

# KENTUCKY

## POLICIES EVALUATED

### Statutes

#### UNIFORM CONTROLLED SUBSTANCES ACT (*No provisions found*)

Title XVIII. Public Health; Chapter 218. Uniform Narcotic Drug Act; Chapter 218A. Controlled Substances

#### MEDICAL PRACTICE ACT

Title XXVI. Occupations and Professions; Chapter 311. Physicians, Osteopaths, and Podiatrists

#### PHARMACY PRACTICE ACT (*No provisions found*)

Title XXVI. Occupations and Professions; Chapter 315. Pharmacists and Pharmacies

#### INTRACTABLE PAIN TREATMENT ACT

*No policy found*

#### PUBLIC HEALTH

Title XVIII. Public Health; Chapter 216. Health Facilities and Services; Suicide Prevention

### Regulations

#### CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)

Title 902. Cabinet for Health Services; Chapter 55. Controlled Substances

#### MEDICAL BOARD REGULATIONS (*No provisions found*)

Title 201. General Government Cabinet; Chapter 9. Board of Medical Licensure

#### PHARMACY BOARD REGULATIONS (*No provisions found*)

Title 201. General Government Cabinet; Chapter 2. Board of Pharmacy

### Other Governmental Policies

#### MEDICAL BOARD GUIDELINE

Kentucky Board of Medical Licensure, KMA Ad Hoc Committee to Study Guidelines for Prescribing Controlled Substances. "Guidelines for Prescribing Controlled Substances." Effective: June 20, 1996.

#### MEDICAL BOARD GUIDELINE

Kentucky Board of Medical Licensure. "Model Guidelines for the Use of Controlled Substances in Pain Treatment." KMA. Vol. 99, July 2001 Effective: March 22, 2001.

# KENTUCKY

## PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

	1	2	3	4	5	6	7	8
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with “addiction”	Other provisions that may enhance pain management
<b>STATUTES</b>								
Controlled Substances Act <sup>1</sup>								
Medical Practice Act <sup>1</sup>								
Pharmacy Practice Act <sup>1</sup>								
Intractable Pain Treatment Act <sup>2</sup>								
Public Health <sup>1</sup>								
<b>REGULATIONS</b>								
Controlled Substances <sup>1</sup>								
Medical Board <sup>1</sup>								
Pharmacy Board <sup>1</sup>								
<b>OTHER GOVERNMENTAL POLICIES</b>								
Medical Board Guideline (1996)						•		
Medical Board Guideline (2001)		•	•	•	•	•	•	•

Note: A dot indicates that one or more provisions were identified

<sup>1</sup> No provisions were found in this policy

<sup>2</sup> No policy found

## KENTUCKY

### PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

	9	10	11	12	13	14	15	16	17
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Perpetuates belief that opioids hasten death	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Practitioners are subject to additional prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
<b>STATUTES</b>									
Controlled Substances Act <sup>1</sup>									
Medical Practice Act									●
Pharmacy Practice Act <sup>1</sup>									
Intractable Pain Treatment Act <sup>2</sup>									
Public Health			●						
<b>REGULATIONS</b>									
Controlled Substances <sup>1</sup>									
Medical Board <sup>1</sup>									
Pharmacy Board <sup>1</sup>									
<b>OTHER GOVERNMENTAL POLICIES</b>									
Medical Board Guideline (1996)	●							●	
Medical Board Guideline (2001)	●								

Note: A dot indicates that one or more provisions were identified

<sup>1</sup> No provisions were found in this policy

<sup>2</sup> No policy found

**STATUTES**  
**Medical Practice Act**

KRS § 311.597

§ 311.597. Acts declared to constitute dishonorable, unethical, or unprofessional conduct

As used in KRS 311.595(9), “dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof” shall include, but not be limited to, the following acts by a licensee:

(1) Prescribes or dispenses any medication:

- 
- 
- 

(d) In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that said amounts so prescribed or dispensed are excessive under accepted and prevailing medical practice standards.

**CRITERION 17:** [-]  
***Provisions that are ambiguous***

*Comment: “Excessive” implies there is a limit, but the limit is not specified.*

**STATUTES**  
**Public Health**

KRS § 216.304

§ 216.304. Actions of licensed health care professional that are not violative of KRS 216.302

(1) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person’s pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, shall not be deemed to have violated KRS 216.302 unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death.

- 
- 
- 

**CRITERION 11:** [-]  
***Perpetuates belief that opioids hasten death***

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline (1996)**

**GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES**

The guidelines outlined below were formulated from various sources and literature. They are offered to assist physicians in safe and appropriate decision making in prescribing controlled substances.

- I. **Diagnosis.** Establish a working diagnosis based on an adequate history, physical examination, and appropriate diagnostic tests.
- II. **Management Plan.** Formulate and document a plan of treatment. Make appropriate referrals if needed for optimum diagnosis and management.
- III. **Eliminate Alternatives.** Before beginning a regimen of controlled drugs, document that other measures and drugs have been inadequate or not tolerated.
- IV. **Be Aware of Drug Seekers.** Learn drug seeking behaviors and obtain personal and family histories of chemical dependency.
- V. **Informed Consent.** Document that patient has acknowledged that he/she has been advised of the risks of the proposed treatment. Family conferences may be helpful to establish ground rules.
- VI. **Monitoring.** Maintain regular monitoring of the patient and his progress. Consider “drug holidays” to monitor compliance and continued need.
- VII. **Control.** Make sure that you are in control of the drug supply. Keep detailed records. Assure that one physician orders the medications and one pharmacy fills all prescriptions. In most cases require the patient to return for refill authorization.
- VIII. **No Self-prescribing.** Physicians should studiously avoid prescribing to self, immediate family, or staff.
- IX. **Anorectic Drugs.** Avoid the use of Schedule III and IV anorectic drugs.
- X. **Muscle Relaxants.** Prescribe muscle relaxants with caution on a chronic basis, particularly those with known addictive potential. Examples include, but are not limited to, carisoprodol (Soma) and diazepam (Valium).
- XI. **Anxiolytic Drugs.** Use as much caution with addictive anxiolytic drugs as with opioid drugs.
- XII. **Common Problems.** Be aware of common problems faced by physicians who come under investigation:
  - (1) Inadequate records/documentation.
  - (2) Failure to document diagnosis (pain is a symptom, not a diagnosis)
  - (3) Prescribing controlled substances without a trial of alternative treatments.
  - (4) Failure to monitor side effects of drugs, and
  - (5) Failure to document rational reason for chronic use of controlled substance.

**A. General Guidelines.** These are simple, general recommendations for the safe and proper use of prescription drugs with abuse potential.<sup>4</sup> “It’s not important what you prescribe but how well you manage the patient’s care and create a record of that care.”

- I. **Diagnosis.** First and foremost before prescribing anything, establish a diagnosis which is supported by adequate history and physical examination and the results of appropriate diagnostic tests. Unfortunately it is often found that a symptom, rather than a diagnosis, is the basis for a given treatment.

(CONTINUED ON NEXT PAGE)

**CRITERION 9:** [-]  
*Opioids are a last resort*

**CRITERION 16:** [-]  
*Other provisions that may impede pain management*

*Comment: “Drug Holidays” are no longer recognized as appropriate medical practice.*

**CRITERION 16:** [-]  
*Other provisions that may impede pain management*

*Comment: Although establishing and documenting a diagnosis is part of ordinary medical practice, this provision may be misunderstood by some healthcare practitioners to mean that it is not legitimate to treat a symptom (i.e., pain).*

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

- II. Management Plan.** Formulate a treatment plan that includes appropriate non-addictive modalities. Make referrals to appropriate specialists, if necessary, to establish the diagnosis and insure that alternative treatment modalities are tried. Include all correspondence and test results in the patient’s chart. One such management plan follows:

  - 1. Determine if patient has had an adequate trial of a non-drug regimen of treatment (Exercise, physical therapy, behavior modification, etc) and if not, initiate such a regimen.
  - 2. Prescribe non-narcotic analgesics, such as NSAIDs, acetaminophen, Midrin, non-habituating muscle relaxants, or Ultram (if still listed as a nonscheduled agent).
  - 3. Prescribe weak opioids (propoxyphene, Talwin, codeine, oxycodone).
  - 4. Prescribe stronger opioids (morphine, Demerol, Dilaudid, etc).
  - 5. Combinations of any of the above may be indicated, even from the beginning.
  
- III. Eliminate Alternatives.** Before beginning a regimen of controlled drugs, make a determination through actual clinical trial or through patient records and history that non-addictive regimens have been inadequate or are unacceptable by comparison, e.g., intolerance or allergy to nonsteroidal anti-inflammatory drugs. The assertion by a patient that a certain narcotic, e.g., Percodan, works well for him/her is not an adequate history of failure of other methods or drugs. Too often physicians who have come under review have instituted treatment with potent opioids apparently without ever considering other forms of treatment. “How much is too much?” is a question often asked. No agency will be able to answer that question specifically. Validity of treatment must be established case by case and by the quality and content of the diagnostic and therapeutic regimens implemented.
  
- IV. Be Aware of Drug Seekers.** Make sure you are not dealing with a drug seeking patient. If the patient is new or otherwise unknown to you, obtain, at a minimum, an oral drug history, and discuss chemical use and family chemical history with the patient. If you have any doubts, you may consider obtaining a chemical dependency evaluation prior to prescribing a potentially addictive substance.
  
- V. Informed Consent.** Before prescribing a potentially addictive drug, assure that the patient has an understanding of the relative risks and benefits of the drug, based on relevant published literature, e.g., PDR, AMA Drug Evaluations, USP DI. It may be beneficial to obtain written informed consent in selected patients. When the possibility of long term use of potentially addictive substances exists, it may be helpful to educate the family to the risks and benefits of the medication. One effective mechanism to accomplish this may be holding a family conference. The refusal of a patient to permit a family conference may be a red flag alerting the physician to potential addictive tendency.
  
- VI. Monitoring.** Maintain regular monitoring of the patient, including regular and frequent updating of the history and physical evaluation. Adequate monitoring may include:

  - 1. History update
    - a. Assessment of compliance
      - (1) Are medications being taken as prescribed?
      - (2) Is patient adhering to/cooperating with alternative non-addicting modalities?
      - (3) Record compliance with time frame (asking for refills before time, “losing” doses of prescriptions, trying to use other physicians or pharmacies).
      - (4) Record when told to return and when refills may be made.
    - b. Document patient’s response to treatment (improved? worse?)
    - c. Document alterations or additions to the management plan.

**CRITERION 6:**      [+]  
*Prescription amount  
alone does not determine  
legitimacy*

(CONTINUED ON NEXT PAGE)

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

2. Physical update
  - a. Vital signs, particularly weight in patients receiving anorectics or narcotics.
  - b. General appearance (does habitus suggest pain, anxiety, depression?).
  - c. Specific signs - pertinent to the individual patient, e.g., improved or decreased range of motion.

**VII. Control.** Make sure that you are in control of the drug supply. To do this, at a minimum keep detailed records of the type, dose and amount of the drug prescribed. **You** must monitor, record, and control all refills. One way to accomplish this is to require the patient to return to obtain prescriptions. Routine call-in of prescription drugs is to be avoided. The physician should keep a chronological drug log of controlled substances, e.g., a flow sheet. Communicate with other treating physicians and the patient's pharmacist. The patient should use one physician and one pharmacy for his/her controlled substance prescriptions. If either changes, the other should be notified.<sup>1</sup>

**VIII. Self-prescribing.** Physicians should avoid prescription of any controlled substance or any drug with addictive potential to self, immediate family, or staff. No prohibitive laws to that effect exist, as far as the committee is aware. However the recommendation is offered to prevent any appearance of impropriety.<sup>2</sup>

**IX. Anorectic Drugs.** Avoid the use of Schedule III and IV anorectic drugs. If the mechanism is in place to adequately assess, monitor, and control the short term use of anorectics and physicians wish to enter that therapeutic arena, then the following criteria should be followed.<sup>3</sup>

1. Prior to initially prescribing any Schedule III or IV anorectic:
  - (a) Obtain a thorough medical and weight loss or gain history;
  - (b) Perform a complete physical examination;
  - (c) Determine that the patient is a medically obese adult;
  - (d) Require the patient to make a substantial good faith effort at weight reduction, under the physician's supervision, without utilizing drugs;
  - (e) Provide the patient with a carefully prescribed diet, together with counseling on exercise, nutrition, an other appropriate supportive therapy.
2. To appropriately prescribe anorectics the physician should:
  - (a) Ask the patient whether he/she has currently or previously obtained or used anorectics from one or more practitioners, and record the answer.
  - (b) Ascertain whether the patient has a history or potential of abuse of drugs, including alcohol.
  - (c) Rule out conditions contradicting the use of anorectics, including but not limited to pregnancy, hypertension, or hypersensitivity or idiosyncrasy to the drugs.
  - (d) Advise the patient of the drug's potential for abuse, and the possibility of leading to dependence.
  - (e) Consider the possibility that the patient will obtain the drug for a nontherapeutic use or distribution to others, and that there is an illicit market for such drugs.
3. A physician should not normally prescribe a Schedule III or IV anorectic drug to any patient:
  - (a) In a daily dosage greater than the maximum FDA approved dosage recommendation; or
  - (b) For an aggregate period in excess of 120 days during any 12 month period.

(CONTINUED ON NEXT PAGE)

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

4. A physician should not institute or continue the prescription of Schedule III or IV anorectic drugs if:
- (a) The patient is not a proper candidate for the use of anorectics;
  - (b) The patient has developed tolerance to the appetite suppressant effect of the drug or has experienced euphoria followed by irritability or depression; or
  - (c) The patient has engaged in excessive use, misuse, or abuse of the anorectic, or has otherwise consumed or disposed of the drug(s) other than in strict compliance with the directions and indications for use given by the physician.

It should be noted that lay literature has been disseminating misinformation about certain anorectics. Touting them as “new” and not having abuse problems, phentermine and fenfluramine have been presented to the public by various publications. Standard pharmacy and medical reference works<sup>1 2</sup> identify them along with the rest of the following as having marked abuse potential:

Amphetamines and their derivatives  
Dextroamphetamine and d. sulfate  
(Dexedrine, Biphetamine) **Cii**  
Phendimetrazine (Bontril et al) **Ciii**  
Mazindol (Sanorex) **Civ**  
Fenfluramine (Pondimin) **Civ**  
Phentermine (Fastin, Ionamin, Adipex) **Civ**  
Benzphetamine (Didrex) **Ciii**  
Methylphenidate (Ritalin) **Cii**

(This list is for your convenience; it is not presented as all-inclusive).

- X. Muscle Relaxants.** Certain muscle relaxants should be prescribed with the same caution as opioids and other controlled substances. Carisoprodol (Soma) is metabolized to meprobamate, which is known to be addictive. Diazepam (Valium), sometimes used as a muscle relaxant, also has addictive potential.
- XI. Anxiolytic Drugs.** Controlled anxiolytic drugs (benzodiazepines in particular) should be used with as much caution as opioid drugs. The same common sense guidelines listed elsewhere should be followed. Functional status and quality of life issues should be examined. Avoid treating subjective complaints. The quality of the initial evaluation, documented follow-up visits, consultations, and alternative treatment and medications, are more important than the absolute amount of the medication given.
- XII. Common Problems.** Problems faced by physicians when coming under review and investigation by the Board of Licensure and other entities, such as governmental agencies or civil litigation, include:
- (1) Inadequate records/documentation.
  - (2) Failure to establish a diagnosis. Subjective complaint of pain is not a diagnosis, it is a symptom.
  - (3) Utilizing controlled substances in treatment without alternative methods having been explored and exhausted.
  - (4) Failure to monitor the side effects of a drug, e.g., monitoring for potential indicators of drug addiction.
  - (5) Failure to document why the continued use of controlled substance(s) is necessary.

(CONTINUED ON NEXT PAGE)

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

References

1. Kennedy L.D. Personal communication.
2. Guidelines for prescribing amphetamine, amphetamine-like and anorectic controlled substances (schedule III and IV). Kentucky Board of Medical Licensure Newsletter. Spring 1994.
3. Physicians Desk Reference. Medical Economics Co. Montvale, NJ. 1996.
4. DI for Providers. US Pharmacopeial Convention. Silver Springs, MD. 1995.
5. Management of prescribing. Minnesota Board of Medical Examiners Update. Fall 1990. 1-5.
6. Portenoy RK. Pharmacologic management of chronic pain. In: Fields H, ed. *Pain Syndromes in Neurology*. Butterworth Heinemann Publisher: CH 11.
7. Fields H, Liebeskind E, eds. Opioid therapy for chronic nonmalignant pain: current status. In: *Pharmacologic Approaches to the Treatment of Chronic Pain: New Concepts and Critical Issues, International Association for the Study of Pain: Progress in Pain Research and Management*. JASP Press; 1994: Vol 1. CH 16, pp 247-287.
8. Self-prescribing and prescribing to immediate family members. Kentucky Board of Medical Licensure Newsletter. Fall 1991.
9. Elements of a good medical record. Kentucky Board of Medical Licensure Newsletter. September 1992.
10. Guidelines on physical examinations by physicians, adopted by the Kentucky Board of Medical Licensure. Kentucky Board of Medical Licensure Newsletter. March 15, 1990.
11. Portnoy R, ed. Special section on pain and addiction. *J Pain & Symptom Management*. 8:5 253-350. July 1993.
12. Portnoy R, ed. Adjunctive analgesics in pain management: part II. *J Pain & Symptom Management*. 9:7 423-453. Oct 1994.

**OTHER GOVERNMENTAL POLICY**  
**Medical Board Guideline (2001)**

MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES  
IN PAIN TREATMENT

Introduction

The Kentucky Board of Medical Licensure (KBML) recognizes that principles of quality medical practice dictate that the people of Kentucky have access to appropriate and effective pain relief. The appropriate application of state-of-the-art treatment modalities can serve not only to improve the quality of life for those patients who suffer from pain but also can reduce the morbidity and costs associated with inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is particularly important for patients who experience pain as a result of terminal illness and can be difficult for patients with chronic nonterminal pain. It is imperative that physicians become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result either from physicians' lack of knowledge about pain management or their misunderstanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of the pain patient. Accordingly, **these guidelines have been developed to clarify the Board's position on pain control, especially as related to the use of controlled substances for nonterminal/nonmalignant chronic pain, in order to alleviate physician uncertainty and to encourage better pain management.**

The Board recognizes that controlled substances (including opioid analgesics, benzodiazepines, and stimulants) may be essential in the treatment of acute pain and chronic pain, whether due to cancer or noncancer origins. Physicians are referred to the US Agency for Health Care Policy and Research Clinical Practice Guidelines<sup>1</sup> for a sound approach to the management of acute and chronic, malignant and non-malignant pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Addiction refers to both dependence on the use of substances for the drug's psychic effects and compulsive use of the drug despite consequences.

The KBML is obligated under the laws of the state of Kentucky to protect the public health and safety. The Board recognizes that the inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek the drugs for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate purposes. The Board believes the adoption of these guidelines will protect legitimate medical uses of controlled substances, while helping to prevent drug diversion and eliminating inappropriate prescribing practices.

Physicians should not fear disciplinary action from the Board for prescribing controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board will consider the prescribing of controlled substances for pain a legitimate medical purpose if such prescribing is (1) based on accepted scientific knowledge of pain treatment and (2) if based on sound clinical grounds. All such prescribing must be grounded in clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis if and when brought to the Board's attention. The Board does not take disciplinary action against a physician who fails to adhere strictly to the provisions of these guidelines if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: (1) whether or not the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis; (2) the patient's individual needs—including improvement in functioning; and (3) a recognition that some types of pain cannot be completely relieved.

(CONTINUED ON NEXT PAGE)

**CRITERION 2:** *Pain management is part of medical practice* [+]

**CRITERION 4:** *Encourages pain management* [+]

**CRITERION 7:** *Physical dependence or analgesic tolerance are not confused with "addiction"* [+]

**CRITERION 8:** *Other provisions that may enhance pain management* [+]

*Comment: This provision reflects the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.*

**CRITERION 5:** *Addresses fear of regulatory scrutiny* [+]

**CRITERION 3:** *Opioids are part of professional practice* [+]

**CRITERION 8:** *Other provisions that may enhance pain management* [+]

*Comment: This provision allows for additional flexibility as long as their prescribing maintains standards of good medical practice.*

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

**CRITERION 6:** [ + ]  
*Prescription amount alone does not determine legitimacy*

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than only on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within acceptable boundaries of professional practice when prescribing for recurrent or persistent chronic pain. The prescribing guidelines for acute pain would be appropriately less stringent but, in principle, the same.

**Guidelines**

The Kentucky Board of Medical Licensure has adopted the following guidelines when evaluating the use of controlled substances for control of recurrent or chronic pain.

**Evaluation of the Patient**

A complete medical history and physical examination must be conducted and documented in the medical record. A family history should be documented with particular reference to any history of first degree relative with chemical dependence problems. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of any substance abuse. The medical record also should document the presence of one or more recognized medical indication(s) for the use of a controlled substance. By definition, pain is a subjective statement of a patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and thereafter. It is the goal of the physician to assist in the relief of suffering no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying reasons for suffering as well as the pain will lead to optimal treatment and utilization of controlled substances.

Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons. Speaking with the patient's significant other or conducting a family conference can be helpful if there is any doubt regarding the patient's integrity. Utilizing the Kentucky All Schedule prescription Electronic Reporting [i.e., The KASPER Report<sup>2</sup>] initially can also aid in documenting the patient's history of drug utilization.

**CRITERION 9:** [ - ]  
*Opioids are a last resort*

**Treatment Plan**

The written treatment plan should state objectives that will be used to determine treatment success such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations, consultations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

**Informed Consents and Treatment Agreements**

The physician should discuss the risks and benefits of the use of controlled substances with the patient or his / her surrogate, including the risk of tolerance and drug dependence. If the patient is determined to be at high risk for medication abuse or has a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including:

- One prescribing doctor and one designated pharmacy.
- Urine / serum drug screening when requested.

(CONTINUED ON NEXT PAGE)

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

- No early refills and no medications called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.
- The reasons for which drug therapy may be is continued such as violation of a documented doctor-patient agreement.

**Periodic Review**

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as reduction in patient's pain intensity and improved physical and / or psychosocial function (i.e., ability to work), need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans. Periodic requests for a KASPER Report could be utilized.

**Consultation**

The physician should be willing to refer the patient as clinically indicated for additional evaluation and in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

**Medical Records**

The physician should keep accurate and complete records, to include:

The medical history and physical examination;  
Diagnostic, therapeutic, and laboratory results;  
Evaluations and consultations;  
Treatment objectives;  
Discussion of risk, benefits, and limitation of treatments;  
Treatments;  
Medications (including date, type, dosage, and quantity prescribed);  
Instructions and agreements;  
Periodic reviews; and  
Records should remain current and be maintained in an accessible manner and readily available for review.

Initial or periodic KASPER Report(s) should not be part of the patient's records and should not be released to the patient or a third party.

**Compliance with Controlled Substances Laws and Regulations**

To prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations. Kentucky physicians can refer to prior Board-published recommendations for prescribing Scheduled II drugs including opioids<sup>3</sup>, benzodiazepines<sup>4</sup>, and stimulants<sup>5</sup>. Physicians should studiously avoid prescribing scheduled drugs for themselves, immediate family, or staff in accordance with the American Medical Association's Code of Medical Ethics and the KRS Medical Practice Act.

(CONTINUED ON NEXT PAGE)

**OTHER GOVERNMENTAL POLICY**

**Medical Board Guideline**

(CONTINUED)

**Conclusion**

By publishing these guidelines, the KBML wishes to encourage Kentucky physicians to utilize adequate medications to treat their patients with serious pain complaints without undue fear of legal or licensure repercussions. Concurrently, the Board strives to prevent as much as possible, drug diversion and inappropriate prescribing practices.

**Refernces**

1. Clinical Practice Guideline No. 9: Management of Cancer Pain. US Agency for Health Care Policy and Research. March 1993. AHCPR publication 94-0592.
2. The KASPER Program. See the 2000 Summer KBML Newsletter or contact The Cabinet for Health Services at 502.564.7985 or via fax at 502.564.2203.
3. Guidelines for prescribing controlled substances [Monitoring Medicine]. [The prior KBML opiate guidelines.] J Ky Med Assoc. 1996; 194:309-312.
4. Considerations when prescribing benzodiazepines [Monitoring Medicine]. J Ky Med Assoc. 1998;96:398.
5. The stimulant regulations: 201 K A R 9:016. Restrictions on use of amphetamines and amphetamine-like anorectic controlled substances. Can also find at the KBML WebPage at [www.state.ky.us/agencies/kbml](http://www.state.ky.us/agencies/kbml)