



Prescribing and Dispensing Profile

Kentucky

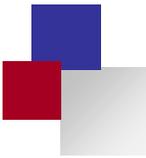


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Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II substances may only be dispensed on the written, faxed, or electronic prescription of a practitioner

- May dispense on faxed prescription for Schedule II narcotic substances for direct administration to a patient by certain methods
- May dispense on faxed prescription for hospice patients or residents of a long term care facility
- Within seven days of the faxed prescription, an original prescription must be delivered to the pharmacy

Schedule II prescriptions are not valid after 60 days from the date of issue

Schedule II prescriptions shall be maintained in a separate prescription file

Schedule II prescriptions shall not be refilled

Schedule III, IV and V Prescribing Limitations (not related to pain clinics)

Schedule III – V prescriptions shall only be dispensed on the written, faxed, electronic, or oral prescription of a practitioner

Schedule III – V prescriptions shall not be filled or refilled more than six months after the date originally issued or refilled more than five times unless renewed by the practitioner

Miscellaneous Prescribing/Dispensing Requirements

Prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone, a practitioner shall:

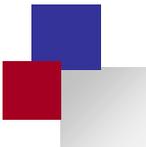
- Obtain a medical history and conduct a physical or mental health examination, as appropriate to the patient's medical complaint, and document the information in the patient's chart
- Query the PMP and appropriately utilize the data in the evaluation and treatment of the patient
- Make a written plan stating the objectives of treatment and further diagnostic examinations required
- Discuss the risks and benefits of using controlled substances with the patient, including the risk of tolerance and drug dependence
- Obtain written consent for treatment

Prior to prescribing or dispensing additional amounts of Schedule II controlled substances or Schedule III controlled substances containing hydrocodone for the same medical complaint and related symptoms, a practitioner shall:

- Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care
- Provide the patient any new information about the treatment
- Modify or terminate treatment as appropriate

If the course of treatment extends beyond three months, the practitioner shall:

- Query the PMP no less than once every three months and review that data before issuing any new prescription or refills for any Schedule II substances or Schedule III substances containing hydrocodone



Miscellaneous Prescribing/Dispensing Requirements, cont'd.

For each patient for whom a practitioner prescribes any Schedule II controlled substance or Schedule III substance containing hydrocodone, the practitioner shall keep accurate, readily accessible, and complete medical records which include:

- Medical history and physical or mental health exam
- Diagnostic, therapeutic, and laboratory results
- Evaluations and consultations
- Treatment objectives
- Discussion of risks, benefits, and limitations of treatment
- Treatments
- Medications, including type, dosage, and quantity prescribed or dispensed
- Instructions and agreements
- Periodic reviews of patient's file

Practitioners shall not dispense greater than a 48 hour supply of any Schedule II substance or Schedule III substance containing hydrocodone unless the dispensing is done as part of a narcotic treatment program

- Physician shall not attempt to circumvent this requirement by dispensing these substances to the patient on consecutive or multiple occasions

Prescriptions must contain the following information:

- Date and signature of prescriber
- Name and address of patient
- Name, address, and registration number of prescriber
- Drug name, strength, dosage form, quantity prescribed, and directions for use

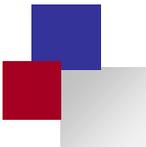
Prescribing/Dispensing Limitations for Dentists

Licensed dentists may prescribe any drug necessary within the scope of their practice

- Must be licensed by law, have a DEA registration, and be registered with the PMP

Prior to prescribing any controlled substance, a dentist shall:

- Review a PMP report for the patient. Does not apply if:
 - The dentist prescribes a Schedule III substance or certain Schedule IV substances after the performance of oral surgery and no more than a 72 hour supply of the drug is prescribed
 - The dentist prescribes or dispenses certain Schedule IV or V substances
 - The dentist prescribes pre-appointment medication for the treatment of procedure anxiety and the prescription is limited to a two day supply with no refills
- Document relevant information in the patient's record and obtain written consent for treatment
- Consider the available information to determine if it is medically appropriate and safe to prescribe a controlled substance
- Obtain a complete medical history and conduct a physical examination of the oral or maxillofacial area of the patient and document the information in the patient's record
- Make a written treatment plan stating the objectives of treatment and further diagnostic examinations required
- Discuss the risks and benefits of using controlled substances with the patient, including the risk of tolerance and drug dependence



Prescribing/Dispensing Limitations for Dentists, cont'd.

Dentist may provide one refill within 30 days of the initial prescription for the same controlled substance for the same amount or less or prescribe a lower schedule drug for the same amount without a clinical reevaluation of the patient

Prescribing/Dispensing Limitations for Optometrists

Any therapeutically certified optometrist licensed by law shall be authorized to prescribe oral medications, except controlled substances classified in Schedules I and II, for any condition which an optometrist is authorized to treat

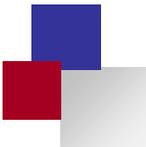
The authority to prescribe Schedule III – V substances is limited to a quantity sufficient to provide treatment for up to 72 hours with no refills

Optometrists authorized to prescribe controlled substances shall have a current DEA number and shall:

- Register with the PMP
- Prescribe controlled substances only for the treatment or relief of pain for a condition of the eye and its appendages
- Prescribe only Schedule III—V substances
- Prescribe controlled substances for a quantity therapeutically sufficient, up to 72 hours
- Examine the patient face-to-face and in-person prior to prescribing a controlled substance
- Verify the fact that the patient being prescribed the controlled substance is who the patient claims to be
- Establish a documented diagnosis through the use of accepted medical practices
- Keep accurate and readily retrievable medical records which include:
 - History and eye examination
 - Diagnostic, therapeutic, and laboratory results
 - Evaluations and consultations
 - Treatment objectives
 - Discussion of risks, benefits, and limitations of treatment
 - Treatments
 - Medications, including type, dosage, and quantity prescribed
 - Instructions and agreements

Optometrist shall not:

- Dispense any controlled substance
- Write a prescription for a controlled substance that is refillable
- Prescribe with the intent or knowledge that a medication will be used, or is likely to be used, for other than a medicinal or therapeutic purpose
- Prescribe with the intent to evade any law with respect to the sale, use, or disposition of the medication



Pain Clinic/Pain Management Regulations

Pain management facility means a facility where the majority of patients of the practitioners of the facility are provided treatment for pain that includes the use of controlled substances and:

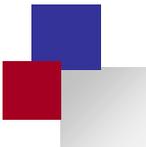
- The facility's primary practice component is the treatment of pain
- The facility advertises in any medium for any type of pain management services
- Does not include:
 - Hospital, a facility owned by a hospital, or the office of a hospital-employed physician
 - A school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians
 - Hospice program or residential hospice facility
 - Ambulatory surgical facility
 - Long term care facility
- A satellite facility means a facility permitted to open and operate under the license of a pain management facility that:
 - Is licensed under this regulation pursuant to the physician-ownership exemption
 - Does not have a pending adverse action

Only a physician having a full and active license to practice medicine in Kentucky shall have an ownership or investment interest in a pain management facility

- At least one of the owners or an owner's designee who is a physician employed by and under the supervision of the owner shall be physically present practicing medicine in the facility at least 50% of the time that patients are present at the facility, and the physician owner or designee shall:
 - Hold a current subspecialty certification in pain management or current certificate of added qualification
 - Hold a current subspecialty certification in hospice and palliative medicine or a current certificate of added qualification
 - Hold a current board certification by the American Board of Pain Medicine
 - Hold a current board certification by the American Board of Interventional Pain Physicians
 - Have completed a fellowship in pain management or an accredited residency program that includes a rotation of at least five months in pain management
 - If the facility is operating under a registration filed with the Kentucky Board of Medical Licensure, have completed or hold, or be making reasonable progress toward completing or holding, a certification or training substantially equivalent to the certifications or training specified in this subsection, as authorized by the Board

Every pain management facility operating in Kentucky as a private office or clinic of a physician shall register with the board and provide the following information:

- The name, business address, profession, current professional licensing status, and nature and extent of ownership or investment interest of each person who has or maintains an ownership or investment interest in the facility
- The names and addresses of every pain management facility in which the person has an ownership or investment interest
- The hours of operation of every facility in which the person has an ownership or investment interest



Pain Clinic/Pain Management Regulations, cont'd.

- The names and professional status of each employee at each practice location owned and operated by that pain management facility
- The name, professional license number, and practice address of the qualified physician owner or owner's designee who will be physically practicing at the pain management facility for at least 50% of the time
 - Facility shall also state its plan for ensuring that the designated physician will be physically present practicing at the facility and, if the facility owns and operates multiple practice locations, the plan to ensure that a physician owner or owner's physician designee is physically present practicing medicine in each practice location for at least 50% of the time that patients are seen at each facility
- For each owner's physician designee who will fulfill the oversight responsibility, an attestation that the physician designee is employed by the owner and the plan for owner supervision of the physician designee
- An attestation by the physician owner that the owner or owner's physician designee:
 - Meets one of the requirements set out above and specifying each qualification met
 - Was an owner of that specific facility prior to and continuing through July 20, 2012 and meets one of the following qualifications:
 - Successfully completed a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry
 - Registered the ownership or investment interest in the facility with the board on or before September 1, 2012, is eligible for and has provided the board with written verification that the licensee has registered to complete the certification examination offered by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians in April 2013, and becomes certified by September 1, 2013

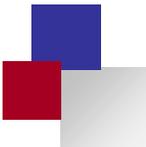
Each facility shall have a medical director which shall:

- Be responsible for complying with all requirements related to the licensure and operation of the facility
- Be physically present and practicing medicine in the facility at least 50% of the time that patients are present in the facility
- Be board certified and have a full, active, and unencumbered license to practice medicine in Kentucky
- Not be permitted to serve in a dual role as the medical director of both the parent facility and a satellite facility

As part of the initial or annual registration, the facility shall identify each practitioner who is employed at the facility in any capacity who will be prescribing or dispensing controlled substances to patients at the facility

Each physician who will prescribe or dispense controlled substances to patients at a facility shall successfully complete a minimum of ten hours of Category I continuing medical education in pain management during each registration period throughout the employment agreement with the facility

At least once each year, the board shall obtain a PMP report for each physician who has or maintains an ownership or investment interest in, or is employed by, or practices in, a pain management facility to determine whether improper, inappropriate, or illegal prescribing is occurring



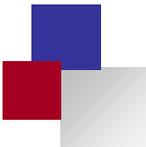
Pain Clinic/Pain Management Regulations, cont'd.

Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician prescribing or dispensing a controlled substance shall:

- Obtain an appropriate medical history relevant to the medical complaint, including a history of the present illness and:
 - If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record
 - If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings
- Obtain and review a PMP report and appropriately utilize that information in the evaluation and treatment of the patient
- After examining the risks and benefits of prescribing or dispensing a controlled substance to the patient, including non-treatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified
- Not prescribe or dispense long acting or controlled release opioids for acute pain that is not directly related to and close in time to a specific surgical procedure
- Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring is has resolved
- Explain to the patient how to safely use and properly dispose of any unused controlled substance

Prior to prescribing or dispensing any controlled substance to a patient 16 years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three months, the physician shall:

- Obtain the following information from the patient and record all relevant information in the patient's medical record:
 - History of present illness
 - Past medical history
 - History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient
 - Past family history of relevant illnesses and treatment
 - Psychosocial history
- Conduct an appropriate physical examination sufficient to support the medical indications for prescribing and dispensing a controlled substance on a long-term basis
- Perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan
- If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information
- If review of prior records is necessary to justify long-term prescribing of a controlled substance, the physician shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient

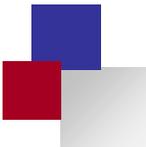


Pain Clinic/Pain Management Regulations, cont'd.

- Based on a consideration of all of the information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms
 - If unable to develop a working diagnosis, the physician should consider the usefulness of additional information, such as specialized evaluation or assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis
 - If still unable to develop a working diagnosis, the physician shall only prescribe the long term use of controlled substances after establishing that its use at a specific level is medically necessary and appropriate
- To the extent that functional improvement is medically expected, the physician shall formulate an appropriate treatment plan which shall include specific and verifiable goals of treatment with a schedule for periodic evaluation
- The physician shall use appropriate screening tools to screen each patient to determine if the patient is presently suffering from another medical condition which may impact the prescribing or dispensing of a controlled substance or presents a significant risk for illegal diversion of a controlled substance
 - If, after screening, the physician determines that the patient does suffer from substance abuse or dependence, or a psychiatric or psychological condition, the physician shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider and shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient
 - If, after screening, the physician determines that there is a risk the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the physician shall use a prescribing agreement that meets professional standards
 - The physician shall obtain and document a baseline drug screen
 - If, after screening, the physician determines that the controlled substance prescribed will be used or is likely to be used for other than an accepted therapeutic purpose, the physician shall not prescribe any controlled substance to that patient
- Physician shall obtain written informed consent
- Physician shall attempt to establish or document previous attempts of other physicians of a trial of non-controlled modalities and lower doses of controlled substances in increasing order to treat the pain and related symptoms associated with the primary medical complaint before continuing with long term prescribing of a controlled substance at a given level

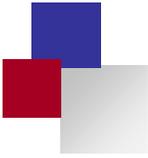
Prior to continuing to prescribe or dispense a controlled substance to a patient 16 years or over beyond three months for pain and related symptoms associated with the primary medical complaint, the physician shall:

- Ensure that the patient is seen at least once monthly initially for evaluation and review of progress
 - Physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician, after s/he has determined:
 - The controlled substance prescribed or dispensed has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms
 - The controlled substance prescribed or dispensed is not causing unacceptable side effects
 - There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substances in an improper or inappropriate manner or divert it for an improper or inappropriate use



Pain Clinic/Pain Management Regulations, cont'd.

- At appropriate intervals, the physician shall:
 - Ensure that a current history is obtained from the patient
 - Ensure that a focused physical examination is considered, and performed, if appropriate
 - Perform appropriate measurable examinations as indicated in the treatment plan
- At appropriate intervals, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any changes in baseline measures
 - Physician shall modify the diagnosis, treatment plan, or controlled substance therapy as appropriate
- If the physician determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the physician shall discontinue the use of the substance or justify its continued use in the patient record
- If the medical complaint and related symptoms continue with no significant improvement in function, and if improvement is medically expected, the physician shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint
- For a patient exhibiting symptoms suggestive of mood, anxiety, or psychotic disorder, the physician shall obtain a psychiatric or psychological consultation for intervention if appropriate
- If a patient reports experiencing episodes of breakthrough pain, the physician shall:
 - Attempt to identify the trigger or triggers for each episode
 - Determine whether the breakthrough pain may be adequately treated through non-controlled treatment
 - If the physician determines that nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an as-needed substance to the regimen, take appropriate steps to minimize the improper or illegal use of the substance
- At least once per year, perform a preventive health screening and physical examination
- At least once every three months, review a PMP report
 - If the physician obtains or receives information that a patient is not taking the substance as directed or is diverting a substance, the physician shall immediately obtain a PMP report and appropriately use the information in the evaluation and treatment of the patient
 - If the PMP report reveals that the patient is receiving controlled substances from another practitioner without the physician's knowledge and approval, s/he shall promptly notify the other physician
- If appropriate, the physician shall conduct random pill counts
- Physician shall use drug screens as appropriate and, if the drug screen indicates the patient is non-compliant, the physician shall:
 - Do a controlled taper
 - Stop prescribing or dispensing the controlled substance immediately
 - Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending on the circumstances
- Physician shall discontinue controlled substance treatment or refer the patient to addiction management if:
 - There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected
 - Controlled substance therapy has produced significant adverse effects
 - The patient exhibits inappropriate drug-seeking behavior or diversion



Training or Education Requirements or Recommendations for Practitioners who Prescribe or Dispense Controlled Substances

Physicians who will prescribe or dispense controlled substances to patients at a pain management facility shall successfully complete a minimum of ten hours of Category I continuing medical education in pain management during each registration period throughout the physician's employment agreement with the facility

Beginning on January 1, 2015, for each three year cycle, a licensee who is authorized to prescribe or dispense controlled substances at any time within that cycle shall complete at least 4.5 hours of approved continuing education hours relating to the use of the PMP, pain management, addiction disorders, or a combination of two or more of those subjects

An optometrist who is authorized to prescribe controlled substances shall earn two credit hours that relate to the use of the PMP, pain management, or addiction disorders

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

Practitioners and pharmacists authorized to prescribe or dispense controlled substances shall register with the Cabinet to use the PMP and shall maintain such registration continuously during the practitioner's or pharmacist's term of licensure

Dentists and optometrists with prescribing authority shall register with the PMP

Prior to initially prescribing or dispensing a Schedule II substance or Schedule III substance containing hydrocodone, a practitioner shall query the PMP

- If the course of treatment extends beyond three months, the practitioner shall query the PMP at least once every three months and review that data before issuing any new prescription or refills for any Schedule II substance or Schedule III substance containing hydrocodone

Practitioner shall review the PMP report at least once every three months when treating a patient with controlled substances for pain

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

None.