

KENTUCKY BOARD OF MEDICAL LICENSURE
201 KAR 9:260 Summary
Updated 11/15/17

*Please note this is a summary of 201 KAR 9:260. Recent changes in the regulation are underlined and in bold font. Physicians are strongly encouraged to review and refer to the actual regulation, which is available at the Board's website, www.kbml.ky.gov.

SECTION 1 – EXCEPTIONS TO STANDARDS OF 201 KAR 9:260

- The following are exceptions to standards in 201 KAR 9:260:
 - Patients as part of the patient's hospice or end-of-life treatment;
 - Patient admitted to a hospital as an inpatient, outpatient, or observation patient;
 - Cancer patients or pain related to cancer treatment;
 - Patients in long-term care facilities;
 - During any period of disaster or mass casualties;
 - In a single dose prescribed or dispensed to relieve anxiety, pain, or discomfort for a diagnostic test or procedure;
 - Any Scheduled V Controlled Substance;
 - **That is a Schedule II controlled substance as part of a narcotic treatment program licensed by the Cabinet for Health & Family Services;**
 - **That is a Schedule II controlled substance immediately prior to, during, or within the 14 days following a major surgery, being any operative or invasive procedure or a delivery, or significant trauma, being an acute blunt, blast or penetrating bodily injury that has risk of death or physical disability or impairment, and the usage does not extend beyond 14 days.**

SECTION 2 – PROFESSIONAL STANDARDS FOR DOCUMENTATION OF PATIENT ASSESSMENT, EDUCATION, TREATMENT AGREEMENT AND INFORMED CONSENT

- Obtain and document all relevant information in a patient's medical record in a legible manner and sufficient detail to provide for:
 - The Board to determine whether the physician is conforming to professional standards for prescribing and dispensing controlled substances and other relevant professional standards.
 - If the physician is unable to conform to the standards in the regulation due to circumstances beyond their control or the physician makes a determination that

it is not appropriate to comply with the specific standard, the physician shall only prescribe or dispense controlled substances to the patient when the record appropriately justifies the action.

SECTION 3 – PROFESSIONAL STANDARDS FOR THE PRESCRIBING OR DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN AND RELATED SYMPTOMS

- Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the primary complaint, the first physician prescribing or dispensing shall:
 - Obtain an appropriate medical history and conduct a physical examination for all medical complaints other than psychiatric conditions and document in the patient’s record. Psychiatrists shall perform evaluation appropriate to condition and document in patient’s record;
 - Obtain and review a KASPER report for the patient for previous 12 month period;
 - Examine the benefits and risks of prescribing or dispensing and make a deliberate decision that it is medically appropriate to prescribe or dispense in amount specified;
 - **Only prescribe Schedule II controlled substances in accordance with the standards established in Section 9 of this regulation;**
 - Not prescribe or dispense long-acting or controlled-release opioids for acute pain not related to a specific surgical procedure;
 - Explain to patient that controlled substances used to treat acute pain are for time limited use and the patient should stop taking the medication once the condition has been resolved.
 - Explain to patient how to safely use and dispose of unused controlled substances.

SECTION 4 - PROFESSIONAL STANDARDS FOR COMMENCING LONG TERM USE OF PRESCRIBING OR DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN AND RELATED SYMPTOMS ASSOCIATED WITH A PRIMARY MEDICAL COMPLAINT

- Before a physician commences to prescribe or dispense to a patient 16 years or older for pain or related symptoms for a period longer than 3 months, the physician must comply with the following standards. These standards may be done by different licensed practitioners in a single group practice at the direction of the physician or on behalf of the physician so long as:
 - Each practitioner has lawful access to patient’s medical record;
 - There is compliance with all applicable standards; and

- Each practitioner is acting within their legal scope of practice;
- The physician shall obtain the following information and record in the patient's medical record:
 - History of present illness;
 - Past medical history;
 - History of substance use and any treatment for such use by patient and history of substance abuse by first degree relatives;
 - Past family history of relevant illnesses and treatment; and
 - Psychosocial history;
- Conduct an appropriate physical examination;
- Perform appropriate baseline assessments;
- If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall only continue the use of controlled substances after determining that continued use of controlled substances is safe and medically appropriate in the absence of such information;
- Obtain prior medical records and incorporate into evaluation and treatment of patient if the physician determines a review of those records are needed to justify treatment;
- Formulate and document a working diagnosis of the source of the patient's medical complaint;
 - If the physician is unable to formulate a working diagnosis, consider information such as specialized evaluations or assessments, referral to appropriate specialists, usefulness of further observation and evaluation, before attempting to formulate a working diagnosis;
 - If the physician is unable to formulate a working diagnosis, despite the use of appropriate specialized evaluations or assessments, only provide long term use of controlled substances after establishing that such use is medically indicated and appropriate;
- Formulate an appropriate treatment plan to the extent that the functional improvement is medically expected based upon the patient's condition;
 - Treatment plan shall include specific and verifiable goals of treatment with a schedule of periodic evaluations;
- Utilize screening tools to determine if patient is suffering from condition that may impact the prescribing or presents a significant risk for illegal diversion;
- If patient is determined to be suffering from substance abuse or dependence, or a psychiatric or psychological condition, facilitate a referral to treatment program or provider. Incorporate information from treatment program into evaluation and treatment;
- If the patient is a high risk for diversion, but the physician decides to continue long-term prescribing – the physicians shall use a prescribing agreement;

- Obtain and document a baseline drug screen;
- If, after screening, it is determined that the controlled substances prescribed to the patient will be used or are likely used other inappropriately, consider whether or not it is appropriate to commence prescribing to the patient;
- Obtain written informed consent;
- Attempt or establish and document a previous attempt by another physician, of a trial of non-controlled modalities and lower doses of controlled substances in increasing order to treat the pain before continuing with long-term prescribing at a given level;

SECTION 5 – PROFESSIONAL STANDARDS FOR CONTINUING LONG-TERM PRESCRIBING OR DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN AND RELATED SYMPTOMS ASSOCIATED WITH A PRIMARY MEDICAL COMPLAINT

- If a physician continues to prescribe or dispense to a patient 16 years or older for pain or related symptoms for a period longer than 3 months, the physician must comply with the following standards **in this Section and also Section 9 if the patient is prescribed a Schedule II controlled substance.** These standards may be accomplished by different licensed practitioners in a single group practice at the direction or on behalf of the prescribing physician as established in Section 4.
- Ensure that the patient is seen at least once a month initially for evaluation. The physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician after the physician has determined:
 - the controlled substances have been titrated to appropriate level for condition;
 - the controlled substances are not causing unacceptable side effects; and
 - there is sufficient monitoring in place to minimize diversion and inappropriate use.
- At appropriate intervals, obtain current history, ensure a focused physical examination is considered and performed if appropriate. Perform appropriate measurable examinations as indicated in treatment plan;
- At appropriate intervals, evaluate the working diagnosis and treatment plan to determine whether there is functional improvement or change in baseline measures. Modify the diagnosis, treatment plan, or controlled substances therapy if appropriate.
- If it is determined patient presents a significant risk of diversion or improper use, discontinue the use of controlled substances or justify continued use in the patient record;
- If medical complaint and symptoms continue with no improvement despite treatment where improvement is medically expected, obtain appropriate consultation to determine if there are undiagnosed conditions that must be addressed;
- Obtain psychiatric or psychological consultations for patients exhibiting symptoms of mood, anxiety and/or psychotic disorders;
- If patient reports breakthrough pain, the physician shall:

- Attempt to identify triggers for such episodes;
- Determine if pain may be treated through non-controlled treatment;
- If determined that non-controlled treatment does not address triggers, take appropriate steps to minimize improper or illegal use of additional controlled substances if the physician determines to add as-needed controlled substances to regimen;
- At least once a year, perform or ensure that patient's primary treating physician performs preventative health screening and physical examination;
- Obtain and review a current KASPER report at least once every 3 months;
 - If physician obtains or receives information patient is not taking the controlled substances as directed, is diverting, or is engaged in improper or illegal use of the drugs, immediately obtain and review a KASPER;
 - If KASPER discloses the patient is obtaining controlled substances from other practitioners without the physician's knowledge and approval that raises suspicion of illegal diversion, promptly notify the other practitioners of the relevant information from the KASPER review;
 - Obtain consultative assistance from a specialist when appropriate;
- When appropriate, conduct random pill counts and incorporate information in evaluation and treatment of patient;
- Utilize drug screens appropriate to the controlled substances and condition, in a random and unannounced manner at appropriate times;
- If the patient is noncompliant:
 - Do a controlled taper **consistent with standards in this Section**;
 - Stop prescribing or dispensing controlled substances immediately; or
 - Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program.
- Discontinue controlled substance treatment and/or refer the patient to addiction management if one or more of the following conditions are exist:
 - There has been no improvement in function and response to medical complaint and symptoms where improvement is medically expected;
 - Controlled substance therapy has produced significant adverse effects , **including but not limited to overdose or events leading to hospitalization or disability**;
 - Patient exhibits drug seeking behavior or diversion; **or**
 - **Patient is taking a high-risk regimen, including but not limited to dosages >50 MME/day or opioids with benzodiazepines, without evidence of benefit.**
- **Taper controlled substances in a manner slow enough to minimize symptoms and signs of opioid withdrawal and collaborate with other specialists as needed to optimize nonopioid pain management and psychosocial support for anxiety related to the taper.**
- **Stop prescribing or dispensing any controlled substance diverted by or from the patient or taken less frequently than once a day.**

SECTION 6 – PROFESSIONAL STANDARDS FOR THE PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES IN AN EMERGENCY ROOM DEPARTMENT

- Comply with standards for initial prescribing for pain and other conditions;
- Physicians are strongly discouraged and shall not routinely:
 - Administer intravenous controlled substances for relief of acute exacerbations of chronic pain, unless it is the only medically appropriate means of delivery;
 - Provide replacement prescriptions that were lost, destroyed, or stolen;
 - Provide replacement doses of methadone, suboxone, or subutex for patients in a treatment program;
 - Prescribe long-acting or controlled release controlled substances or replacement doses of such medication;
 - Administer Meperidine to the patient;
 - Prescribe or dispense more than minimum amount medically necessary to treat patient's condition until patient can be seen by their primary treating physician or another physician, with no refills. If the prescribing exceeds 7 days (**or exceeds 3 days if a Schedule II controlled substance**), the patient record must justify the amount prescribed.

SECTION 7 – PROFESSIONAL STANDARDS FOR THE PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF OTHER CONDITIONS

- Obtain an appropriate medical history and conduct a physical examination for all medical complaints other than psychiatric conditions and document in the patient's record. Psychiatrists shall perform evaluation appropriate to condition and document in patient's record;
- Obtain and review a KASPER report for the patient for previous 12 month period;
- Examine the benefits and risks of prescribing or dispensing and make a deliberate decision that it is medically appropriate to prescribe or dispense in amount specified;
- Avoid providing more controlled substances than necessary;
- Explain to patient that controlled substances used to treat an acute medical complaint are for time limited use and the patient should stop taking the medication once the condition has been resolved.
- Explain to patient how to safely use and dispose of unused controlled substances.
- If the physician continues to prescribe or dispense controlled substances to the patient for the same medical complaint and conditions, conform to the standards of acceptable

and prevailing practice for the treatment of that medical complaint and use of controlled substances.

- When a physician receives a request from an established patient to prescribe or dispense a limited amount of controlled substances to assist the patient in responding to the anxiety or depression resulting from a non-recurring single episode or event, the physician shall:
 - Obtain and review a KASPER report for the previous 12 months;
 - Make a decision that it is medically appropriate to prescribe or dispense in the amount specified, without requiring a personal encounter with the patient;
 - Prescribe or dispense the minimum amount of controlled substances to appropriately treat the situational anxiety or depression;

SECTION 8 – RESPONSIBILITY TO EDUCATE PATIENTS REGARDING THE DANGERS OF CONTROLLED SUBSTANCES

- Take appropriate steps to educate patients receiving controlled substances;
- Educational materials related to patient education may be found on the board’s website, www.kbml.ky.gov;

SECTION 9 – ADDITIONAL STANDARDS FOR PRESCRIBING OR DISPENSING SCHEDULE II CONTROLLED SUBSTANCES

- In addition to the other standards in this regulation, prior to the initial prescribing or dispensing of a controlled substance containing to a patient, a physician shall:
 - Obtain a medical history and conduct a physical or mental health examination appropriate to medical complaint and document in the medical record;
 - Query KASPER for 12 month period prior to patient encounter and utilize data in evaluation and treatment of patient;
 - Make a written plan stating objectives of the treatment and further diagnostic examinations required;
 - Discuss the risks and benefits of the use of controlled substances with patient, the patient’s parent if the patient is unemancipated minor child, or the patient’s legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and
 - Obtain written consent;

- **In addition to the other standards in this regulation, for the purposes of treating pain as or related to an acute medical condition, a physician shall not prescribe more than a 3 day supply of a Schedule II controlled substance, unless the physician determines that more than a 3 day supply is medically necessary and physician documents the acute medical condition and lack of alternative medical treatment options to justify the amount of the controlled substance prescribed.**

- In addition to the other standards in this regulation, physicians prescribing or dispensing additional amounts of a Schedule II controlled substance for the same medical complaint and related symptoms shall:
 - Review, at reasonable intervals, based on the patient's individual circumstances and course of treatment, the plan of care;
 - Provide to patient any new information about the treatment; and
 - Modify or terminate the treatment as appropriate;

- If the course of treatment goes beyond 3 months, the physician shall:
 - Query KASPER no less than once every 3 months for all available data on the patient for the preceding 12 month period;
 - Review the data before issuing a new prescriptions or refills for the patient;

- To the extent not already required by this regulation, for Schedule II controlled substances or Schedule III controlled substances with Hydrocodone, the physician shall keep accurate, readily accessible and complete medical records which include as appropriate:
 - Medical history and physical or mental health examination;
 - Diagnostic, therapeutic, and laboratory results;
 - Evaluations and consultations;
 - Treatment objectives;
 - Discussion of risk, benefits, and limitations of treatments;
 - Treatments;
 - Medications, including data, type, dosage, and quantity prescribed or dispensed;
 - Instructions and agreements, and
 - Periodic reviews of patient's file.

- ***EXEMPTIONS FROM THE ADDITIONAL STANDARDS INVOLVING SCHEDULE II CONTROLLED SUBSTANCES:***
 - **Prescribing or administering controlled substances immediately prior to, during, or within 14 days following a major surgery, being an operative or invasive procedure or a delivery , or significant trauma, being an acute blunt, blast or penetrating bodily injury that has a risk of death or physical disability or impairment if the prescribing or administering is medically related to the**

operative or invasive procedure or delivery and medication usage does not extend beyond the 14 days;

- Prescribing or dispensing for administration to a patient admitted to a hospital or long-term care facility if the facility or practitioner places a KASPER report on the chart within 12 hours;
- Prescribing or dispensing as part of a narcotic treatment program licensed by the Cabinet for Health & Family Services;
- Prescribing or dispensing a substitute prescription within 7 days of the initial prescription so long as any refills to the initial prescription are cancelled and the patient is required to dispose of any unused medication;
- Prescribing or dispensing to the same patient for the same condition by a partner in practice with the initial prescriber or other cover arrangement within 90 days of the initial prescription; or
- Prescribing or dispensing to a research subject enrolled in an IRB-approved single, double or triple blind study, or is otherwise covered by an NIH certificate of confidentiality.

SECTION 10 – VIOLATIONS

- Any violation of the professional standards in this regulation or in KRS 218A.172 shall constitute a violation of KRS 311.595(12) and (9) which may result in disciplinary sanctions by the board, pursuant to KRS 311.595;
- Each violation of the professional standards in this regulation or KRS 218A.172 shall be established by expert testimony by one or more physicians retained by the board, following a review of the licensee's patient records and other available information including KASPER ports.