

HB 1 Regulations – Board of Medical Licensure

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Faculty Disclosure

- I have not had any relevant financial relationships during the past 12 months
- I do not intend to discuss an off-label use of a product during this activity

Educational Need/Practice Gap

In 2012, HB 1:

- Established new procedures for the Board of Medical Licensure
- Established new requirements for physicians
- Required specific sanctions for certain conduct
- Required Board to set out prescribing/dispensing standards in regulations
- Established ownership and other requirements for pain management facilities

Objectives

Upon completion of this educational activity, you will be able to:

- Describe new obligations of prescribers
- Discuss potential sanctions for certain conduct
- Recognize the prescribing/dispensing standards
- Relate the ownership and other requirements for pain management facilities

Expected Outcomes

Prescribers should be able to:

- Meet their new legal requirements
- Conform their prescribing/dispensing practices to the applicable standards
- Meet all legal requirements for ownership of or practice in a pain management facility

New Requirements for Doctors – KASPER Registration

- To lawfully prescribe a controlled substance in Kentucky:
 1. Must have valid DEA permit AND
 2. Be registered to use KASPER system
- Sanctions:
 1. Each prescription is violation and basis for action
 2. Emergency Order of Restriction until registered

New Requirements for Doctors - CME

- 4.5 hours each 3-year cycle - pain management, KASPER use, addiction disorders, or any combination
- May complete in single or multiple sessions
- May be live, webinar, or online presentation
- Must be approved by Board in advance
- Pro-rated for less than 3-year cycles
- Sanction – Emergency Order of Restriction until in compliance

New Requirements – Reporting Convictions/Pleas & Board Actions

- Each licensee must now report:
 - a. Any criminal conviction/plea
 - b. Any action against their license by another state licensing board.
- Must report action within 10 days of event
- Sanction for failure to report: Minimum fine of \$5,000 and any other sanction appropriate for action involved.

Mandatory Bans on Ability to Prescribe/Dispense

- If a doctor is convicted or pleads guilty to an offense “relating to controlled substances,” Board must:
 - impose permanent ban upon ability to prescribe/dispense controlled substances if offense was felony
 - impose ban of 2-5 years if misdemeanor
- Board may impose additional sanctions, including revocation, based upon facts.

Mandatory Bans on Ability to Prescribe/Dispense

- Conviction/plea “relating to controlled substances”
 - conduct involving improper, inappropriate or illegal act involving controlled substances
 - Board will look at all facts
 - not determined by title of plea offense
 - applies to any form of plea, regardless of adjudication

Mandatory Sanction Based Upon Action by Another Board

If doctor has license in another state sanctioned by that state's licensing board, Board:

- must, at a minimum, impose same substantive sanctions as other board
- may impose any additional sanction, including revocation, based upon facts

Dispensing Restriction

- For Schedule II controlled substances and Schedule III controlled substances with hydrocodone, shall not dispense more than a 48-hour supply to any patient
- May not avoid limit by prescribing on consecutive or multiple occasions

Exception: Dispensing is part of licensed narcotic treatment program.

Prescribing/Dispensing Standards - Format

- Exceptions
- Documentation Requirements
- Initial Prescribing for Pain
- Decision to Prescribe Beyond 3 Months – Pain
- Long – Term Prescribing for Pain
- Prescribing in ER Department
- Prescribing for Other Conditions
- Responsibility to Educate

Prescribing/Dispensing Standards - Exceptions

Standards do not apply:

- To patient as part of hospice/end-of-life care
- To patient admitted to hospital as part of expected course of care at hospital
- To patient for pain/treatment of cancer
- To registered patient of long-term-care facility
- To Schedule V substances
- In single dose to relieve anxiety, pain or discomfort related to diagnostic test/procedure

Standards for Documentation

- Each prescriber/dispenser must obtain/record all relevant info in patient record:
 - in a legible manner
 - in sufficient detail for Board to determine whether physician is conforming to standards
- For Schedule II and III w/hydrocodone, accurate, readily accessible and complete with, as appropriate:

Standards for Documentation

- Medical history and physical/mental health eval
- Diagnostic, therapeutic and lab results
- Evaluations and consultations
- Treatment objectives
- Discussion of tx risks, benefits and limitations
- Treatments
- Medications – date, type, dosage, amounts
- Instructions and agreements
- Periodic reviews

Standards for Documentation

- Physician must document all relevant circumstances if:
 - unable to meet specific standard(s) for reasons beyond their control; OR
 - makes professional decision that it is not appropriate to comply with specific standard(s) based upon specific facts applicable to patient's diagnosis and treatment

Standards – Initial Prescribing for Treatment of Pain

Prior to initial prescribing/dispensing of controlled substances for treatment of pain or other symptoms of same primary medical complaint, first prescriber/dispenser shall:

- a. Obtain appropriate medical history relevant to medical complaint, including HPI;
- b. Conduct physical exam or mental health evaluation appropriate to medical complaint

Standards – Initial Prescribing for Treatment of Pain

- c. Obtain and review KASPER for 12 months prior to visit and appropriately use info
- d. After appropriate risk-benefit analysis, including non-treatment, make deliberate decision that it is medically appropriate to prescribe/dispense amount specified
- e. Not prescribe/dispense long-acting or controlled-release opioid not directly related to and close in time to specific surgical procedure

Standards – Initial Prescribing for Treatment of Pain

- f. Explain to patient that use of controlled substance for acute pain is for time-limited use, and to discontinue use when condition requiring controlled substance use has resolved
- g. Explain to patient how to safely use and properly dispose of any unused controlled substance

Standards – Initial Prescribing for Treatment of Pain

- Schedule II and III w/hydrocodone:
 - written plan with treatment objectives and further diagnostic exams required AND
 - Informed consent after risk-benefit discussionUNLESS script written in first 7 days to same patient for same condition AND doctor:
 - Cancels any refills on initial prescription
 - Requires patients to dispose of unused meds

Standards – Decision to Extend Treatment of Pain Beyond 3 mos

Before continuing to prescribe/dispense to 16 yo or older for treatment of pain and related symptoms, physician shall:

- a. Obtain and document complete history:
 1. HPI
 2. Past medical history
 3. History of substance use/treatment for pt, and history of abuse for first-degree relatives

Standards – Before Beyond 3 mos

4. Past family history of relevant illness/treatment
5. Psychosocial history
- b. Obtain appropriate physical exam sufficient to support long-term use of cs
- c. Perform appropriate baseline assessments to establish and monitor treatment plan
- d. Obtain prior records if review is necessary to justify long-term use of cs

Standards – Before Beyond 3 mos

- e. Promptly establish working diagnosis
- f. If unable to formulate working diagnosis, despite best efforts, physician shall:
 1. consider usefulness of other information
 2. only prescribe long-term after establishing use at specific level is indicated/appropriate
- g. If functional improvement is expected, prepare treatment plan with specific/verifiable goals and schedule for periodic evaluations

Standards – Before Beyond 3 mos

- h. Obtain baseline drug screen
- i. Screen for other conditions that may impact cs use and for potential for illegal diversion
- j. If reasonable likelihood patient is suffering from substance use disorder or mental health condition, facilitate appropriate referral
- k. If risk of diversion, use prescribing agreement
- l. If doctor determines patient will use cs illegally, cannot prescribe/dispense

Standards – Before Beyond 3 mos

- j. Obtain informed consent, after risk-benefit discussion with patient
- k. To extent possible, initially attempt or document prior attempt of trial of non-controlled modalities and lower doses of cs in increasing order to treat condition, before continuing at given level.

Standards – Before Beyond 3 mos

Standards may be accomplished by different practitioners in single group practice at direction of or on behalf of prescribing physician if:

- each has lawful access to patient record
- there is compliance with all standards AND
- each is acting within legal scope of practice

*** This also applies to standards for long-term prescribing.

Standards – Long-Term Prescribing

If physician continues to prescribe/dispense to patient 16 yo or older for pain and related symptoms, physician shall:

- a. Ensure patient is seen at least monthly at first
- b. May move to less frequent visits after:
 1. cs titrated to appropriate level;
 2. cs not causing unacceptable side effects
 3. sufficient monitoring in place to prevent inappropriate/illegal use or diversion

Standards – Long-Term Prescribing

- c. At appropriate intervals:
 - 1. obtain appropriate history
 - 2. conduct focused physical exam
 - 3. perform appropriate measurable exams
 - 4. evaluate working diagnosis and treatment plan and modify, as appropriate
- d. If patient presents significant risk of abuse/diversion, discontinue cs use or justify continued use in patient record

Standards – Long-Term Prescribing

- e. If improvement expected, but not seen, obtain appropriate consults to determine if there are undiagnosed conditions that need to be addressed
- f. If patient exhibits symptoms of mood, anxiety or psychotic disorder, obtain consult for intervention if appropriate
- g. At least annually, ensure patient receives preventive health screening/exam appropriate to patient's status.

Standards – Long-Term Prescribing

- h. If patient reports breakthrough pain,
 1. attempt to identify trigger(s)
 2. try to treat with non-controlled therapy
 3. take appropriate steps to minimize risk of improper/illegal use, after risk-benefit choice
- i. Obtain and review KASPER quarterly
- j. Immediately obtain KASPER if report of illegal/improper use or diversion

Standards – Long-Term Prescribing

- k. If KASPER shows doctor-shopping, notify other prescribers
- l. Obtain specialist assistance if appropriate
- m. If appropriate, conduct random pill counts
- n. Use drug screens, appropriate to substance and condition, at appropriate times, in random and unannounced manner
- o. If indication patient is non-compliant:
 1. do controlled taper

Standards – Long-Term Prescribing

2. Immediately stop use of cs; OR
 3. Make appropriate referral of patient
- p. Discontinue cs use and refer to addiction management if:
1. No improvement where expected
 2. CS therapy has produced significant adverse side effects, OR
 3. Patient exhibits inappropriate drug-seeking behavior or diversion

Standards - Prescribing in ER

- In addition to meeting standards for initial prescribing, ER prescriber must not routinely:
- a. Administer IV cs for relief of acute pain unless that is only appropriate means of delivery;
 - b. Provide replacement cs prescription for one that was lost, stolen or destroyed
 - c. Provide replacement dose of methadone, suboxone or subutex for patient in treatment program

Standards – Prescribing in ER

- d. Prescribe long-acting or controlled release cs or replacement dose of such cs
- e. Administer Meperidine to patient, or
- f. Prescribe/dispense more than minimum necessary to treat patient until patient can be seen by primary or other physician. If longer than 7 day supply, must justify in record.

Standards – Other Conditions

Initial Prescribing:

- a. Must meet initial prescribing standards for treatment of pain
- b. For Schedule II and III w/hydrocodone, must obtain informed consent and include written plan, unless 7-day exception applies

Continued Prescribing

- a. Must meet standards for use of that substance and treatment of that condition

Standards – Other Conditions

- b. Must obtain quarterly KASPERs for Schedule II and III w/hydrocodone

For treatment of anxiety/depression associated with single episode or event, shall:

- a. Obtain and review KASPER for prior 12 mos
- b. Make deliberate decision it is appropriate to prescribe/dispense w/o personal encounter or evaluation
- c. Prescribe/dispense minimum necessary

Pain Management Facility - Defined

- Facility where majority of patients are provided treatment for pain that includes use of controlled substance AND
- Meets one of the following conditions:
 1. Primary practice component is treatment of pain OR
 2. Facility advertises in any medium for any type of pain management services

Board will look at 30-day period to establish first requirement

Pain Management Facility – Ownership Requirements

To lawfully own a facility, owner must:

1. Be a physician currently licensed to practice in Kentucky; AND
2. Not currently be subject to any final order, agreed order or letter of agreement issued by Board

Owner must immediately divest if becomes disqualified

NOTE: Limited “grandfather” provision

Pain Management Facility - Registration

Before September 1 of each year, each facility must :

- a. register with Board, providing required information; and
- b. pay \$500 fee

Must file amended registration within 14 calendar days if change in ownership or supervision

Any new pain management facility must register within 14 calendar days

Pain Management Facility - Supervision

- Owner or approved designee must be present practicing in the facility at least 50% of the time that patients are present
- Owner or designee must meet qualifications set out in statute and regulation

Pain Management Facility - Prescribers

- Physician may not prescribe/dispense in a facility if they have:
 1. Been denied ability to prescribe/dispense
 2. Had DEA permit revoked
 3. Been convicted of or entered plea to any felony or misdemeanor relating to controlled substances in any court; OR

Pain Management Facilities - Prescribers

4. Had their ability to prescribe/dispense revoked, limited or restricted by licensing board unless:
 - a. Underlying conduct was directly related to prescriber's substance abuse impairment;
 - b. Order imposing sanction is no longer in effect;
 - c. Physician has reached appropriate level of recovery; AND
 - d. Board has approved practice site

Pain Management Facilities – Enforcement

- Board may obtain injunctive relief against unlawful owners
- Board may issue Emergency Orders of Restriction and sanction unlawful prescribers or physicians prescribing in unlawful facility
- Board may conduct random inspections
- Board will obtain annual KASPER reviews for prescribers in facilities

Thank You/Good Luck

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