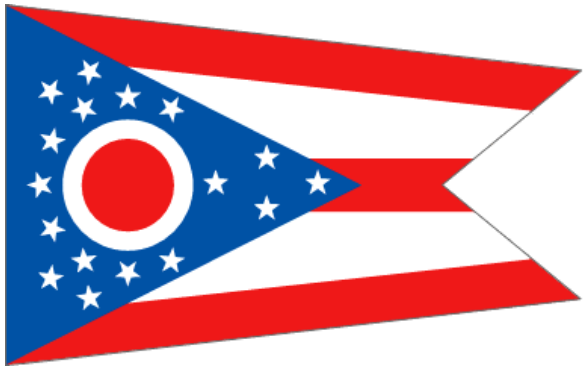
Prescribing and Dispensing Profile

Ohio



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II substances may only be dispensed upon the written prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in accordance with federal law
- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - For a resident of a long term care facility
  - A Schedule II narcotic substance to be compounded for direct administration to a patient by certain methods

Schedule II prescriptions shall be maintained in a separate file from other prescriptions

Schedule II prescriptions shall not be refilled

See ADC 4731-11-03 and ADC 4731-11-04 for specific regulations on when and how certain Schedule II substances may be prescribed

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

Pharmacist may dispense or sell a controlled substance, other than a Schedule II, without a written or oral prescription if all of the following conditions are met:

- The pharmacy has a record of the prescription but the prescription does not have a refill or the time permitted by rules for providing refills has elapsed
- The pharmacist is unable to obtain authorization for a refill from the prescriber
- In the exercise of the pharmacist's professional judgment:
  - The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient
  - Failure to dispense or sell the drug could result in harm to the health of the patient
- The amount of the drug that is dispensed or sold does not exceed a 72 hour supply

Schedule III – V prescriptions shall be maintained in a separate file from other prescriptions

Schedule III and IV prescriptions may not be refilled more than five times in any six month period

Miscellaneous Prescribing/Dispensing Requirements

Physicians may not personally furnish more than a 72-hour supply of a controlled substance to a patient and, in any 30 day period, personally furnishing quantities supplied to all patients shall not exceed 2,500 dosage units

Before initiating treatment utilizing a Schedule II controlled substance stimulant, the physician must obtain a thorough history, perform a thorough physical examination of the patient, and rule out the existence of any recognized contraindications to the use of the controlled substance

Miscellaneous Prescribing/Dispensing Requirements, cont'd.

Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, a physician shall not prescribe, dispense, or otherwise provide or cause to be provided any controlled substance to a person who the physician has never personally examined and diagnosed

- Does not apply in the following situations:
  - Provision of controlled substances to a person who is a patient of a colleague of the physician, if the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians
  - Provision of controlled substances by a physician to a person who the physician has accepted as a patient, if the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment
  - Provision of controlled substances by a physician who is a medical director or hospice physician of a hospice program to a patient who is enrolled in that hospice program

Prescriptions shall contain the following information:

- Date and signature of practitioner
- Full name and address of patient
- Full name, address, professional title, telephone number, and registry number of practitioner
- Drug name and strength
- Quantity
- Appropriate and explicit directions for use
- Number of refills

Prescribing/Dispensing Limitations for Dentists

Dentists are authorized to write prescriptions for drugs or dangerous drugs in the course of their professional practice

Prescribing/Dispensing Limitations for Optometrists

Optometrists who hold a therapeutic pharmaceutical agents certification and a valid DEA license number are authorized to employ, apply, administer, and prescribe Schedule III controlled substances that are determined to be appropriate for use in optometry

- May prescribe Schedule III narcotics and narcotic preparations as follows:
  - Preparations used for the treatment of pain that contain no more than 60 mg of codeine per dosage unit and also contains other non-narcotic active ingredients in a recognized therapeutic amount
  - Preparations used for the treatment of pain that contains not more than 7.5 mg of hydrocodone per dosage unit and also contains other non-narcotic active ingredients in a recognized therapeutic amount
- The total quantity prescribed shall not exceed a four day supply per episode of illness, injury, and/or treatment

Optometrists may be certified to prescribe or administer topical ocular pharmaceuticals

Pain Clinic/Pain Management Regulations

Chronic pain means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months, and does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition

When a physician diagnoses a patient as having chronic pain, the physician may treat the pain by managing it with controlled substances and products containing tramadol

- For the purpose of assisting in the diagnosis of chronic pain, the physician shall obtain and review all medical records or detailed written summaries of the patient's treatment for chronic pain or the condition causing the chronic pain
    - Recommended that the physician have the patient evaluated by one or more physicians who specialize in the area, system, or organ of the body perceived to be the source of the pain
- Physician shall maintain a written record of all of the following:
    - Medical history and physical examination of the patient
    - Diagnosis of chronic pain, including signs, symptoms, and causes
    - Plant of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment, including all of the following:
        - Documentation that other medically reasonable treatments for relief of the patient's chronic pain have been offered or attempted without adequate or reasonable success
        - Periodic assessment and documentation of the patient's functional status, including the ability to engage in work and other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient
        - Periodic assessment and documentation of the patient's progress toward treatment objectives, including the intended role of controlled substances
        - Periodic assessment and documentation for indicators of possible addiction, drug abuse, or drug diversion
        - Notation of any adverse drug effects
    - The dates on which controlled substances were prescribed, furnished, or administered, the name and address of the patient, and the amounts or dosage forms for the controlled substances
    - A copy of any record or report made by another physician that was used for the purpose of diagnosing the patient's chronic pain or treating the patient for chronic pain
- Physician shall address with the patient the risks associated with protracted treatment with controlled substances, including informing the patient of the risk of the potential for dependence, tolerance, and addiction and the clinical or monitoring tools the physician may use if signs of addiction, drug abuse, or drug diversion are present

Pain management clinic means:

- The primary component of the practice is treatment of pain or chronic pain
- The majority of patients of the prescribers of the facility are provided treatment for chronic pain through the use of controlled substances, tramadol, or other drugs specified in regulation
    - Calculation of the majority of patients will be based on the number of patients treated in a calendar month
        - Patients receiving controlled substances for treatment of an injury or illness that lasts or is expected to last 30 days or less shall not be considered in the calculation

Pain Clinic/Pain Management Regulations, cont'd.

- It does not include:
  - Hospitals, facilities operated by a hospital for the treatment of chronic pain, a physician practice owned or controlled by a hospital or other entity that owns or controls a hospital, an educational institution to the extent that it provides instruction to health care practitioners, hospice program, ambulatory surgical facility, interdisciplinary pain rehabilitation program, nursing home, facility conducting clinical research

Each clinic shall be owned and operated by one or more physicians

- Physician owners shall meet one of the following requirements:
- Hold current subspecialty certification in pain management or hold a current certificate of added qualification in pain management
- Hold current subspecialty certification in hospice and palliative medicine or hold a current certificate of added qualification in hospice and palliative medicine
- Hold current certification by the American board of pain medicine
- Hold current certification by the American board of interventional pain physicians
- Meet both of the following:
  - Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology
  - Demonstrate conformance with the minimal standards of care

Each clinic shall be licensed as a category III terminal distributor of dangerous drugs with a pain management classification

Each owner shall supervise, control, and direct the activities of each individual, including an employee, volunteer, or individual under contract, who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment

- Physician owner shall establish and ensure compliance with the following:
  - A requirement that a log of patients be maintained for each day the clinic is in operation
    - Log sheets shall contain the date, the legible first and last name of each patient
    - Patients shall sign the log at each visit
  - A requirement that providers obtain informed consent for each patient prior to the commencement of treatment
  - An ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides the opportunities to improve the clinic's performance and quality of care
  - A requirement that the background, training, certification, and licensure of all clinical staff be documented
  - A requirement that adequate billing records be maintained for all patients and made available to the board immediately upon request
  - A requirement that adequate patient records are maintained for all patients and made available to the board immediately upon request

Pain Clinic/Pain Management Regulations, cont'd.

- Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the course and results of treatment accurately, by including, at a minimum:
  - Patient history and physical exam, including history of drug abuse or dependence
  - Diagnostic, therapeutic, and laboratory results, including drug testing results
  - Reports of evaluations, consultations, and hospitalizations
  - Treatment objectives, including discussions of risks and benefits
  - Records of drugs prescribed, dispensed, or administered
  - Treatments
  - Receipt and assessment of drug database or PMP reports
  - Copies of records or other documentation received from other health care practitioners

When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

- An initial evaluation of the patient including a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of co-existing illnesses, diseases, or conditions; and an appropriate physical exam
- Medical diagnosis shall be established and documented in the patient record that documents not only the presence of intractable pain, but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism
- Individualized treatment plan shall be formulated and documented in the patient's medical record
  - Treatment plan shall specify the medical justification of the treatment of intractable pain with prescription drugs, the intended role of prescription drug therapy, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without reasonable or adequate success
  - Physician shall document patient's response to the treatment and modify the plan as necessary
- Shall obtain patient consent to treatment
- Diagnosis of intractable pain shall be made either after having the patient evaluated by a physician who specializes in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain or by obtaining a copy of the medical records or detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain

Upon a practitioner's judgment that continued use of controlled substances is medically warranted for the treatment of the patient, a practitioner may continue to prescribe such substances provided that the practitioner continues to adhere to the accepted and prevailing standards of care which shall include, but not be limited to, the following:

- Patients shall be seen at appropriate periodic intervals to assess the efficacy of treatment, assure that drug therapy remains indicated, evaluate the patient's progress toward treatment objectives, and note any adverse drug effects
  - Attention shall be given to the patient's ability to function or the patient's quality of life, as well as indications of possible addiction, drug abuse, or diversion

Pain Clinic/Pain Management Regulations, cont'd.

- Subjective reports from the patient should be supported by objective data
  - Objective measures are determined by ongoing assessments of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient
- Physicians may obtain drug screens of the patient based on evidence or behavioral indicators of drug abuse
  - If patient refuses to submit to a drug screen, the physician shall refer the patient for a consultation with an addiction medicine specialist or other substance abuse professional to obtain a formal assessment of addiction or drug abuse
- Physician shall document in the record the necessity of using more than one controlled substance in the management of the patient's intractable pain

If the physician believes or has reason to believe the patient is suffering from addiction or drug abuse, the physician shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain a formal assessment of addiction or drug abuse

- Physician shall do all of the following:
  - Document the recommendations of the consultation in the record
  - Continue to actively monitor the patient for signs of addiction, drug abuse, or diversion
  - Maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made
- Prescription drug therapy may be continued consistent with the recommendations of the consultation
  - If the consultant believes the patient is suffering from addiction or drug abuse, prompt referral shall be made to one of the following:
    - An addiction medicine specialist or substance abuse professional
    - An addiction medicine or substance abuse treatment facility

Tolerance and physical dependency are normal physiological consequences of extended opioid therapy and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy

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

Board shall approve one or more continuing education courses that assist doctors in diagnosing and treating chronic pain

Each physician owner of a pain management clinic and each physician providing care at a pain management clinic shall complete at least 20 hours of Category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction

Board encourages practitioners who encounter patients with intractable pain to complete continuing education related to the treatment of chronic pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

Dentists, optometrists, and physicians shall register with the PMP

An applicant for renewal of a license to practice medicine and who prescribes or personally furnishes opioid analgesics or benzodiazepines shall certify to the board whether the applicant has been granted access to the PMP

Pharmacists who dispense or plan to dispense controlled substances shall certify, as part of their application to practice as a pharmacist, that they have been granted access to the PMP

Physicians, dentists or their delegates shall check the PMP prior to initially prescribing or furnishing an opioid analgesic or benzodiazepine as part of a patient's treatment for a particular condition

- If the practitioner practices primarily in a county that adjoins another state, the practitioner or delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county
- If the patient's course of treatment for the condition continues for more than 90 days after the initial report is requested, the practitioner or delegate shall make periodic requests for reports until the course of treatment is ended
  - Requests shall be made at intervals not exceeding 90 days
- Shall also check the PMP when prescribing or furnishing Schedule II – V controlled substances to a patient on a protracted basis once the practitioner has reason to believe that treatment will be required on a protracted basis and at least annually thereafter
  - Protracted basis means a period in excess of twelve continuous weeks

Optometrists shall, when prescribing or furnishing Schedule II – V controlled substances to a patient on a protracted basis, check the PMP once the optometrist has reason to believe the treatment will be protracted and at least annually thereafter

- Protracted basis means a period in excess of twelve continuous weeks

Pharmacists shall request and review a PMP report prior to dispensing a prescription and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:

- Receiving reported drugs from multiple providers
- Receiving reported drugs for more than 12 consecutive weeks
- Abusing or misusing reported drugs
  - Over-utilization; early refills; appears overly sedated or intoxicated upon presenting a prescription for a reported drug; or an unfamiliar patient requesting a drug by specific name, street name, color, or identifying marks
- Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar
- Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" State Medical Board, 2013

These guidelines are intended to address the use of opioids for the treatment of chronic, non-terminal pain and the 80 mg MED is the maximum daily dose at which the prescriber's actions are triggered

- 80 mg MED trigger point is not an endorsement to utilize that dose or greater

Health care providers are not obligated to use opioids when a favorable risk-benefit balance cannot be documented

- Providers should first consider non-pharmacologic and non-opioid therapies
- Providers must be vigilant to the wide range of potential adverse effects associated with long term opioid therapy and misuse of extended release formulations
- Providers should avoid starting a patient on long term opioid therapy when treating chronic pain
- Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects

Providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than three continuous months should strongly consider doing the following to optimize therapy and help ensure patient safety:

- Reestablish informed consent, including providing the patient with written information on the potential adverse effects of long term opioid therapy
- Review the patient's functional status and documentation, including the four A's of chronic pain:
  - Activities of daily living
  - Adverse effects
  - Analgesia
  - Aberrant behavior
- Review the patient's progress toward treatment objectives for the duration of the treatment
- Utilize the PMP as an additional check on patient compliance
- Consider a patient pain treatment agreement that may include:
  - More frequent office visits
  - Different treatment options
  - Drug screens
  - Use of one pharmacy and one provider for the prescription of pain medications
  - Consequences for non-compliance
  - Reconsider having the patient evaluated by one or more providers who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain