(24) “Law enforcement officer” has the same meaning as provided in s. [943.10](#).

(25) “Marriage and family therapist” means a person licensed to practice marriage and family therapy under s. [491.005](#) or s. [491.006](#).

(26) “Mental health counselor” means a person licensed to practice mental health counseling under s. [491.005](#) or s. [491.006](#).

(27) “Mental health overlay program” means a mobile service that provides an independent examination for voluntary admission and a range of supplemental onsite services to persons with a mental illness in a residential setting such as a nursing home, an assisted living facility, or an adult family-care home or a nonresidential setting such as an adult day care center. Independent examinations provided through a mental health overlay program must only be provided under contract with the department or be attached to a public receiving facility that is also a community mental health center.

(28) “Mental illness” means an impairment of the mental or emotional processes that exercise conscious control of one’s actions or of the ability to perceive or understand reality, which impairment substantially interferes with the person’s ability to meet the ordinary demands of living. For the purposes of this part, the term does not include a developmental disability as defined in chapter 393, intoxication, or conditions manifested only by antisocial behavior or substance abuse.

(29) “Minor” means an individual who is 17 years of age or younger and who has not had the disability of nonage removed pursuant to s. [743.01](#) or s. [743.015](#).

(30) “Mobile crisis response service” means a nonresidential crisis service available 24 hours per day, 7 days per week which provides immediate intensive assessments and interventions, including screening for admission into a mental health receiving facility, an addictions receiving facility, or a detoxification facility, for the purpose of identifying appropriate treatment services.

(31) “Patient” means any person, with or without a co-occurring substance abuse disorder, who is held or accepted for mental health treatment.

(32) “Physician” means a medical practitioner licensed under chapter 458 or chapter 459 who has experience in the diagnosis and treatment of mental illness or a physician employed by a facility operated by the United States Department of Veterans Affairs or the United States Department of Defense.

(33) “Physician assistant” means a person licensed under chapter 458 or chapter 459 who has experience in the diagnosis and treatment of mental disorders.

(34) “Private facility” means a hospital or facility operated by a for-profit or not-for-profit corporation or association which provides mental health or substance abuse services and is not a public facility.

(35) “Psychiatric nurse” means an advanced registered nurse practitioner certified under s. [464.012](#) who has a master’s or doctoral degree in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advanced practice nurse, and has 2 years of post-master’s clinical experience under the supervision of a physician.

(36) “Psychiatrist” means a medical practitioner licensed under chapter 458 or chapter 459 for at least 3 years, inclusive of psychiatric residency.

(37) “Public facility” means a facility that has contracted with the department to provide mental health services to all persons, regardless of ability to pay, and is receiving state funds for such purpose.

(38) “Qualified professional” means a physician or a physician assistant licensed under chapter 458 or chapter 459; a psychiatrist licensed under chapter 458 or chapter 459; a psychologist as defined in s. 490.003(7); or a psychiatric nurse as defined in this section.

(39) “Receiving facility” means a public or private facility or hospital designated by the department to receive and hold or refer, as appropriate, involuntary patients under emergency conditions for mental health or substance abuse evaluation and to provide treatment or transportation to the appropriate service provider. The term does not include a county jail.

(40) “Representative” means a person selected to receive notice of proceedings during the time a patient is held in or admitted to a receiving or treatment facility.

(41) “Restraint” means:

(a) A physical restraint, including any manual method or physical or mechanical device, material, or equipment attached or adjacent to an individual’s body so that he or she cannot easily remove the restraint and which restricts freedom of movement or normal access to one’s body. “Physical restraint” includes the physical holding of a person during a procedure to forcibly administer psychotropic medication. “Physical restraint” does not include physical devices such as orthopedically prescribed appliances, surgical dressings and bandages, supportive body bands, or other physical holding when necessary for routine physical examinations and tests or for purposes of orthopedic, surgical, or other similar medical treatment when used to provide support for the achievement of functional body position or proper balance or when used to protect a person from falling out of bed.

(b) A drug or medication used to control a person’s behavior or to restrict his or her freedom of movement which is not part of the standard treatment regimen of a person with a diagnosed mental illness.

(42) “Seclusion” means the physical segregation or involuntary isolation of a person in a room or area from which the person is prevented from leaving. The prevention may be by physical barrier or by a staff member who is acting in a manner, or who is physically situated, so as to prevent the person from leaving the room or area. For purposes of this part, the term does not mean isolation due to a person’s medical condition or symptoms.

(43) “Secretary” means the Secretary of Children and Families.

(44) “Service provider” means a receiving facility, a facility licensed under chapter 397, a treatment facility, an entity under contract with the department to provide mental health or substance abuse services, a community mental health center or clinic, a psychologist, a clinical social worker, a marriage and family therapist, a mental health counselor, a physician, a

psychiatrist, an advanced registered nurse practitioner, a psychiatric nurse, or a qualified professional as defined in s. 39.01.

(45) “Substance abuse impairment” means a condition involving the use of alcoholic beverages or any psychoactive or mood-altering substance in such a manner that a person has lost the power of self-control and has inflicted or is likely to inflict physical harm on himself, herself, or another.

(46) “Transfer evaluation” means the process by which a person who is being considered for placement in a state treatment facility is evaluated for appropriateness of admission to such facility.

(47) “Treatment facility” means a state-owned, state-operated, or state-supported hospital, center, or clinic designated by the department for extended treatment and hospitalization, beyond that provided for by a receiving facility, of persons who have a mental illness, including facilities of the United States Government, and any private facility designated by the department when rendering such services to a person pursuant to the provisions of this part. Patients treated in facilities of the United States Government shall be solely those whose care is the responsibility of the United States Department of Veterans Affairs.

(48) “Triage center” means a facility that has medical, mental health, and substance abuse professionals present or on call to provide emergency screening and evaluation for mental health or substance abuse disorders for individuals transported to the center by a law enforcement officer.

**History.**—s. 3, ch. 71-131; s. 1, ch. 72-396; s. 1, ch. 73-133; s. 25, ch. 73-334; s. 199, ch. 77-147; s. 2, ch. 79-298; s. 1, ch. 80-398; s. 5, ch. 82-212; s. 46, ch. 83-218; s. 3, ch. 84-285; s. 11, ch. 85-54; s. 11, ch. 86-145; s. 10, ch. 87-238; s. 17, ch. 87-252; s. 41, ch. 89-526; s. 28, ch. 90-306; s. 21, ch. 92-33; s. 65, ch. 93-268; s. 705, ch. 95-148; s. 54, ch. 95-228; s. 2, ch. 96-169; s. 8, ch. 97-82; s. 21, ch. 97-198; s. 213, ch. 97-264; s. 92, ch. 2000-318; s. 1, ch. 2000-349; s. 1, ch. 2004-385; s. 1, ch. 2006-171; s. 17, ch. 2006-197; s. 37, ch. 2006-227; s. 24, ch. 2007-230; s. 2, ch. 2009-38; s. 11, ch. 2013-162; s. 78, ch. 2014-19; s. 1, ch. 2015-111; s. 7, ch. 2016-127; s. 87, ch. 2016-241.

To assist the public and governmental agencies in understanding the requirements and exemptions to Florida's open government laws, the Attorney General's Office compiles a comprehensive guide known as the Government-in-the-Sunshine manual. The manual is published each year at no taxpayer expense by the First Amendment Foundation in Tallahassee.

Florida began its tradition of openness back in 1909 with the passage of [Chapter 119](#) of the Florida Statutes or the "Public Records Law." This law provides that any records made or received by any public agency in the course of its official business are available for inspection, unless specifically exempted by the Florida Legislature. Over the years, the definition of what constitutes "public records" has come to include not just traditional written documents such as papers, maps and books, but also tapes, photographs, film, sound recordings and records stored in computers.

Florida's Government-in-the-Sunshine Law was enacted in 1967. Today, the Sunshine Law regarding open government can be found in [Chapter 286](#) of the Florida Statutes. These statutes establish a basic right of access to most meetings of boards, commissions and other governing bodies of state and local governmental agencies or authorities.

Throughout the history of Florida's open government, its courts have consistently supported the public's right of access to governmental meetings and records. As such, they also have been defining and redefining what a public record is and who is covered under the open meetings law. One area of public concern was whether or not the Legislature was covered under the open meetings requirements. To address that concern, a Constitutional amendment was passed overwhelmingly by the voters in 1990 providing for open meetings in the legislative branch of government.

The Attorney General's Office has consistently sought to safeguard Florida's pioneering Government-in-the-Sunshine laws. Our attorneys have worked, both in the courtroom and out, to halt public records violations. In 1991, a decision by the Florida Supreme Court raised questions which made it clear that the best way to ensure the public's right of access to all three branches of government was to secure that right through the Florida Constitution. The Attorney General's Office then drafted a definitive constitutional amendment, which guaranteed continued openness in the state's government and reaffirmed the application of open government to the legislative branch and expanded it to the judiciary. This amendment passed in 1992.

**CHAPTER 286**

**PUBLIC BUSINESS: MISCELLANEOUS PROVISIONS**

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**286.001 Reports statutorily required; filing, maintenance, retrieval, and provision of copies.—**

(1) Unless otherwise specifically provided by law, any agency or officer of the executive, legislative, or judicial branches of state government, the State Board of Education, the Board of Governors of the State University System, or the Public Service Commission required or authorized by law to make reports regularly or periodically shall fulfill such requirement by filing an abstract

of the report with the statutorily or administratively designated recipients of the report and an abstract and one copy of the report with the Division of Library and Information Services of the Department of State, unless the head of the reporting entity makes a determination that the additional cost of providing the entire report to the statutorily or administratively designated recipients is justified. A one-page summary justifying the determination shall be submitted to the chairs of the governmental operations committees of both houses of the Legislature. The abstract of the contents of such report shall be no more than one-half page in length. The actual report shall be retained by the reporting agency or officer, and copies of the report shall be provided to interested parties and the statutorily or administratively designated recipients of the report upon request.

(2) With respect to reports statutorily required of agencies or officers within the executive, legislative, or judicial branches of state government, the State Board of Education, the Board of Governors of the State University System, or the Public Service Commission, it is the duty of the division, in addition to its duties under s. 257.05, to:

(a) Regularly compile and update bibliographic information on such reports for distribution as provided in paragraph (b). Such bibliographic information may be included in the bibliographies prepared by the division pursuant to s. 257.05(3).

(b) Provide for at least quarterly distribution of bibliographic information on reports to:

1. Agencies and officers within the executive, legislative, and judicial branches of state government, the State Board of Education, the Board of Governors of the State University System, and the Public Service Commission, free of charge; and

2. Other interested parties upon request properly made and upon payment of the actual cost of duplication pursuant to s. 119.07(1).

(3) As soon as practicable, the administrative head of each executive, legislative, or judicial agency and each agency of the State Board of Education, the Board of Governors of the State University System, and the Public Service Commission required by law to make reports periodically shall ensure that those reports are created, stored, managed, updated, retrieved, and disseminated through electronic means.

(4) This section may not be construed to waive or modify the requirement in s. 257.05(2) pertaining to the provision of copies of state publications to the division.

**History.**—ss. 26, 28, 29, ch. 84-254; s. 12, ch. 92-98; s. 104, ch. 92-142; s. 29, ch. 95-196; s. 34, ch. 2007-217; s. 8, ch. 2015-117.

**286.0105 Notices of meetings and hearings must advise that a record is required to appeal.**—Each board, commission, or agency of this state or of any political subdivision thereof shall include in the notice of any meeting or hearing, if notice of the meeting or hearing is required, of such board, commission, or agency, conspicuously on such notice, the advice that, if a

person decides to appeal any decision made by the board, agency, or commission with respect to any matter considered at such meeting or hearing, he or she will need a record of the proceedings, and that, for such purpose, he or she may need to ensure that a verbatim record of the proceedings is made, which record includes the testimony and evidence upon which the appeal is to be based. The requirements of this section do not apply to the notice provided in s. 200.065(3).

*History.*—s. 1, ch. 80-150; s. 14, ch. 88-216; s. 209, ch. 95-148.

**286.011 Public meetings and records; public inspection; criminal and civil penalties.—**

(1) All meetings of any board or commission of any state agency or authority or of any agency or authority of any county, municipal corporation, or political subdivision, except as otherwise provided in the Constitution, including meetings with or attended by any person elected to such board or commission, but who has not yet taken office, at which official acts are to be taken are declared to be public meetings open to the public at all times, and no resolution, rule, or formal action shall be considered binding except as taken or made at such meeting. The board or commission must provide reasonable notice of all such meetings.

(2) The minutes of a meeting of any such board or commission of any such state agency or authority shall be promptly recorded, and such records shall be open to public inspection. The circuit courts of this state shall have jurisdiction to issue injunctions to enforce the purposes of this section upon application by any citizen of this state.

(3)(a) Any public officer who violates any provision of this section is guilty of a noncriminal infraction, punishable by fine not exceeding \$500.

(b) Any person who is a member of a board or commission or of any state agency or authority of any county, municipal corporation, or political subdivision who knowingly violates the provisions of this section by attending a meeting not held in accordance with the provisions hereof is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(c) Conduct which occurs outside the state which would constitute a knowing violation of this section is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.

(4) Whenever an action has been filed against any board or commission of any state agency or authority or any agency or authority of any county, municipal corporation, or political subdivision to enforce the provisions of this section or to invalidate the actions of any such board, commission, agency, or authority, which action was taken in violation of this section, and the court determines that the defendant or defendants to such action acted in violation of this section, the court shall assess a reasonable attorney's fee against such agency, and may assess a reasonable attorney's fee against the individual filing such an action if the court finds it was filed in bad faith or was frivolous. Any fees so assessed may be assessed against the individual member or members of such board or commission; provided, that in any case where the board or commission seeks the advice of its attorney and such advice is followed, no such fees shall be assessed against the individual

member or members of the board or commission. However, this subsection shall not apply to a state attorney or his or her duly authorized assistants or any officer charged with enforcing the provisions of this section.

(5) Whenever any board or commission of any state agency or authority or any agency or authority of any county, municipal corporation, or political subdivision appeals any court order which has found said board, commission, agency, or authority to have violated this section, and such order is affirmed, the court shall assess a reasonable attorney's fee for the appeal against such board, commission, agency, or authority. Any fees so assessed may be assessed against the individual member or members of such board or commission; provided, that in any case where the board or commission seeks the advice of its attorney and such advice is followed, no such fees shall be assessed against the individual member or members of the board or commission.

(6) All persons subject to subsection (1) are prohibited from holding meetings at any facility or location which discriminates on the basis of sex, age, race, creed, color, origin, or economic status or which operates in such a manner as to unreasonably restrict public access to such a facility.

(7) Whenever any member of any board or commission of any state agency or authority or any agency or authority of any county, municipal corporation, or political subdivision is charged with a violation of this section and is subsequently acquitted, the board or commission is authorized to reimburse said member for any portion of his or her reasonable attorney's fees.

(8) Notwithstanding the provisions of subsection (1), any board or commission of any state agency or authority or any agency or authority of any county, municipal corporation, or political subdivision, and the chief administrative or executive officer of the governmental entity, may meet in private with the entity's attorney to discuss pending litigation to which the entity is presently a party before a court or administrative agency, provided that the following conditions are met:

(a) The entity's attorney shall advise the entity at a public meeting that he or she desires advice concerning the litigation.

(b) The subject matter of the meeting shall be confined to settlement negotiations or strategy sessions related to litigation expenditures.

(c) The entire session shall be recorded by a certified court reporter. The reporter shall record the times of commencement and termination of the session, all discussion and proceedings, the names of all persons present at any time, and the names of all persons speaking. No portion of the session shall be off the record. The court reporter's notes shall be fully transcribed and filed with the entity's clerk within a reasonable time after the meeting.

(d) The entity shall give reasonable public notice of the time and date of the attorney-client session and the names of persons who will be attending the session. The session shall commence at an open meeting at which the persons chairing the meeting shall announce the commencement and

estimated length of the attorney-client session and the names of the persons attending. At the conclusion of the attorney-client session, the meeting shall be reopened, and the person chairing the meeting shall announce the termination of the session.

(e) The transcript shall be made part of the public record upon conclusion of the litigation.

**History.**—s. 1, ch. 67-356; s. 159, ch. 71-136; s. 1, ch. 78-365; s. 6, ch. 85-301; s. 33, ch. 91-224; s. 1, ch. 93-232; s. 210, ch. 95-148; s. 1, ch. 95-353; s. 2, ch. 2012-25.

**286.0111 Legislative review of certain exemptions from requirements for public meetings and recordkeeping by governmental entities.**—The provisions of s. 119.15, the Open Government Sunset Review Act, apply to the provisions of law which provide exemptions to s. 286.011, as provided in s. 119.15.

**History.**—s. 9, ch. 84-298; s. 2, ch. 85-301; s. 3, ch. 95-217; s. 53, ch. 2008-4.

**286.0113 General exemptions from public meetings.**—

(1) That portion of a meeting that would reveal a security system plan or portion thereof made confidential and exempt by s. 119.071(3)(a) is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution.

(2)(a) For purposes of this subsection:

1. “Competitive solicitation” means the process of requesting and receiving sealed bids, proposals, or replies in accordance with the terms of a competitive process, regardless of the method of procurement.

2. “Team” means a group of members established by an agency for the purpose of conducting negotiations as part of a competitive solicitation.

(b)1. Any portion of a meeting at which a negotiation with a vendor is conducted pursuant to a competitive solicitation, at which a vendor makes an oral presentation as part of a competitive solicitation, or at which a vendor answers questions as part of a competitive solicitation is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution.

2. Any portion of a team meeting at which negotiation strategies are discussed is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution.

(c)1. A complete recording shall be made of any portion of an exempt meeting. No portion of the exempt meeting may be held off the record.

2. The recording of, and any records presented at, the exempt meeting are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until such time as the agency provides notice of an intended decision or until 30 days after opening the bids, proposals, or final replies, whichever occurs earlier.

3. If the agency rejects all bids, proposals, or replies and concurrently provides notice of its intent to reissue a competitive solicitation, the recording and any records presented at the exempt meeting remain exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until such

time as the agency provides notice of an intended decision concerning the reissued competitive solicitation or until the agency withdraws the reissued competitive solicitation. A recording and any records presented at an exempt meeting are not exempt for longer than 12 months after the initial agency notice rejecting all bids, proposals, or replies.

**History.**—s. 2, ch. 2001-361; s. 44, ch. 2005-251; s. 2, ch. 2006-158; s. 2, ch. 2006-284; s. 13, ch. 2010-151; s. 2, ch. 2011-140; s. 2, ch. 2016-49.

**286.0114 Public meetings; reasonable opportunity to be heard; attorney fees.—**

(1) For purposes of this section, “board or commission” means a board or commission of any state agency or authority or of any agency or authority of a county, municipal corporation, or political subdivision.

(2) Members of the public shall be given a reasonable opportunity to be heard on a proposition before a board or commission. The opportunity to be heard need not occur at the same meeting at which the board or commission takes official action on the proposition if the opportunity occurs at a meeting that is during the decisionmaking process and is within reasonable proximity in time before the meeting at which the board or commission takes the official action. This section does not prohibit a board or commission from maintaining orderly conduct or proper decorum in a public meeting. The opportunity to be heard is subject to rules or policies adopted by the board or commission, as provided in subsection (4).

(3) The requirements in subsection (2) do not apply to:

(a) An official act that must be taken to deal with an emergency situation affecting the public health, welfare, or safety, if compliance with the requirements would cause an unreasonable delay in the ability of the board or commission to act;

(b) An official act involving no more than a ministerial act, including, but not limited to, approval of minutes and ceremonial proclamations;

(c) A meeting that is exempt from s. 286.011; or

(d) A meeting during which the board or commission is acting in a quasi-judicial capacity. This paragraph does not affect the right of a person to be heard as otherwise provided by law.

(4) Rules or policies of a board or commission which govern the opportunity to be heard are limited to those that:

(a) Provide guidelines regarding the amount of time an individual has to address the board or commission;

(b) Prescribe procedures for allowing representatives of groups or factions on a proposition to address the board or commission, rather than all members of such groups or factions, at meetings in which a large number of individuals wish to be heard;

(c) Prescribe procedures or forms for an individual to use in order to inform the board or commission of a desire to be heard; to indicate his or her support, opposition, or neutrality on a

proposition; and to indicate his or her designation of a representative to speak for him or her or his or her group on a proposition if he or she so chooses; or

(d) Designate a specified period of time for public comment.

(5) If a board or commission adopts rules or policies in compliance with this section and follows such rules or policies when providing an opportunity for members of the public to be heard, the board or commission is deemed to be acting in compliance with this section.

(6) A circuit court has jurisdiction to issue an injunction for the purpose of enforcing this section upon the filing of an application for such injunction by a citizen of this state.

(7)(a) Whenever an action is filed against a board or commission to enforce this section, the court shall assess reasonable attorney fees against such board or commission if the court determines that the defendant to such action acted in violation of this section. The court may assess reasonable attorney fees against the individual filing such an action if the court finds that the action was filed in bad faith or was frivolous. This paragraph does not apply to a state attorney or his or her duly authorized assistants or an officer charged with enforcing this section.

(b) Whenever a board or commission appeals a court order that has found the board or commission to have violated this section, and such order is affirmed, the court shall assess reasonable attorney fees for the appeal against such board or commission.

(8) An action taken by a board or commission which is found to be in violation of this section is not void as a result of that violation.

**History.**—s. 1, ch. 2013-227.

**286.01141 Criminal justice commissions; public meetings exemption.—**

(1) As used in this section, the term:

(a) “Duly constituted criminal justice commission” means an advisory commission created by municipal or county ordinance whose membership is comprised of individuals from the private sector and the public sector and whose purpose is to examine local criminal justice issues.

(b) “Active” has the same meaning as provided in s. 119.011.

(c) “Criminal intelligence information” has the same meaning as provided in s. 119.011.

(d) “Criminal investigative information” has the same meaning as provided in s. 119.011.

(2) That portion of a meeting of a duly constituted criminal justice commission at which members of the commission discuss active criminal intelligence information or active criminal investigative information that is currently being considered by, or which may foreseeably come before, the commission is exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution, provided that at any public meeting of the criminal justice commission at which such matter is being considered, the commission members publicly disclose the fact that the matter has been discussed.

(3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2018, unless reviewed and saved from repeal through reenactment by the Legislature.

History.—s. 1, ch. 2013-196.

**286.0115 Access to local public officials; quasi-judicial proceedings on local government land use matters.—**

(1)(a) A county or municipality may adopt an ordinance or resolution removing the presumption of prejudice from ex parte communications with local public officials by establishing a process to disclose ex parte communications with such officials pursuant to this subsection or by adopting an alternative process for such disclosure. However, this subsection does not require a county or municipality to adopt any ordinance or resolution establishing a disclosure process.

(b) As used in this subsection, the term “local public official” means any elected or appointed public official holding a county or municipal office who recommends or takes quasi-judicial action as a member of a board or commission. The term does not include a member of the board or commission of any state agency or authority.

(c) Any person not otherwise prohibited by statute, charter provision, or ordinance may discuss with any local public official the merits of any matter on which action may be taken by any board or commission on which the local public official is a member. If adopted by county or municipal ordinance or resolution, adherence to the following procedures shall remove the presumption of prejudice arising from ex parte communications with local public officials.

1. The substance of any ex parte communication with a local public official which relates to quasi-judicial action pending before the official is not presumed prejudicial to the action if the subject of the communication and the identity of the person, group, or entity with whom the communication took place is disclosed and made a part of the record before final action on the matter.

2. A local public official may read a written communication from any person. However, a written communication that relates to quasi-judicial action pending before a local public official shall not be presumed prejudicial to the action, and such written communication shall be made a part of the record before final action on the matter.

3. Local public officials may conduct investigations and site visits and may receive expert opinions regarding quasi-judicial action pending before them. Such activities shall not be presumed prejudicial to the action if the existence of the investigation, site visit, or expert opinion is made a part of the record before final action on the matter.

4. Disclosure made pursuant to subparagraphs 1., 2., and 3. must be made before or during the public meeting at which a vote is taken on such matters, so that persons who have opinions contrary to those expressed in the ex parte communication are given a reasonable opportunity to

refute or respond to the communication. This subsection does not subject local public officials to part III of chapter 112 for not complying with this paragraph.

(2)(a) Notwithstanding the provisions of subsection (1), a county or municipality may adopt an ordinance or resolution establishing the procedures and provisions of this subsection for quasi-judicial proceedings on local government land use matters. The ordinance or resolution shall provide procedures and provisions identical to this subsection. However, this subsection does not require a county or municipality to adopt such an ordinance or resolution.

(b) In a quasi-judicial proceeding on local government land use matters, a person who appears before the decisionmaking body who is not a party or party-intervenor shall be allowed to testify before the decisionmaking body, subject to control by the decisionmaking body, and may be requested to respond to questions from the decisionmaking body, but need not be sworn as a witness, is not required to be subject to cross-examination, and is not required to be qualified as an expert witness. The decisionmaking body shall assign weight and credibility to such testimony as it deems appropriate. A party or party-intervenor in a quasi-judicial proceeding on local government land use matters, upon request by another party or party-intervenor, shall be sworn as a witness, shall be subject to cross-examination by other parties or party-intervenors, and shall be required to be qualified as an expert witness, as appropriate.

(c) In a quasi-judicial proceeding on local government land use matters, a person may not be precluded from communicating directly with a member of the decisionmaking body by application of ex parte communication prohibitions. Disclosure of such communications by a member of the decisionmaking body is not required, and such nondisclosure shall not be presumed prejudicial to the decision of the decisionmaking body. All decisions of the decisionmaking body in a quasi-judicial proceeding on local government land use matters must be supported by substantial, competent evidence in the record pertinent to the proceeding, irrespective of such communications.

(3) This section does not restrict the authority of any board or commission to establish rules or procedures governing public hearings or contacts with local public officials.

**History.**—s. 1, ch. 95-352; s. 31, ch. 96-324.

**286.012 Voting requirement at meetings of governmental bodies.**—A member of a state, county, or municipal governmental board, commission, or agency who is present at a meeting of any such body at which an official decision, ruling, or other official act is to be taken or adopted may not abstain from voting in regard to any such decision, ruling, or act; and a vote shall be recorded or counted for each such member present, unless, with respect to any such member, there is, or appears to be, a possible conflict of interest under s. 112.311, s. 112.313, s. 112.3143, or additional or more stringent standards of conduct, if any, adopted pursuant to s. 112.326. If there is, or appears to be, a possible conflict under s. 112.311, s. 112.313, or s. 112.3143, the

member shall comply with the disclosure requirements of s. 112.3143. If the only conflict or possible conflict is one arising from the additional or more stringent standards adopted pursuant to s. 112.326, the member shall comply with any disclosure requirements adopted pursuant to s. 112.326. If the official decision, ruling, or act occurs in the context of a quasi-judicial proceeding, a member may abstain from voting on such matter if the abstention is to assure a fair proceeding free from potential bias or prejudice.

**History.**—s. 1, ch. 72-311; s. 9, ch. 75-208; s. 2, ch. 84-357; s. 13, ch. 94-277; s. 19, ch. 2013-36; s. 7, ch. 2014-183.

**286.021 Department of State to hold title to patents, trademarks, copyrights, etc.**—The legal title and every right, interest, claim or demand of any kind in and to any patent, trademark or copyright, or application for the same, now owned or held, or as may hereafter be acquired, owned and held by the state, or any of its boards, commissions or agencies, is hereby granted to and vested in the Department of State for the use and benefit of the state; and no person, firm or corporation shall be entitled to use the same without the written consent of said Department of State.

**History.**—s. 1, ch. 21959, 1943; ss. 22, 35, ch. 69-106; s. 2, ch. 70-440; s. 15, ch. 79-65.

**Note.**—Former s. 272.01.

**286.031 Authority of Department of State in connection with patents, trademarks, copyrights, etc.**—The Department of State is authorized to do and perform any and all things necessary to secure letters patent, copyright and trademark on any invention or otherwise, and to enforce the rights of the state therein; to license, lease, assign, or otherwise give written consent to any person, firm or corporation for the manufacture or use thereof, on a royalty basis, or for such other consideration as said department shall deem proper; to take any and all action necessary, including legal actions, to protect the same against improper or unlawful use or infringement, and to enforce the collection of any sums due the state and said department for the manufacture or use thereof by any other party; to sell any of the same and to execute any and all instruments on behalf of the state necessary to consummate any such sale; and to do any and all other acts necessary and proper for the execution of powers and duties herein conferred upon said department for the benefit of the state.

**History.**—s. 2, ch. 21959, 1943; ss. 22, 35, ch. 69-106; s. 2, ch. 70-440; s. 16, ch. 79-65.

**Note.**—Former s. 272.02.

**286.035 Constitution Revision Commission; powers of chair; assistance by state and local agencies.**—

(1) The chair of the Constitution Revision Commission, appointed pursuant to s. 2, Art. XI of the State Constitution, is authorized to employ personnel and to incur expenses related to the official

operation of the commission or its committees, to sign vouchers, and to otherwise expend funds appropriated to the commission for carrying out its official duties.

(2) All state and local agencies are hereby authorized and directed to assist, in any manner necessary, the Constitution Revision Commission established pursuant to s. 2, Art. XI of the State Constitution upon its request or the request of its chair.

*History.*—s. 1, ch. 77-201; s. 211, ch. 95-148.

**286.036 Taxation and Budget Reform Commission; powers.—**

(1) The Taxation and Budget Reform Commission appointed pursuant to s. 6, Art. XI of the State Constitution, is authorized to employ personnel and to incur expenses related to the official operation of the commission or its committees, and to expend funds appropriated to the commission for carrying out its official duties. Commission members and staff are entitled to per diem and reimbursement of travel expenses incurred in carrying out their duties, as provided in s. 112.061.

(2) All state and regional agencies and governments are authorized and directed to assist, in any manner necessary, the Taxation and Budget Reform Commission upon its request.

(3) All local governments are authorized to assist the Taxation and Budget Reform Commission in any manner necessary. Municipal and county governments are encouraged to cooperate with the commission, examine their taxation and budgetary policies, and submit recommendations to the commission in the form and manner prescribed by the commission.

(4) Each Taxation and Budget Reform Commission established pursuant to s. 6, Art. XI of the State Constitution and this section may not act or operate later than June 30 of the third year following the year in which the commission is required to be established.

(5) The Taxation and Budget Reform Commission is assigned, for administrative purposes, to the legislative branch. The Office of Legislative Services is directed to expedite, where possible, the business of the commission consistent with prudent financial and management practices.

(6) The Legislative Auditing Committee may at any time, without regard to whether the Legislature is then in session or out of session, take under consideration any matter within the scope of the duties of the Taxation and Budget Reform Commission, and in connection therewith may exercise the powers of subpoena by law vested in a standing committee of the Legislature.

*History.*—s. 12, ch. 90-203; s. 6, ch. 2007-98.

**286.041 Prohibited requirements of bidders on contracts for public works relative to income tax returns.—**

(1) The state or any of its departments, agencies, bureaus, commissions, and officers and the counties, consolidated governments, municipalities, school districts, special districts, and other public bodies of this state, and the departments, agencies, bureaus, commissions, and officers thereof, shall not require, directly or indirectly, an audit or inspection of any federal or state

income tax returns of any company, corporation, or person as a prior condition before entering into contracts with said company, corporation, or person to construct any public work or to supply any materials, labor, equipment or services, or any combination thereof.

(2) Any person who violates the provisions of this section is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.083, except that the fine shall not be less than \$100.

History.—s. 1, ch. 72-130.

**286.043 Limitation on use of funds for discriminatory contract or bid specifications relating to car rental concessions at airports.**—No public funds shall be used by a unit of local government for the purpose of promulgating contract or bid specifications relating to car rental concessions at airports which would preclude a corporation authorized to do business in this state from submitting bids or entering into such contracts with such unit of local government. Nothing in this section shall prevent the local government from providing in such specifications a minimum annual guarantee of revenue to be paid to such unit of local government.

History.—s. 4, ch. 79-119.

**286.23 Real property conveyed to public agency; disclosure of beneficial interests; notice; exemptions.**—

(1) Any person or entity holding real property in the form of a partnership, limited partnership, corporation, trust, or any form of representative capacity whatsoever for others, except as otherwise provided in this section, shall, before entering into any contract whereby such real property held in representative capacity is sold, leased, taken by eminent domain, or otherwise conveyed to the state or any local governmental unit, or an agency of either, make a public disclosure in writing, under oath and subject to the penalties prescribed for perjury, which shall state his or her name and address and the name and address of every person having a beneficial interest in the real property, however small or minimal. This written disclosure shall be made to the chief officer, or to his or her officially designated representative, of the state, local governmental unit, or agency of either, with which the transaction is made at least 10 days prior to the time of closing or, in the case of an eminent domain taking, within 48 hours after the time when the required sum is deposited in the registry of the court. Notice of the deposit shall be made to the person or entity by registered or certified mail before the 48-hour period begins.

(2) The state or local governmental unit, or an agency of either, shall send written notice by registered mail to the person required to make disclosures under this section, prior to the time when such disclosures are required to be made, which written request shall also inform the person required to make such disclosure that such disclosure must be made under oath, subject to the penalties prescribed for perjury.

(3)(a) The beneficial interest in any entity registered with the Federal Securities Exchange Commission or registered pursuant to chapter 517, whose interest is for sale to the general public, is hereby exempt from the provisions of this section. When disclosure of persons having beneficial interests in nonpublic entities is required, the entity or person shall not be required by the provisions of this section to disclose persons or entities holding less than 5 percent of the beneficial interest in the disclosing entity.

(b) In the case of an eminent domain taking, any entity or person other than a public officer or public employee, holding real property in the form of a trust which was created more than 3 years prior to the deposit of the required sum in the registry of the court, is hereby exempt from the provisions of this section. However, in order to qualify for the exemption set forth in this section, the trustee of such trust shall be required to certify within 48 hours after such deposit, under penalty of perjury, that no public officer or public employee has any beneficial interest whatsoever in such trust. Disclosure of any changes in the trust instrument or of persons having beneficial interest in the trust shall be made if such changes occurred during the 3 years prior to the deposit of said sum in the registry of the court.

(4) This section shall be liberally construed to accomplish the purpose of requiring the identification of the actual parties benefiting from any transaction with a governmental unit or agency involving the procurement of the ownership or use of property by such governmental unit or agency.

**History.**—ss. 1, 2, 3, 4, 5, ch. 74-174; s. 1, ch. 77-174; s. 72, ch. 86-186; s. 7, ch. 91-56; s. 212, ch. 95-148.

**286.25 Publication or statement of state sponsorship.**—Any nongovernmental organization which sponsors a program financed partially by state funds or funds obtained from a state agency shall, in publicizing, advertising, or describing the sponsorship of the program, state: “Sponsored by (name of organization) and the State of Florida.” If the sponsorship reference is in written material, the words “State of Florida” shall appear in the same size letters or type as the name of the organization.

**History.**—s. 1, ch. 77-224.

**286.26 Accessibility of public meetings to the physically handicapped.**—

(1) Whenever any board or commission of any state agency or authority, or of any agency or authority of any county, municipal corporation, or other political subdivision, which has scheduled a meeting at which official acts are to be taken receives, at least 48 hours prior to the meeting, a written request by a physically handicapped person to attend the meeting, directed to the chairperson or director of such board, commission, agency, or authority, such chairperson or director shall provide a manner by which such person may attend the meeting at its scheduled site or reschedule the meeting to a site which would be accessible to such person.

(2) If an affected handicapped person objects in the written request, nothing contained in the provisions of this section shall be construed or interpreted to permit the use of human physical assistance to the physically handicapped in lieu of the construction or use of ramps or other mechanical devices in order to comply with the provisions of this section.

**History.**—s. 1, ch. 77-277; s. 1, ch. 79-170; s. 116, ch. 79-400; s. 1, ch. 81-268.

**286.27 Use of state funds for greeting cards prohibited.**—No state funds shall be expended for the purchase, preparation, printing, or mailing of any card the sole purpose of which is to convey holiday greetings.

**History.**—s. 1, ch. 92-21.

**286.29 Climate-friendly public business.**—The Legislature recognizes the importance of leadership by state government in the area of energy efficiency and in reducing the greenhouse gas emissions of state government operations. The following shall pertain to all state agencies when conducting public business:

(1) The Department of Management Services shall develop the “Florida Climate-Friendly Preferred Products List.” In maintaining that list, the department, in consultation with the Department of Environmental Protection, shall continually assess products currently available for purchase under state term contracts to identify specific products and vendors that offer clear energy efficiency or other environmental benefits over competing products. When procuring products from state term contracts, state agencies shall first consult the Florida Climate-Friendly Preferred Products List and procure such products if the price is comparable.

(2) Effective July 1, 2008, state agencies shall contract for meeting and conference space only with hotels or conference facilities that have received the “Green Lodging” designation from the Department of Environmental Protection for best practices in water, energy, and waste efficiency standards, unless the responsible state agency head makes a determination that no other viable alternative exists. The Department of Environmental Protection is authorized to adopt rules to implement the “Green Lodging” program.

(3) Each state agency shall ensure that all maintained vehicles meet minimum maintenance schedules shown to reduce fuel consumption, which include: ensuring appropriate tire pressures and tread depth; replacing fuel filters and emission filters at recommended intervals; using proper motor oils; and performing timely motor maintenance. Each state agency shall measure and report compliance to the Department of Management Services through the Equipment Management Information System database.

(4) When procuring new vehicles, all state agencies, state universities, community colleges, and local governments that purchase vehicles under a state purchasing plan shall first define the intended purpose for the vehicle and determine which of the following use classes for which the vehicle is being procured:

- (a) State business travel, designated operator;
- (b) State business travel, pool operators;
- (c) Construction, agricultural, or maintenance work;
- (d) Conveyance of passengers;
- (e) Conveyance of building or maintenance materials and supplies;
- (f) Off-road vehicle, motorcycle, or all-terrain vehicle;
- (g) Emergency response; or
- (h) Other.

Vehicles described in paragraphs (a) through (h), when being processed for purchase or leasing agreements, must be selected for the greatest fuel efficiency available for a given use class when fuel economy data are available. Exceptions may be made for individual vehicles in paragraph (g) when accompanied, during the procurement process, by documentation indicating that the operator or operators will exclusively be emergency first responders or have special documented need for exceptional vehicle performance characteristics. Any request for an exception must be approved by the purchasing agency head and any exceptional performance characteristics denoted as a part of the procurement process prior to purchase.

(5) All state agencies shall use ethanol and biodiesel blended fuels when available. State agencies administering central fueling operations for state-owned vehicles shall procure biofuels for fleet needs to the greatest extent practicable.

**History.**—s. 23, ch. 2008-227.

# E-FORCSE Home Page

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E-FORCSE, Florida Prescription

Physicians that are not treating patients for chronic nonmalignant pain are not required to register as controlled substance prescribers.

The Department has received numerous calls in recent weeks from physicians expressing concerns that some pharmacists are not filling controlled substance prescriptions if the physician is not listed as a controlled substance prescriber on the practitioner profile on Department of Health's website. While there may be many reasons a pharmacist may decide in his or her professional judgment not to fill a prescription, the Department wants to ensure that any confusion concerning the physician registration requirements is addressed.

The lack of a designation on the physician profile concerning controlled substances does not necessarily mean that the physician cannot prescribe controlled substances. Section 456.44, F.S. requires a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes controlled substances listed in Schedule II, Schedule III, or Schedule IV *for the treatment of chronic nonmalignant pain*, to designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile. This requirement is only applicable to those physicians that are treating patients for chronic nonmalignant pain. Therefore, physicians that are not treating patients for chronic nonmalignant pain are not required to register and may continue prescribing controlled substances for other diagnoses.

Welcome to E-FORCSE®, Florida's Prescription Drug Monitoring Program

The Florida Prescription Drug Monitoring Program, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program), was created by the 2009 Florida Legislature in an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida.

E-FORCSE® has selected Health Information Designs, LLC, to develop a database that collects and stores prescribing and dispensing data for controlled substances in Schedules II, III, and IV. The purpose of the PDMP is to provide the information that is collected in the database to health care practitioners to guide their decisions in prescribing and dispensing these highly abused prescription drugs.

Section 893.055, Florida Statutes, requires health care practitioners to report to the PDMP each time a controlled substance is dispensed to an individual. The information is reported through the electronic system as soon as possible but not more than 7 days after dispensing. This reporting timeframe ensures that health care practitioners have the most up-to-date information available.

E-FORCSE® complies with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The information collected in the system will be used by the PDMP to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida.

## Pharmacy & Dispensing Practitioner Controlled Substance Reporting Requirements:

The Department of Health's Prescription Drug Monitoring Program called E-FORCSE collects, maintains, and stores controlled substance prescription dispensing information in its database and makes the information available to health care practitioners and law enforcement and regulatory agencies during active investigations. Section 893.055, F.S., requires all practitioners who dispense controlled substances listed in schedules II, III, or IV, as defined in section 893.03, F.S., to report to E-FORCSE within 7 days each time a controlled substance is dispensed to an individual, unless it is one of the acts of dispensing or administering which are exempt from reporting under subsection 893.055(5), F.S. For more information visit, <http://www.floridahealth.gov/statistics-and-data/e-forcse/>.

## Wholesale Distributor, Manufacturer or Repackager Controlled Substance Reporting Requirements:

The Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics Program, Controlled Substance Registry collects and stores controlled

substance receipts and distributions in its registry. Section 499.0121(14), Florida Statutes (F.S.) requires each prescription drug wholesale distributor, whether in state or out-of-state, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances to report receipts and distributions of controlled substances listed in Schedule II through V, as provided in s. 893.03, F.S., monthly by the 20th of the next month. For more information visit <http://www.myfloridalicense.com/dbpr/ddc/CSR.html>.

**This project was supported by Grant No. 2009-PM-BX-4004 awarded by the Bureau of Justice Assistance, Office of Justice Program, U.S. Department of Justice.**

## States with Formularies for NP Prescribing

### 1. Alabama

- a. (6) The Joint Committee shall have the authority to recommend to the Board of Nursing and State Board of Medical Examiners:(a) Rules and regulations governing the collaborative relationship between physicians and certified registered nurse practitioners and certified nurse midwives engaged in advanced practice nursing.(b) Model practice protocols to be used by the certified registered nurse practitioner and certified nurse midwife.(c) A formulary of legend drugs that may be prescribed by a certified registered nurse practitioner and a certified nurse midwife.

Ala. Admin. Code 610-X-5-.02

- b. Notwithstanding any other provisions of this article, the joint committee shall recommend model practice protocols to be used by certified registered nurse practitioners and certified nurse midwives and a formulary of legend drugs that may be prescribed by these advanced practice nurses, subject to approval by both the State Board of Medical Examiners and the Board of Nursing.

Ala. Code § 34-21-87

- c. (d)(1) The board may establish protocols, formularies, or medical regimens which relate to, govern, or regulate a QACSC, and any such protocol, formulary, or medical regimen shall not be considered a rule under the Alabama Administrative Procedure Act.(2) The formulary of controlled substances that may be prescribed by CRNPs and CNMs shall be approved by the certifying board upon the recommendation of the joint practice committee established by Article 5, commencing with Section 34-21-80, Chapter 21, Title 34, but the formulary shall not be considered a rule under the Alabama Administrative Procedure Act.

Ala. Code § 20-2-251

### 2. Hawaii

- a. (a) The board shall grant prescriptive authority to qualified advanced practice registered nurses and shall designate the requirements for advanced nursing practice related to prescriptive authority. The board shall determine the exclusionary formulary for qualified advanced practice registered nurses who are granted prescriptive authority.(b) The department of commerce and consumer affairs shall establish a joint formulary advisory committee composed of:(1) Two persons licensed as advanced practice registered nurses and appointed by the board;(2) Two persons licensed in medicine by the Hawaii medical board and appointed by the Hawaii medical board;(3) Three persons licensed as pharmacists and appointed by the board of pharmacy;(4) One representative of the University of Hawaii John A. Burns school of medicine appointed by the dean of the University of Hawaii John A. Burns school of medicine; and(5) One representative from a school of nursing with an advanced practice registered

nurse program. The joint formulary advisory committee shall recommend the applicable formulary for persons recognized under this section. The board shall consider the recommendations of the joint formulary advisory committee in adopting the formulary.

Haw. Rev. Stat. Ann. § 457-8.6

- b. (a) The board of nursing shall consider the recommendations of the joint formulary advisory committee to determine the drugs or categories of drugs listed in the exclusionary formulary for APRNs granted prescriptive authority. The current formulary, attached to this chapter as "Exhibit A", lists the drugs or categories of drugs that shall not be prescribed by the APRN. (b) The Exclusionary Formulary, and any revised formularies, shall be made available to licensed pharmacies at the request of the pharmacy at no cost. (c) The APRN shall comply with all applicable state and federal laws and rules relating to prescribing and administering of drugs. The APRN with prescriptive authority shall only prescribe, order, and dispense medical devices and equipment appropriate to the APRN's specialty. (d) Prescriptions by an APRN with prescriptive authority shall be written in accordance with section 16-95-82.

Haw. Code R. 16-89-122

- c. The purpose of this subchapter is to establish the requirements of the board for APRN prescriptive authority. APRNs who are granted prescriptive authority shall only prescribe drugs appropriate to their practice specialties as recognized by the board and in accordance with the exclusionary formulary.

Haw. Code R. 16-89-116

- d. "Drug" means a device, appliance, medicine, or preparation for internal or external use by a human being and shall not include any substance included in the exclusionary formulary.

"Exclusionary formulary" means the listing of drugs or categories of drugs designated and published by the board of nursing, based on the recommendations of the joint formulary advisory committee, that shall not be prescribed by an APRN granted prescriptive authority.

...

"Joint formulary advisory committee" means (in accordance with section 457-8.6, HRS) the committee established by the department of commerce and consumer affairs to recommend the applicable formulary for persons recognized under this chapter to the board of nursing. The committee shall be composed of two persons recognized as APRN and appointed by the board; two persons licensed in medicine by the Hawaii medical board and appointed by the Hawaii medical board; three persons licensed in pharmacy and appointed by the board of pharmacy; one representative from the University of Hawaii John A. Burns school of medicine appointed by the dean of the University of Hawaii John A. Burns school of medicine; and one representative from a school of nursing with an

APRN program.

Haw. Code R. 16-89-2

3. Kentucky

- a. Limitations for specific controlled substances which are identified as having the greatest potential for abuse or diversion, based on the best available scientific and law enforcement evidence, shall be established in an administrative regulation promulgated by the Kentucky Board of Nursing. The regulation shall be based on recommendations from the Controlled Substances Formulary Development Committee, which is hereby created. The committee shall be composed of two (2) advanced practice registered nurses appointed by the Kentucky Board of Nursing, one (1) of whom shall be designated as a committee co-chair; two (2) physicians appointed by the Kentucky Board of Medical Licensure, one (1) of whom shall be designated as a committee co-chair; and one (1) pharmacist appointed by the Kentucky Board of Pharmacy. The initial regulation shall be promulgated on or before August 15, 2006, and shall be reviewed at least annually thereafter by the committee.

Ky. Rev. Stat. Ann. § 314.011

- b. Section 1. Specific Controlled Substances. The following controlled substances have been identified as having the greatest potential for abuse or diversion:(1) Diazepam (Valium), a Schedule IV medication;(2) Clonazepam (Klonopin), a Schedule IV medication;(3) Lorazepam (Ativan), a Schedule IV medication;(4) Alprazolam (Xanax), a Schedule IV medication; and(5) Carisoprodol (Soma), a Schedule IV medication. Section 2. Limitations. Prescriptions for the medications listed in Section 1 of this administrative regulation shall be limited to a thirty (30) day supply without any refills.

201 Ky. Admin. Regs. 20:059

4. Ohio

- a. (A) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not prescribe any drug or therapeutic device that is not included in the types of drugs and devices listed on the formulary established in rules adopted under section 4723.50 of the Revised Code.

...

(F) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner may personally furnish to a patient a complete or partial supply of a drug or therapeutic device included in the types of drugs and devices listed on the formulary, except that all of the following conditions apply:(1) The clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall personally furnish only antibiotics, antifungals, scabicides, contraceptives, prenatal vitamins, antihypertensives, drugs and devices used in the treatment of diabetes, drugs and devices used in the treatment of asthma, and drugs used in

the treatment of dyslipidemia.(2) The clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall not furnish the drugs and devices in locations other than a health department operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code, a federally funded comprehensive primary care clinic, or a nonprofit health care clinic or program.(3) The clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall comply with all safety standards for personally furnishing supplies of drugs and devices, as established in rules adopted under section 4723.50 of the Revised Code.(G) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner shall comply with section 3719.061 of the Revised Code if the nurse prescribes for a minor, as defined in that section, an opioid analgesic, as defined in section 3719.01 of the Revised Code.

Ohio Rev. Code Ann. § 4723.481

- b. (A) The committee on prescriptive governance shall organize by selecting a chairperson from among its members who are nurses or collaborating physicians. The committee may select a new chairperson at any time.(B) Five members constitute a quorum for the transaction of official business. The clinical pharmacist member may participate in any meeting of the committee, but shall be included as a voting member only when the committee is considering one of the following:(1) The composition of the formulary of drugs and therapeutic devices that may be prescribed by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code;(2) The manner in which a nurse may personally furnish to patients drugs and therapeutic devices packaged as samples and may personally furnish partial or complete supplies of other drugs and therapeutic devices;(3) Recommendations to be given to the board of nursing for use in adopting rules under section 4723.50 of the Revised Code pertaining to the matters specified in divisions (B)(1) and (2) of this section.(C) Members shall serve without compensation but shall receive payment for their actual and necessary expenses incurred in the performance of their official duties. The expenses shall be paid by the board of nursing.

Ohio Rev. Code Ann. § 4723.491

- c. A) In accordance with Chapter 119. of the Revised Code, the board of nursing shall adopt rules as necessary to implement the provisions of this chapter pertaining to the authority of clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners to prescribe drugs and therapeutic devices and the issuance and renewal of certificates to prescribe.The board shall adopt rules that are consistent with the recommendations the board receives from the committee on prescriptive governance pursuant to section 4723.492 of the Revised Code. After reviewing a recommendation submitted by the committee,

the board may either adopt the recommendation as a rule or ask the committee to reconsider and resubmit the recommendation. The board shall not adopt any rule that does not conform to a recommendation made by the committee.(B) The board shall adopt rules under this section that do all of the following:(1) Establish a formulary listing the types of drugs and therapeutic devices that may be prescribed by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner. The formulary may include controlled substances, as defined in section 3719.01 of the Revised Code.

Ohio Rev. Code Ann. § 4723.50

- d. (A) The formulary, as established by the committee on prescriptive governance, shall be available on the Ohio board of nursing web site, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015).(B) The committee on prescriptive governance shall review the formulary, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015), for additions or deletions at least twice a year.(C) The committee on prescriptive governance shall establish a formulary, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015), and may exclude subtypes or individual drugs within the following types of drugs:(1) Nutrients and nutritional agents;(2) Hematological agents;(3) Endocrine and metabolic agents;(4) Cardiovascular agents;(5) Renal and genitourinary agents;(6) Respiratory agents;(7) Central nervous system agents;(8) Gastrointestinal agents;(9) Anti-infective and systemic agents;(10) Biologic/immunologic agents;(11) Dermatologic agents;(12) Ophthalmic and otic agents;(13) Antineoplastic agents; and(14) Diagnostic aids.(D) Except as provided in paragraph (D)(4) of this rule, a nurse with a current valid certificate to prescribe may prescribe a schedule II controlled substance only in situations where all of the following apply:(1) A patient has a terminal condition, as defined in section 2133.01 of the Revised Code;(2) The nurse's collaborating physician initially prescribed the substance for the patient; and(3) The prescription is for a quantity that does not exceed the amount necessary for the patient's use in a single, twenty-four hour period.(4) A nurse holding a current valid certificate to prescribe may prescribe a schedule II controlled substance, if authorized by the formulary, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015), if the nurse issues the prescription to the patient from any of the following locations:(a) A hospital registered under section 3701.07 of the Revised Code;(b) An entity owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;(c) A health care facility operated by the department of mental health or the department of developmental disabilities;(d) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code;(e) A county home or district home operated under Chapter 5155. of the Revised Code that is certified under the medicare or medicaid program;(f) A hospice care program, as defined in section 3712.01 of the Revised Code;(g) A community mental health agency, as defined in section

5122.01 of the Revised Code;(h) An ambulatory surgical facility, as defined in section 3702.30 of the Revised Code;(i) A freestanding birthing center, as defined in section 3702.141 of the Revised Code;(j) A federally qualified health center, as defined in section 3701.047 of the Revised Code;(k) A federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;(l) A health care office or facility operated by the board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code; or(m) A site where a medical practice is operated, but only if the practice is comprised of one or more physicians who also are owners of the practice; the practice is organized to provide direct patient care; and the clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner providing services at the site has a standard care arrangement and collaborates with at least one of the physician owners who practices primarily at that site.(5) A nurse shall not issue to a patient a prescription for a schedule II controlled substance from a convenience care clinic even if the clinic is owned or operated by an entity specified in paragraph (D)(4) of this rule.(E) A nurse holding a current valid certificate to prescribe may prescribe any drug or therapeutic device in any form and route of administration that is included on the formulary, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015), and as agreed to by the collaborating physician in the standard care arrangement. The ability to prescribe the drug or therapeutic device must be within the nurse's scope of practice.(F) Drugs approved by the FDA but not yet reviewed and approved by the committee on prescriptive governance may be prescribed, unless later disapproved by the committee on prescriptive governance, if :.(1) The ability to prescribe the drug is within the nurse's scope of practice;(2) The drug type or subtype is included on the formulary, located at <http://www.nursing.ohio.gov/Practice.htm> (effective 2015), as one that may be prescribed, or may be prescribed according to the nurse's standard care arrangement; and(3) The collaborating physician has agreed in the standard care arrangement that the nurse may prescribe drugs approved by the FDA, that meet the criteria set forth in paragraphs (F)(1) and (F)(2) of this rule, that have not yet been reviewed and approved by the committee on prescriptive governance.(G) For purposes of interpreting the formulary, located at <http://www.nursing.ohio.gov/Practice-CTP.htm> (effective 2015), the following definitions shall apply:(1) "Physician consultation" means a nurse holding a current, valid certificate to prescribe may initiate the medication after direct communication with the collaborating physician regarding a particular patient and documenting the consultation in the patient record. Once the medication is initially authorized by the collaborating physician, a nurse holding a current valid certificate to prescribe may continue, modify, or discontinue the medication without further consultation.(2) "Physician initiation" means the collaborating physician is required to have personally examined and evaluated the patient before therapy is initiated in accordance with rule 4731-11-09 of the Administrative Code. Following discussion with the collaborating physician, the

initial order or prescription may be written by an advanced practice nurse holding a current valid certificate to prescribe. Once therapy has been initiated, the advanced practice nurse may continue, modify, or discontinue the medication without further consultation. Credits

Ohio Admin. Code 4723-9-10

5. Oklahoma

- a. The rules regarding prescriptive authority recognition promulgated by the Oklahoma Board of Nursing pursuant to paragraphs 6 through 9, 11 and 12 of Section 567.3a of this title shall:

...

9. a. Establish a Formulary Advisory Council that shall develop and submit to the Board recommendations for an exclusionary formulary that shall list drugs or categories of drugs that shall not be prescribed by advanced practice nurses recognized to prescribe by the Oklahoma Board of Nursing. The Formulary Advisory Council shall also develop and submit to the Board recommendations for practice-specific prescriptive standards for each category of advanced practice nurse recognized to prescribe by the Oklahoma Board of Nursing pursuant to the provisions of the Oklahoma Nursing Practice Act. The Board shall either accept or reject the recommendations made by the Council. No amendments to the recommended exclusionary formulary may be made by the Board without the approval of the Formulary Advisory Council. b. The Formulary Advisory Council shall be composed of twelve (12) members as follows: (1) four members, to include a pediatrician, an obstetrician-gynecological physician, a general internist, and a family practice physician; provided that three of such members shall be appointed by the Oklahoma State Medical Association, and one shall be appointed by the Oklahoma Osteopathic Association, (2) four members who are registered pharmacists, appointed by the Oklahoma Pharmaceutical Association, and (3) four members, one of whom shall be an advanced registered nurse practitioner, one of whom shall be a clinical nurse specialist, one of whom shall be a certified nurse-midwife, and one of whom shall be a current member of the Oklahoma Board of Nursing, all of whom shall be appointed by the Oklahoma Board of Nursing. c. All professional members of the Formulary Advisory Council shall be in active clinical practice, at least fifty percent (50%) of the time, within their defined area of specialty. The members of the Formulary Advisory Council shall serve at the pleasure of the appointing authority for a term of three (3) years. The terms of the members shall be staggered. Members of the Council may serve beyond the expiration of their term of office until a successor is appointed by the original appointing authority. A vacancy on the Council shall be filled for the balance of the unexpired term by the original appointing authority. d. Members of the Council shall elect a chair and a vice-chair from among the membership of the Council. For the transaction of business, at least seven members, with a minimum of two members present from each of the identified categories of physicians, pharmacists and advanced practice nurses, shall constitute a quorum. The Council shall recommend and the Board shall approve and implement an initial exclusionary formulary on or before January 1, 1997. The Council and the Board shall annually review the approved exclusionary formulary and shall make any

necessary revisions utilizing the same procedures used to develop the initial exclusionary formulary.

Okla. Stat. Ann. tit. 59, § 567.4a

- b. (a) The Advanced Practice Registered Nurse may prescribe in writing, orally, or by other means of telecommunication, drugs or medical supplies which are not listed on the exclusionary formulary approved by the Board, and which are within the scope of practice for the Advanced Practice Registered Nurse, and that are not otherwise prohibited by law.

Okla. Admin. Code 485:10-16-5

## 6. Pennsylvania

- a. (a) The Board adopts the American Hospital Formulary Service Pharmacologic-Therapeutic Classification to identify drugs which the CRNP may prescribe and dispense subject to the parameters identified in this section.(b) A CRNP with current prescriptive authority approval from the Board may prescribe, dispense and administer drugs and therapeutic or corrective measures consistent with the prescriptive authority collaborative agreement and relevant to the CRNP's specialty from the following categories:(1) Antihistamines.(2) Anti-infective agents.(3) Antineoplastic agents, unclassified therapeutic agents, devices and pharmaceutical aids.(4) Autonomic drugs.(5) Blood formation, coagulation and anticoagulation drugs, and thrombolytic and antithrombolytic agents.(6) Cardiovascular drugs.(7) Central nervous system agents.(8) Contraceptives including foams and devices.(9) Diagnostic agents.(10) Disinfectants for agents used on objects other than skin.(11) Electrolytic, caloric and water balance.(12) Enzymes.(13) Antitussive, expectorants and mucolytic agents.(14) Gastrointestinal drugs.(15) Local anesthetics.(16) Eye, ear, nose and throat preparations.(17) Serums, toxoids and vaccines.(18) Skin and mucous membrane agents.(19) Smooth muscle relaxants.(20) Vitamins.(21) Hormones and synthetic substitutes.(c) A CRNP may not prescribe or dispense a drug from the following categories:(1) Gold compounds.(2) Heavy metal antagonists.(3) Radioactive agents.(4) Oxytocics.(5) Schedule I controlled substances as defined by section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § 780-104).(d) Restrictions on CRNP prescribing and dispensing practices are as follows:(1) A CRNP may write a prescription for a Schedule II controlled substance for up to a 30-day supply as identified in the collaborative agreement.(2) A CRNP may prescribe a Schedule III or IV controlled substance for up to a 90 day supply as identified in the collaborative agreement.(e) A CRNP may not delegate prescriptive authority.

49 Pa. Code § 21.284

## 7. West Virginia

- a. (b) The board shall promulgate legislative rules in accordance with chapter twenty-nine-a of this code governing the eligibility and extent to which an

advanced practice registered nurse may prescribe drugs. Such rules shall provide, at a minimum, a state formulary classifying those categories of drugs which shall not be prescribed by advanced practice registered nurse including, but not limited to, Schedules I and II of the Uniform Controlled Substances Act, antineoplastics, radiopharmaceuticals and general anesthetics.

W. Va. Code Ann. § 30-7-15a (*Language here updated after final signing of 2016 HB 4334, expected to become law in Summer 2016*)

- b. 5.1. The advanced practice registered nurse shall not prescribe from the following categories of drugs: 5.1.a. Schedules I and II of the Uniform Controlled Substances Act; 5.1.b. Antineoplastics; 5.1.c. Radio-pharmaceuticals; or 5.1.d. General anesthetics. 5.1.e. MAO Inhibitors, except when in a collaborative agreement with a psychiatrist. 5.2. Drugs listed under Schedule III and benzodiazepines are limited to a 72 hour supply without refill. 5.3. The advanced practice registered nurse may prescribe drugs from Schedules IV through V in a quantity necessary for up to a 90 day supply, with only 1 refill, and shall provide that the prescription expires in 6 months, with the following exceptions: 5.3.a. Prescriptions for phenothiazines shall be limited to up to a 30 day supply and shall be non-refillable; 5.3.b. Prescriptions for non-controlled substances of antipsychotics, and sedatives prescribed by the advanced practice registered nurse shall not exceed the quantity necessary for a 90 day supply, shall provide for no more than 1 prescription refill and shall expire in 6 months. 5.4. Pursuant to a collaborative agreement as set forth in the law governing prescriptive authority the advanced practice registered nurse may prescribe an annual supply of any drug, with the exception of controlled substances, which is prescribed for the treatment of a chronic condition, other than chronic pain management. 5.5. The maximum dosage of any drug, including antidepressants, prescribed by the advanced practice registered nurse shall be consistent with the advanced practice registered nurse's area of practice. 5.6. Each prescription and subsequent refills given by the advanced practice registered nurse shall be entered on the patient's chart. 5.7. Advanced practice registered nurse shall not prescribe other prescription drugs or refill for a period exceeding 6 months; provided, that this limitation shall not include contraceptives or those treating a chronic condition as defined in WV Code § 30-7-15a and section 19-8-5.4 of this rule. 5.8. An advanced practice registered nurse may administer local anesthetics. 5.9. The advanced practice registered nurse who has been approved for limited prescriptive authority by the board may sign for, accept, and provide to patients samples of drugs received from a drug company representative. 5.10. The prescription authorized by an advanced practice registered nurse shall comply with all applicable state and federal laws and regulations; must be signed by the prescriber with the legal designation or the designated certification title of the prescriber and must include the prescriber's identification number assigned by the board or the prescriber's national provider identifier assigned by the National Provider System pursuant to 45 CFR §

162.408. 5.10.a. All prescriptions shall include the following information: 5.10.a.1. The name, title, address and phone number of the prescribing advanced practice registered nurse; 5.10.a.2. The name and date of birth of the patient; 5.10.a.3. The date of the prescription; 5.10.a.4. The full name of the drug, the dosage, the route of administration and directions, for its use; 5.10.a.5. The number of refills; 5.10.a.6. The Drug Enforcement Agency number of the prescriber, when required by federal laws; and 5.10.a.7. The prescriptive authority identification number issued by the board. 5.10.b. An advanced practice registered nurse shall at the time of the initial prescription record in the patient record the plan for continued evaluation of the effectiveness of the controlled substances prescribed. 5.10.c. An advanced practice registered nurse shall prescribe refills of controlled substances according to current laws and standards. 5.10.d. Drugs considered to be proved human teratogens shall not be prescribed during a known pregnancy by the advanced practice registered nurse. This prohibition includes all Category D and X drugs from the Federal Drug Administration Categories of teratogen risks (21 CFR 201.57). Category C drugs should be given only if the patient benefit justifies the potential risks to the fetus and only after consultation with the collaborating physician. 5.11. The board may approve a formulary classifying pharmacologic categories of all drugs which may be prescribed by an advanced practice registered nurse with prescriptive authority.

W. Va. Code R. 19-8-5



American Association of  
NURSE PRACTITIONERS™

*The Voice of the Nurse Practitioner®*

American Association of Nurse Practitioners  
PO Box 12846  
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May 3<sup>rd</sup>, 2016

Department of Health  
Board of Nursing  
4052 Bald Cypress Way  
Bin C-02  
Tallahassee, FL 32399-3252

Dear Mr. Baker,

On behalf of our Florida nurse practitioner membership and their patients, the American Association of Nurse Practitioners (AANP) looks forward to improved access to medication therapies in the state in Florida as a result HB 423. AANP will be working with our leadership in Florida to provide comment on the proposed regulations in the coming months, and look forward to participating in the process.

In preparation for our comments on upcoming regulations, AANP pulled the statutes and regulations in the handful of states where formularies are still requirements for nurse practitioner prescribing. Our AANP Region 11 Director, Jean Aertker, thought that these may be valued advanced planning documents for the Board and committee, and requested that we forward these. The state with the most recent formulary change is Kentucky, where the change was specific to a multi-disciplinary committee and specific to controlled substances. It's noteworthy that the majority of states have years of safe NP prescribing without formularies. While AANP recognizes that the Board is bound by the existing statute in regards to the mandate for a formulary, our experience has been that when regulations most closely align with statute to balance patient safety, evidence-based recommendations and access to care that patients benefit most.

Please let me or Jean Aertker know if AANP may provide any additional background information as you and the committee begin this important work. We look forward to improving the health of Florida together.

Sincerely,

Tay Kopanos, DNP, FNP  
Vice President, State Government Affairs

Please note: An erratum has been published for this issue. To view the erratum, please click [here](#).

Centers for Disease Control and Prevention

# MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 65 / No. 1

March 18, 2016

## CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



**U.S. Department of Health and Human Services**  
Centers for Disease Control and Prevention

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### Disclosure of Relationship

The Core Expert Group (CEG) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Pam Archer discloses authorship of the Oklahoma Emergency Department and Urgent Care Clinic Opioid Prescribing Guidelines and the Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office Based Setting; Bonnie Burman discloses authorship of the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain; Jane Ballantyne discloses that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC, and has special advisory committee responsibilities on the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies committee; Phillip Coffin discloses that in 2012 he provided expert testimony to the California State Assembly regarding a bill to expand naloxone access and reports that he is the principal investigator on a research study of methamphetamine dependence that receives donated injectable naltrexone from Alkermes, Inc.; Gary Franklin discloses authorship of the AMDG Interagency Guideline on Prescribing Opioids for Pain; Erin Krebs discloses that she represented the American College of Physicians at a 2014 Food and Drug Administration meeting on Abuse Deterrent Opioid Formulations; Lewis Nelson discloses his ad-hoc membership on the FDA Drug Safety and Risk Management Advisory Committee; Trupti Patel discloses authorship of the Arizona Opioid Prescribing Guidelines; Robert “Chuck” Rich discloses that he was an author of the 2013 American Academy of Family Physicians position paper on opioids and pain management; Joanna Starrels discloses that she received honoraria from the Betty Ford Institute; Thomas Tape discloses that he was an author of the 2013 American College of Physicians policy

position paper on prescription drug abuse. CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support. No foundation or industry support was accepted.

The Opioid Guideline Workgroup (OGW) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Anne Burns discloses that she participated in a congressional briefing sponsored by Reps. Carter and DeSaulnier on the pharmacist’s role of furnishing Naloxone and that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit. Chinazo Cunningham discloses that her husband is employed by Quest Diagnostics and Dr. Cunningham was recused from any discussion related to urine drug testing. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Erin Krebs discloses that she served on the CDC Opioid Prescribing Guideline CEG. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG. Greg Terman discloses that he serves as the President of the American Pain Society. Mark Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone formulation to treat acute postoperative pain and Dr. Wallace was recused from any discussion related to abuse-deterrent drugs.

The NCIPC Board of Scientific Counselors (BSC) members disclose that they have no financial conflicts of interest. Two BSC members, Traci Green and Christina Porucznik, served on the Opioid Guideline Workgroup. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG.

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# CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Prepared by  
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## Summary

*This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. 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. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (<http://stacks.cdc.gov/view/cdc/38025>) as well as a website (<http://www.cdc.gov/drugoverdose/prescribingresources.html>) with additional tools to guide clinicians in implementing the recommendations.*

## Introduction

### Background

Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription (1). In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills (2). Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties (3). Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication (2).

Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients, particularly members of racial and ethnic minority groups, women, the elderly, persons with

cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment (4). Patients can experience persistent pain that is not well controlled. There are clinical, psychological, and social consequences associated with chronic pain including limitations in complex activities, lost work productivity, reduced quality of life, and stigma, emphasizing the importance of appropriate and compassionate patient care (4). Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options.

Chronic pain has been variably defined but is defined within this guideline as pain that typically lasts >3 months or past the time of normal tissue healing (5). Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (4). Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated that 14.6% of adults have current widespread or localized pain lasting at least 3 months (6). Based on a survey conducted during 2001–2003 (7), the overall prevalence of common, predominantly musculoskeletal pain conditions (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the

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United States, although minimum duration of symptoms was not specified. Most recently, analysis of data from the 2012 National Health Interview Study showed that 11.2% of adults report having daily pain (8). Clinicians should consider the full range of therapeutic options for the treatment of chronic pain. However, it is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Evidence supports short-term efficacy of opioids for reducing pain and improving function in noncancer nociceptive and neuropathic pain in randomized clinical trials lasting primarily  $\leq 12$  weeks (9,10), and patients receiving opioid therapy for chronic pain report some pain relief when surveyed (11–13). However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting  $>3$  months) with outcomes examined at least 1 year later (14). On the basis of data available from health systems, researchers estimate that 9.6–11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005 (15).

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States (16). In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly (17). Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths (18). The Drug Abuse Warning Network estimated that  $>420,000$  emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available (19). Although clinical criteria have varied over time, opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home (20). This diagnosis has also been referred to as “abuse or dependence” and “addiction” in the literature, and is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped), both of which can exist without a diagnosed disorder. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (21). Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder (22–24), highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years

receiving opioids for chronic noncancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages  $>200$  morphine milligram equivalents (MME) died from opioid-related overdose (25).

This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last  $>3$  months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. Although the guideline does not focus broadly on pain management, appropriate use of long-term opioid therapy must be considered within the context of all pain management strategies (including nonopioid pain medications and nonpharmacologic treatments). CDC’s recommendations are made on the basis of a systematic review of the best available evidence, along with input from experts, and further review and deliberation by a federally chartered advisory committee. The guideline is intended to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient’s clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

## Rationale

Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids (26). Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain (27). These attitudes and beliefs, combined with increasing trends in opioid-related overdose, underscore the need for better clinician guidance on opioid prescribing. Clinical practice guidelines focused on prescribing can improve clinician knowledge, change prescribing practices (28), and ultimately benefit patient health.

Professional organizations, states, and federal agencies (e.g., the American Pain Society/American Academy of Pain Medicine, 2009; the Washington Agency Medical Directors Group, 2015; and the U.S. Department of Veterans Affairs/Department of Defense, 2010) have developed guidelines for opioid prescribing (29–31). Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest (32). Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

This CDC guideline offers clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain) (24,33,34). Using guidelines to address problematic prescribing has the potential to optimize care and improve patient safety based on evidence-based practice (28), as well as reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic.

## Scope and Audience

This guideline is intended for primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians has been above average (3). Primary care clinicians include physicians as well as nurse practitioners and physician assistants. Although the focus is on primary care clinicians, because clinicians work within team-based care, the recommendations refer to and promote integrated pain management and collaborative working relationships with other providers (e.g., behavioral health providers, pharmacists, and pain management specialists). Although the transition from use of opioid therapy for acute pain to use for chronic pain is hard to predict

and identify, the guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.

This guideline is intended to apply to patients aged  $\geq 18$  years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms (35). End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. Patients within the scope of this guideline include cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, and are under cancer surveillance only. The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant women) and in populations with conditions posing special risks (e.g., a history of substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and harms of long-term opioid therapy in children and adolescents is limited, and few opioid medications provide information on the label regarding safety and effectiveness in pediatric patients. However, observational research shows significant increases in opioid prescriptions for pediatric populations from 2001 to 2010 (36), and a large proportion of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries (e.g., in one study, 50% of adolescents presenting with headache received a prescription for an opioid pain medication [37,38]). Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions (39), with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs (40). Use of prescribed opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse (41). Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use (42). Thus, risk of opioid medication use in pediatric populations is of great concern. Additional clinical trial and observational research is needed,

and encouraged, to inform development of future guidelines for this critical population.

The recommendations are not intended to provide guidance on use of opioids as part of medication-assisted treatment for opioid use disorder. 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 this guideline. Readers are referred to other sources for prescribing recommendations within acute care settings and in dental practice, such as the American College of Emergency Physicians' guideline for prescribing of opioids in the emergency department (43); the American Society of Anesthesiologists' guideline for acute pain management in the perioperative setting (44); the Washington Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Part II: Prescribing Opioids in the Acute and Subacute Phase (30); and the Pennsylvania Guidelines on the Use of Opioids in Dental Practice (45). In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (46).

## Guideline Development Methods

### Guideline Development Using the Grading of Recommendations Assessment, Development, and Evaluation Method

CDC developed this guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (<http://www.gradeworkinggroup.org>). This method specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. The method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP) (47). CDC has applied the ACIP translation of the GRADE framework in this guideline. Within the ACIP GRADE framework, the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence in the effect of a clinical action on health outcomes. The categories include type 1 evidence (randomized clinical trials or overwhelming evidence from observational studies), type 2 evidence (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 evidence (observational studies or randomized clinical trials with notable limitations), and type 4 evidence (clinical

experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). Type of evidence is categorized by study design as well as limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and a constellation of plausible biases that could change observations of effects. Type 1 evidence indicates that one can be very confident that the true effect lies close to that of the estimate of the effect; type 2 evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; type 3 evidence means that confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect; and type 4 evidence indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect (47,48). When no studies are present, evidence is considered to be insufficient. The ACIP GRADE framework places recommendations in two categories, Category A and Category B. Four major factors determine the category of the recommendation: the quality of evidence, the balance between desirable and undesirable effects, values and preferences, and resource allocation (cost). Category A recommendations apply to all persons in a specified group and indicate that most patients should receive the recommended course of action. Category B recommendations indicate that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (47). According to the GRADE methodology, a particular quality of evidence does not necessarily imply a particular strength of recommendation (48–50). Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs. Category B recommendations are made when the advantages and disadvantages of a clinical action are more balanced. GRADE methodology is discussed extensively elsewhere (47,51). The U.S. Preventive Services Task Force (USPSTF) follows different methods for developing and categorizing recommendations (<http://www.uspreventiveservicestaskforce.org>). USPSTF recommendations focus on preventive services and are categorized as A, B, C, D, and I. Under the Affordable Care Act, all “nongrandfathered” health plans (that is, those health plans not in existence prior to March 23, 2010 or those with significant changes to their coverage) and expanded Medicaid plans are required to cover

preventive services recommended by USPSTF with a category A or B rating with no cost sharing. The coverage requirements went into effect September 23, 2010. Similar requirements are in place for vaccinations recommended by ACIP, but do not exist for other recommendations made by CDC, including recommendations within this guideline.

A previously published systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness and risks of long-term opioid treatment of chronic pain (14,52) initially served to directly inform the recommendation statements. This systematic clinical evidence review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk-prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, addiction, abuse, or misuse. For the current guideline development, CDC conducted additional literature searches to update the evidence review to include more recently available publications and to answer an additional clinical question about the effect of opioid therapy for acute pain on long-term use. More details about the literature search strategies and GRADE methods applied are provided in the Clinical Evidence Review (<http://stacks.cdc.gov/view/cdc/38026>). CDC developed GRADE evidence tables to illustrate the quality of the evidence for each clinical question.

As identified in the AHRQ-sponsored clinical evidence review, the overall evidence base for the effectiveness and risks of long-term opioid therapy is low in quality per the GRADE criteria. Thus, contextual evidence is needed to provide information about the benefits and harms of nonpharmacologic and nonopioid pharmacologic therapy and the epidemiology of opioid pain medication overdose and inform the recommendations. Further, as elucidated by the GRADE Working Group, supplemental information on clinician and patient values and preferences and resource allocation can inform judgments of benefits and harms and be helpful for translating the evidence into recommendations. CDC conducted a contextual evidence review to supplement the clinical evidence review based on systematic searches of the literature. The review focused on the following four areas: effectiveness of nonpharmacologic and nonopioid pharmacologic treatments; benefits and harms related to opioid therapy (including additional studies not included in the clinical evidence review such as studies that evaluated outcomes at any duration or used observational study designs related to specific opioid pain medications, high-dose opioid therapy, co-prescription of opioids with other controlled substances, duration of opioid use, special populations, risk

stratification/mitigation approaches, and effectiveness of treatments for addressing potential harms of opioid therapy); clinician and patient values and preferences; and resource allocation. CDC constructed narrative summaries of this contextual evidence and used the information to support the clinical recommendations. More details on methods for the contextual evidence review are provided in the Contextual Evidence Review (<http://stacks.cdc.gov/view/cdc/38027>).

On the basis of a review of the clinical and contextual evidence (review methods are described in more detail in subsequent sections of this report), CDC drafted recommendation statements focused on determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. To help assure the draft guideline's integrity and credibility, CDC then began a multistep review process to obtain input from experts, stakeholders, and the public to help refine the recommendations.

## Solicitation of Expert Opinion

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology.\* CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

Prior to their participation, CDC asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Experts could not serve if they had conflicts that might have a direct and predictable effect on the recommendations. CDC excluded experts who had a financial or promotional relationship with a company

\* A list of the members appears at the end of this report. The recommendations and all statements included in this guideline are those of CDC and do not necessarily represent the official position of any persons or organizations providing comments on the draft guideline.

that makes a product that might be affected by the guideline. CDC reviewed potential nonfinancial conflicts carefully (e.g., intellectual property, travel, public statements or positions such as congressional testimony) to determine if the activities would have a direct and predictable effect on the recommendations. CDC determined the risk of these types of activities to be minimal for the identified experts. All experts completed a statement certifying that there was no potential or actual conflict of interest. Activities that did not pose a conflict (e.g., participation in Food and Drug Administration [FDA] activities or other guideline efforts) are disclosed.

CDC provided to each expert written summaries of the scientific evidence (both the clinical and contextual evidence reviews conducted for this guideline) and CDC's draft recommendation statements. Experts provided individual ratings for each draft recommendation statement based on the balance of benefits and harms, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC hosted an in-person meeting of the experts that was held on June 23–24, 2015, in Atlanta, Georgia, to seek their views on the evidence and draft recommendations and to better understand their premeeting ratings. CDC sought the experts' individual opinions at the meeting. Although there was widespread agreement on some of the recommendations, there was disagreement on others. Experts did not vote on the recommendations or seek to come to a consensus. Decisions about recommendations to be included in the guideline, and their rationale, were made by CDC. After revising the guideline, CDC sent written copies of it to each of the experts for review and asked for any additional comments; CDC reviewed these written comments and considered them when making further revisions to the draft guideline. The experts have not reviewed the final version of the guideline.

## Federal Partner Engagement

Given the scope of this guideline and the interest of agencies across the federal government in appropriate pain management, opioid prescribing, and related outcomes, CDC invited its National Institute of Occupational Safety and Health and CDC's federal partners to observe the expert meeting, provide written comments on the full draft guideline after the meeting, and review the guideline through an agency clearance process; CDC reviewed comments and incorporated changes. Interagency collaboration will be critical for translating these recommendations into clinical practice. Federal partners included representatives from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, FDA, the U.S. Department of Veterans Affairs,

the U.S. Department of Defense, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, AHRQ, and the Office of National Drug Control Policy.

## Stakeholder Comment

Given the importance of the guideline for a wide variety of stakeholders, CDC also invited review from a Stakeholder Review Group (SRG) to provide comment so that CDC could consider modifications that would improve the recommendations' specificity, applicability, and ease of implementation. The SRG included representatives from professional organizations that represent specialties that commonly prescribe opioids (e.g., pain medicine, physical medicine and rehabilitation), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organizations with interests in pain management and opioid prescribing.\* Representatives from each of the SRG organizations were provided a copy of the guideline for comment. Each of these representatives provided written comments. Once input was received from the full SRG, CDC reviewed all comments and carefully considered them when revising the draft guideline.

## Constituent Engagement

To obtain initial perspectives from constituents on the recommendation statements, including clinicians and prospective patients, CDC convened a constituent engagement webinar and circulated information about the webinar in advance through announcements to partners. CDC hosted the webinar on September 16 and 17, 2015, provided information about the methodology for developing the guideline, and presented the key recommendations. A fact sheet was posted on the CDC Injury Center website (<http://www.cdc.gov/injury>) summarizing the guideline development process and clinical practice areas addressed in the guideline; instructions were included on how to submit comments via email. CDC received comments during and for 2 days following the first webinar. Over 1,200 constituent comments were received. Comments were reviewed and carefully considered when revising the draft guideline.

## Peer Review

Per the final information quality bulletin for peer review (<https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf>), peer review requirements applied to this guideline because it provides influential

scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations.\* CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified. CDC placed the names of peer reviewers on the CDC and the National Center for Injury Prevention and Control Peer Review Agenda websites that are used to provide information about the peer review of influential documents. CDC reviewed peer review comments and revised the draft guideline accordingly.

### Public Comment

To obtain comments from the public on the full guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the guideline and the supporting clinical and contextual evidence reviews for public comment. The comment period closed January 13, 2016. CDC received more than 4,350 comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when revising the draft guideline.

### Federal Advisory Committee Review and Recommendation

The National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) is a federal advisory committee that advises and makes recommendations to the Secretary of the Department of Health and Human Services, the Director of CDC, and the Director of NCIPC.\* The BSC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. CDC sought the BSC's advice on the draft guideline. BSC members are special government employees appointed as CDC advisory committee members; as such, all members completed an OGE Form 450

to disclose relevant interests. BSC members also reported on their disclosures during meetings. Disclosures for the BSC are reported in the guideline.

To assist in guideline review, on December 14, 2015, via Federal Register notice, CDC announced the intent to form an Opioid Guideline Workgroup (OGW) to provide observations on the draft guideline to the BSC. CDC provided the BSC with the draft guideline as well as summaries of comments provided to CDC by stakeholders, constituents, and peer reviewers, and edits made to the draft guideline in response. During an open meeting held on January 7, 2016, the BSC recommended the formation of the OGW. The OGW included a balance of perspectives from audiences directly affected by the guideline, audiences that would be directly involved with implementing the recommendations, and audiences qualified to provide representation. The OGW comprised clinicians, subject matter experts, and a patient representative, with the following perspectives represented: primary care, pain medicine, public health, behavioral health, substance abuse treatment, pharmacy, patients, and research.\* Additional sought-after attributes were appropriate academic and clinical training and relevant clinical experience; high scientific standing; and knowledge of the patient, clinician, and caregiver perspectives. In accordance with CDC policy, two BSC committee members also served as OGW members, with one serving as the OGW Chair. The professional credentials and interests of OGW members were carefully reviewed to identify possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Only OGW members whose interests were determined to be minimal were selected. When an activity was perceived as having the potential to affect a specific aspect of the recommendations, the activity was disclosed, and the OGW member was recused from discussions related to that specific aspect of the recommendations (e.g., urine drug testing and abuse-deterrent formulations). Disclosures for the OGW are reported. CDC and the OGW identified ad-hoc consultants to supplement the workgroup expertise, when needed, in the areas of pediatrics, occupational medicine, obstetrics and gynecology, medical ethics, addiction psychiatry, physical medicine and rehabilitation, guideline development methodology, and the perspective of a family member who lost a loved one to opioid use disorder or overdose.

The BSC charged the OGW with reviewing the quality of the clinical and contextual evidence reviews and reviewing each of the recommendation statements and accompanying rationales. For each recommendation statement, the OGW considered the quality of the evidence, the balance of benefits and risks, the values and preferences of clinicians and patients, the cost feasibility, and the category designation

of the recommendation (A or B). The OGW also reviewed supplementary documents, including input provided by the CEG, SRG, peer reviewers, and the public. OGW members discussed the guideline accordingly during virtual meetings and drafted a summary report of members' observations, including points of agreement and disagreement, and delivered the report to the BSC.

NCIPC announced an open meeting of the NCIPC BSC in the Federal Register on January 11, 2015. The BSC met on January 28, 2016, to discuss the OGW report and deliberate on the draft guideline itself. Members of the public provided comments at this meeting. After discussing the OGW report, deliberating on specific issues about the draft guideline identified at the meeting, and hearing public comment, the BSC voted unanimously: to support the observations made by the OGW; that CDC adopt the guideline recommendations that, according to the workgroup's report, had unanimous or majority support; and that CDC further consider the guideline recommendations for which the group had mixed opinions. CDC carefully considered the OGW observations, public comments, and BSC recommendations, and revised the guideline in response.

## Summary of the Clinical Evidence Review

### Primary Clinical Questions

CDC conducted a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain, consistent with the GRADE approach (47,48). Long-term opioid therapy is defined as use of opioids on most days for >3 months. A previously published AHRQ-funded systematic review on the effectiveness and risks of long-term opioid therapy for chronic pain comprehensively addressed four clinical questions (14,52). CDC, with the assistance of a methodology expert, searched the literature to identify newly published studies on these four original questions. Because long-term opioid use might be affected by use of opioids for acute pain, CDC subsequently developed a fifth clinical question (last in the series below), and in collaboration with a methodologist conducted a systematic review of the scientific evidence to address it. In brief, five clinical questions were addressed:

- The effectiveness of long-term opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for long term ( $\geq 1$  year) outcomes related to pain, function, and quality of life, and how effectiveness varies according to

the type/cause of pain, patient demographics, and patient comorbidities (Key Question [KQ] 1).

- The risks of opioids versus placebo or no opioids on abuse, addiction, overdose, and other harms, and how harms vary according to the type/cause of pain, patient demographics, patient comorbidities, and dose (KQ2).
- The comparative effectiveness of opioid dosing strategies (different methods for initiating and titrating opioids; immediate-release versus ER/LA opioids; different ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled, continuous versus as-needed dosing; dose escalation versus dose maintenance; opioid rotation versus maintenance; different strategies for treating acute exacerbations of chronic pain; decreasing opioid doses or tapering off versus continuation; and different tapering protocols and strategies) (KQ3).
- The accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse; the effectiveness of risk mitigation strategies (use of risk prediction instruments); effectiveness of risk mitigation strategies including opioid management plans, patient education, urine drug testing, prescription drug monitoring program (PDMP) data, monitoring instruments, monitoring intervals, pill counts, and abuse-deterrent formulations for reducing risk for opioid overdose, addiction, abuse, or misuse; and the comparative effectiveness of treatment strategies for managing patients with addiction (KQ4).
- The effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain on long-term use (KQ5).

The review was focused on the effectiveness of long-term opioid therapy on long-term (>1 year) outcomes related to pain, function, and quality of life to ensure that findings are relevant to patients with chronic pain and long-term opioid prescribing. The effectiveness of short-term opioid therapy has already been established (10). However, opioids have unique effects such as tolerance and physical dependence that might influence assessments of benefit over time. These effects raise questions about whether findings on short-term effectiveness of opioid therapy can be extrapolated to estimate benefits of long-term therapy for chronic pain. Thus, it is important to consider studies that provide data on long-term benefit. For certain opioid-related harms (overdose, fractures, falls, motor vehicle crashes), observational studies were included with outcomes measured at shorter intervals because such outcomes can occur early during opioid therapy, and such harms are not captured well in short-term clinical trials. A detailed listing of the key questions is provided in the Clinical Evidence Review (<http://stacks.cdc.gov/view/cdc/38026>).

## Clinical Evidence Systematic Review Methods

Complete methods and data for the 2014 AHRQ report, upon which this updated systematic review is based, have been published previously (14,52). Study authors developed the protocol using a standardized process (53) with input from experts and the public and registered the protocol in the PROSPERO database (54). For the 2014 AHRQ report, a research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL for English-language articles published January 2008 through August 2014, using search terms for opioid therapy, specific opioids, chronic pain, and comparative study designs. Also included were relevant studies from an earlier review (10) in which searches were conducted without a date restriction, reference lists were reviewed, and ClinicalTrials.gov was searched. CDC updated the AHRQ literature search using the same search strategies as in the original review including studies published before April, 2015. Seven additional studies met inclusion criteria and were added to the review. CDC used the GRADE approach outlined in the ACIP Handbook for Developing Evidence-Based Recommendations (47) to rate the quality of evidence for the full body of evidence (evidence from the 2014 AHRQ review plus the update) for each clinical question. Evidence was categorized into the following types: type 1 (randomized clinical trials or overwhelming evidence from observational studies), type 2 (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 (observational studies, or randomized clinical trials with notable limitations), or type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). When no studies were present, evidence was considered to be insufficient. Per GRADE methods, type of evidence was categorized by study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects. Results were synthesized qualitatively, highlighting new evidence identified during the update process. Meta-analysis was not attempted due to the small numbers of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of the studies. More detailed information about data sources and searches, study selection, data extraction and quality assessment, data synthesis, and update search yield and new evidence for the current review is provided in the Clinical Evidence Review (<http://stacks.cdc.gov/view/cdc/38026>).

## Summary of Findings for Clinical Questions

The main findings of this updated review are consistent with the findings of the 2014 AHRQ report (14). In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly  $\leq 12$  weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events (10).

The GRADE evidence summary with type of evidence ratings for the five clinical questions for the current evidence review are outlined (Table 1). This summary is based on studies included in the AHRQ 2014 review (35 studies) plus additional studies identified in the updated search (seven studies). Additional details on findings from the original review are provided in the full 2014 AHRQ report (14,52). Full details on the clinical evidence review findings supporting this guideline are provided in the Clinical Evidence Review (<http://stacks.cdc.gov/view/cdc/38026>).

### Effectiveness

For KQ1, no study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for chronic pain evaluated long-term ( $\geq 1$  year) outcomes related to pain, function, or quality of life. Most placebo-controlled randomized clinical trials were  $\leq 6$  weeks in duration. Thus, the body of evidence for KQ1 is rated as insufficient (0 studies contributing) (14).

### Harms

For KQ2, the body of evidence is rated as type 3 (12 studies contributing; 11 from the original review plus one new study). One fair-quality cohort study found that long-term opioid therapy is associated with increased risk for an opioid abuse or dependence diagnosis (as defined by ICD-9-CM codes) versus no opioid prescription (22). Rates of opioid abuse or dependence diagnosis ranged from 0.7% with lower-dose ( $\leq 36$  MME) chronic therapy to 6.1% with higher-dose ( $\geq 120$  MME) chronic therapy, versus 0.004% with no opioids prescribed. Ten fair-quality uncontrolled studies reported estimates of opioid abuse, addiction, and related outcomes (55–65). In primary care settings, prevalence of opioid dependence

(using DSM-IV criteria) ranged from 3% to 26% (55,56,59). In pain clinic settings, prevalence of addiction ranged from 2% to 14% (57,58,60,61,63–65).

Factors associated with increased risk for misuse included history of substance use disorder, younger age, major depression, and use of psychotropic medications (55,62). Two studies reported on the association between opioid use and risk for overdose (66,67). One large fair-quality retrospective cohort study found that recent opioid use was associated with increased risk for any overdose events and serious overdose events versus nonuse (66). It also found higher doses associated with increased risk. Relative to 1–19 MME/day, the adjusted hazard ratio (HR) for any overdose event (consisting of mostly nonfatal overdose) was 1.44 for 20 to 49 MME/day, 3.73 for 50–99 MME/day, and 8.87 for  $\geq 100$  MME/day. A similar pattern was observed for serious overdose. A good-quality population-based, nested case-control study also found a dose-dependent association with risk for overdose death (67). Relative to 1–19 MME/day, the adjusted odds ratio (OR) was 1.32 for 20–49 MME/day, 1.92 for 50–99 MME/day, 2.04 for 100–199 MME/day, and 2.88 for  $\geq 200$  MME/day.

Findings of increased fracture risk for current opioid use, versus nonuse, were mixed in two studies (68,69). Two studies found an association between opioid use and increased risk for cardiovascular events (70,71). Indirect evidence was found for endocrinologic harms (increased use of medications for erectile dysfunction or testosterone from one previously included study; laboratory-defined androgen deficiency from one newly reviewed study) (72,73). One study found that opioid dosages  $\geq 20$  MME/day were associated with increased odds of road trauma among drivers (74).

## Opioid Dosing Strategies

For KQ3, the body of evidence is rated as type 4 (14 studies contributing; 12 from the original review plus two new studies). For initiation and titration of opioids, the 2014 AHRQ report found insufficient evidence from three fair-quality, open-label trials to determine comparative effectiveness of ER/LA versus immediate-release opioids for titrating patients to stable pain control (75,76). One new fair-quality cohort study of Veterans Affairs patients found initiation of therapy with an ER/LA opioid associated with greater risk for nonfatal overdose than initiation with an immediate-release opioid, with risk greatest in the first 2 weeks after initiation of treatment (77).

For comparative effectiveness and harms of ER/LA opioids, the 2014 AHRQ report included three randomized, head-to-head trials of various ER/LA opioids that found no clear differences in 1-year outcomes related to pain or function (78–80) but had methodological shortcomings. A fair-quality retrospective cohort study based on national Veterans Health

Administration system pharmacy data found that methadone was associated with lower overall risk for all-cause mortality versus morphine (81), and a fair-quality retrospective cohort study based on Oregon Medicaid data found no statistically significant differences between methadone and long-acting morphine in risk for death or overdose symptoms (82). However, a new observational study (83) found methadone associated with increased risk for overdose versus sustained-release morphine among Tennessee Medicaid patients. The observed inconsistency in study findings suggests that risks of methadone might vary in different settings as a function of different monitoring and management protocols, though more research is needed to understand factors associated with safer methadone prescribing.

For dose escalation, the 2014 AHRQ report included one fair-quality randomized trial that found no differences between more liberal dose escalation and maintenance of current doses after 12 months in pain, function, all-cause withdrawals, or withdrawals due to opioid misuse (84). However, the difference in opioid dosages prescribed at the end of the trial was relatively small (mean 52 MME/day with more liberal dosing versus 40 MME/day). Evidence on other comparisons related to opioid dosing strategies (ER/LA versus immediate-release opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled continuous dosing versus as-needed dosing; or opioid rotation versus maintenance of current therapy; long-term effects of strategies for treating acute exacerbations of chronic pain) was not available or too limited to determine effects on long-term clinical outcomes. For example, evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies (85–87).

## Risk Assessment and Mitigation

For KQ4, the body of evidence is rated as type 3 for the accuracy of risk assessment tools and insufficient for the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms (six studies contributing; four from the original review plus two new studies). The 2014 AHRQ report included four studies (88–91) on the accuracy of risk assessment instruments, administered prior to opioid therapy initiation, for predicting opioid abuse or misuse. Results for the Opioid Risk Tool (ORT) (89–91) were extremely inconsistent; evidence for other risk assessment instruments was very sparse, and studies had serious methodological shortcomings. One additional fair-quality (92) and one poor-quality (93) study identified for this update compared the predictive accuracy of the ORT, the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview.

For the ORT, sensitivity was 0.58 and 0.75 and specificity 0.54 and 0.86; for the SOAPP-R, sensitivity was 0.53 and 0.25 and specificity 0.62 and 0.73; and for the Brief Risk Interview, sensitivity was 0.73 and 0.83 and specificity 0.43 and 0.88. For the ORT, positive likelihood ratios ranged from noninformative (positive likelihood ratio close to 1) to moderately useful (positive likelihood ratio >5). The SOAPP-R was associated with noninformative likelihood ratios (estimates close to 1) in both studies.

No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.

### Effects of Opioid Therapy for Acute Pain on Long-Term Use

For KQ5, the body of evidence is rated as type 3 (two new studies contributing). Two fair-quality retrospective cohort studies found opioid therapy prescribed for acute pain associated with greater likelihood of long-term use. One study evaluated opioid-naïve patients who had undergone low-risk surgery, such as cataract surgery and varicose vein stripping (94). Use of opioids within 7 days of surgery was associated with increased risk for use at 1 year. The other study found that among patients with a workers' compensation claim for acute low back pain, compared to patients who did not receive opioids early after injury (defined as use within 15 days following onset of pain), patients who did receive early opioids had an increased likelihood of receiving five or more opioid prescriptions 30–730 days following onset that increased with greater early exposure. Versus no early opioid use, the adjusted OR was 2.08 (95% CI = 1.55–2.78) for 1–140 MME/day and increased to 6.14 (95% confidence interval [CI] = 4.92–7.66) for ≥450 MME/day (95).

## Summary of the Contextual Evidence Review

### Primary Areas of Focus

Contextual evidence is complementary information that assists in translating the clinical research findings into recommendations. CDC conducted contextual evidence reviews on four topics to supplement the clinical evidence review findings:

- Effectiveness of nonpharmacologic (e.g., cognitive behavioral therapy [CBT], exercise therapy, interventional treatments, and multimodal pain treatment) and nonopioid pharmacologic treatments (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, and anticonvulsants), including studies of any duration.
  - Benefits and harms of opioid therapy (including additional studies not included in the clinical evidence review, such as studies that were not restricted to patients with chronic pain, evaluated outcomes at any duration, performed ecological analyses, or used observational study designs other than cohort and case-cohort control studies) related to specific opioids, high-dose therapy, co-prescription with other controlled substances, duration of use, special populations, and potential usefulness of risk stratification/mitigation approaches, in addition to effectiveness of treatments associated with addressing potential harms of opioid therapy (opioid use disorder).
  - Clinician and patient values and preferences related to opioids and medication risks, benefits, and use.
  - Resource allocation including costs and economic efficiency of opioid therapy and risk mitigation strategies.
- CDC also reviewed clinical guidelines that were relevant to opioid prescribing and could inform or complement the CDC recommendations under development (e.g., guidelines on nonpharmacologic and nonopioid pharmacologic treatments and guidelines with recommendations related to specific clinician actions such as urine drug testing or opioid tapering protocols).

### Contextual Evidence Review Methods

CDC conducted a contextual evidence review to assist in developing the recommendations by providing an assessment of the balance of benefits and harms, values and preferences, and cost, consistent with the GRADE approach. Given the public health urgency for developing opioid prescribing recommendations, a rapid review was required for the contextual evidence review for the current guideline. Rapid reviews are used when there is a need to streamline the systematic review process to obtain evidence quickly (96). Methods used to streamline the process include limiting searches by databases, years, and languages considered, and truncating quality assessment and data abstraction protocols. CDC conducted “rapid reviews” of the contextual evidence on nonpharmacologic and nonopioid pharmacologic treatments, benefits and harms, values and preferences, and resource allocation.

Detailed information about contextual evidence data sources and searches, inclusion criteria, study selection, and

data extraction and synthesis are provided in the Contextual Evidence Review (<http://stacks.cdc.gov/view/cdc/38027>). In brief, CDC conducted systematic literature searches to identify original studies, systematic reviews, and clinical guidelines, depending on the topic being searched. CDC also solicited publication referrals from subject matter experts. Given the need for a rapid review process, grey literature (e.g., literature by academia, organizations, or government in the forms of reports, documents, or proceedings not published by commercial publishers) was not systematically searched. Database sources, including MEDLINE, PsycINFO, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews, varied by topic. Multiple reviewers scanned study abstracts identified through the database searches and extracted relevant studies for review. CDC constructed narrative summaries and tables based on relevant articles that met inclusion criteria, which are provided in the Contextual Evidence Review (<http://stacks.cdc.gov/view/cdc/38027>).

Findings from the contextual reviews provide indirect evidence and should be interpreted accordingly. CDC did not formally rate the quality of evidence for the studies included in the contextual evidence review using the GRADE method. The studies that addressed benefits and harms, values and preferences, and resource allocation most often employed observational methods, used short follow-up periods, and evaluated selected samples. Therefore the strength of the evidence from these contextual review areas was considered to be low, comparable to type 3 or type 4 evidence. The quality of evidence for nonopioid pharmacologic and nonpharmacologic pain treatments was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines (e.g., for treatment of chronic neuropathic pain, low back pain, osteoarthritis, and fibromyalgia). Similarly, the quality of evidence on pharmacologic and psychosocial opioid use disorder treatment was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines.

## Summary of Findings for Contextual Areas

Full narrative reviews and tables that summarize key findings from the contextual evidence review are provided in the Contextual Evidence Review (<http://stacks.cdc.gov/view/cdc/38027>).

### Effectiveness of Nonpharmacologic and Nonopioid Pharmacologic Treatments

Several nonpharmacologic and nonopioid pharmacologic treatments have been shown to be effective in managing chronic pain in studies ranging in duration from 2 weeks to 6 months. For example, CBT that trains patients in behavioral techniques

and helps patients modify situational factors and cognitive processes that exacerbate pain has small positive effects on disability and catastrophic thinking (97). Exercise therapy can help reduce pain and improve function in chronic low back pain (98), improve function and reduce pain in osteoarthritis of the knee (99) and hip (100), and improve well-being, fibromyalgia symptoms, and physical function in fibromyalgia (101). Multimodal and multidisciplinary therapies (e.g., therapies that combine exercise and related therapies with psychologically based approaches) can help reduce pain and improve function more effectively than single modalities (102,103). Nonopioid pharmacologic approaches used for pain include analgesics such as acetaminophen, NSAIDs, and cyclooxygenase 2 (COX-2) inhibitors; selected anticonvulsants; and selected antidepressants (particularly tricyclics and serotonin and norepinephrine reuptake inhibitors [SNRIs]). Multiple guidelines recommend acetaminophen as first-line pharmacotherapy for osteoarthritis (104–109) or for low back pain (110) but note that it should be avoided in liver failure and that dosage should be reduced in patients with hepatic insufficiency or a history of alcohol abuse (109). Although guidelines also recommend NSAIDs as first-line treatment for osteoarthritis or low back pain (106,110), NSAIDs and COX-2 inhibitors do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks (111). FDA has recently strengthened existing label warnings that NSAIDs increase risks for heart attack and stroke, including that these risks might increase with longer use or at higher doses (112). Several guidelines agree that first- and second-line drugs for neuropathic pain include anticonvulsants (gabapentin or pregabalin), tricyclic antidepressants, and SNRIs (113–116). Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain (117–119). Epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (120).

### Benefits and Harms of Opioid Therapy

Balance between benefits and harms is a critical factor influencing the strength of clinical recommendations. In particular, CDC considered what is known from the epidemiology research about benefits and harms related to specific opioids and formulations, high dose therapy, co-prescription with other controlled substances, duration of use, special populations, and risk stratification and mitigation approaches. Additional information on benefits and harms of long-term opioid therapy from studies meeting rigorous selection criteria is provided in the clinical evidence review (e.g., see KQ2). CDC also considered the number of persons experiencing chronic pain, numbers potentially benefiting

from opioids, and numbers affected by opioid-related harms. A review of these data is presented in the background section of this document, with detailed information provided in the Contextual Evidence Review (<http://stacks.cdc.gov/view/cdc/38027>). Finally, CDC considered the effectiveness of treatments that addressed potential harms of opioid therapy (opioid use disorder).

Regarding specific opioids and formulations, as noted by FDA, there are serious risks of ER/LA opioids, and the indication for this class of medications is for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain (121). Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study (122). Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (123).

Regarding high-dose therapy, several epidemiologic studies that were excluded from the clinical evidence review because patient samples were not restricted to patients with chronic pain also examined the association between opioid dosage and overdose risk (23,24,124–126). Consistent with the clinical evidence review, the contextual review found that opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. Two of these studies (23,24), as well as the two studies in the clinical evidence review (66,67), evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were between 1.3 (67) and 1.9 (24) for dosages of 20 to <50 MME/day, between 1.9 (67) and 4.6 (24) for dosages of 50 to <100 MME/day, and between 2.0 (67) and 8.9 (66) for dosages of ≥100 MME/day. Compared with dosages of 1–<20 MME/day, absolute risk difference approximation for 50–<100 MME/day was 0.15% for fatal overdose (24) and 1.40% for any overdose (66), and for ≥100 MME/day was 0.25% for fatal overdose (24) and 4.04% for any overdose (66). A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were

prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day) (127). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually (128). A listing of common opioid medications and their MME equivalents is provided (Table 2).

Regarding coprescription of opioids with benzodiazepines, epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (67,128,129). In one of these studies (67), among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time (130). Patients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use (131).

Regarding populations potentially at greater risk for harm, risk is greater for patients with sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders. Interpretation of clinical data on the effects of opioids on sleep-disordered breathing is difficult because of the types of study designs and methods employed, and there is no clear consensus regarding association with risk for developing obstructive sleep apnea syndrome (132). However, opioid therapy can decrease respiratory drive, a high percentage of patients on long-term opioid therapy have been reported to have an abnormal apnea-hypopnea index (133), opioid therapy can worsen central sleep apnea in obstructive sleep apnea patients, and it can cause further desaturation in obstructive sleep apnea patients not on continuous positive airway pressure (CPAP) (31). Reduced renal or hepatic function can result in greater peak effect and longer duration of action and reduce the dose at which respiratory depression and overdose occurs (134). Age-related changes in patients aged ≥65 years, such as reduced renal function and medication clearance, even in the absence of renal disease (135), result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose. Older adults might also be at increased risk for falls and fractures related to opioids (136–138). Opioids used

in pregnancy can be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with birth defects, including neural tube defects (139,140), congenital heart defects (140), and gastroschisis (140); preterm delivery (141), poor fetal growth (141), and stillbirth (141). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome (142). Patients with mental health comorbidities and patients with histories of substance use disorders might be at higher risk than other patients for opioid use disorder (62,143,144). Recent analyses found that depressed patients were at higher risk for drug overdose than patients without depression, particularly at higher opioid dosages, although investigators were unable to distinguish unintentional overdose from suicide attempts (145). In case-control and case-cohort studies, substance abuse/dependence was more prevalent among patients experiencing overdose than among patients not experiencing overdose (12% versus 6% [66], 40% versus 10% [24], and 26% versus 9% [23]).

Regarding risk stratification approaches, limited evidence was found regarding benefits and harms. Potential benefits of PDMPs and urine drug testing include the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder, and help determine which patients will benefit from greater caution and increased monitoring or interventions when risk factors are present. For example, one study found that most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose (124,146) that are available to prescribers in the PDMP (124). However, limited evaluation of PDMPs at the state level has revealed mixed effects on changes in prescribing and mortality outcomes (28). Potential harms of risk stratification include underestimation of risks of opioid therapy when screening tools are not adequately sensitive, as well as potential overestimation of risk, which could lead to inappropriate clinical decisions.

Regarding risk mitigation approaches, limited evidence was found regarding benefits and harms. Although no studies were found to examine prescribing of naloxone with opioid pain medication in primary care settings, naloxone distribution through community-based programs providing prevention services for substance users has been demonstrated to be associated with decreased risk for opioid overdose death at the community level (147).

Concerns have been raised that prescribing changes such as dose reduction might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (148) or interference with appropriate pain treatment (149). With the exception of a study noting

an association between an abuse-deterrent formulation of OxyContin and heroin use, showing that some patients in qualitative interviews reported switching to another opioid, including heroin, for many reasons, including cost and availability as well as ease of use (150), CDC did not identify studies evaluating these potential outcomes.

Finally, regarding the effectiveness of opioid use disorder treatments, methadone and buprenorphine for opioid use disorder have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin (151–153). Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy; for example, by reducing opioid misuse and increasing retention during maintenance therapy, and improving compliance after detoxification (154,155).

### Clinician and Patient Values and Preferences

Clinician and patient values and preferences can inform how benefits and harms of long-term opioid therapy are weighted and estimate the effort and resources required to effectively provide implementation support. Many physicians lack confidence in their ability to prescribe opioids safely (156), to predict (157) or detect (158) prescription drug abuse, and to discuss abuse with their patients (158). Although clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (159), most consider prescription drug abuse to be a “moderate” or “big” problem in their community, and large proportions are “very” concerned about opioid addiction (55%) and death (48%) (160). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs (161,162), urine drug testing (163), and opioid treatment agreements (164). This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems) (165), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results (166).

Many patients do not have an opinion about “opioids” or know what this term means (167). Most are familiar with the term “narcotics.” About a third associated “narcotics” with addiction or abuse, and about half feared “addiction” from long-term “narcotic” use (168). Most patients taking opioids experience side effects (73% of patients taking hydrocodone for noncancer pain [11], 96% of patients taking opioids for chronic pain [12]), and side effects, rather than pain relief,

have been found to explain most of the variation in patients' preferences related to taking opioids (12). For example, patients taking hydrocodone for noncancer pain commonly reported side effects including dizziness, headache, fatigue, drowsiness, nausea, vomiting, and constipation (11). Patients with chronic pain in focus groups emphasized effectiveness of goal setting for increasing motivation and functioning (168). Patients taking high dosages report reliance on opioids despite ambivalence about their benefits (169) and regardless of pain reduction, reported problems, concerns, side effects, or perceived helpfulness (13).

## Resource Allocation

Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. CDC searched for evidence on opioid therapy compared with other treatments; costs of misuse, abuse, and overdose from prescription opioids; and costs of specific risk mitigation strategies (e.g., urine drug testing). Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be \$53.4 billion for nonmedical use of prescription opioids (170); \$55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids (171); and \$20.4 billion for direct and indirect costs related to opioid-related overdose alone (172). In 2012, total expenses for outpatient prescription opioids were estimated at \$9.0 billion, an increase of 120% from 2002 (173). Although there are perceptions that opioid therapy for chronic pain is less expensive than more time-intensive nonpharmacologic management approaches, many pain treatments, including acetaminophen, NSAIDs, tricyclic antidepressants, and massage therapy, are associated with lower mean and median annual costs compared with opioid therapy (174). COX-2 inhibitors, SNRIs, anticonvulsants, topical analgesics, physical therapy, and CBT are also associated with lower median annual costs compared with opioid therapy (174). Limited information was found on costs of strategies to decrease risks associated with opioid therapy; however, urine drug testing, including screening and confirmatory tests, has been estimated to cost \$211–\$363 per test (175).

## Recommendations

The recommendations are grouped into three areas for consideration:

- Determining when to initiate or continue opioids for chronic pain.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
- Assessing risk and addressing harms of opioid use.

There are 12 recommendations (Box 1). Each recommendation is followed by a rationale for the recommendation, with considerations for implementation noted. In accordance with the ACIP GRADE process, CDC based the recommendations on consideration of the clinical evidence, contextual evidence (including benefits and harms, values and preferences, resource allocation), and expert opinion. For each recommendation statement, CDC notes the recommendation category (A or B) and the type of the evidence (1, 2, 3, or 4) supporting the statement (Box 2). Expert opinion is reflected within each of the recommendation rationales. While there was not an attempt to reach consensus among experts, experts from the Core Expert Group and from the Opioid Guideline Workgroup (“experts”) expressed overall, general support for all recommendations. Where differences in expert opinion emerged for detailed actions within the clinical recommendations or for implementation considerations, CDC notes the differences of opinion in the supporting rationale statements.

Category A recommendations indicate that most patients should receive the recommended course of action; category B recommendations indicate that different choices will be appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations. Consistent with the ACIP (47) and GRADE process (48), category A recommendations were made, even with type 3 and 4 evidence, when there was broad agreement that the advantages of a clinical action greatly outweighed the disadvantages based on a consideration of benefits and harms, values and preferences, and resource allocation. Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation. All recommendations are category A recommendations, with the exception of recommendation 10, which is rated as category B. Recommendations were associated with a range of evidence types, from type 2 to type 4.

In summary, the categorization of recommendations was based on the following assessment:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

**BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care****Determining When to Initiate or Continue Opioids for Chronic Pain**

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.

**Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation**

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  $\geq 50$  morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/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 seven 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 other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

**Assessing Risk and Addressing Harms of Opioid Use**

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 ( $\geq 50$  MME/day), 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.

\*All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

**BOX 2. Interpretation of recommendation categories and evidence type****Recommendation Categories**

Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).

**Category A recommendation:** Applies to all persons; most patients should receive the recommended course of action.

**Category B recommendation:** Individual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

**Evidence Type**

Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.

**Type 1 evidence:** Randomized clinical trials or overwhelming evidence from observational studies.

**Type 2 evidence:** Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.

**Type 3 evidence:** Observational studies or randomized clinical trials with notable limitations.

**Type 4 evidence:** Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

evidence that exercise therapy (a prominent modality in physical therapy) for hip (100) or knee (99) osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months. Previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (176). Exercise therapy also can help reduce pain and improve function in low back pain and can improve global well-being and physical function in fibromyalgia (98,101). Multimodal therapies and multidisciplinary biopsychosocial rehabilitation—combining approaches (e.g., psychological therapies with exercise) can reduce long-term pain and disability compared with usual care and compared with physical treatments (e.g., exercise) alone. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients. Interventional approaches such as arthrocentesis and intraarticular glucocorticoid injection for pain associated with rheumatoid arthritis (117) or osteoarthritis (118) and subacromial corticosteroid injection for rotator cuff disease (119) can provide short-term improvement in pain and function. Evidence is insufficient to determine the extent to which repeated glucocorticoid injection increases potential risks such as articular cartilage changes (in osteoarthritis) and sepsis (118). Serious adverse events are rare but have been reported with epidural injection (120).

Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain. Selected anticonvulsants such as pregabalin and gabapentin can improve pain in diabetic neuropathy and post-herpetic neuralgia (contextual evidence review). Pregabalin, gabapentin, and carbamazepine are FDA-approved for treatment of certain neuropathic pain conditions, and pregabalin is FDA approved for fibromyalgia management. In patients with or without depression, tricyclic antidepressants and SNRIs provide effective analgesia for neuropathic pain conditions including diabetic neuropathy and post-herpetic neuralgia, often at lower dosages and with a shorter time to onset of effect than for treatment of depression (see contextual evidence review). Tricyclics and SNRIs can also relieve fibromyalgia symptoms. The SNRI duloxetine is FDA-approved for the treatment of diabetic neuropathy and fibromyalgia. Because patients with chronic pain often suffer from concurrent depression (144), and depression can exacerbate physical symptoms including pain (177), patients with co-occurring pain and depression are especially likely to benefit from antidepressant medication (see Recommendation 8). Nonopioid pharmacologic therapies

## Determining When to Initiate or Continue Opioids for Chronic Pain

### 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 (recommendation category: A, evidence type: 3).**

Patients with pain should receive treatment that provides the greatest benefits relative to risks. The contextual evidence review found that many nonpharmacologic therapies, including physical therapy, weight loss for knee osteoarthritis, psychological therapies such as CBT, and certain interventional procedures can ameliorate chronic pain. There is high-quality

are not generally associated with substance use disorder, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review). For example, acetaminophen, NSAIDs, and opioid pain medication were involved in 881, 228, and 16,651 pharmaceutical overdose deaths in the United States in 2010 (178). However, nonopioid pharmacologic therapies are associated with certain risks, particularly in older patients, pregnant patients, and patients with certain co-morbidities such as cardiovascular, renal, gastrointestinal, and liver disease (see contextual evidence review). For example, acetaminophen can be hepatotoxic at dosages of >3–4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease (109). NSAID use has been associated with gastritis, peptic ulcer disease, cardiovascular events (111,112), and fluid retention, and most NSAIDs (choline magnesium trisilicate and selective COX-2 inhibitors are exceptions) interfere with platelet aggregation (179). Clinicians should review FDA-approved labeling including boxed warnings before initiating treatment with any pharmacologic therapy.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy (KQ1). While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury (KQ2). At a population level, more than 165,000 persons in the United States have died from opioid pain-medication-related overdoses since 1999 (see Contextual Evidence Review).

Integrated pain management requires coordination of medical, psychological, and social aspects of health care and includes primary care, mental health care, and specialist services when needed (180). Nonpharmacologic physical and psychological treatments such as exercise and CBT are approaches that encourage active patient participation in the care plan, address the effects of pain in the patient's life, and can result in sustained improvements in pain and function without apparent risks. Despite this, these therapies are not always or fully covered by insurance, and access and cost can be barriers for patients. For many patients, aspects of these approaches can be used even when there is limited access to specialty care. For example, previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (176) and maintenance of

activity for patients with low back pain (110). A randomized trial found no difference in reduced chronic low back pain intensity, frequency or disability between patients assigned to relatively low-cost group aerobics and individual physiotherapy or muscle reconditioning sessions (181). Low-cost options to integrate exercise include brisk walking in public spaces or use of public recreation facilities for group exercise. CBT addresses psychosocial contributors to pain and improves function (97). Primary care clinicians can integrate elements of a cognitive behavioral approach into their practice by encouraging patients to take an active role in the care plan, by supporting patients in engaging in beneficial but potentially anxiety-provoking activities, such as exercise (179), or by providing education in relaxation techniques and coping strategies. In many locations, there are free or low-cost patient support, self-help, and educational community-based programs that can provide stress reduction and other mental health benefits. Patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, can be referred for formal therapy with a mental health specialist (e.g., psychologist, psychiatrist, clinical social worker). Multimodal therapies should be considered for patients not responding to single-modality therapy, and combinations should be tailored depending on patient needs, cost, and convenience.

To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Detailed recommendations on diagnosis are provided in other guidelines (110,179), but evaluation should generally include a focused history, including history and characteristics of pain and potentially contributing factors (e.g., function, psychosocial stressors, sleep) and physical exam, with imaging or other diagnostic testing only if indicated (e.g., if severe or progressive neurologic deficits are present or if serious underlying conditions are suspected) (110,179). For complex pain syndromes, pain specialty consultation can be considered to assist with diagnosis as well as management. Diagnosis can help identify disease-specific interventions to reverse or ameliorate pain; for example, improving glucose control to prevent progression of diabetic neuropathy; immune-modulating agents for rheumatoid arthritis; physical or occupational therapy to address posture, muscle weakness, or repetitive occupational motions that contribute to musculoskeletal pain; or surgical intervention to relieve mechanical/compressive pain (179). The underlying mechanism for most pain syndromes can be categorized as neuropathic (e.g., diabetic neuropathy, postherpetic neuralgia, fibromyalgia), or nociceptive (e.g., osteoarthritis, muscular back pain). The diagnosis and pathophysiologic mechanism of pain have implications for symptomatic pain treatment with medication. For example, evidence is limited or insufficient

for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain (182), headache (183), and fibromyalgia (184). Although NSAIDs can be used for exacerbations of nociceptive pain, other medications (e.g., tricyclics, selected anticonvulsants, or transdermal lidocaine) generally are recommended for neuropathic pain. In addition, improvement of neuropathic pain can begin weeks or longer after symptomatic treatment is initiated (179). Medications should be used only after assessment and determination that expected benefits outweigh risks given patient-specific factors. For example, clinicians should consider falls risk when selecting and dosing potentially sedating medications such as tricyclics, anticonvulsants, or opioids, and should weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults as well as patients with hypertension, renal insufficiency, or heart failure, or those with risk for peptic ulcer disease or cardiovascular disease. Some guidelines recommend topical NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) over oral NSAIDs in patients aged  $\geq 75$  years to minimize systemic effects (176).

Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue  $>3$  months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care, given small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms; although evidence on long-term benefits of nonopioid therapies is also limited, these therapies are also associated with short-term benefits, and risks are much lower. This does not mean that patients should be required to sequentially “fail” nonpharmacologic and nonopioid pharmacologic therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., headache or fibromyalgia), expected benefits of initiating opioids are unlikely to outweigh risks regardless of previous nonpharmacologic and nonopioid pharmacologic therapies used. In other situations (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. In addition, when opioid pain medication is used, it is more likely to be effective if integrated with nonpharmacologic therapy. Nonpharmacologic approaches such as exercise and CBT should be used to reduce pain and improve function in patients with chronic pain. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be

combined with nonpharmacologic therapy to reduce pain and improve function. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

**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 opioid 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 (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent. In addition, studies on currently available risk assessment instruments were sparse and showed inconsistent results (KQ4). The clinical evidence review for the current guideline considered studies with outcomes examined at  $\geq 1$  year that compared opioid use versus nonuse or placebo. Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves (185). These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients. Opioid therapy should not be initiated without consideration of an “exit strategy” to be used if the therapy is unsuccessful.

Experts agreed that before opioid therapy is initiated for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should determine how effectiveness will be evaluated and should establish treatment goals with patients. Because the line between acute pain and initial chronic pain is not always clear, it might be difficult for clinicians to determine when they are initiating opioids for chronic pain rather than treating acute pain. Pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition) is generally no longer considered acute. However, establishing treatment goals with a patient who has already received opioid therapy for 3 months would defer this discussion well past the point of

initiation of opioid therapy for chronic pain. Clinicians often write prescriptions for long-term use in 30-day increments, and opioid prescriptions written for  $\geq 30$  days are likely to represent initiation or continuation of long-term opioid therapy. Before writing an opioid prescription for  $\geq 30$  days, clinicians should establish treatment goals with patients. Clinicians seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy. Although the clinical evidence review did not find studies evaluating the effectiveness of written agreements or treatment plans (KQ4), clinicians and patients who set a plan in advance will clarify expectations regarding how opioids will be prescribed and monitored, as well as situations in which opioids will be discontinued or doses tapered (e.g., if treatment goals are not met, opioids are no longer needed, or adverse events put the patient at risk) to improve patient safety.

Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). However, there are some clinical circumstances under which reductions in pain without improvement in physical function might be a more realistic goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma). Experts noted that function can include emotional and social as well as physical dimensions. In addition, experts emphasized that mood has important interactions with pain and function. Experts agreed that clinicians may use validated instruments such as the three-item “Pain average, interference with Enjoyment of life, and interference with General activity” (PEG) Assessment Scale (186) to track patient outcomes. Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function (187). Monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities) can also contribute to the assessment of functional improvement. Clinicians should use these goals in assessing benefits of opioid therapy for individual patients and in weighing benefits against risks of continued opioid therapy (see Recommendation 7, including recommended intervals for follow-up). Because depression, anxiety, and other psychological co-morbidities often coexist with and can interfere with resolution of pain, clinicians should use validated instruments to assess for these conditions (see Recommendation 8) and ensure that treatment for these conditions is optimized. If patients receiving opioid therapy for chronic pain do not experience meaningful improvements in both pain and function compared with prior to initiation of opioid therapy, clinicians should consider working with patients to taper and discontinue opioids (see Recommendation 7) and should use nonpharmacologic and

nonopioid pharmacologic approaches to pain management (see Recommendation 1).

**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 (recommendation category: A, evidence type: 3).**

The clinical evidence review did not find studies evaluating effectiveness of patient education or opioid treatment plans as risk-mitigation strategies (KQ4). However, the contextual evidence review found that many patients lack information about opioids and identified concerns that some clinicians miss opportunities to effectively communicate about safety. Given the substantial evidence gaps on opioids, uncertain benefits of long-term use, and potential for serious harms, patient education and discussion before starting opioid therapy are critical so that patient preferences and values can be understood and used to inform clinical decisions. Experts agreed that essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.

Clinicians should involve patients in decisions about whether to start or continue opioid therapy. Given potentially serious risks of long-term opioid therapy, clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives to opioids before starting or continuing opioid therapy. Clinicians are encouraged to have open and honest discussions with patients to inform mutual decisions about whether to start or continue opioid therapy. Important considerations include the following:

- Be explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely (clinical evidence review, KQ1).
- Emphasize improvement in function as a primary goal and that function can improve even when pain is still present.
- Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
- Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase

hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.

- Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
- Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
- Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.
- Discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient, and that young children are susceptible to unintentional ingestion. Discuss storage of opioids in a secure, preferably locked location and options for safe disposal of unused opioids (188).
- Discuss the importance of periodic reassessment to ensure that opioids are helping to meet patient goals and to allow opportunities for opioid discontinuation and consideration of additional nonpharmacologic or nonopioid pharmacologic treatment options if opioids are not effective or are harmful.
- Discuss planned use of precautions to reduce risks, including use of prescription drug monitoring program information (see Recommendation 9) and urine drug testing (see Recommendation 10). Consider including discussion of naloxone use for overdose reversal (see Recommendation 8).
- Consider whether cognitive limitations might interfere with management of opioid therapy (for older adults in particular) and, if so, determine whether a caregiver can responsibly co-manage medication therapy. Discuss the importance of reassessing safer medication use with both the patient and caregiver.

Given the possibility that benefits of opioid therapy might diminish or that risks might become more prominent over time, it is important that clinicians review expected benefits and risks of continued opioid therapy with patients periodically, at least every 3 months (see Recommendation 7).

## Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

### 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. The clinical evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids (77). The clinical evidence review did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/LA opioids reduces risks for opioid misuse or addiction (KQ3).

In 2014, the FDA modified the labeling for ER/LA opioid pain medications, noting serious risks and recommending that ER/LA opioids be reserved for “management of pain severe enough to require daily, around-the-clock, long-term opioid treatment” when “alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain” and not used as “as needed” pain relievers (121). FDA has also noted that some ER/LA opioids are only appropriate for opioid-tolerant patients, defined as patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week (189). Time-scheduled opioid use can be associated with greater total average daily opioid dosage compared with intermittent, as-needed opioid use (contextual evidence review). In addition, experts indicated that there was not enough evidence to determine the safety of using immediate-release opioids for breakthrough pain when ER/LA opioids are used for chronic pain outside of active cancer pain, palliative care, or end-of-life care, and that this practice might be associated with dose escalation.

Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (190), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent

opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The “abuse-deterrent” label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

In comparing different ER/LA formulations, the clinical evidence review found inconsistent results for overdose risk with methadone versus other ER/LA opioids used for chronic pain (KQ3). The contextual evidence review found that methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for chronic pain. In addition, methadone is associated with cardiac arrhythmias along with QT prolongation on the electrocardiogram, and it has complicated pharmacokinetics and pharmacodynamics, including a long and variable half-life and peak respiratory depressant effect occurring later and lasting longer than peak analgesic effect. Experts noted that the pharmacodynamics of methadone are subject to more inter-individual variability than other opioids. In regard to other ER/LA opioid formulations, experts noted that the absorption and pharmacodynamics of transdermal fentanyl are complex, with gradually increasing serum concentration during the first part of the 72-hour dosing interval, as well as variable absorption based on factors such as external heat. In addition, the dosing of transdermal fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing. Experts thought that these complexities might increase the risk for fatal overdose when methadone or transdermal fentanyl is prescribed to a patient who has not used it previously or by clinicians who are not familiar with its effects.

Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, clinicians should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance. Clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to patients with renal or hepatic dysfunction because decreased clearance of drugs among these patients can lead to accumulation of drugs to toxic levels and persistence in the

body for longer durations. Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

- Methadone should not be the first choice for an ER/LA opioid. Only clinicians who are familiar with methadone’s unique risk profile and who are prepared to educate and closely monitor their patients, including risk assessment for QT prolongation and consideration of electrocardiographic monitoring, should consider prescribing methadone for pain. A clinical practice guideline that contains further guidance regarding methadone prescribing for pain has been published previously (191).
- Because dosing effects of transdermal fentanyl are often misunderstood by both clinicians and patients, only clinicians who are familiar with the dosing and absorption properties of transdermal fentanyl and are prepared to educate their patients about its use should consider prescribing it.

**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 considering increasing dosage to  $\geq 50$  morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq 90$  MME/day or carefully justify a decision to titrate dosage to  $\geq 90$  MME/day (recommendation category: A, evidence type: 3).**

Benefits of high-dose opioids for chronic pain are not established. The clinical evidence review found only one study (84) addressing effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. (These groups were prescribed average dosages of 52 and 40 MME/day, respectively, at the end of the trial.) At the same time, risks for serious harms

related to opioid therapy increase at higher opioid dosage. The clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose (KQ2). The clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50–<100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–<20 MME/day, and that dosages  $\geq 100$  MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–<20 MME/day. In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose (127).

The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages. Experts agreed that lower dosages of opioids reduce the risk for overdose, but that a single dosage threshold for safe opioid use could not be identified. Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks, that dosages <50 MME/day are safer than dosages of 50–100 MME/day, and that dosages <20 MME/day are safer than dosages of 20–50 MME/day. One expert thought that a specific dosage at which the benefit/risk ratio of opioid therapy decreases could not be identified. Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function and that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosages to  $\geq 50$  MME/day. Most experts also agreed that opioid dosages should not be increased to  $\geq 90$  MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.

When opioids are used for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should start opioids at the lowest possible effective dosage (the lowest starting dosage on product labeling for patients not already taking opioids and according to product labeling guidance regarding tolerance for patients already taking opioids). Clinicians should use additional caution when initiating opioids for patients aged  $\geq 65$  years and for patients with renal or hepatic insufficiency because decreased clearance of drugs in these patients can result in accumulation of drugs to toxic levels. Clinicians should use caution when increasing opioid dosages and increase dosage by the smallest practical

amount because overdose risk increases with increases in opioid dosage. Although there is limited evidence to recommend specific intervals for dosage titration, a previous guideline recommended waiting at least five half-lives before increasing dosage and waiting at least a week before increasing dosage of methadone to make sure that full effects of the previous dosage are evident (31). Clinicians should re-evaluate patients after increasing dosage for changes in pain, function, and risk for harm (see Recommendation 7). Before increasing total opioid dosage to  $\geq 50$  MME/day, clinicians should reassess whether opioid treatment is meeting the patient's treatment goals (see Recommendation 2). If a patient's opioid dosage for all sources of opioids combined reaches or exceeds 50 MME/day, clinicians should implement additional precautions, including increased frequency of follow-up (see Recommendation 7) and considering offering naloxone and overdose prevention education to both patients and the patients' household members (see Recommendation 8). Clinicians should avoid increasing opioid dosages to  $\geq 90$  MME/day or should carefully justify a decision to increase dosage to  $\geq 90$  MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at  $\geq 90$  MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids (see Recommendation 7), and consider consulting a pain specialist. Some states require clinicians to implement clinical protocols at specific dosage levels. For example, before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington state must obtain consultation from a pain specialist who agrees that this is indicated and appropriate (30). Clinicians should be aware of rules related to MME thresholds and associated clinical protocols established by their states.

Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages ( $\geq 90$  MME/day) that there is

now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (see Recommendation 7). Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages. Clinicians should remain alert to signs of anxiety, depression, and opioid use disorder (see Recommendations 8 and 12) that might be unmasked by an opioid taper and arrange for management of these co-morbidities. For patients agreeing to taper to lower opioid dosages as well as for those remaining on high opioid dosages, clinicians should establish goals with the patient for continued opioid therapy (see Recommendation 2), maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1), and consider consulting a pain specialist as needed to assist with pain management.

**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 seven days will rarely be needed (recommendation category: A, evidence type: 4).**

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (192–194) and other settings (195,196) have recommended prescribing  $\leq 3$  days of opioids in most cases, whereas others have recommended  $\leq 7$  days (197) or  $< 14$  days (30). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions

with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a  $\leq 3$  days' supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (198). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of  $\leq 3$ –5 days or  $\leq 3$ –7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, nonsurgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (30). Clinicians should not prescribe additional opioids to patients “just in case” pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

**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 other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).**

Although the clinical evidence review did not find studies evaluating the effectiveness of more frequent monitoring intervals (KQ4), it did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder (KQ2); therefore, follow-up earlier than 3 months might be necessary to provide the greatest opportunity to prevent the development of opioid use disorder. In addition, risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment (KQ3). The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months. Although evidence is insufficient to determine at what point within the first 3 months of opioid therapy the risks for opioid use disorder increase, reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications. Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when methadone or transdermal fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.

Clinicians should evaluate patients to assess benefits and harms of opioids within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Clinicians should consider follow-up intervals within the lower end of this range when ER/LA opioids are started or increased or when total daily opioid dosage is  $\geq 50$  MME/day. Shorter follow-up intervals (within 3 days) should be strongly considered when starting or increasing the dosage of methadone. At follow up, clinicians should assess benefits in function, pain control, and quality of life using tools such as the three-item “Pain average, interference with Enjoyment of life, and interference with General activity” (PEG) Assessment Scale (186) and/or asking patients about progress toward functional goals that have meaning for them (see Recommendation 2). Clinicians should also ask patients about common adverse effects such as

constipation and drowsiness (see Recommendation 3), as well as asking about and assessing for effects that might be early warning signs for more serious problems such as overdose (e.g., sedation or slurred speech) or opioid use disorder (e.g., craving, wanting to take opioids in greater quantities or more frequently than prescribed, or difficulty controlling use). Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.

Because of potential changes in the balance of benefits and risks of opioid therapy over time, clinicians should regularly reassess all patients receiving long-term opioid therapy, including patients who are new to the clinician but on long-term opioid therapy, at least every 3 months. At reassessment, clinicians should determine whether opioids continue to meet treatment goals, including sustained improvement in pain and function, whether the patient has experienced common or serious adverse events or early warning signs of serious adverse events, signs of opioid use disorder (e.g., difficulty controlling use, work or family problems related to opioid use), whether benefits of opioids continue to outweigh risks, and whether opioid dosage can be reduced or opioids can be discontinued. Ideally, these reassessments would take place in person and be conducted by the prescribing clinician. In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other issues make follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through video and audio could be conducted, with in-person visits occurring at least once per year. Clinicians should re-evaluate patients who are exposed to greater risk of opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking  $\geq 50$  MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. If clinically meaningful improvements in pain and function are not sustained, if patients are taking high-risk regimens (e.g., dosages  $\geq 50$  MME/day or opioids combined with benzodiazepines) without evidence of benefit, if patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation, or if patients experience overdose or other serious adverse events (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events, clinicians should work with patients to reduce opioid dosage or to discontinue opioids when possible. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to assist with pain management.

## Considerations for Tapering Opioids

Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued (KQ3), tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines (199), and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose (30). Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years). Opioid withdrawal during pregnancy has been associated with spontaneous abortion and premature labor.

When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point; experts agreed that tapering plans may be individualized based on patient goals and concerns. Experts noted that at times, tapers might have to be paused and restarted again when the patient is ready and might have to be slowed once patients reach low dosages. Tapers may be considered successful as long as the patient is making progress. Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped when taken less frequently than once a day. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced overdose on their current dosage). Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (200). Clinicians should access appropriate expertise if considering tapering opioids during pregnancy because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal. Patients who are not taking opioids (including patients who are diverting all opioids they obtain) do not require tapers. Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose. Primary care clinicians should collaborate with mental health providers and with other specialists as needed to optimize nonopioid pain management (see Recommendation 1), as well as psychosocial support for anxiety related to the taper. More detailed guidance on tapering, including management of withdrawal symptoms has been published previously (30,201). If a patient exhibits signs of opioid use disorder, clinicians should offer or arrange for treatment of opioid use disorder (see Recommendation 12) and consider offering naloxone for overdose prevention (see Recommendation 8).

## Assessing Risk and Addressing Harms of Opioid Use

- 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 ( $\geq 50$  MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities (KQ2). However, based on the contextual evidence review and expert opinion, certain risk factors are likely to increase susceptibility to opioid-associated harms and warrant incorporation of additional strategies into the management plan to mitigate risk. Clinicians should assess these risk factors periodically, with frequency varying by risk factor and patient characteristics. For example, factors that vary more frequently over time, such as alcohol use, require more frequent follow up. In addition, clinicians should consider offering naloxone, re-evaluating patients more frequently (see Recommendation 7), and referring to pain and/or behavioral health specialists when factors that increase risk for harm, such as history of overdose, history of substance use disorder, higher dosages of opioids ( $\geq 50$  MME/day), and concurrent use of benzodiazepines with opioids, are present.

### Patients with Sleep-Disordered Breathing, Including Sleep Apnea

Risk factors for sleep-disordered breathing include congestive heart failure, and obesity. Experts noted that careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. Clinicians should avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing whenever possible to minimize risks for opioid overdose (contextual evidence review).

### Pregnant Women

Opioids used in pregnancy might be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with stillbirth, poor fetal growth, pre-term delivery, and birth defects (contextual evidence review). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome. Clinicians and patients together should carefully weigh risks and benefits when making decisions

about whether to initiate opioid therapy for chronic pain during pregnancy. In addition, before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any future pregnancy. For pregnant women already receiving opioids, clinicians should access appropriate expertise if considering tapering opioids because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal (see Recommendation 7). For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine or methadone has been associated with improved maternal outcomes and should be offered (202) (see Recommendation 12). Clinicians caring for pregnant women receiving opioids for pain or receiving buprenorphine or methadone for opioid use disorder should arrange for delivery at a facility prepared to monitor, evaluate for, and treat neonatal opioid withdrawal syndrome. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for neonatal opioid withdrawal syndrome, and transfer the newborn for additional treatment if needed. Neonatal toxicity and death have been reported in breast-feeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breast feeding and, if used, should be limited to the lowest possible dose and to a 4-day supply (203).

### **Patients with Renal or Hepatic Insufficiency**

Clinicians should use additional caution and increased monitoring (see Recommendation 7) to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, given their decreased ability to process and excrete drugs, susceptibility to accumulation of opioids, and reduced therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review; see Recommendations 4, 5, and 7).

### **Patients Aged $\geq 65$ Years**

Inadequate pain treatment among persons aged  $\geq 65$  years has been documented (204). Pain management for older patients can be challenging given increased risks of both nonopioid pharmacologic therapies (see Recommendation 1) and opioid therapy in this population. Given reduced renal function and medication clearance even in the absence of renal disease, patients aged  $\geq 65$  years might have increased susceptibility to accumulation of opioids and a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review). Some older adults suffer from cognitive impairment, which can

increase risk for medication errors and make opioid-related confusion more dangerous. In addition, older adults are more likely than younger adults to experience co-morbid medical conditions and more likely to receive multiple medications, some of which might interact with opioids (such as benzodiazepines). Clinicians should use additional caution and increased monitoring (see Recommendations 4, 5, and 7) to minimize risks of opioids prescribed for patients aged  $\geq 65$  years. Experts suggested that clinicians educate older adults receiving opioids to avoid risky medication-related behaviors such as obtaining controlled medications from multiple prescribers and saving unused medications. Clinicians should also implement interventions to mitigate common risks of opioid therapy among older adults, such as exercise or bowel regimens to prevent constipation, risk assessment for falls, and patient monitoring for cognitive impairment.

### **Patients with Mental Health Conditions**

Because psychological distress frequently interferes with improvement of pain and function in patients with chronic pain, using validated instruments such as the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for anxiety, post-traumatic stress disorder, and/or depression (205), might help clinicians improve overall pain treatment outcomes. Experts noted that clinicians should use additional caution and increased monitoring (see Recommendation 7) to lessen the increased risk for opioid use disorder among patients with mental health conditions (including depression, anxiety disorders, and PTSD), as well as increased risk for drug overdose among patients with depression. Previous guidelines have noted that opioid therapy should not be initiated during acute psychiatric instability or uncontrolled suicide risk, and that clinicians should consider behavioral health specialist consultation for any patient with a history of suicide attempt or psychiatric disorder (31). In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose (see Recommendation 11). Clinicians should ensure that treatment for depression and other mental health conditions is optimized, consulting with behavioral health specialists when needed. Treatment for depression can improve pain symptoms as well as depression and might decrease overdose risk (contextual evidence review). For treatment of chronic pain in patients with depression, clinicians should strongly consider using tricyclic or SNRI antidepressants for analgesic as well as antidepressant effects if these medications are not otherwise contraindicated (see Recommendation 1).

## Patients with Substance Use Disorder

Illicit drugs and alcohol are listed as contributory factors on a substantial proportion of death certificates for opioid-related overdose deaths (contextual evidence review). Previous guidelines have recommended screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids. However, the clinical evidence review found that currently available risk-stratification tools (e.g., Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain Version 1, SOAPP-R, and Brief Risk Interview) show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse (KQ4). Clinicians should always exercise caution when considering or prescribing opioids for any patient with chronic pain outside of active cancer, palliative, and end-of-life care and should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.

Clinicians should ask patients about their drug and alcohol use. Single screening questions can be used (206). For example, the question “How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?” (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview (207). Validated screening tools such as the Drug Abuse Screening Test (DAST) (208) and the Alcohol Use Disorders Identification Test (AUDIT) (209) can also be used. Clinicians should use PDMP data (see Recommendation 9) and drug testing (see Recommendation 10) as appropriate to assess for concurrent substance use that might place patients at higher risk for opioid use disorder and overdose. Clinicians should also provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol (see Recommendation 3) and ensure that patients receive effective treatment for substance use disorders when needed (see Recommendation 12).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder (KQ2), although a history of substance use disorder was associated with misuse. Similarly, based on contextual evidence, patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. If clinicians consider opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care for patients with drug or alcohol use disorders, they should discuss increased risks for opioid use disorder and overdose with patients, carefully consider whether benefits of opioids outweigh increased risks, and incorporate strategies to mitigate risk into

the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed. Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse. Experts also noted that clinicians should communicate with patients' substance use disorder treatment providers if opioids are prescribed.

## Patients with Prior Nonfatal Overdose

Although studies were not identified that directly addressed the risk for overdose among patients with prior nonfatal overdose who are prescribed opioids, based on clinical experience, experts thought that prior nonfatal overdose would substantially increase risk for future nonfatal or fatal opioid overdose. If patients experience nonfatal opioid overdose, clinicians should work with them to reduce opioid dosage and to discontinue opioids when possible (see Recommendation 7). If clinicians continue opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care in patients with prior opioid overdose, they should discuss increased risks for overdose with patients, carefully consider whether benefits of opioids outweigh substantial risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed.

## Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

Naloxone is an opioid antagonist that can reverse severe respiratory depression; its administration by lay persons, such as friends and family of persons who experience opioid overdose, can save lives. Naloxone precipitates acute withdrawal among patients physically dependent on opioids. Serious adverse effects, such as pulmonary edema, cardiovascular instability, and seizures, have been reported but are rare at doses consistent with labeled use for opioid overdose (210). The contextual evidence review did not find any studies on effectiveness of prescribing naloxone for overdose prevention among patients prescribed opioids for chronic pain. However, there is evidence for effectiveness of naloxone provision in preventing opioid-related overdose death at the community level through community-based distribution (e.g., through overdose education and naloxone distribution programs in community service agencies) to persons at risk for overdose

(mostly due to illicit opiate use), and it is plausible that effectiveness would be observed when naloxone is provided in the clinical setting as well. Experts agreed that it is preferable not to initiate opioid treatment when factors that increase risk for opioid-related harms are present. Opinions diverged about the likelihood of naloxone being useful to patients and the circumstances under which it should be offered. However, most experts agreed that clinicians should consider offering naloxone when prescribing opioids to patients at increased risk for overdose, including patients with a history of overdose, patients with a history of substance use disorder, patients taking benzodiazepines with opioids (see Recommendation 11), patients at risk for returning to a high dose to which they are no longer tolerant (e.g., patients recently released from prison), and patients taking higher dosages of opioids ( $\geq 50$  MME/day). Practices should provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households. Experts noted that naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists. Resources for prescribing naloxone in primary care settings can be found through Prescribe to Prevent at <http://prescribetoprevent.org>.

**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 (recommendation category: A, evidence type: 4).**

PDMPs are state-based databases that collect information on controlled prescription drugs dispensed by pharmacies in most states and, in select states, by dispensing physicians as well. In addition, some clinicians employed by the federal government, including some clinicians in the Indian Health Care Delivery System, are not licensed in the states where they practice, and do not have access to PDMP data. Certain states require clinicians to review PDMP data prior to writing each opioid prescription (see state-level PDMP-related policies on the National Alliance for Model State Drug Laws website at <http://www.namsdl.org/prescription-monitoring-programs.cfm>). The clinical evidence review did not find studies evaluating the effectiveness of PDMPs on outcomes related to overdose, addiction, abuse, or misuse (KQ4). However, even though evidence is limited on the effectiveness of PDMP implementation at the state level on prescribing and mortality

outcomes (28), the contextual evidence review found that most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages; information on both of these risk factors for overdose are available to prescribers in the PDMP. PDMP data also can be helpful when patient medication history is not otherwise available (e.g., for patients from other locales) and when patients transition care to a new clinician. The contextual evidence review also found that PDMP information could be used in a way that is harmful to patients. For example, it has been used to dismiss patients from clinician practices (211), which might adversely affect patient safety.

The contextual review found variation in state policies that affect timeliness of PDMP data (and therefore benefits of reviewing PDMP data) as well as time and workload for clinicians in accessing PDMP data. In states that permit delegating access to other members of the health care team, workload for prescribers can be reduced. These differences might result in a different balance of benefits to clinician workload in different states. Experts agreed that PDMPs are useful tools that should be consulted when starting a patient on opioid therapy and periodically during long-term opioid therapy. However, experts disagreed on how frequently clinicians should check the PDMP during long-term opioid therapy, given PDMP access issues and the lag time in reporting in some states. Most experts agreed that PDMP data should be reviewed every 3 months or more frequently during long-term opioid therapy. A minority of experts noted that, given the current burden of accessing PDMP data in some states and the lack of evidence surrounding the most effective interval for PDMP review to improve patient outcomes, annual review of PDMP data during long-term opioid therapy would be reasonable when factors that increase risk for opioid-related harms are not present.

Clinicians should review PDMP data for opioids and other controlled medications patients might have received from additional prescribers to determine whether a patient is receiving high total opioid dosages or dangerous combinations (e.g., opioids combined with benzodiazepines) that put him or her at high risk for overdose. Ideally, PDMP data should be reviewed before every opioid prescription. This is recommended in all states with well-functioning PDMPs and where PDMP access policies make this practicable (e.g., clinician and delegate access permitted), but it is not currently possible in states without functional PDMPs or in those that do not permit certain prescribers to access them. As vendors and practices facilitate integration of PDMP information into regular clinical workflow (e.g., data made available in electronic health records), clinicians' ease of access in reviewing PDMP data is expected to improve.

In addition, improved timeliness of PDMP data will improve their value in identifying patient risks.

If patients are found to have high opioid dosages, dangerous combinations of medications, or multiple controlled substance prescriptions written by different clinicians, several actions can be taken to augment clinicians' abilities to improve patient safety:

- Clinicians should discuss information from the PDMP with their patient and confirm that the patient is aware of the additional prescriptions. Occasionally, PDMP information can be incorrect (e.g., if the wrong name or birthdate has been entered, the patient uses a nickname or maiden name, or another person has used the patient's identity to obtain prescriptions).
- Clinicians should discuss safety concerns, including increased risk for respiratory depression and overdose, with patients found to be receiving opioids from more than one prescriber or receiving medications that increase risk when combined with opioids (e.g., benzodiazepines) and consider offering naloxone (see Recommendation 8).
- Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care (see Recommendation 11).
- Clinicians should calculate the total MME/day for concurrent opioid prescriptions to help assess the patient's overdose risk (see Recommendation 5). If patients are found to be receiving high total daily dosages of opioids, clinicians should discuss their safety concerns with the patient, consider tapering to a safer dosage (see Recommendations 5 and 7), and consider offering naloxone (see Recommendation 8).
- Clinicians should discuss safety concerns with other clinicians who are prescribing controlled substances for their patient. Ideally clinicians should first discuss concerns with their patient and inform him or her that they plan to coordinate care with the patient's other prescribers to improve the patient's safety.
- Clinicians should consider the possibility of a substance use disorder and discuss concerns with their patient (see Recommendation 12).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal (see Recommendations 7 and 10). A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should

consider other possible reasons for this test result (see Recommendation 10).

Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder [see Recommendation 12]).

**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 (recommendation category: B, evidence type: 4).**

Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. Urine drug tests do not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain (KQ4). The contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care). Routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use. Although random drug testing also might destigmatize urine drug testing, experts thought that truly random testing was not feasible in clinical practice. Some clinics obtain a urine specimen at every visit, but only send it for testing on a random schedule. Experts noted that in addition to direct costs of urine drug testing, which often are not covered fully by insurance and can be a burden for patients, clinician time is needed to interpret, confirm, and communicate results.

Experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should

use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. There was some difference of opinion among experts as to whether this recommendation should apply to all patients, or whether this recommendation should entail individual decision making with different choices for different patients based on values, preferences, and clinical situations. While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up interval should be left to the discretion of the clinician. Previous guidelines have recommended more frequent urine drug testing in patients thought to be at higher risk for substance use disorder (30). However, experts thought that predicting risk prior to urine drug testing is challenging and that currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance use disorder.

In most situations, initial urine drug testing can be performed with a relatively inexpensive immunoassay panel for commonly prescribed opioids and illicit drugs. Patients prescribed less commonly used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard immunoassays or on the presence of unexpected urine drug test results. Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. For example, a positive “opiates” immunoassay detects morphine, which might reflect patient use of morphine, codeine, or heroin, but this immunoassay does not detect synthetic opioids (e.g., fentanyl or methadone) and might not detect semisynthetic opioids (e.g., oxycodone). However, many laboratories use an oxycodone immunoassay that detects oxycodone and oxymorphone. In some cases, positive results for specific opioids might reflect metabolites from opioids the patient is taking and might not mean the patient is taking the specific opioid for which the test was positive. For example, hydromorphone is a metabolite of hydrocodone, and oxymorphone is a metabolite of oxycodone. Detailed guidance on interpretation of urine drug test results, including which tests to order and expected results, drug detection time in urine, drug metabolism, and other considerations has been published previously (30). Clinicians should not test for substances

for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahydrocannabinol (THC). In addition, restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of urine drug testing, given the substantial costs associated with confirmatory testing methods. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results. Clinicians should explain to patients that urine drug testing is intended to improve their safety and should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient). Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs. Clinicians should discuss unexpected results with the local laboratory or toxicologist and with the patient. Discussion with patients prior to specific confirmatory testing can sometimes yield a candid explanation of why a particular substance is present or absent and obviate the need for expensive confirmatory testing on that visit. For example, a patient might explain that the test is negative for prescribed opioids because she felt opioids were no longer helping and discontinued them. If unexpected results are not explained, a confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted to clarify the situation.

Clinicians should use unexpected results to improve patient safety (e.g., change in pain management strategy [see Recommendation 1], tapering or discontinuation of opioids [see Recommendation 7], more frequent re-evaluation [see Recommendation 7], offering naloxone [see Recommendation 8], or referral for treatment for substance use disorder [see Recommendation 12], all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper. Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

#### **11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently**

**whenever possible (recommendation category: A, evidence type: 3).**

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. The clinical evidence review did not address risks of benzodiazepine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzodiazepine use in large proportions of opioid-related overdose deaths, and a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone (212). Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. In addition, given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9) and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants. Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first (see Recommendation 7). Clinicians should taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death (contextual evidence review). A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (213,214). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper (213). If benzodiazepines prescribed for anxiety are tapered or discontinued, or if patients receiving opioids require treatment for anxiety, evidence-based psychotherapies (e.g., CBT) and/or specific anti-depressants or other nonbenzodiazepine medications approved for anxiety should be offered. Experts emphasized that clinicians should communicate with mental health professionals managing the

patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care.

**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 (recommendation category: A, evidence type: 2).**

Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year (<http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf>) (20).

The clinical evidence review found prevalence of opioid dependence (using DSM-IV diagnosis criteria) in primary care settings among patients with chronic pain on opioid therapy to be 3%–26% (KQ2). As found in the contextual evidence review and supported by moderate quality evidence, opioid agonist or partial agonist treatment with methadone maintenance therapy or buprenorphine has been shown to be more effective in preventing relapse among patients with opioid use disorder (151–153). Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification (154,155); behavioral therapies are also recommended by clinical practice guidelines (215). The cited studies primarily evaluated patients with a history of illicit opioid use, rather than prescription opioid use for chronic pain. Recent studies among patients with prescription opioid dependence (based on DSM-IV criteria) have found maintenance therapy with buprenorphine and buprenorphine-naloxone effective in preventing relapse (216,217). Treatment need in a community is often not met by capacity to provide buprenorphine or methadone maintenance therapy (218), and patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited (219). Oral or long-acting injectable formulations of naltrexone can also be used as medication-assisted treatment for opioid use disorder in nonpregnant adults, particularly for highly motivated persons (220,221). Experts agreed that clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community and should work together to ensure sufficient treatment capacity for opioid use disorder at the practice level.

If clinicians suspect opioid use disorder based on patient concerns or behaviors or on findings in prescription drug monitoring program data (see Recommendation 9) or from urine drug testing (see Recommendation 10), they should discuss their concern with their patient and provide an opportunity for the patient to disclose related concerns or problems. Clinicians should assess for the presence of opioid use disorder using DSM-5 criteria (20). Alternatively, clinicians can arrange for a substance use disorder treatment specialist to assess for the presence of opioid use disorder. For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies. Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in non-pregnant adults. Naltrexone blocks the effects of opioids if they are used but requires adherence to daily oral therapy or monthly injections. For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine (without naloxone) or methadone has been associated with improved maternal outcomes and should be offered (see Recommendation 8). Clinicians should also consider offering naloxone for overdose prevention to patients with opioid use disorder (see Recommendation 8). For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids (see Recommendation 7). For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.

Physicians not already certified to provide buprenorphine in an office-based setting can undergo training to receive a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that allows them to prescribe buprenorphine to treat patients with opioid use disorder. Physicians prescribing opioids in communities without sufficient treatment capacity for opioid use disorder should strongly consider obtaining this waiver. Information about qualifications and the process to obtain a waiver are available from SAMHSA (222). Clinicians do not need a waiver to offer naltrexone for opioid use disorder as part of their practice.

Additional guidance has been published previously (215) on induction, use, and monitoring of buprenorphine treatment (see Part 5) and naltrexone treatment (see Part 6) for opioid use disorder and on goals, components of, and types of effective psychosocial treatment that are recommended in conjunction with pharmacological treatment of opioid use disorder (see Part 7). Clinicians unable to provide treatment themselves should arrange for patients with opioid use disorder to receive

care from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider, or from an opioid treatment program certified by SAMHSA to provide supervised medication-assisted treatment for patients with opioid use disorder. Clinicians should assist patients in finding qualified treatment providers and should arrange for patients to follow up with these providers, as well as arranging for ongoing coordination of care. Clinicians should not dismiss patients from their practice because of a substance use disorder because this can adversely affect patient safety and could represent patient abandonment. Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment. In addition, although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use nonpharmacologic and nonopioid pharmacologic pain treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to provide optimal pain management.

Resources to help with arranging for treatment include SAMHSA's buprenorphine physician locator ([http://buprenorphine.samhsa.gov/bwns\\_locator](http://buprenorphine.samhsa.gov/bwns_locator)); SAMHSA's Opioid Treatment Program Directory (<http://dpt2.samhsa.gov/treatment/directory.aspx>); SAMHSA's Provider Clinical Support System for Opioid Therapies (<http://pcss-o.org>), which offers extensive experience in the treatment of substance use disorders and specifically of opioid use disorder, as well as expertise on the interface of pain and opioid misuse; and SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (<http://pcssmat.org>), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

## Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings. CDC will translate this guideline into user-friendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and clinicians and engage in dissemination efforts. CDC has provided a

checklist for prescribing opioids for chronic pain (<http://stacks.cdc.gov/view/cdc/38025>), additional resources such as fact sheets (<http://www.cdc.gov/drugoverdose/prescribing/resources.html>), and will provide a mobile application to guide clinicians in implementing the recommendations. CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic health records to assist clinicians' treatment decisions at the point of care; identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice. In addition, policy initiatives that address barriers to implementation of the guidelines, such as increasing accessibility of PDMP data within and across states, e-prescribing, and availability of clinicians who can offer medication-assisted treatment for opioid use disorder, are strategies to consider to enhance implementation of the recommended practices. CDC will work with federal partners and payers to evaluate strategies such as payment reform and health care delivery models that could improve patient health and safety. For example, strategies might include strengthened coverage for nonpharmacologic treatments, appropriate urine drug testing, and medication-assisted treatment; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care.

As highlighted in the forthcoming report on the National Pain Strategy, an overarching federal effort that outlines a comprehensive population-level health strategy for addressing pain as a public health problem, clinical guidelines complement other strategies aimed at preventing illnesses and injuries that lead to pain. A draft of the National Pain Strategy has been published previously (180). These strategies include strengthening the evidence base for pain prevention and treatment strategies, reducing disparities in pain treatment, improving service delivery and reimbursement, supporting professional education and training, and providing public education. It is important that overall improvements be made in developing the workforce to address pain management in general, in addition to opioid prescribing specifically. This guideline also complements other federal efforts focused on addressing the opioid overdose epidemic including prescriber training and education, improving access to treatment for opioid use disorder, safe storage and disposal programs, utilization management mechanisms, naloxone distribution programs, law enforcement and supply reduction efforts, prescription drug

monitoring program improvements, and support for community coalitions and state prevention programs.

This guideline provides recommendations that are based on the best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. To inform future guideline development, more research is necessary to fill in critical evidence gaps. The evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy. As highlighted by an expert panel in a recent workshop sponsored by the National Institutes of Health on the role of opioid pain medications in the treatment of chronic pain, "evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain" (223). The National Institutes of Health panel recommended that research is needed to improve our understanding of which types of pain, specific diseases, and patients are most likely to be associated with benefit and harm from opioid pain medications; evaluate multidisciplinary pain interventions; estimate cost-benefit; develop and validate tools for identification of patient risk and outcomes; assess the effectiveness and harms of opioid pain medications with alternative study designs; and investigate risk identification and mitigation strategies and their effects on patient and public health outcomes. It is also important to obtain data to inform the cost feasibility and cost-effectiveness of recommended actions, such as use of nonpharmacologic therapy and urine drug testing. Research that contributes to safer and more effective pain treatment can be implemented across public health entities and federal agencies (4). Additional research can inform the development of future guidelines for special populations that could not be adequately addressed in this guideline, such as children and adolescents, where evidence and guidance is needed but currently lacking. CDC is committed to working with partners to identify the highest priority research areas to build the evidence base. Yet, given that chronic pain is recognized as a significant public health problem, the risks associated with long-term opioid therapy, the availability of effective nonpharmacological and nonopioid pharmacologic treatment options for pain, and the potential for improvement in the quality of health care with the implementation of recommended practices, a guideline for prescribing is warranted with the evidence that is currently available. The balance between the benefits and the risks of long-term opioid therapy for chronic pain based on both clinical and contextual evidence is strong enough to support the issuance of category A recommendations in most cases.

CDC will revisit this guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the guideline. Until this research is conducted, clinical practice guidelines will have to be based on the best available evidence and expert opinion. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

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**TABLE 1. Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain**

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
<b>Effectiveness and comparative effectiveness (KQ1)</b>							
<b>Effectiveness of long-term opioid therapy versus placebo or no opioid therapy for long-term (≥1 year) outcomes</b>							
Pain, function, and quality of life	None	—†	—	—	Insufficient	—	No evidence
<b>Harms and adverse events (KQ2)</b>							
<b>Risks of opioids versus placebo or no opioids on opioid abuse, addiction, and related outcomes; overdose; and other harms</b>							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found long-term use of prescribed opioids associated with an increased risk of abuse or dependence diagnosis versus no opioid use (adjusted OR ranged from 14.9 to 122.5, depending on dose).
Abuse or addiction	10 uncontrolled studies (n = 3,780)	Very serious limitations	Very serious inconsistency	No imprecision	4	None identified	In primary care settings, prevalence of opioid abuse ranged from 0.6% to 8% and prevalence of dependence from 3% to 26%. In pain clinic settings, prevalence of misuse ranged from 8% to 16% and addiction from 2% to 14%. Prevalence of aberrant drug-related behaviors ranged from 6% to 37%.
Overdose	1 cohort study (n = 9,940)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Current opioid use associated with increased risk of any overdose events (adjusted HR 5.2, 95% CI = 2.1–12) and serious overdose events (adjusted HR 8.4, 95% CI = 2.5–28) versus current nonuse.
Fractures	1 cohort study (n = 2,341) and 1 case-control study (n = 21,739 case patients)	Serious limitations	No inconsistency	No imprecision	3	None identified	Opioid use associated with increased risk of fracture in 1 cohort study (adjusted HR 1.28, 95% CI = 0.99–1.64) and 1 case-control study (adjusted OR 1.27, 95% CI = 1.21–1.33).
Myocardial infarction	1 cohort study (n = 426,124) and 1 case-control study (n = 11,693 case patients)	No limitations	No inconsistency	No imprecision	3	None identified	Current opioid use associated with increased risk of myocardial infarction versus nonuse (adjusted HR 1.28, 95% CI = 1.19–1.37 and incidence rate ratio 2.66, 95% CI = 2.30–3.08).
Endocrinologic harms	1 cross-sectional study (n = 11,327)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Long-term opioid use associated with increased risk for use of medications for erectile dysfunction or testosterone replacement versus nonuse (adjusted OR 1.5, 95% CI = 1.1–1.9).
<b>How do harms vary depending on the opioid dose used?</b>							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found higher doses of long-term opioid therapy associated with increased risk of opioid abuse or dependence than lower doses. Compared to no opioid prescription, the adjusted odds ratios were 15 (95% CI = 10–21) for 1 to 36 MME/day, 29 (95% CI = 20–41) for 36 to 120 MME/day, and 122 (95% CI = 73–205) for ≥120 MME/day.
Overdose	1 cohort study (n = 9,940) and 1 case-control study (n = 593 case patients in primary analysis)	Serious limitations	No inconsistency	No imprecision	3	Magnitude of effect, dose response relationship	Versus 1 to <20 MME/day, one cohort study found an adjusted HR for an overdose event of 1.44 (95% CI = 0.57–3.62) for 20 to <50 MME/day that increased to 8.87 (95% CI = 3.99–19.72) at ≥100 MME/day; one case-control study found an adjusted OR for an opioid-related death of 1.32 (95% CI = 0.94–1.84) for 20 to 49 MME/day that increased to 2.88 (95% CI = 1.79–4.63) at ≥200 MME/day.
Fractures	1 cohort study (n = 2,341)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Risk of fracture increased from an adjusted HR of 1.20 (95% CI = 0.92–1.56) at 1 to <20 MME/day to 2.00 (95% CI = 1.24–3.24) at ≥50 MME/day; the trend was of borderline statistical significance.

See table footnotes on page 47.

**TABLE 1. (Continued) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain**

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Myocardial infarction	1 cohort study (n = 426,124)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Relative to a cumulative dose of 0 to 1,350 MME during a 90-day period, the incidence rate ratio for myocardial infarction for 1350 to <2700 MME was 1.21 (95% CI = 1.02–1.45), for 2,700 to <8,100 MME was 1.42 (95% CI = 1.21–1.67), for 8,100 to <18,000 MME was 1.89 (95% CI = 1.54–2.33), and for ≥18,000 MME was 1.73 (95% CI = 1.32–2.26).
Motor vehicle crash injuries	1 case–control study (n = 5,300 case patients)	No limitations	Unknown (1 study)	No imprecision	3	None identified	No association between opioid dose and risk of motor vehicle crash injuries even though opioid doses >20 MME/day were associated with increased odds of road trauma among drivers.
Endocrinologic harms	1 cross-sectional study (n = 11,327) New for update: 1 additional cross-sectional study (n=1,585)	Serious limitations	Consistent	No imprecision	3	None identified	Relative to 0 to <20 MME/day, the adjusted OR for ≥120 MME/day for use of medications for erectile dysfunction or testosterone replacement was 1.6 (95% CI = 1.0–2.4). One new cross-sectional study found higher-dose long-term opioid therapy associated with increased risk of androgen deficiency among men receiving immediate-release opioids (adjusted OR per 10 MME/day 1.16, 95% CI = 1.09–1.23), but the dose response was very weak among men receiving ER/LA opioids.
<b>Dosing strategies (KQ3)</b>							
<b>Comparative effectiveness of different methods for initiating opioid therapy and titrating doses</b>							
Pain	3 randomized trials (n = 93)	Serious limitations	Serious inconsistency	Very serious imprecision	4	None identified	Trials on effects of titration with immediate-release versus ER/LA opioids reported inconsistent results and had additional differences between treatment arms in dosing protocols (titrated versus fixed dosing) and doses of opioids used.
Overdose	New for update: 1 cohort study (n = 840,606)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One new cross-sectional study found initiation of therapy with an ER/LA opioid associated with increased risk of overdose versus initiation with an immediate-release opioid (adjusted HR 2.33, 95% CI = 1.26–4.32).
<b>Comparative effectiveness of different ER/LA opioids</b>							
Pain and function	3 randomized trials (n = 1,850)	Serious limitations	No inconsistency	No imprecision	3	None identified	No differences
All-cause mortality	1 cohort study (n = 108,492) New for update: 1 cohort study (n = 38,756)	Serious limitations	Serious inconsistency	No imprecision	4	None identified	One cohort study found methadone to be associated with lower all-cause mortality risk than sustained-release morphine in a propensity-adjusted analysis (adjusted HR 0.56, 95% CI = 0.51–0.62) and one cohort study among Tennessee Medicaid patients found methadone to be associated with higher risk of all-cause mortality than sustained-release morphine (adjusted HR 1.46, 95% CI = 1.17–1.73).
Abuse and related outcomes	1 cohort study (n = 5,684)	Serious limitations	Unknown (1 study)	Serious imprecision	4	None identified	One cohort study found some differences between ER/LA opioids in rates of adverse outcomes related to abuse, but outcomes were nonspecific for opioid-related adverse events, precluding reliable conclusions.
<b>ER/LA versus immediate-release opioids</b>							
Endocrinologic harms	New for update: 1 cross-sectional study (n = 1,585)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One cross-sectional study found ER/LA opioids associated with increased risk of androgen deficiency versus immediate-release opioids (adjusted OR 3.39, 95% CI = 2.39–4.77).

See table footnotes on page 47.

**TABLE 1. (Continued) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain**

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
<b>Dose escalation versus dose maintenance or use of dose thresholds</b>							
Pain, function, or withdrawal due to opioid misuse	1 randomized trial (n = 140)	Serious limitations	Unknown (1 study)	Very serious imprecision	3	None identified	No difference between more liberal dose escalation versus maintenance of current doses in pain, function, or risk of withdrawal due to opioid misuse, but there was limited separation in opioid doses between groups (52 versus 40 MME/day at the end of the trial).
<b>Immediate-release versus ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled and continuous versus as-needed dosing of opioids; or opioid rotation versus maintenance of current therapy</b>							
Pain, function, quality of life, and outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Effects of decreasing or tapering opioid doses versus continuation of opioid therapy</b>							
Pain and function	1 randomized trial (n = 10)	Very serious limitations	Unknown (1 study)	Very serious imprecision	4	None identified	Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine.
<b>Comparative effectiveness of different tapering protocols and strategies</b>							
Opioid abstinence	2 nonrandomized trials (n = 150)	Very serious limitations	No inconsistency	Very serious imprecision	4	None identified	No clear differences between different methods for opioid discontinuation or tapering in likelihood of opioid abstinence after 3–6 months
<b>Risk assessment and risk mitigation strategies (KQ4)</b>							
<b>Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse among patients with chronic pain being considered for long-term opioid therapy</b>							
Opioid risk tool	3 studies of diagnostic accuracy (n = 496) New for update: 2 studies of diagnostic accuracy (n = 320)	Serious limitations	Very serious inconsistency	Serious imprecision	4	None identified	Based on a cutoff score of >4 (or unspecified), five studies (two fair-quality, three poor-quality) reported sensitivity that ranged from 0.20 to 0.99 and specificity that ranged from 0.16 to 0.88.
Screeener and Opioid Assessment for Patients with Pain, Version 1	2 studies of diagnostic accuracy (n = 203)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of ≥8, sensitivity was 0.68 and specificity was 0.38 in one study, for a positive likelihood ratio of 1.11 and a negative likelihood ratio of 0.83. Based on a cutoff score of >6, sensitivity was 0.73 in one study.
Screeener and Opioid Assessment for Patients with Pain-Revised	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of >3 or unspecified, sensitivity was 0.25 and 0.53 and specificity was 0.62 and 0.73 in two studies, for likelihood ratios close to 1.
Brief Risk Interview	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a “high risk” assessment, sensitivity was 0.73 and 0.83 and specificity was 0.43 and 0.88 in two studies, for positive likelihood ratios of 1.28 and 7.18 and negative likelihood ratios of 0.63 and 0.19.

See table footnotes on page 47.

**TABLE 1. (Continued) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain**

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
<b>Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain</b>							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse</b>							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain</b>							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse</b>							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids</b>							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
<b>Effects of opioid therapy for acute pain on long-term use (KQ5)</b>							
Long-term opioid use	New for update: 2 cohort studies (n = 399,852)	Serious limitations	No inconsistency	No imprecision	3	None identified	One study found use of opioids within 7 days of low-risk surgery associated with increased likelihood of opioid use at 1 year (adjusted OR 1.44, 95% CI = 1.39–1.50), and one study found use of opioids within 15 days of onset of low back pain among workers with a compensation claim associated with increased risk of late opioid use (adjusted OR 2.08, 95% CI = 1.55–2.78 for 1 to 140 MME/day and OR 6.14, 95% CI = 4.92–7.66 for ≥450 MME/day).

**Abbreviations:** CI = confidence interval; ER/LA = extended release/long-acting; HR = hazard ratio; MME = morphine milligram equivalents; OR = odds ratio.  
 \*Ratings were made per GRADE quality assessment criteria; “no limitations” indicates that limitations assessed through the GRADE method were not identified.  
 † Not applicable as no evidence was available for rating.

**TABLE 2. Morphine milligram equivalent (MME) doses for commonly prescribed opioids**

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

**Source:** Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (<http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>).

\* Multiply the dose for each opioid by the conversion factor to determine the dose in MMEs. For example, tablets containing hydrocodone 5 mg and acetaminophen 300 mg taken four times a day would contain a total of 20 mg of hydrocodone daily, equivalent to 20 MME daily; extended-release tablets containing oxycodone 10mg and taken twice a day would contain a total of 20mg of oxycodone daily, equivalent to 30 MME daily. The following cautions should be noted: 1) All doses are in mg/day except for fentanyl, which is mcg/hr. 2) Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics. 3) Do not use the calculated dose in MMEs to determine the doses to use when converting opioid to another; when converting opioids the new opioid is typically dosed at substantially lower than the calculated MME dose to avoid accidental overdose due to incomplete cross-tolerance and individual variability in opioid pharmacokinetics. 4) Use particular caution with methadone dose conversions because the conversion factor increases at higher doses. 5) Use particular caution with fentanyl since it is dosed in mcg/hr instead of mg/day, and its absorption is affected by heat and other factors.

† Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

## Recommendations and Reports

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**64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.**

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access <http://www.deadiversion.usdoj.gov/ecommm/index.html>.

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Program's Database;

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose; and,

(e) The laws and rules related to the prescribing and dispensing of controlled substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

(7) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

*Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History—New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.*

### **64B8-9.012 Standards for the Prescription of Obesity Drugs.**

The prescription of medication for the purpose of enhancing weight loss should only be performed by physicians qualified by training and experience to treat obesity. All licensees are expected to abide by the following guidelines and standards in the utilization of any drug, any synthetic compound, any nutritional supplement, or herbal treatment, for the purpose of providing medically assisted weight loss.

(1) To justify the use of weight loss enhancers as set forth above, 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 prescription of such weight loss enhancers is not generally appropriate for children. Any time such prescriptions are made for children, the prescribing physician must obtain a written informed consent from the parent or legal guardian of the minor patient in addition to complying with the other guidelines and standards set forth in this rule. BMI is calculated by use of the formula  $BMI = kg/m^2$ .

(2) 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.

(3) 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 licensed pursuant to Chapter 458, 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.

(4) 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. 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.

(5) 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.

(6) 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.

(7) 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 Rule 64B8-9.003, F.A.C., and must also reflect compliance with all requirements of this rule.

(8) 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.

(9) 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.

*Specific Authority 458.336 FS. Law Implemented 458.336 FS. History—New 12-4-97, Amended 2-17-98.*

### **64B8-9.013 Standards for the Use of Controlled Substances for the Treatment of Pain.**

#### **(1) Pain management principles.**

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these standards have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

#### **(2) 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.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, “analgesic tolerance” is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(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.

(f) Physical Dependence. For the purpose of this rule, “physical dependence” on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, “pseudoaddiction” is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, “substance abuse” is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, “tolerance” is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(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 should 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 should document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy 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 should 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 should 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 should 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. At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician’s evaluation of the patient’s progress. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should 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.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The medical history and 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; and
9. Periodic reviews. Records must remain current and be maintained in an accessible manner and readily available for review.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

*Specific Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.326, 458.331(1)(g), (t), (v) FS. History—New 12-21-99, Amended 11-10-02, 10-19-03.*

**64B8-9.014 Standards for Telemedicine Prescribing Practice.**

(1) 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.

(2) 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.

(3) The provisions of this rule are not applicable in an emergency situation. For purposes of this rule an emergency situation means those situations in which the prescribing physician or physician assistant determines that the immediate administration of the medication is necessary for the proper treatment of the patient, and that it is not reasonably possible for the prescribing physician or physician assistant to comply with the provision of this rule prior to providing such prescription.

(4) 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.

(5) For purposes of this rule, the term "telemedicine" shall include, but is not limited to, prescribing legend drugs to patients through the following modes of communication:

(a) Internet;

(b) Telephone; and

(c) Facsimile.

*Specific Authority 458.309, 458.331(1)(v) FS. Law Implemented 458.331(1)(q), (t), (v) FS. History—New 9-14-03.*

**64B8-30.008 Formulary.**

(1) Physician Assistants approved to prescribe medicinal drugs under the provisions of Section 458.347(4)(e) or 459.022(4)(e), F.S., are not authorized to prescribe the following medicinal drugs, in pure form or combination:

- (a) Controlled substances, as defined in Chapter 893, F.S.
- (b) General, spinal or epidural anesthetics.
- (c) Radiographic contrast materials.

(2) A supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are used in the supervising physician's practice, not listed in subsection (1).

(3) Subject to the requirements of this subsection, Sections 458.347 and 459.022, F.S., and the rules enacted thereunder, drugs not appearing on this formulary may be delegated by a supervising physician to a prescribing physician assistant to prescribe.

(4) Nothing herein prohibits a supervising physician from delegating to a physician assistant the authority to order medicinal drugs for a hospitalized patient of the supervising physician, nor does anything herein prohibit a supervising physician from delegating to a physician assistant the administration of a medicinal drug under the direction and supervision of the physician.

*Rulemaking Authority 458.309, 458.347(4)(f)1. FS. Law Implemented 458.347(4)(e), (f) FS. History—New 3-12-94, Formerly 61F6-17.0038, Amended 11-30-94, 2-22-95, 1-24-96, 11-13-96, 3-26-97, Formerly 59R-30.008, Amended 11-26-97, 1-11-99, 12-28-99, 6-20-00, 11-13-00, 2-15-02, 7-30-03, 8-2-09.*