

KENTUCKY BOARD OF MEDICAL LICENSURE SUMMARY OF HB 1

The following is a summary of HB 1, which was passed during the “Special Session” of the Kentucky General Assembly in April of 2012. Please note that a copy of HB 1 is available for review on the Board’s website, www.kbml.ky.gov.

PAIN MANAGEMENT FACILITIES

Definition: facility where majority of patients provided controlled substances for pain
AND

- a) primary practice component is treatment of pain; or
- b) facility advertises any type of pain management services

Exemptions: Definition does not apply to:

- Hospital, including critical access; hospital-owned facility or office of hospital-employed physician;
- Educational institution/program to extent it provides education to potential health care licensees
- Hospice program or residential hospice facility
- Ambulatory surgical center
- Long-term care facility.

Ownership Requirement: Only physician with full active license may own or has investment interest in pain management facility.

Grandfather provision: This requirement does not apply to any facility existing/operating as of July 20, unless there is administrative sanction/criminal conviction, relating to controlled substances, imposed on facility or employee for act/omission done within scope of facility’s license or person’s employment

Oversight Requirement: At least one physician-owner or physician-designee must be on-site practicing medicine at least 50% of the time.

To qualify, physician-owner or physician-designee must:

- Hold current ABMS subspecialty certification or current AOABOS certificate of added qualification in pain management, or
- Hold current ABMS subspecialty certification or AOABOS certificate of added qualification in hospice and palliative care; or
- Hold current board certification by American Board of Pain Medicine; or
- Hold current board certification by American Board of Interventional Pain Physicians; or
- Have completed accredited residency or fellowship in pain management.

Method of Payment

1. Facility must accept private health insurance as one means of payment for goods/services
2. Facility must only accept payment for goods/services from patient, patient's insurer or guarantor, patient's parent or spouse or patient's guardian or legal custodian.

Means of Enforcement

1. Cabinet for Health and Family Services will enforce these provisions for facilities licensed by Cabinet.
2. Board of Medical Licensure will enforce these provisions for facilities operating as private office or clinic of licensed physician.

Criminal Sanction Violation of any provision of this section is Class A Misdemeanor.

INTER-AGENCY REPORTING

Definition: "Reporting Agency" includes

- Kentucky State Police
- Office of Attorney General
- Cabinet for Health and Family Services
- Applicable licensing boards.

Sharing of Prescribing/Dispensing Reports Any reporting agency who receives a report of improper, inappropriate or illegal controlled substance prescribing or dispensing may report it to the other reporting agencies within 3 business days.

Reporting of Criminal Actions County and Commonwealth Attorneys shall report felony charges against a licensed person to the Attorney General and applicable licensing Board within 3 business days if the indictment relates to manufacture of, trafficking in, prescribing, dispensing, or possession of a controlled substance.

REQUIRED BOARD REGULATIONS

Board Involved:

- Medical Licensure
- Nursing
- Dentistry
- Optometric Examiners
- Podiatry
- Any board licensing/regulating persons entitled to prescribe/dispense controlled substances.

Required Regulations By September 1, 2012, each involved Board must promulgate the following regulations:

1. mandatory prescribing and dispensing standards for controlled substances;
2. 48-hour limit on licensee dispensing Schedule II or III hydrocodone substances unless dispensing is part of narcotic treatment program licensed by Cabinet
3. Procedures for emergency suspension or restriction of licensee when there is substantial likelihood that their practice constitutes danger to patients or public
4. Process for expedited review of allegations of improper, inappropriate or illegal prescribing/dispensing of controlled substances, with following timelines:
 - Must commence investigation within 7 days of report
 - Must produce charging decision within 120 days of report
5. Mandatory licensing standards that include:
 - Reporting requirement for criminal convictions or licensing actions relating to controlled substances
 - Permanent ban on prescribing/dispensing controlled substances for felony conviction relating to controlled substances
 - Less than permanent ban on prescribing/dispensing controlled substances for misdemeanor conviction relating to controlled substances
 - Restrictions mirroring disciplinary action taken by another licensing board relating to prescribing/dispensing controlled substances
6. Process for continuous reporting disciplinary actions to National Practitioner Data Bank
7. Process for obtaining FBI or KSP criminal background and National Practitioner Data Bank checks on initial applicants
8. CME requirements ensuring licensees obtain 7.5% of their required CME for reporting period in pain management, addiction disorders, or electronic monitoring

Necessary Regulations Although not mandated, requirements for Boards would likely require regulations on the following subjects:

1. Regulation of physicians operating pain management office or clinic
2. Ensure Board does not require grievances to be notarized or sworn to.
3. Determine whether to allow anonymous grievances, with assurance there is sufficient corroborative information to warrant investigation
4. Determine actions taken against licensees not registered with KASPER

Suggested Regulation The Office of Drug Control Policy has asked the Board to convert its Opinion of the Use of Suboxone to a regulation.

NEW RESPONSIBILITIES FOR BOARDS

Regulation of Pain Management Clinics Boards must enforce provisions of Pain Management Clinic section if it clinic is physician's office or clinic.

Use of Consultants Boards must employ or obtain services of pain treatment and drug addiction specialists to evaluate investigations to determine if licensee is engaged in improper, inappropriate or illegal practices relating to prescribing/dispensing practices, if Board or its staff does not possess such expertise.

Cooperation Boards must cooperate to fullest extent permitted with law enforcement agencies and other licensing boards

PROFESSIONAL STANDARDS FOR PRESCRIBING/DISPENSING SCHEDULE II OR SCHEDULE III WITH HYDROCODONE

Requirements Before Prescribing/Dispensing Before initial prescribing/dispensing Schedule II or Schedule III with hydrocodone controlled substance, licensee shall:

1. Obtain complete medical history and document in record
2. Conduct physical examination and document in record
3. Query KASPER for all available data on patient
4. Make a written treatment plan setting out objectives of treatment and further diagnostic exams required
5. Discuss risks/benefits of controlled substance use, including risk of tolerance and dependence, with patient, patient's parent if minor, or patient's legal guardian or surrogate, and
6. Obtain written consent for treatment.

Ongoing Evaluation

- Practitioner must review course of treatment at reasonable intervals, based upon patient's individual circumstance.
- Practitioner must provide patient with any new information about treatment.
- Practitioner must obtain KASPER at least once every 3 months for all available date on patient.
- Practitioner must review KASPER report before issuing any prescriptions or refills for these substances.

Record-Keeping Practitioner must keep accurate, readily accessible and complete medical records on each patient receiving Schedule II and III including hydrocodone, which must include:

- Medical history and physical exam
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion or risk, benefits, and limitations of treatments
- Treatments
- Medications, including date, type, dosage, and quantity prescribed or dispensed

- Instructions and agreements, and
- Periodic reviews of patient's file

Exemptions: The following practitioner's are exempt from these requirements:

1. Licensee administering substance or anesthesia immediately prior to or during surgery;
2. Licensee administering controlled substance necessary to treat in emergency situation:
 - At the scene of an emergency
 - In licensed ground or air ambulance, or
 - In ED or ICU of licensed hospital
3. Licensed pharmacist or Board of Pharmacy licensee dispensing drugs to licensed pharmacy;
4. Licensee prescribing/dispensing for hospice patient in scope of hospice program or inpatient unit. Hospice program shall maintain plan of care in accordance with federal regulations
5. Optometrist prescribing Schedule III, IV or V substance
6. Licensee prescribing 3-day supply of Schedule III substance following oral surgery by dentist.

KASPER

Program Administrator KASPER continues to be housed in and run by Cabinet for Health and Family Services.

Required Registration

- Every practitioner authorized to prescribe/dispense controlled substances shall register with Cabinet to use KASPER
- Every practitioner authorized to prescribe/dispense controlled substances shall maintain their KASPER registration continuously during their licensing

Enforcement: Cabinet will report failure to comply to licensing boards, who will treat it as complaint.

Exceptions to KASPER Reporting KASPER reporting is not required for:

- Drug administered directly to a patient, unless drug is Schedule II or III with hydrocodone
- Drug dispensed by practitioner/facility licensed by Cabinet for no more than 48 hours, unless drug is Schedule II or III with hydrocodone.

Expansion of Practitioner's Ability to Obtain KASPER Data:

- Employee of practice may obtain KASPER data on behalf of practitioner, if under specific direction of practitioner

- May obtain KASPER report on prospective patient, in addition to bona fide patient
- May obtain KASPER for purposes of:
 - 1) reviewing and assessing individual prescribing/dispensing patterns of the practitioner(Physicians can request a KASPER report on their own prescribing practices); and
 - 2) determining accuracy and completeness of KASPER information

Expanded Use of KASPER Info

- Practitioner may share KASPER report with patient or patient's agent
- Practitioner may place KASPER report in patient's medical record, subject to disclosure on same terms as ordinary medical record

Error Resolution Process Cabinet must promulgate regulation to provide for error resolution process. This would allow patient to request correction of inaccurate information relating to that patient in the KASPER system.

Cabinet for Health and Family Services Reporting

- Cabinet shall proactively use data for investigations
- Cabinet shall notify licensing boards of possible improper, inappropriate or illegal prescribing/dispensing
- Board will consider each report and may obtain follow-up report or analysis containing relevant information about prescriber/dispenser or their patients, after giving due consideration to practice area, specialty, board certification, and standards of care
- If Cabinet deems it necessary and appropriate, may respond to board request to provide identity of prescribers, dispensers, and patients used to compile trend reports.

Hospital/Facility Reviews Hospitals or health care facilities may ask Cabinet to review KASPER data to determine if employees are engaged in inappropriate prescribing/dispensing. Cabinet may conduct investigations as appropriate and request assistance from hospital or facility relating to investigation.

Criminal Sanctions Good faith use of KASPER Reports is protected. The criminal sanctions for failure to input data and for intentional unauthorized disclosure were reduced from felonies to misdemeanors.

OTHER SECTIONS The Bill also includes sections relating to Coroner reporting and data compilation, and interstate exchange of KASPER information.