GENERAL GOVERNMENT CABINET
Kentucky Board of Medical Licensure
(Draft Amendment for Senate and House Standing Committees on Judiciary)

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

RELATES TO: KRS 218A.205, 311.530-311.620, 311.990
STATUTORY AUTHORITY: KRS ***218A.205(3)(a),*** 311.565(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licenses. ***KRS 218A.205(3)(a) requires the board to establish mandatory prescribing and dispensing standards related to controlled substances.*** This administrative regulation establishes the professional standards for prescribing and dispensing controlled substances. ***[Each physician who is authorized to prescribe or dispense controlled substances shall conform to the following mandatory professional standards relating to controlled substances while practicing within the Commonwealth of Kentucky. The following standards shall be considered the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky for prescribing and dispensing controlled substances for the various conditions or settings described, subject to the enumerated exceptions.]***

Section 1. ***Applicability[Exceptions]***. (1) ***A physician who is authorized to prescribe or dispense a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing and dispensing a controlled substance[requirements] established in [KRS 218A.172 and] this administrative regulation.***

(2) [The standards of acceptable and prevailing medical practice for prescribing and dispensing a controlled substance in Kentucky shall include:

(a)][These exceptions do not apply to][The standards for Schedule II controlled substances and Schedule III controlled substances with hydrocodone established in KRS 218A.172; and

(b) The requirements established in this administrative regulation.

(3)][(2)] **The professional standards established in this administrative regulation shall not apply to *a physician[physicians]* prescribing or dispensing *a* controlled *substance[substances]*:**

(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 which has a direct impact upon the physician's practice;

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

(g) That *has[have]* been classified as a Schedule V controlled substance.

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician prescribing or dispensing *a* controlled *substance[substances]* shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to *enable the[provide for:*

(a) This]* board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards.*[:]

(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances due to circumstances beyond *the physician's[~~their~~]* control, or the physician 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 physician shall *document those circumstances in the patient's record and* only prescribe or dispense *a* controlled *substance[~~substances~~]* to the patient *if[~~when~~]* the patient record appropriately justifies the prescribing or dispensing of *a* controlled *substance[~~substances~~]* under the circumstances.

Section 3. Professional Standards for the Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. *[~~(1)~~]* Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician prescribing or dispensing *a* controlled *substance[~~substances~~]* shall:

(1)[~~(a)~~]* Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and*:

(a) 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*[~~, for all medical complaints other than psychiatric conditions,~~]* and document the information in the patient's medical record*; or

***(b) If the complaint relates to a psychiatric condition,[~~. Psychiatrists, or other designated mental health providers, shall~~]* 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;**

***(2)[~~(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;**

***(3)[~~(c)~~]* After examining the benefits and risks of prescribing or dispensing *a* controlled *substance[~~substances~~]* to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled *substance[~~substances~~]* in the amount specified;**

***(4)[~~(d)~~]* Not prescribe or dispense *a* long-acting or controlled-release *opioid[~~opioids~~]* (e.g. OxyContin, fentanyl patches, *or[~~and~~]* methadone) for acute pain that is not directly related to and close in time to a specific surgical procedure;**

***(5)[~~(e)~~]* Explain to the patient that *a* controlled *substance[~~substances~~]* used to treat an acute medical complaint *is[~~are~~]* for time-limited use, and that the patient should discontinue the use of *the* controlled *substance[~~substances~~]* when the condition requiring the controlled substance use has resolved; and**

***(6)[~~(f)~~]* Explain to the patient how to safely use and properly dispose of any unused controlled *substance[~~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. (1) Before a physician commences to prescribe or dispense 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 physician shall comply with the *[~~following~~]* 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 prescribing physician *if[~~so long as~~]*:

(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[~~their~~] legal scope of practice.

(2)(a) The physician 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[~~such~~]* 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 physician shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing or dispensing *a* controlled *substance[~~substances~~]* on a long-term basis.

(c) The physician 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 physician shall only continue the use of *a* controlled *substance[~~substances~~]* after determining that continued use of *the* controlled *substance[~~substances~~]* is safe and medically appropriate in the absence of *that[~~such~~]* information.

(e) If the physician 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 of *a* controlled *substance[~~substances~~]*, the physician 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 physician 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[~~. It is not sufficient to simply describe or list~~]* the related symptoms.

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

3. If the physician is unable to formulate a working diagnosis, despite the use of *an* appropriate specialized *evaluation or assessment[~~evaluations or assessments~~]*, the physician shall only *prescribe[~~provide~~]* long term use of *a* controlled *substance[~~substances~~]* after establishing that *its[~~such~~]* 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 physician 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 physician 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 or dispensing of *a* controlled *substance;[~~substances,~~]* or

b. Presents a significant risk for illegal diversion of *a* controlled *substance[~~substances~~]*.

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

3. If, after screening, the physician determines that there is a risk that the patient may illegal-

ly divert *a* controlled *substance[~~substances~~]*, but determines to continue long term prescribing of *the* controlled *substance[~~substances~~]*, the physician 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 physician shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled *substance[~~substances~~]* prescribed to the patient will be used or *is[~~are~~]* likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall *not prescribe any[~~consider whether or not it is appropriate to commence prescribing~~]* controlled *substance[~~substances~~]* to that patient.

(i) After explaining the risks and benefits of long-term use of *a* controlled *substance[~~substances~~]*, the physician shall obtain the written informed consent of the patient in a manner that meets professional standards.

(j) The physician 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[~~substances~~]* in increasing order to treat the pain and related *symptoms[~~symptom~~]* associated with the primary medical complaint, before continuing with long term prescribing of *a* controlled *substance[~~substances~~]* 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. (1) If a physician continues to prescribe or dispense *a* controlled *substance[~~substances~~]* beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the physician shall comply with the *[~~following~~]* 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 prescribing physician as *established[~~set forth~~]* in Section 4(1) of this administrative regulation.

(2)(a)1. The physician shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:

a. The controlled *substance[~~substances~~]* prescribed or dispensed *has[~~have~~]* been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

b. The controlled *substance[~~substances~~]* prescribed or dispensed *is[~~are~~]* not causing unacceptable side effects; and

c. There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled *substance[~~substances~~]* in an improper or inappropriate manner or divert *it[~~them~~]* for an improper or inappropriate use.

(b) At appropriate intervals, the physician shall*:*

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

2.[~~, shall~~] Ensure that a focused physical examination is considered, and performed, if appropriate*;[~~,~~]* and

3.[~~shall~~] Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the physician 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. *[~~If appropriate,~~]* The physician shall modify the diagnosis, treatment plan, or controlled *substance[~~substances~~]* therapy, as appropriate.

(d) If the physician determines that the patient presents a significant risk of diversion or improper use of *a* controlled *substance[~~substances~~]*, the physician shall discontinue the use of *the* controlled *substance[~~substances~~]* or justify *its[~~their~~]* 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[~~substances~~]*, *and if[~~where~~]* improve-

ment is medically expected, the physician shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions *to[~~that must~~]* be addressed *in order* to resolve the medical complaint.

(f) For *a patient[~~patients~~]* exhibiting symptoms suggestive of *a* mood, anxiety, *or[~~and/or~~]* psychotic *disorder[~~disorders~~]*, the physician shall obtain *a* psychiatric or psychological *consultation[~~consultations~~]* for intervention if appropriate.

(g) If a patient reports *[~~that they are~~]* experiencing episodes of *["]*breakthrough*["]* pain, the physician shall:

1. Attempt to identify the trigger or triggers for *each episode[~~such episodes~~]*;

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

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

(h) At least once a year, the physician 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 physician 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 physician obtains or receives specific information that the patient is not taking the controlled *substance[~~substances~~]* as directed, is diverting *a* controlled *substance[~~substances~~]*, or is engaged in any improper or illegal use of *a* controlled *substance[~~substances~~]*, the physician 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[~~substances~~]* from *another practitioner[~~other practitioners~~]* without the physician's knowledge and approval, in a manner that raises suspicion of illegal diversion, the physician shall promptly notify the other *practitioner[~~practitioners~~]* of the relevant information from the KASPER review.

4. The physician shall obtain consultative assistance from a specialist *if[~~when~~]* appropriate.

(j) *If[~~When~~]* appropriate, the physician 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 or dispensing of *a* controlled *substance[~~substances~~]*, the physician shall utilize drug screens, appropriate to the controlled *substance[~~substances~~]* and the patient's condition, in a random and unannounced manner at appropriate times*. If the drug screen or other information available to the physician indicates that [~~and, if appropriate, in cases where~~]* the patient is noncompliant*, the physician shall*:

a. Do a controlled taper;

b. Stop prescribing or dispensing *the* controlled *substance[~~substances~~]* 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 physician shall discontinue controlled substance treatment *or[~~and/or~~]* refer the patient to addiction management if *[~~one (1) or more of the following conditions exist~~]*:

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

b. Controlled substance therapy has produced significant adverse effects; or

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

Section 6. Professional Standards for the Prescribing and Dispensing of Controlled Substances in an Emergency Department. *[~~(1)~~]* In addition to complying with the standards for the

initial prescribing or dispensing of a controlled substance as *established[~~detailed~~]* in Sections *3[~~4~~]* and 7 of this administrative regulation, a physician prescribing or dispensing a controlled substance for a specific medical complaint and related symptoms to a patient in an emergency department *[~~is strongly discouraged and~~]* shall not routinely:

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

(2)[~~(b)~~] Provide *a* replacement *prescription[~~prescriptions~~]* for *a* controlled *substance[~~substances~~]* that *was[~~were~~]* lost, destroyed, or stolen;

(3)[~~(c)~~] Provide *a* replacement *dose[~~doses~~]* of methadone, suboxone, or subutex for *a patient[~~patients~~]* in a treatment program;

(4)[~~(d)~~] Prescribe *a* long-acting or controlled-release controlled *substance[~~substances~~]*, such as OxyContin, fentanyl patches, or methadone or *a* replacement *dose[~~doses~~]* of *that medication[~~such medications~~]*;

(5)[~~(e)~~] Administer Meperidine to the patient; or

(6)[~~(f)~~] Prescribe or dispense more than the minimum amount medically necessary to treat the patient's medical condition until the patient can be seen by *the[~~their~~]* primary treating physician or another physician, with no refills. If the controlled *substance prescription[~~substances prescribing~~]* exceeds seven (7) days in length, the patient record *shall[~~must~~]* justify the amount of *the* controlled *substance[~~substances~~]* prescribed.

Section 7. Professional Standards for the Prescribing and Dispensing of Controlled Substances for the Treatment of Other Conditions. (1) Before initially prescribing or dispensing *a* controlled *substance[~~substances~~]* to *a patient[~~patients~~]* for *a condition[~~conditions~~]* other than pain, the physician 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*[~~, for all medical complaints other than psychiatric conditions,~~]* and document the information in the patient's medical record*; or*

2. If the complaint relates to a psychiatric condition,[~~. Psychiatrists or other designated mental health providers shall~~] 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[~~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 or dispensing *a* controlled *substance[~~substances~~]* to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled *substance[~~substances~~]* in the amount specified;

(d) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of *a* controlled *substance[~~substances~~]* needed to treat the specific medical complaint;

(e) Explain to the patient that *a* controlled *substance[~~substances~~]* used to treat an acute medical complaint *is[~~are~~]* for time-limited use, and that the patient should discontinue the use of *a* controlled *substance[~~substances~~]* 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[~~substances~~]*.

(2) If the physician continues to prescribe or dispense *a* controlled *substance[~~substances~~]* to

a patient for the same medical complaint and related symptoms, the physician 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[~~substances~~]*.

(3) *If[~~When~~]* a physician receives a request from an established patient to prescribe or dispense a limited amount of *a* controlled *substance[~~substances~~]* to assist the patient in responding to the anxiety or depression resulting from a nonrecurring single episode or event, the physician 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 or dispense the controlled *substance[~~substances~~]* 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 prescribe or dispense the controlled substance,* prescribe or dispense the minimum amount of *the* controlled *substance[~~substances~~]* to appropriately treat the situational anxiety or depression.

Section 8. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) *A physician[~~Physicians~~]* prescribing or dispensing *a* controlled *substance[~~substances~~]* shall take appropriate steps to educate *a patient[~~patients~~]* receiving *a* controlled *substance[~~substances~~]*.

(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov*[~~, and are incorporated by reference into this administrative regulation~~]*.

Section 9. *Additional Standards for Prescribing or Dispensing Schedule II Controlled Substances or Schedule III Controlled Substances Containing Hydrocodone. (1) In addition to the other standards established in this administrative regulation, prior to the initial prescribing or dispensing of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a physician shall:*

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

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

(d) Discuss the risks 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

(e) Obtain written consent for the treatment.

(2)(a) In addition to the other standards established in this administrative regulation, a physician prescribing or dispensing additional amounts of a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;

2. Provide to the patient any new information about the treatment; and

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the physician shall:

1. Query KASPER no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

(3) To the extent not already required by the standards established in this administrative regulation, for each patient for whom a physician prescribes or dispenses a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, the physician shall keep accurate, readily accessible, and complete medical records which 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.

(4) The additional standards for prescribing or dispensing a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone established in this section shall not apply to:

(a) A physician prescribing or administering that controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or delivery and the medication usage does not extend beyond the fourteen (14) days; or

(b) A physician prescribing or dispensing that controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a physician in those hospitals or facilities if no institutional account exists, queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query, within twelve (12) hours of the patient's or resident's admission, and places a copy of the query in the patient's or resident's medical records for use during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

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

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

b. Cancels any refills for the initial prescription; and

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

6. 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; or

7. 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.

Section 10. **Violations. (1) Any violation of the professional standards established in this administrative regulation** *[~~or in KRS 218A.172~~]* **shall constitute a violation of KRS 311.595(12) and (9), which may result in the imposition of disciplinary sanctions by the board, pursuant to KRS 311.595.**

(2) Each violation of the professional standards established in this administrative regulation *[~~or in KRS 218A.172~~]* 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.[~~The professional standards established in this administrative regulation shall not apply to physicians prescribing or dispensing controlled substances:~~

~~(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, during and as part of a normal and expected part of the patient's course of admission at that hospital;~~

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

~~(d) To a patient who is a registered resident of a skilled long-term care facility; or~~

~~(e) As a direct part of their professional responsibilities in an emergency department and in accordance with the professional standards established in Section 5 of this administrative regulation.~~

~~(2) These exceptions do not apply to the standards established in KRS 218A.172.~~

~~Section 2. Professional Standards for Initial Prescribing or Dispensing of Controlled Substances. Prior to the initial prescribing or dispensing of any controlled substance for a specific medical complaint and related symptoms, each physician shall:~~

~~(a) Verify the identity of the patient by a current and valid government-issued photographic identification. If the physician does not have a copy of that identification in the patient's medical record, that physician shall ensure that the identification is copied and placed in the patient's medical record for future reference;~~

~~(b) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and conduct a physical examination of the patient relevant to the medical complaint and related symptoms, for all medical complaints other than psychiatric conditions, and document the information in the patient's medical record;~~

~~(c) Obtain and review a KASPER report for all available data on the patient, document relevant information in the patient's record and consider the available information to determine whether it is medically appropriate and safe to prescribe or dispense controlled substances. This requirement to obtain and review a KASPER report shall not apply to:~~

~~1. A physician prescribing or dispensing controlled substances to a patient, who is younger than eighteen (18) years of age at the time of prescribing or dispensing, for the treatment of Attention Deficit Hyperactive Disorder or Attention Deficit Disorder; or,~~

~~2. A physician prescribing or dispensing Schedule IV or V controlled substances other than those listed in this specific subsection. The physician shall obtain and review a KASPER report before initially prescribing or dispensing any of the following Schedule IV controlled substances:~~

~~(a) Ambien;~~
~~(b) Anorexics;~~
~~(c) Ativan;~~
~~(d) Klonopin;~~
~~(e) Librium;~~
~~(f) Nubain;~~
~~(g) Oxazepam;~~
~~(h) Phentermine;~~
~~(i) Soma;~~
~~(j) Stadol;~~
~~(k) Stadol NS;~~
~~(l) Tramadol;~~
~~(m) Valium;~~
~~(n) Versed; and~~
~~(o) Xanax; or~~

3. A physician who is unable to obtain and review a KASPER report in a timely manner for reasons beyond the physician's control determines, upon the available facts, that it is medically appropriate to prescribe controlled substances in the absence of a KASPER report. For this exception, the physician shall document as soon as possible the circumstances that made it impossible to obtain and review a KASPER report before prescribing and the reason(s) the physician determined it was medically appropriate to prescribe controlled substances in the absence of KASPER information.

(d) After examining the benefits and risks of prescribing or dispensing controlled substances to the patient, including non-treatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substances in the amount specified. When the identified risks are significant or unique, the physician shall document in the patient's record the reasoning underlying the decision to prescribe or dispense controlled substances in spite of those risks;

(f) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of controlled substances needed to treat the specific medical complaint, for a definite, pre-determined time period;

(g) Not prescribe or dispense long-acting or controlled-release opioids (e.g. OxyContin, fentanyl patches, and methadone) for acute pain;

(h) Explain to the patient that controlled substances used to treat an acute medical complaint are for time-limited use, and that the patient should discontinue the use of controlled substances when the condition requiring the controlled substance use has resolved;

(i) Explain to the patient how to safely and properly dispose of any unused controlled substances.

Section 3. Professional Standards to Commence the Long-Term Use of Any Controlled Substance. Before a physician continues to prescribe or dispense any controlled substance to a patient for a medical complaint or its associated symptoms for a total period of longer than three (3) months, the physician shall comply with the following mandatory professional standards:

Patient History. (1) The physician shall obtain the following information from the patient and record all relevant information in the patient's medical record in a legible manner, in sufficient detail to provide for meaningful diagnosis and treatment of the patient, or to allow for another practitioner to assume the medical care of the patient at any given time in a safe and medically appropriate manner:

(a) History of present illness, including each of its components;

(b) Past medical history, including past diagnostic efforts and treatments for the present medical complaint and other medical complaints;

(c) History of legal or illegal substance use by the patient and by first degree relatives of patient, including treatments for abuse or dependence;

(d) Past family history of illnesses and treatment relevant to the medical complaint and related symptoms; and,

(e) Psychosocial history.

(2) If a physician's practice utilizes a patient questionnaire as a primary source of obtaining such information, the physician shall ensure that:

(a) All questions are completely answered;

(b) Any material conflict in the answers is clarified with the patient;

(c) Complete information is obtained regarding any significant disclosure; and,

(d) All relevant information is incorporated into the patient's record and utilized in the development of the working diagnosis.

Physical Evaluations and Assessments. (1) The physician shall conduct a comprehensive physical examination of the patient for all medical conditions and related symptoms, other than psychiatric conditions, and properly document the findings of each evaluation or assessment in the patient's record, including but not limited to:

(a) Appropriate clinical examination addressing the medical complaint and related symptoms

~~of a sufficient degree to support the medical indications for prescribing or dispensing controlled substances on a long-term basis;~~

~~(b) Measurable examinations that will establish baselines and will assist in establishing and periodically evaluating the functional goals of any treatment plan.~~

~~(4) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall arrange for such evaluation as quickly as possible in order to be able to incorporate the findings into the working diagnosis and treatment plan. The physician shall document the relevant information obtained from the evaluation. If the physician determines that such an evaluation is necessary and the patient declines or fails to complete the evaluations in a timely manner for any reason, then the physician shall not continue the use of controlled substances unless the physician determines that continued use of controlled substances is safe and medically appropriate in the absence of such information. In that event, the physician shall document the reasons that the patient failed to complete the evaluation and the reasoning supporting the continued use of controlled substances in the absence of that relevant information;~~

~~Obtaining Medical Records from Other Practitioners. (1) If the physician 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 of controlled substances, the physician shall request a copy of the other physician's records regarding the patient as quickly as possible, in order to incorporate such information into the working diagnosis and treatment plan;~~

~~(2) If the physician has requested a copy of the other physician's records and has not received them within a reasonable time, the physician will take appropriate steps to follow up and obtain such records. If the physician is unable, after reasonable attempts, to obtain the relevant records, the physician shall document the efforts made to obtain the records, the failure to receive the records, and the impact the inability to obtain such records has upon the physician's decision whether to continue or modify treatment, particularly the use of controlled substances, for that patient;~~

~~(3) Each physician, who receives a written request from another physician for a copy of records relating to that physician's prior treatment of a specific patient, shall promptly provide a copy of the patient's medical record to the requesting physician.~~

~~Establishing a Working Diagnosis. (1) Based upon consideration of all information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms. It is not sufficient to simply describe or list the related symptoms;~~

~~(2) If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician shall consider the usefulness of additional information, such as specialized evaluations or assessments, referral to appropriate specialists, usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis;~~

~~(3) If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician must determine whether long term use of controlled substances is indicated and appropriate. The physician may determine that a different or lower level of treatment is more appropriate until a working diagnosis can be established;~~

~~(4) The physician shall document the working diagnosis or all of the efforts taken in their unsuccessful attempt to formulate a working diagnosis and the reasons for their decision whether or not to utilize controlled substances on a long-term basis in the absence of a working diagnosis.~~

~~Formulating a Treatment Plan. (1) The physician shall formulate and document in the patient's medical record the proposed treatment plan, based upon the working diagnosis of the medical complaint and related symptoms, along with relevant baseline information obtained in the evaluation of the patient;~~

~~(2) The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations, which will permit the physician to assess whether a treatment is ap-~~

~~propriately addressing the medical complaint and improving the patient's functional abilities. Statements such as "treat [medical] condition and related symptoms", "to make patient feel better," or "prescribe controlled substances" are not sufficient treatment goals. The treatment plan shall include an exit strategy for the termination of use of any treatment modality, including controlled substances, for appropriate reasons;~~

~~Patient Screening. (1) The physician shall utilize appropriate screening tools to screen each patient to determine if the patient:~~

~~(a) Is presently suffering from abuse or dependence of any substance, including alcohol;~~

~~(b) Is presently suffering from a psychiatric or psychological condition that requires treatment or that may impact the patient's treatment with controlled substances; or~~

~~(c) Presents a significant risk for illegal diversion of controlled substances, based upon information, gained by obtaining and reviewing a current KASPER report for all available data on that patient, that the patient has obtained controlled substances from multiple practitioners or has refilled prescriptions for controlled substances inappropriately.~~

~~(2) If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, the physician shall refer the patient to an appropriate treatment program or provider, or to an addiction specialist. If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from a qualifying psychiatric or psychological condition, the physician shall refer the patient for a psychological or psychiatric consultation, if appropriate. After making such referral, the physician shall consider the recommendations of the treatment program or specialist, before determining whether to continue with the long-term use of controlled substances with that patient, and, if so, appropriate treatment measures and monitoring. The physician shall document all relevant information about the screen, the referral, the recommendations, and any resulting prescribing decisions in the patient's medical record;~~

~~(3) If, after screening, the physician determines that there is a significant likelihood that the patient may illegally divert controlled substances, the physician must determine whether the use of a "prescribing agreement" would be sufficient to prevent diversion. This determination necessarily requires the physician to determine whether they have the professional resources to conduct necessary monitoring of the patient's controlled substance use. The terms of a "prescribing agreement" shall include, but not be limited to the patient's agreement to:~~

~~(a) Avoid improper use of controlled substances;~~

~~(b) Identify other licensed professionals providing medical care to the patient and authorize the physician to communicate with these other providers to coordinate care, particularly prescribing or dispensing of controlled substances;~~

~~(c) Only obtain controlled substances from the designated physician;~~

~~(d) Only fill controlled substances prescriptions at an approved pharmacy;~~

~~(e) Submit to urine drug screens or pill counts on request;~~

~~(f) Not seek early refills or call-in prescriptions of controlled substances;~~

~~(g) To produce an official police report for any effort to replace controlled substances that were lost or stolen;~~

~~(h) If necessary, submit to third-party administration of controlled substances prescribed if determined appropriate.~~

~~In order to avoid confusion and for the benefit of both parties, the physician shall consider including in the agreement the consequences for a violation of each provision. The "prescribing agreement" and informed consent document may be combined into one document.~~

~~(4) The physician shall obtain and document a baseline urine drug screen to determine whether the medications that are being prescribed are in the patient's system and to determine whether any un-prescribed or illegal controlled substances are in the patient's system.~~

~~(5) If, after screening, the physician determines that the controlled substances prescribed to the patient will be used or are likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe controlled substances to that patient;~~

~~Obtaining Informed Consent. (1) The physician shall explain the risks and benefits of long term use of controlled substances and obtain informed consent from the patient for such prescribing. The decision to provide controlled substances to a patient on a long-term basis should be a deliberate and conscious decision by both the physician and the patient, after full consideration of the risks and benefits of such treatment;~~

~~(2) After explaining the risks and benefits of long-term use of controlled substances, the physician shall obtain the informed consent of the patient, in a writing that specifically sets out each risk and benefit discussed with the patient, and shall include and maintain that written informed consent in the patient's medical record. The informed consent document and any "prescribing agreement" may be combined into one document.~~

~~Initial Trial of Other Treatments; Titration. (1) Controlled substances shall only be utilized on a long-term basis after other appropriate non-controlled therapies have been attempted and have proven unsuccessful in appropriately treating the medical complaint and related symptoms. If controlled substances are utilized on a long-term basis, the physician shall prescribe or dispense controlled substances at the lowest level and for the shortest duration necessary to appropriately treat the medical complaint and related symptoms;~~

~~(2) The physician shall initially attempt, to the extent possible, or to establish and document a previous attempt by another physician, in increasing order, the following steps to treat the medical complaint and related symptoms:~~

~~(a) Use of physical therapy modalities alone or use of non-steroidal anti-inflammatory medication alone;~~

~~(b) Use of physical therapy modalities in conjunction with non-steroidal anti-inflammatory medication;~~

~~(c) Use of lowest level of controlled substances considered effective to treat the medical complaint and related symptoms, as part of an opioid trial; and,~~

~~(d) Titration of levels of controlled substances in measured steps until the level of controlled substances adequately treats the medical complaint and related symptoms.~~

~~Section 4. Professional Standards for Long-Term Prescribing or Dispensing of Controlled Substances. If a physician continues to prescribe or dispense controlled substances beyond three (3) months for a specific medical complaint and related symptoms, the physician shall comply with the following mandatory professional standards:~~

~~Patient Visits. (1) The physician shall personally see the patient at least once a month initially for evaluation and review of progress. The physician may see the patient less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:~~

~~(a) The controlled substances prescribed or dispensed have been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;~~

~~(b) The controlled substances prescribed or dispensed are not causing harmful side effect; and,~~

~~(c) There is sufficient monitoring in place to ensure that the patient will not use the controlled substances in an improper or inappropriate manner or divert them for an improper or inappropriate use.~~

~~(2) At each patient visit, the physician shall obtain a current history from the patient, shall conduct a focused physical examination, and shall perform appropriate measurable examinations as indicated in the treatment plan. The physician shall document all relevant information into the patient's medical record;~~

~~(3) At each patient visit, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained during that encounter to determine whether there has been functional improvement or any change in baseline measures. If appropriate, the physician shall modify the diagnosis or treatment plan, or both, as appropriate. The reasons for any modification shall be documented in the patient's medical record.~~

~~Reviewing Functional Goals; Specialty Consultations. (1) The physician shall regularly review~~

and determine whether the patient is exhibiting improved function, by meeting treatment goals jointly set, and is responding favorably to the medical treatment, including controlled substance therapy;

(2) For patients presenting a significant risk of diversion or improper use of controlled substances, the physician shall obtain the patient's consent to discuss the patient's treatment with independent sources, including family members, in order to verify:

(a) The patient's progress toward or achievement of treatment goals; and,

(b) The patient's use of controlled substances and any side effects of that use, through independent sources;

(3) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with controlled substances, the physician shall obtain consultative assistance to determine whether there are undiagnosed conditions that must be addressed to resolve the medical complaint, such as psychiatry, neurology, internal medicine, physical medicine and rehabilitation, orthopedics, addiction medicine, rheumatology, or oncology;

(4) For patients exhibiting symptoms suggestive of mood, anxiety and/or psychotic disorders, the physician shall obtain psychiatric or psychological consultations for intervention if such condition is affecting treatment;

Managing Breakthrough Pain. (1) If a patient reports that they are experiencing episodes of "breakthrough" pain, the physician shall:

(a) Attempt to identify the trigger or triggers for such episodes;

(b) Determine whether the breakthrough pain may be adequately treated through non-controlled treatment;

(c) If the episodes continue and the non-medication treatments do not adequately address the triggers, and after considering the risks and benefits, the physician determines to add an as-needed controlled substance to the regimen, the physician must take appropriate steps to minimize the improper or illegal use of the additional controlled substances by prescribing or dispensing only the amount of controlled substances needed to treat the specific medical complaint, for a definite, pre-determined time period. The physician shall also include appropriate monitoring of the additional controlled substance;

Preventive Medicine. (1) At least once a year, the physician shall perform or shall ensure that the patient's primary treating physician performs preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition. The physician shall ensure that the patient is provided treatment appropriate to the findings and results of such screening. The physician shall document in the patient's medical record the annual preventive health screening performed or the results of the screening performed by the primary treating physician, the findings and results, and the treatment provided, if any;

Periodic KASPER Reviews and Monitoring Adherance. (1) At least once every three months, the physician shall obtain and review a current KASPER report to ensure that the patient is properly filling the prescriptions issued and that the patient is not obtaining controlled substances from other practitioners without the physician's knowledge and approval;

(2) If, at any time while the physician is prescribing or dispensing controlled substances to a patient, the physician obtains or receives specific information that the patient is not taking the controlled substances as directed, is diverting controlled substances, or is engaged in any improper or illegal use of controlled substances, the physician shall immediately obtain and review a KASPER report for the purposes specified in subsection (1), supra;

(3) If a KASPER report discloses that the patient is not filling the controlled substance prescriptions as directed or is obtaining controlled substances from other practitioners without the prescribing physician's knowledge and approval, the physician shall immediately address those issues with the patient. The physician shall not prescribe or dispense any more controlled substances unless the physician has addressed the issues with the patient and has determined that it is medically appropriate and safe to continue prescribing or dispensing controlled substances to the patient;

(4) If a KASPER report discloses that the patient is obtaining controlled substances from oth-

er practitioners without the physician's knowledge and approval, the physician shall promptly notify the appropriate law enforcement agency and the other practitioners of the relevant information from the KASPER review;

(5) The physician shall document in the patient's medical record each time a KASPER review is performed, information obtained; and, if applicable, the patient's account of any irregularities noted in the review; and, the physician's determination of what actually occurred;

(6) If the physician should determine that it is medically appropriate and safe to continue or resume prescribing or dispensing controlled substances to the patient after assessing their failure to fill prescriptions as directed or their obtaining controlled substances from other practitioners without the prescribing physician's knowledge and approval, the physician shall fully document in the patient's medical record the physician's rationale for resuming such prescribing or dispensing, to include an analysis of the risks and benefits of that decision, along with the increased monitoring or oversight measures being put into place to ensure controlled substances are not illegally diverted or used;

(7) The physician shall obtain consultative assistance from a specialist when appropriate.

Random Pill Counts. (1) When appropriate, the physician shall conduct unannounced random pill counts to determine whether the patient is taking the controlled substances as directed;

(2) If the physician discovers irregularity in the pill count, the physician shall immediately address those findings with the patient. The physician must use all available information, including a discussion with the patient, to determine whether the patient is illegally diverting controlled substances;

(3) If the physician determines that the patient has diverted controlled substances, the physician should immediately discontinue the prescribing or dispensing of controlled substances to that patient, if medically feasible. If it is not medically feasible to immediately discontinue the prescribing or dispensing of controlled substances, the physician shall immediately begin a tapering process to safely discontinue prescribing or dispensing controlled substances, after putting in place specific protections that will ensure that no further diversion occurs, such as requiring storage and administration of the controlled substances to the patient by a person designated by the physician, with additional random pill counts;

(4) The physician shall fully document the results of each pill count conducted, the physician's determination of the reasons for any shortage, and the physician's decisions regarding continued treatment, in the patient's medical record.

Urine Drug Screens. (1) During the course of long-term prescribing or dispensing of controlled substances, the physician shall utilize urine drug screens in a random manner at appropriate times to determine whether the patient is taking prescribed medications or taking illegal substances or medications not prescribed by the physician.

(2) If the patient tested negative for controlled substances prescribed or dispensed by the physician and confirmatory testing substantiates a "red flag," the physician shall do one of the following:

(a) Do a controlled taper;

(b) Stop prescribing or dispensing controlled substances immediately; or,

(c) Refer the patient to an addiction specialist or drug treatment program, depending upon the circumstances.

(3) The physician shall discontinue controlled substance treatment and/or refer the patient to addiction management if one or more of the following conditions exist:

(a) There has been no improvement in function and response to the medical complaint and related symptoms;

(b) Controlled substance therapy has produced significant adverse effects; and/or

(c) The patient exhibits drug-seeking behavior or diversion.

Section 5. Professional Standards for Prescribing or Dispensing Controlled Substances in an Emergency Department Setting. The following professional standards apply to physicians who prescribe or dispense controlled substances in an emergency department setting:

~~(1) Before prescribing or dispensing a controlled substance in an emergency department setting, the physician shall:~~

~~(a) Obtain an appropriate medical history relevant to the medical complaint and 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;~~

~~(b) Obtain and review a KASPER report for all available data on the patient, document relevant information in the patient's record, and consider the available information to determine whether it is medically appropriate and safe to prescribe or dispense controlled substances. If the physician cannot obtain a KASPER report for review in sufficient time to make the determination whether to prescribe or dispense controlled substances, the physician shall not prescribe or dispense controlled substances unless demonstrated and documented in the patient's medical record that the medical necessity for and safety in prescribing or dispensing the controlled substance substantially outweigh the risk of unlawful use or diversion of the controlled substances, particularly considering the nature and severity of the patient's presenting complaint;~~

~~(c) After examining the benefits and risks of prescribing or dispensing controlled substances to the patient, including non-treatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substances in the amount specified, and document that decision in the patient's record and, if appropriate, the reasoning underlying that decision.~~

~~(2) The physician is strongly discouraged from and shall not routinely:~~

~~(a) Administer intravenous and/or intramuscular controlled substances for the relief of acute exacerbations of chronic pain;~~

~~(b) Provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen;~~

~~(c) Provide replacement doses of methadone, suboxone, or subutex for patients in a treatment program;~~

~~(d) Prescribe long-acting or controlled-release controlled substances, such as OxyContin, fentanyl patches, or methadone or replacement doses of such medications;~~

~~(e) Administer Demerol (Meperadine) to the patient;~~

~~(f) Prescribe or dispense more than a three (3) day supply of controlled substances, with no refills.~~

~~(3) If the physician determines that exceptional circumstances exist which warrant prescribing or dispensing controlled substances in a manner that is strongly discouraged in Section 2(1), supra, the physician shall document in the patient's medical record the exceptional circumstances that warranted such prescribing or dispensing.~~

~~(4) The physician shall ensure that each patient receiving controlled substances by dispensing or prescription is given is informed, by handout or display signage, of the standards established in this regulation regarding the prescribing or dispensing of controlled substances.~~

~~(5) These standards shall not apply or be enforced during periods involving disaster, mass casualties, or extreme emergency.~~

~~Section 6. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician shall document all relevant information in a patient's medical record in a legible manner and in sufficient detail to provide for:~~

~~(a) Meaningful diagnosis and treatment of the patient;~~

~~(b) The safe and medically appropriate assumption of care by another physician at any given time; and,~~

~~(c) This board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards. Such information includes, but is not limited to:~~

~~(a) Medical history and physical examinations;~~

~~(b) Diagnostic and laboratory test results and therapeutic outcomes;~~

~~(c) Evaluations and consultations;~~

~~(d) Records of past treatment outcomes including indicators of benefits, such as functional outcomes, and indicators of risk, such as adverse effects;~~

~~(e) Medications (including date prescribed, type, dosage, strength and quantity);~~

~~(f) Intensity levels of medical complaint and related symptoms;~~

~~(g) Subjective complaints of the patient;~~

~~(h) Objective findings related to subjective complaints, including impact on functioning and quality of life;~~

~~(i) Diagnostic impressions, and potential treatment options;~~

~~(j) Treatment objectives;~~

~~(k) Discussion of risks and benefits;~~

~~(l) Informed consent;~~

~~(m) Instructions and agreements; and~~

~~(n) Periodic review of treatments, including adverse effects, functional goals, and any other outcomes that reflect benefits or problems with the treatment.~~

~~(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances, to the professional standards established by KRS 218A.172, or to other professional standards, due to circumstances beyond their control, the physician shall appropriately document such circumstances and the physician's response to the inability to conform to the specific standards and the impact upon the continuing care of the patient.~~

~~Section 7. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) It is the acceptable and prevailing medical practice within the Commonwealth of Kentucky for physicians prescribing or dispensing controlled substances to educate patients receiving controlled substances about the following subjects through verbal or written counseling:~~

~~(a) Proper use;~~

~~(b) Impact upon driving and work safety;~~

~~(c) Effect of use during pregnancy;~~

~~(d) Potential for overdose and appropriate response to overdose;~~

~~(e) Safe storage of controlled substances;~~

~~(f) Proper disposal;~~

~~(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov, and are incorporated by reference into this provision.~~

~~Section 8. Violations. (1) Any violation of the professional standards established in this regulation or in KRS 218A.172 shall constitute a violation of KRS 311.595(12) and (9), which may result in the imposition of disciplinary sanctions pursuant to KRS 311.595;~~

~~(2) Each violation of the professional standards established in this regulation or in 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 reports.~~]