Summary of Controlled Substance Regulations

The following is a summary of certain portions of the Kentucky Board of Medical Licensure's revised controlled substance regulations and the Cabinet for Health and Family Services, Office of Inspector General's KASPER regulation, which went into effect on March 4, 2013. A link to the revised regulations can be found on the KBML's website and the OIG's website, respectively. Physicians must also review the regulations themselves, as this summary is not comprehensive nor intended to take the place of reading the regulations. The information in this summary should not be considered legal advice or a legal opinion. For specific legal advice, please consult an attorney familiar with such issues.

KBML CONTROLLED SUBSTANCE REGULATION
201 KAR 9:220 [as amended]

RESTRICTION ON DISPENSING SCHEDULE II CONTROLLED SUBSTANCES AND SCHEDULE III CONTROLLED SUBSTANCES CONTAINING HYDROCODONE

Physicians shall not dispense more than a 48 hour supply of any Schedule II Controlled Substance or Schedule III Controlled Substance containing Hydrocodone unless the dispensing is done as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services ("Cabinet"). This restriction must not be avoided by dispensing such medications to a patient on consecutive or multiple occasions. Violation of this restriction shall constitute a violation of the Medical Practices Act and shall constitute a legal basis for disciplinary action.

KBML CONTROLLED SUBSTANCE REGULATION
201 KAR 9:260 [as amended]

GENERAL DOCUMENTATION REQUIREMENTS

Physicians prescribing or dispensing any controlled substance(s) must document all relevant information in the patient's medical record in a legible manner and in sufficient detail. If physicians are unable to conform to the prescribing and dispensing standards found in the KBML controlled substance regulations or any other professional standards due to reasons beyond their control, or based upon the physician's professional determination that it is not appropriate to comply with a specific standard, physicians shall only prescribe or dispense controlled substances after documenting the justification for non-conformance in the patient's record.

PATIENT EDUCATION REQUIREMENTS

Physicians must educate patients receiving controlled substances about the dangers of controlled substance use. Educational materials relating to such dangers can be found at www.kbml.ky.gov.

EXCEPTIONS TO THE FOLLOWING REQUIREMENTS

The professional standards for prescribing and dispensing controlled substances established in the KBML regulations (summarized in the following pages) do not apply to physicians prescribing or dispensing any controlled substance:

1. To a patient as part of the patient's hospice or end-of-life treatment;
2. To a patient for the treatment of pain associated with cancer or with the treatment of cancer;
3. 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. To be exempt for the prescribing or dispensing of Schedule II Controlled Substances and Schedule III Controlled Substances containing Hydrocodone in this situation, the hospital must query KASPER within 12 hours of admission and place a copy of the KASPER report in the patient's chart (practitioner must do this if no institutional account exists);
4. To a patient who is a registered resident of a long-term-care facility as defined in KRS 216.510. To be exempt for the prescribing or dispensing of Schedule II Controlled Substances and Schedule III Controlled Substances containing Hydrocodone in this situation, the long-term care facility must query KASPER within 12 hours of admission and place a copy of the KASPER report in the resident's chart (practitioner must do this if no institutional account exists);
5. During any period of disaster or mass casualties which has a direct impact upon the physician's practice;
6. 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
7. That has been classified as a Schedule V controlled substance.

Physicians are further exempt from the prescribing and dispensing standards established by the KBML regulations for Schedule II Controlled Substances and Schedule III Controlled Substances containing Hydrocodone in the following additional situations:

1. Prescribing or administering no more than a 14-day supply to a patient following an operative or invasive procedure or delivery;
2. 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;
3. Prescribing or dispensing to the same patient for the same condition by a partner in a practice with the initial prescriber (or other coverage arrangement) within 90 days of the initial prescription;
4. Prescribing or dispensing to a research subject enrolled in an IRB-approved single, double or triple blind drug study, or a study that is otherwise covered by National Institutes of Health certificate of confidentiality.

MANDATORY PRESCRIBING AND DISPENSING STANDARDS

Unless an exception applies (see page 2), a physician who is authorized to prescribe or dispense a controlled substance must comply with the prescribing and dispensing standards established in the KBML controlled substance regulation and summarized as follows:

Section 3: Initial Prescribing or Dispensing of Controlled Substances for Treatment of Pain and Related Symptoms Associated with Pain as a Primary Medical Complaint	Section 4: Commencement of Long Term Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with Pain as a Primary Medical Complaint	Section 5: Continuation of Long Term Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with Pain as a Primary Medical Complaint	Section 6: Emergency Department Standards	Section 7: Treatment of Other Conditions Not Addressed in Other Sections
Prior to the initial prescribing or dispensing of a controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician shall: 1. Obtain an appropriate medical history and conduct a physical exam (or for psychiatric conditions, other appropriate evaluation by a psychiatrist or other mental health worker) 2. Obtain and review KASPER report for previous 12 month period 3. Make a deliberate decision to prescribe or dispense that is medically appropriate 4. Not prescribe or dispense	***Before commencing long term treatment (3 months or longer) with controlled substances for pain and related symptoms with a patient sixteen (16) years or older, the physician shall:*** 1. Obtain history of present illness, past medical history, history of substance use and any prior treatment for such use, history of substance abuse by first degree relatives of patient, past family history of relevant illnesses and treatment, and psychosocial history 2. Perform an appropriate physical exam 3. Establish appropriate baseline assessments to evaluate progress over time 4. If a specific or specialized evaluation is necessary for the	***If the physician continues to prescribe or dispense controlled 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:*** 1. Evaluate the patient monthly, initially, until it is determined that the controlled substance is appropriately titrated, is not causing unacceptable side effects, and sufficient monitoring is in place to minimize the likelihood of improper use or diversion 2. Update H&P at appropriate intervals and perform measurable examinations and document in the record	***In addition to complying with Sections 3 and 7, a physician prescribing or dispensing a controlled substance for a specific medical complaint and related symptoms to a patient in an Emergency Department shall not routinely:*** 1. Administer an IV controlled substance for the relief of acute exacerbations of chronic pain, unless IV is the only medically appropriate means of delivery available 2. Provide replacement prescriptions for those	***Prior to initial prescription of any controlled substance for conditions other than pain, the physician shall:*** 1. Obtain an appropriate medical history and conduct physical exam (or for psychiatric conditions, other appropriate evaluation by a psychiatrist or other mental health provider) 2. Obtain and review KASPER report for previous 12 month period 3. Make a deliberate decision to prescribe or dispense that is medically appropriate 4. Do not prescribe or dispense more than is medically necessary to treat the specific complaint

long-acting or controlled-release controlled substances for acute pain not directly related to or close in time to surgery 5. Explain to the patient that the medication is being prescribed to treat an acute medical complaint for time-limited use, to discontinue the medicine when the condition has resolved, and how to safely/properly dispose of the medicine ***For Schedule II Controlled Substances and Schedule III Controlled Substances with Hydrocodone, the physician must also:*** 6. Make a written plan stating the objectives of the treatment and further diagnostic examinations required 7. Discuss the risks and benefits of controlled substances use with the patient 8. Obtain written consent for the treatment from the patient	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 5. Obtain medical records of other providers if needed to justify the long-term prescribing of controlled substance 6. Formulate and document a working diagnosis. If unable to do so, consider whether referral to specialist is appropriate and if still unable to formulate a working diagnosis despite the use of appropriate specialized evaluations or assessments, the physician shall only provide long-term use of controlled substances after establishing that such use at a specific level is medically indicated and appropriate 7. Document a treatment plan which includes specific goals of treatment and a schedule of evaluations 8. Utilize appropriate screening tools to screen each patient to determine if presently suffering from another medical condition which may impact the prescribing or dispensing of controlled substances, or presents a significant risk for illegal diversion of controlled substances. If after	3. Evaluate the working diagnosis and treatment plan at appropriate intervals to determine whether patient is exhibiting improved functionality or any change in baseline measures; Physician shall modify the diagnosis, treatment plan, or therapy as appropriate 4. If patient presents a significant risk of diversion or improper use of controlled substance, either discontinue prescribing or justify the continued use in the record 5. If patient exhibits no significant improvement in function despite treatment (and improvement is medically expected), obtain consultative assistance to determine whether there are undiagnosed conditions to be addressed. 6. If patient exhibits mood, anxiety, or psychiatric or psychological symptoms, obtain a psychiatric consult, if appropriate 7. If patient experiences “breakthrough” pain, attempt to identify triggers and determine if the breakthrough pain can be adequately treated with non-controlled	that are lost, destroyed, or stolen 3. Provide replacement doses of methadone, suboxone, or subutex for patients in treatment programs 4. Prescribe long-acting or controlled-release medications, or replacement doses of the same 5. Administer Meperidine 6. Prescribe or dispense more than the minimum amount necessary until the patient can be seen in follow-up by primary treating or other physician, with no refills. If prescribing > 7 day supply, document rationale in the record	5. Explain to the patient that the medication is being used to treat an acute medical complaint for time-limited use, to discontinue the medicine when the condition has resolved, and how to safely/properly dispose of the medicine 6. If the physician continues to prescribe or dispense, the physician shall comply with the accepted and prevailing standards of medical practice for the treatment of that medical complaint and for the use of controlled substances ***For Schedule II Controlled Substances and Schedule III Controlled Substances with Hydrocodone, the physician must also:*** 7. Make a written plan stating the objectives of the treatment and further diagnostic examinations required 8. Discuss the risks and benefits of controlled substances use with the patient 9. Obtain written consent for the treatment from the patient

	screening, the physician determines there is reasonable likelihood that the patient suffers from either substance abuse or a psychiatric or psychological condition, the physician shall take action to facilitate a referral to an appropriate treatment program or provider and incorporate information into evaluation and treatment of patient. If screening indicates a significant risk of illegal diversion, enter into a Prescribing Agreement. 9. Obtain a baseline drug screen. If physician determines that controlled substances 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. 10. Obtain written informed consent from the patient for the use of controlled substances 11. Attempt, establish, or document a previous attempt by another physician of a trial of non-controlled modalities and lower doses of controlled substances in increasing order before continuing with long-term prescribing at a given level ***These standards may be accomplished by different licensed practitioners in a single group practice at the direction of***	substances. If prescribing controlled substances for break-through pain, only prescribe in an amount needed and take appropriate steps to minimize improper/illegal use 8. Ensure the patient receives annual preventive health screening and physical exam 9. KASPER Monitoring: a. Obtain and review a current KASPER report at least once every three months to use in the evaluation and treatment of the patient b. Obtain a KASPER report immediately if the physician obtains information that the patient is not taking prescriptions as directed, is diverting, or is engaged in illegal or improper use of controlled substances c. If KASPER report discloses patient is obtaining controlled substances from other practitioners without the physician's knowledge and approval, in a manner that raises suspicion of illegal diversion, the physician shall notify the other prescribing practitioners 10. Seek consultative assistance from a specialist		10. If the treatment continues beyond 3 months, query KASPER once every 3 months for previous 12 month period and review that data before prescribing or dispensing any new prescription or refills ***Requests from established patients to prescribe or dispense a limited amount of controlled substances to treat a single event/non-recurring episode of anxiety/depression:*** 1. Obtain KASPER report for previous 12 month period 2. Make a deliberate decision to prescribe or dispense that is medically appropriate with or without requiring an in-person evaluation 3. Prescribe or dispense the minimum amount of controlled substances to appropriately treat the situational anxiety or depression

	or on behalf of the prescribing physician so long as: 1. Each practitioner involved has lawful access to the patient's medical record 2. There is compliance with all applicable standards 3. Each practitioner performing an action to meet the required standards is acting within their legal scope of practice	when appropriate 11. Conduct random pill counts when appropriate and use in the evaluation and treatment of the patient 12. Perform random and unannounced drug screens appropriate to the controlled substance and the patient's condition, and if noncompliant: a. do a controlled taper b. stop prescribing or dispensing immediately or c. refer the patient to an addiction specialist, mental health professional, pain managements specialist, or drug treatment program 13. Stop prescribing and refer to addiction management if: a. there is no response or improvement where medically expected b. there are significant adverse effects or c. the patient exhibits inappropriate drug-seeking behavior or diversion ***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 so long as: 1. Each practitioner involved has lawful access to the patient's medical record 2. There is compliance with all applicable standards 3. Each practitioner performing an action to meet the required standards is acting within their legal scope of practice		

VIOLATIONS

Violations by physicians of the professional standards established by the KBML controlled substance regulation shall constitute a violation of KRS 311.595(9) and (12) and may result in disciplinary sanctions by the KBML. Each violation shall be established by the testimony of one or more expert retained by the KMBL.

KBML CONTROLLED SUBSTANCE REGULATION
201 KAR 9:310 [as amended]

CONTINUING MEDICAL EDUCATION REQUIREMENTS

For each three year continuing education cycle beginning on January 1, 2015, a licensee who is authorized to prescribe or dispense controlled substances in Kentucky at any time during that cycle requires:	4.5 hours of approved continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Licensee may satisfy the CME requirement by completing a single approved program or by completing multiple approved programs.
Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky from July 20, 2012 through the end of the three year continuing education cycle beginning January 1, 2012 and ending December 31, 2014 requires:	4.5 hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects. Licensee may satisfy the CME requirement by completing a single approved program or by completing multiple approved programs.
Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky during calendar years 2013 and 2014, but not 2012 requires:	3.0 hours of approved Category I Credit continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects.
Each physician licensed to practice medicine or osteopathy within Kentucky who is authorized to prescribe or dispense controlled substances within Kentucky during calendar year 2014, but not 2012 or 2013 requires:	1.5 hours of approved Category I Credit continuing education hours relating to the use of KASPER, pain management, addiction disorders or a combination of two or more of those subjects.

The KBML will maintain a current listing of approved continuing education programs on its official website – www.kbml.ky.gov.

VIOLATIONS

If the KBML determines that a physician has failed to complete the required CME hours or provide written verification of completion within the time specified, an emergency order restricting the physician from prescribing or dispensing controlled substances can be issued until such time as the physician has completed the CME hours or provided written verification thereof. In addition, each instance of prescribing or dispensing of controlled substances shall constitute a separate violation of the Medical Practices Act and shall constitute a legal basis for disciplinary action.

CHFS OFFICE OF INSPECTOR GENERAL KASPER REGULATION
902 KAR 55:110 [as amended and in relevant part]

DATA REPORTING (who must report to KASPER and when)

A dispenser or a health facility that has a DEA number shall report all dispensed Schedule II, III, IV, or V controlled substances, except during circumstances specified in KRS 218A.202(3)(a) (b) and (c).

Prior to July 1, 2013, the required data shall be transmitted within 7 days of the date of dispensing unless the Cabinet grants an extension.

Prior to July 1, 2013, a dispenser that dispenses a controlled substance for the direct administration of the controlled substance to or for a patient in a licensed health facility shall not be required to report the required data.

Effective July 1, 2013, the required data shall be transmitted no later than close of business on the business day immediately following the dispensing unless the Cabinet grants an extension.

An extension may be granted by the Cabinet if:

1. The dispenser suffers a mechanical or electronic failure; or
2. The dispenser cannot meet the deadline established by the regulation because of reasons beyond his or her control.

To request an extension, a dispenser shall apply to the branch in writing within 24 hours of discovery of the circumstances necessitating the request or on the next date state offices are open for business, following the discovery. An application for an extension shall state the justification for the extension and the period of time for which the extension is necessary.

An extension shall be granted to a dispenser if the Cabinet or its agent is unable to receive electronic reports transmitted by the dispenser.

ERROR RESOLUTION (how to correct errors in KASPER reports)

A patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic who has received a KASPER report as permitted by law or regulation may request that information contained in KASPER be corrected if any of those persons or entities believe that any information is inaccurate. To do so, the person or entity must:

1. Contact the dispenser who reported the information; and
2. Request that the dispenser correct the information.

If the dispenser confirms that the information was reported in error, the dispenser must:

1. Send corrected information to update the KASPER database within 7 days of the request for correction; and

2. Notify the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic that the information has been sent to KASPER for correction.

If the dispenser maintains that the information was correctly reported to KASPER but the KASPER system generates inaccurate information, the dispenser must contact the Drug Enforcement and Professional Practices Branch (DEPPB) to identify the source of the error. The Cabinet shall correct the information in the KASPER database and notify the patient, patient's representative, practitioner, pharmacist, health facility, or private practitioner's office or clinic within 5 working days of the correction.

DISCLOSURE OF DATA OR REPORT

The KASPER statute, KRS 218A.202, provides a list of individuals and entities to whom KASPER data may be provided. That list has been expanded in order to accommodate the concept of an institutional KASPER account for use in hospitals and long-term care facilities. A new subsection (f) allows the Cabinet to also disclose KASPER data to: the chief medical officer of a hospital or long-term care facility, an employee of the hospital or long-term care facility as designated by the chief medical officer and who is working under his or her direction, or a physician designee if the hospital or facility has no chief medical officer, if the officer, employee, or designee certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective patient or resident in the hospital or facility.

Before the Cabinet will provide KASPER data and/or reports as described above, a hospital or long-term care facility must maintain, and provide upon request by the Cabinet, a copy of its policy for the management of KASPER data and/or reports, which must:

1. Describe the internal procedures for educating the designated employee or employees on the proper use of KASPER, the prohibition on the improper use or intentional disclosure of KASPER data to unauthorized individuals, and the sanctions imposed for a violation of such prohibition, which includes criminal misdemeanor offenses; and
2. Describe the internal procedures for auditing the KASPER account, including the manner in which an employee is added or removed from access to the account if such employee ends employment or is no longer designated to query KASPER and the actions taken if an employee intentionally misuses his or her privileges to KASPER data and/or reports, which shall include an incident report to the Office of Inspector General.

A practitioner who obtains KASPER data and/or reports to provide medical treatment to a bona fide current or prospective patient, or who in good faith believes that a person, including a patient, has violated the law in attempting to obtain a prescription for a controlled substance, may report suspected improper or illegal use of a controlled substance to law enforcement or the appropriate licensing board.