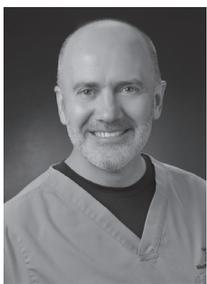


# KENTUCKY'S UPDATED *Controlled Substances Regulations*

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"We have strict statutes" - Wm. Shakespeare, Measure for Measure



The Kentucky Board of Medical Licensure (KBML) has updated its controlled substance prescribing regulations (REF 1). It is imperative that physicians become familiar with these new rules. Regulations are not the same as clinical guidelines or standards of care. Kentucky's regulations do not merely advise physicians on how they *should* act; they tell us how we *shall* act. While not a substitute for one's personal reading of the actual regulations, the following is an overview of salient aspects of these newly added rules.

Among the changes are four prominent dictates:

- (1) A three-day limit on prescribing for acute conditions
- (2) Steps to take with noncompliant patients
- (3) What is expected when tapering medications
- (4) When it is necessary to refer for substance abuse treatment

## (1) THREE-DAY LIMIT

Hopefully, by now you have heard of a new Kentucky law designed to impose a three-day limit on prescribing Schedule II pain medications for acute conditions (REF 2). Per protocol, this law, (titled House Bill 333) spawned important modifications to the KBML. These additions to the regulations were updated on November 15, 2017, and are available for viewing on the KBML website (REF 3).

Describing this new law, which *only* applies to Schedule II drugs as a "limit" is somewhat misleading, as there are exemptions that allow physicians to prescribe for more than three days.

In addition to the previously published general exemptions found in the KBML controlled substances regulations (see below), the updated prescribing regulations offer a new exemption specific to the three-day limit for Schedule II medications. Simply stated, the three-day limit does **not** apply if the physician adequately documents these three particulars:

- a. A *description* of the acute condition,
- b. An *assessment* that more than three days is necessary
- c. *Available* alternative treatments are inadequate.

Thus, if one decides a patient needs more than three days of Schedule II pain medications, they **can** be prescribed, but the reasons must be clearly documented.

As mentioned above, the KBML updated prescribing regulations still contain the previously published general exemptions where the regulations (including the new rules about Schedule II drugs for acute pain) do not apply:

1. Hospice or end-of-life treatment
2. Hospital admissions as an inpatient, outpatient or observation patient
3. Cancer patients or pain related to cancer treatment

4. Patients in long-term care facilities
5. Any period of disaster or mass casualties
6. A single dose to relieve anxiety, pain or discomfort for a diagnostic test or procedure
7. Any Schedule V controlled substance
8. As part of a licensed narcotic treatment program
9. Immediately prior to, during, or within the 14 days following a major surgery for no longer than 14 days

As a reminder, please note that in all cases (that are not exempt) the *initial* prescription of a controlled substance still requires documentation of:

1. An appropriate medical history and a physical examination
2. A KASPER report (REF 4)
3. A decision (assessment) that a controlled substance is appropriate
4. Instruction that controlled substances for acute pain are for a limited time
5. How to safely use and dispose of unused controlled substances
6. Long-acting or extended-release opioids are not to be used for acute pain

The story does not end here. There are more changes to the KBML regulations that have not been so well publicized as the three-day limit, but are no less mandatory. Here are some of these additional regulation changes:

## (2) NONCOMPLIANT PATIENTS

If and when any information becomes available indicating the patient is *noncompliant*, the physician now must do at least one of the following:

- a. Taper and collaborate
- b. Stop prescribing (or)
- c. Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program

Granted, the term “noncompliant” can have a wide range of interpretations. This illustrates one of the problems when objective prescriber actions are made dependent upon such ill-defined and subjective conditions, but these are the regulations we have. Regardless, it is imperative to document one’s rationale behind choosing any of the three options listed above.

## (3) TAPERING

Suffice it to say that the information below deserves more elucidation than the brevity of this article allows. Nevertheless, Kentucky physicians must now be aware that when tapering a patient’s medications,

the prescriber is now required to manage the taper:

- a. In a manner slow enough to minimize symptoms and signs of opioid withdrawal
- b. In collaboration with other specialists *as needed*
  - i. To optimize non-opioid pain management and
  - ii. To optimize psychosocial support for anxiety related to the taper

In a related section of the KBML regulations there is a new dictum regarding two specific scenarios where the physician must stop prescribing:

A physician shall stop prescribing or dispensing any controlled substance:

- a. Diverted by or from the patient or
- b. Taken less frequently than once a day

## (4) REFERRAL TO ADDICTION MANAGEMENT

Another *if...then* passage in the pain regulations now reads like this:

The physician shall discontinue controlled substance treatment or refer the patient to addiction management if:

- a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected (or)
- b. Controlled substance therapy has produced significant adverse effects, including *instances such as an overdose* or events leading to hospitalization or disability (or)
- c. The patient exhibits inappropriate drug-seeking behavior or diversion (or)
- d. The patient is taking a high-risk regimen, such as dosages fifty morphine milligram equivalents/day or opioids with benzodiazepines, without evidence of benefit

## GUIDELINES VS. STANDARDS OF CARE VS. REGULATIONS

The most influential guideline in recent years is the 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (REF 5). This guideline is referenced in the first paragraph of Kentucky’s updated regulations:

... to establish mandatory prescribing and dispensing standards related to controlled substances, ***and in accordance with the Centers for Disease Control and Prevention (CDC) guidelines, to establish a prohibition on a practitioner issuing a prescription for a Schedule II controlled substance for more than a three (3) day supply if intended to treat pain as an acute medical condition, unless an exception applies.***

As regulatory agencies, such as the KBML, continue looking to

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the CDC Guideline for direction, it is important they remain cognizant of the fact that, because the guideline is “based on emerging evidence, including observational studies or randomized clinical trials with notable limitations” (REF 6), the CDC considers recommendations in the document to be **voluntary**:

*“The recommendations in the guideline are voluntary, rather than prescriptive standards.”*

- Introduction, 2016 CDC Guideline for Prescribing Opioids for Chronic Pain

Similarly, our government’s top physician drug abuse researcher has weighed in on the CDC Guideline (REF 6):

*“Although they are not rules that legally bind doctors in their treatment of pain patients, the guidelines provide valuable advice that physicians, who currently receive little training in pain management, will welcome.”*

—Dr. Nora Volkow, Director, National Institute on Drug Abuse, April 06, 2016

In addition, a recently published comprehensive review of a wide range of relevant prescribing guidelines (including the CDC Guideline) found little evidence to support the notion that any of our current guidelines should be viewed as beyond reproach (REF 7).

*“Pain guidelines to date have been hindered by the paucity of quality clinical research in the area of pain management and must be interpreted and implemented within the context of the appreciable limitations of the data on which they are based. These recommendations should not be interpreted as a standard of care.”*

- *Drug and Alcohol Dependence*, April 1, 2017

Physicians are often judged by whether or not they practiced within the standard of care. The AMA Journal of Ethics has described the standard of care as “...a measure of the duty practitioners owe patients to make medical decisions in accordance with any other prudent practitioner’s treatment of the same condition in a similar patient” (REF 8). Regulations may be *related* to the standard of care but are *not equivalent* to the standard of care. Regulations are written by regulators - not necessarily by physicians’ peers. Regulatory mandates often lag behind the evolution of what is considered to be current best practices. They also, among other limitations, can be based on low quality evidence (REF 9). Nonetheless, to legally practice, medicine regulations must be followed.

## CONCLUSIONS

Without a doubt, prescribing controlled substances is increasingly challenging for physicians. The burgeoning number of regulations, that differ significantly from jurisdiction to jurisdiction, can leave prescribers feeling vulnerable to legal or even criminal actions, making them reticent to prescribe adequately and further diminishing patients’ access to adequate pain care (REF 10). All physicians have

a duty to alleviate suffering (REF 11). When meeting this obligation includes prescribing controlled substances, Kentucky physicians must know the KBML regulations, follow the regulations, and clearly meet documentation requirements. 

*James Patrick Murphy, MD, MMM, a past-president of the Greater Louisville Medical Society, is the American Society of Addiction Medicine’s nominee to the new United States Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force.*

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### Quote:

“All physicians have a duty to alleviate suffering. When meeting this obligation includes prescribing controlled substances, Kentucky physicians must know the KBML regulations, follow the regulations, and clearly meet documentation requirements.”