201 KAR 9:260. Professional standards for prescribing, dispensing, and administering controlled substances.

RELATES TO: KRS 218A.172, 218A.205, 311.530-311.620, 311.990, 311.840-311.862
STATUTORY AUTHORITY: KRS 218A.205(3)(a), (b), 311.565(1)(a), 311.842(1)(b)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218A.205(3)(a) and (b) require the board, in consultation with the Kentucky Office of Drug Control Policy, to establish mandatory prescribing and dispensing standards related to controlled substances, and in accordance with the Centers for Disease Control and Prevention (CDC) guidelines, to establish a prohibition on a practitioner issuing a prescription for a Schedule II controlled substance for more than a three (3) day supply if intended to treat pain as an acute medical condition, unless an exception applies. KRS 311.842(1)(b) requires that the board promulgate administrative regulations establishing professional standards for prescribing and administering controlled substances by physician assistants. This administrative regulation establishes the professional standards for prescribing and dispensing controlled substances for any licensee authorized to prescribe, dispense, or administer controlled substances.

Section 1. Applicability. (1) Any licensee who is authorized to prescribe, dispense, or administer a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing, dispensing, or administering a controlled substance established in this administrative regulation.

(2) A physician assistant shall only prescribe or administer a controlled substance to the extent delegated by the supervising physician in the applications required under KRS 311.854 and 311.858. This administrative regulation, including any exemptions stated herein, shall not alter the prescribing limits established in KRS 311.858 or the requirements for delegation from a supervising physician established in KRS 311.854.

(a) Any change in the supervising physician application, including changes in practice address, scope of practice, or scope of delegated prescriptive authority, required under KRS 311.854 and 311.858 shall be reported in writing to the board within ten (10) days of the change.

(b) If the physician assistant's supervising physician changes or the supervising physician becomes restricted or suspended from the practice of medicine or osteopathy, the physician assistant shall cease prescribing or administering controlled substances until the restriction or suspension is terminated or a new supervising physician is approved.

(c) Prescribing or administering controlled substances without the applications required under KRS 311.854 and 311.858 shall constitute a violation of this administrative regulation and shall be grounds for an emergency order of restriction or suspension.

(3) The professional standards established in this administrative regulation shall not apply to prescribing, dispensing, or administering a controlled substance:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a licensed hospital as an inpatient, outpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital;

(c) To a patient for the treatment of pain associated with cancer or with the treatment of cancer;

(d) To a patient who is a registered resident of a long-term-care facility as defined in KRS 216.510;

(e) During the effective period of any period of disaster or mass casualties that has a direct impact upon the physician's practice;

(f) In a single dose to relieve the anxiety, pain, or discomfort experienced by that patient submitting to a diagnostic test or procedure;

(g) That has been classified as a Schedule V controlled substance;

(h) That is a Schedule II controlled substance as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;

(i) Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

1. Is done as a substitute for the initial prescribing or dispensing;

2. Cancels any refills for the initial prescription; and

3. Requires the patient to dispose of any remaining unconsumed medication;

(j) Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another physician in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition;

(k) To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department for Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health; or

(l) 1. To a patient immediately prior to, during, or within the fourteen (14) days following:

a. A major surgery, being any operative or invasive procedure or a delivery; or

b. A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; and

2. The usage does not extend beyond fourteen (14) days.

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes, and Monitoring. (1) Each licensee prescribing, dispensing, or administering a controlled substance shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee is conforming to professional standards for prescribing, dispensing, or administering controlled substances and other relevant professional standards. Relevant information shall include as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

(2) If a licensee is unable to conform to professional standards for prescribing, dispensing, or administering controlled substances due to circumstances beyond the licensee's control, or the licensee makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the licensee shall document those circumstances in the patient's record and only prescribe, dispense, or administer a controlled substance to the patient if the patient record appropriately justifies the prescribing, dispensing, or administering of a controlled

substance under the circumstances.

Section 3. Professional Standards for the Prescribing, Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. Prior to the initial prescribing, dispensing, or administering of any controlled substance for pain or other symptoms associated with the same primary medical complaint:

(1) The first licensee prescribing, dispensing, or administering a controlled substance shall:

(a) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

1. If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

2. If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(b) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(c) After examining the benefits and risks of prescribing, dispensing, or administering a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe, dispense, or administer the controlled substance in the minimum amount necessary to treat the medical complaint;

(d) Not prescribe, dispense, or administer a long-acting or controlled-release opioid for acute pain that is not directly related to and close in time to a specific surgical procedure;

(e) Discuss the risk and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence and explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring the controlled substance use has resolved; and

(f) Explain to the patient how to safely use and properly dispose of any unused controlled substance and educate the patient in accordance with Section 8 of this administrative regulation; and

(2) If the controlled substance is a Schedule II, a physician shall also:

(a) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(b) Obtain written consent for the treatment; and

(c) Not prescribe or dispense more than a three (3) day supply of a Schedule II controlled substance, unless the physician:

1. Determines that more than a three (3) day supply is medically necessary; and

2. Documents the acute medical condition and lack of alternative medical treatment options to justify the amount of the controlled substance prescribed or dispensed.

Section 4. Professional Standards for Commencing Long Term Use of Prescribing, Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) Before a licensee commences to prescribe, dispense, or administer any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a

total period of longer than three (3) months, the licensee shall comply with the mandatory professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the licensee if:

(a) Each practitioner involved has lawful access to the patient's medical record;

(b) There is compliance with all applicable standards; and

(c) Each practitioner performing an action to meet the required standards is acting within the practitioner's legal scope of practice.

(2)(a) The licensee shall obtain the following information from the patient and record all relevant information in the patient's medical record:

1. History of present illness;

2. Past medical history;

3. History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient;

4. Past family history of relevant illnesses and treatment; and

5. Psychosocial history.

(b) The licensee shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing, dispensing, or administering a controlled substance on a long-term basis.

(c) The licensee shall perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan.

(d) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the licensee shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information.

(e) If the licensee determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing, dispensing, or administering of a controlled substance, the licensee shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient.

(f)1. Based upon consideration of all information available, the licensee shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms.

2. If the licensee is unable, despite best efforts, to formulate a working diagnosis, the licensee shall consider the usefulness of additional information, such as a specialized evaluation or assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis.

3. If the licensee is unable to formulate a working diagnosis, despite the use of an appropriate specialized evaluation or assessment, the licensee shall only prescribe, dispense, or administer long term use of a controlled substance after establishing that its use at a specific level is medically indicated and appropriate.

(g)1. To the extent that functional improvement is medically expected based upon the patient's condition, the licensee shall formulate an appropriate treatment plan.

2. The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations.

(h)1. The licensee shall utilize appropriate screening tools to screen each patient to determine if the patient:

a. Is presently suffering from another medical condition which may impact the prescribing,

dispensing, or administering of a controlled substance; or

b. Presents a significant risk for illegal diversion of a controlled substance.

2. If, after screening, the licensee determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, or a psychiatric or psychological condition, the licensee shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider. The licensee shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient.

3. If, after screening, the licensee determines that there is a risk that the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the licensee shall use a prescribing agreement that meets professional standards. The prescribing agreement and informed consent document may be combined into one (1) document.

4. The licensee shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed or dispensed to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the licensee shall not prescribe or dispense any controlled substance to that patient.

(i) After explaining the risks and benefits of long-term use of a controlled substance, the licensee shall obtain the written informed consent of the patient in a manner that meets professional standards and educate the patient in accordance with Section 8 of this administrative regulation.

(j) The licensee shall initially attempt, to the extent possible, or establish and document a previous attempt by another physician, of a trial of noncontrolled modalities and lower doses of a controlled substance in increasing order to treat the pain and related symptoms associated with the primary medical complaint, before continuing with long term prescribing, dispensing, or administering of a controlled substance at a given level.

Section 5. Professional Standards for Continuing Long Term Prescribing, Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) If a licensee continues to prescribe, dispense, or administer a controlled substance beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the licensee shall comply with the professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the licensee as established in Section 4(1) of this administrative regulation.

(2)(a) The licensee shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The licensee may determine that the patient is to be evaluated less frequently, on a schedule determined by the licensee’s professional judgment after the licensee has determined:

1. The controlled substance prescribed, dispensed, or administered has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

2. The controlled substance prescribed, dispensed, or administered is not causing unacceptable side effects; and

3. There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substance in an improper or inappropriate manner or divert it for an improper or inappropriate use.

(b) At appropriate intervals, the licensee shall:

1. Ensure that a current history is obtained from the patient;

2. Ensure that a focused physical examination is considered, and performed, if appropriate; and

3. Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the licensee shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any change in baseline measures. The licensee shall modify the diagnosis, treatment plan, or controlled substance therapy, as appropriate.

(d) If the licensee determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the licensee shall discontinue the use of the controlled substance or justify its continued use in the patient record.

(e) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with a controlled substance, and if improvement is medically expected, the licensee shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint.

(f) For a patient exhibiting symptoms suggestive of a mood, anxiety, or psychotic disorder, the licensee shall obtain a psychiatric or psychological consultation for intervention if appropriate.

(g) If a patient reports experiencing episodes of breakthrough pain, the licensee shall:

1. Attempt to identify the trigger or triggers for each episode;

2. Determine whether the breakthrough pain may be adequately treated through noncontrolled treatment; and

3. If the licensee determines that the nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an as-needed controlled substance to the regimen, take appropriate steps to minimize the improper or illegal use of the additional controlled substance.

(h) At least once a year, the licensee shall perform or shall ensure that the patient's primary treating physician performs a preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition.

(i)1. At least once every three (3) months, the licensee shall obtain and review a current KASPER report, for the twelve (12) month period immediately preceding the request, and appropriately use that information in the evaluation and treatment of the patient.

2. If the licensee obtains or receives specific information that the patient is not taking the controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the licensee shall immediately obtain and review a KASPER report and appropriately use the information in the evaluation and treatment of the patient.

3. If a KASPER report discloses that the patient is obtaining a controlled substance from another practitioner without the licensee's knowledge and approval, in a manner that raises suspicion of illegal diversion, the licensee shall promptly notify the other practitioner of the relevant information from the KASPER review.

4. The licensee shall obtain consultative assistance from a specialist if appropriate.

(j) If appropriate, the licensee shall conduct random pill counts and appropriately use that information in the evaluation and treatment of the patient.

(k)1. During the course of long-term prescribing, dispensing, or administering of a controlled substance, the licensee shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the licensee indicates that the patient is noncompliant, the licensee shall:

a. Do a controlled taper, consistent with subparagraph 3 of this paragraph;

b. Stop prescribing, dispensing, or administering the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending upon the circumstances.

2. The licensee shall discontinue controlled substance treatment or refer the patient to addiction management if:

a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected;

b. Controlled substance therapy has produced significant adverse effects, including instances such as an overdose or events leading to hospitalization or disability;

c. The patient exhibits inappropriate drug-seeking behavior or diversion; or

d. The patient is taking a high-risk regimen, such as dosages ≥ fifty (50) MME/day or opioids with benzodiazepines, without evidence of benefit.

3. The licensee shall:

a. Taper controlled substances in a manner slow enough to minimize symptoms and signs of opioid withdrawal; and

b. Collaborate with other specialists as needed to optimize nonopioid pain management and psychosocial support for anxiety related to the taper.

4. A licensee shall stop prescribing, dispensing, or administering any controlled substance diverted by or from the patient or taken less frequently than once a day.

Section 6. Professional Standards for the Prescribing, Dispensing, or Administering of Controlled Substances in an Emergency Department. In addition to complying with the standards for the initial prescribing, dispensing, or administering of a controlled substance as established in Sections 3 and 7 of this administrative regulation, a licensee prescribing, dispensing, or administering a controlled substance for a specific medical complaint and related symptoms to a patient in an emergency department shall not routinely:

(1) Administer an intravenous controlled substance for the relief of acute exacerbations of chronic pain, unless intravenous administration is the only medically appropriate means of delivery;

(2) Provide a replacement prescription for a controlled substance that was lost, destroyed, or stolen;

(3) Provide a replacement dose of methadone, suboxone, or subutex for a patient in a treatment program;

(4) Prescribe a long-acting or controlled-release controlled substance, such as OxyContin, fentanyl patches, or methadone or a replacement dose of that medication;

(5) Administer Meperidine to the patient; or

(6) Prescribe, dispense, or administer more than the minimum amount medically necessary to treat the patient’s medical condition until the patient can be seen by the primary treating physician or another practitioner, with no refills. If the controlled substance prescription exceeds seven (7) days in length or exceeds three (3) days if a Schedule II controlled substance, the patient record shall justify the amount of the controlled substance prescribed.

Section 7. Professional Standards for the Prescribing, Dispensing, or Administering of Controlled Substances for the Treatment of Other Conditions. (1) Before initially prescribing, dispensing, or administering a controlled substance to a patient for a condition other than pain, the licensee shall comply with the standards as established in Section 3 of this administrative regulation.

(2) If the licensee continues to prescribe, dispense, or administer a controlled substance to a patient for the same medical complaint and related symptoms, the licensee shall fully

conform to the standards of acceptable and prevailing practice for treatment of that medical complaint and for the use of the controlled substance.

(3) If a licensee receives a request from an established patient to prescribe, dispense, or administer a limited amount of a controlled substance to assist the patient in responding to the anxiety or depression resulting from a nonrecurring single episode or event, the licensee shall:

(a) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient request and appropriately utilize the information obtained in the evaluation and treatment of the patient;

(b) Make a deliberate decision that it is medically appropriate to prescribe, dispense, or administer the controlled substance in the amount specified, with or without requiring a personal encounter with the patient to obtain a more detailed history or to conduct a physical examination; and

(c) If the decision is made that it is medically appropriate to use a controlled substance, prescribe, dispense, or administer the minimum amount of the controlled substance to appropriately treat the situational anxiety or depression.

Section 8. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) A licensee prescribing, dispensing, or administering a controlled substance shall:

(a) Take appropriate steps to educate a patient receiving a controlled substance; and

(b) Discuss with each patient the effect the patient's medical condition and medication use may have on the patient's ability to safely operate a vehicle in any mode of transportation.

(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov.

Section 9. Violations. (1) Any violation of the professional standards established in this administrative regulation shall constitute a violation of KRS 311.595(12) and (9) or KRS 311.850(1)(p) and (s), which may result in the imposition of disciplinary sanctions by the board, pursuant to KRS 311.595 or KRS 311.850.

(2) Each violation of the professional standards established in this administrative regulation shall be established by expert testimony by one (1) or more physicians retained by the board, following a review of the licensee's patient records and other available information including KASPER reports. (39 Ky.R. 671; 1177; 1668; 2002; eff. 3-4-2013; 44 Ky.R. 265, 736, 905; eff. 11-15-2017; 45 Ky.R. 743; eff. 12-12-2018; 47 Ky.R. 374, 944; eff. 11-19-2020.)