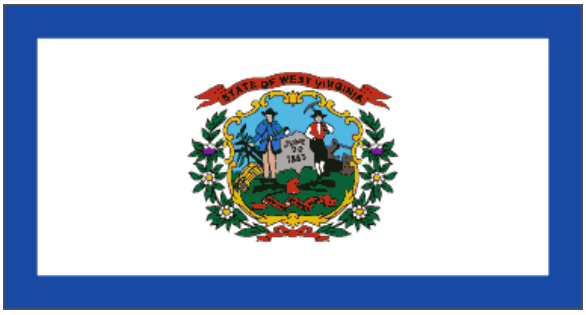
Prescribing and Dispensing Profile

West Virginia



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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 on the written or electronic prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in an emergency
  - Must be promptly reduced to writing
  - If the prescriber is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call-back to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his or her identity
  - The quantity prescribed must be limited to an amount adequate to treat the patient during the emergency period
  - Prescriber must deliver a written prescription to the pharmacist within seven days
- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - Prescription for a narcotic Schedule II substance to be compounded for the direct administration to the patient by certain methods
  - Prescription for the resident of a long term care facility
  - Prescription for a hospice patient

Schedule II prescriptions are valid for 90 days from the date issued

- Pharmacist may fill the prescription after the 90 day limit if s/he confirms with the prescriber that s/he still wants the prescription filled

Prescriber may issue multiple prescriptions for a Schedule II substance authorizing the patient to receive a total of up to a 90-day supply

- Each separate prescription must provide instructions indicating the earliest date on which the prescription may be dispensed

Schedule II prescriptions may not be refilled

Records of Schedule II prescriptions shall be maintained separately

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

Schedule III – V substances may only be dispensed on the written, electronic, or oral prescription of a practitioner

Schedule III – IV prescriptions may not be filled or refilled more than six months after the date originally written or refilled more than five times unless renewed by the practitioner
No prescription order may be refilled after twelve months from the original dispensing

Schedule V substances shall only be distributed or dispensed for a medical purpose

Records of Schedule III – V prescriptions shall be maintained separately or in a form that is readily retrievable from ordinary business records

Miscellaneous Prescribing/Dispensing Requirements

An individual practitioner may administer or dispense a Schedule II – V controlled substance in the course of his or her professional practice without a prescription

It is unprofessional conduct for a physician to prescribe, dispense, or administer a prescription drug, including any controlled substance, other than in good faith and in a therapeutic manner in accordance with accepted medical standards and in the course of the physician's professional practice

- A physician who discharges his or her professional obligation to relieve the pain and suffering and promote the dignity and autonomy of dying patients in his or her care and, in so doing, exceeds the average dosing of pain relieving controlled substances does not violate this article

A pharmacist may not dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing a valid practitioner-patient relationship

- An online or telephonic evaluation by questionnaire or on online or telephonic consultation is inadequate to establish a valid practitioner-patient relationship
- This prohibition does not apply:
  - In a documented emergency
  - In an on call or cross coverage situation
  - Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medicines

No prescription may be dispensed more than twelve months from the date of issuance by the practitioner unless the prescriber confirms that he or she still wants the prescription filled

A pharmacist may dispense an emergency supply of a life-sustaining prescription drug to a patient without a prescription when, in the professional judgment of the pharmacist, the emergency supply is appropriate and the prescribing practitioner is not available

- The emergency supply may not be more than a 10 day supply
- Pharmacist shall immediately document the dispensing indicating the patient name, drug and its strength and amount, date filled, the name of the dispensing pharmacist, and the reasons for emergency dispensing
- Dispensing pharmacist shall contact the prescribing practitioner as soon as possible subsequent to the drugs being dispensed

Prescriptions shall contain the following information:

- Date of issue and signature of prescriber
- Name, address, telephone number, and DEA registration number of prescriber

Prescribing/Dispensing Limitations for Dentists

Dentists may prescribe drugs necessary for the practice of dentistry

Prescribing/Dispensing Limitations for Optometrists

Optometrists may prescribe the following:

- Topical pharmaceutical agents
- Oral pharmaceutical agents that are included in the drug formulary established by the board, which include the following:
  - Oral antibiotics, oral non-steroidal anti-inflammatory drugs, oral carbonic anhydrase inhibitors, antihistamines, oral corticosteroids (may be prescribed for a duration of no more than six days), analgesics (no oral narcotic analgesic may be prescribed for a duration of more than three days), nutritional supplements
- Contact lenses that contain and deliver pharmaceutical agents

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

- 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

Pain management clinic means all privately owned clinics, facilities, or offices not otherwise exempted from this article and which meets both of the following criteria:

- Where in any month more than 50% of patients of the prescribers or dispensers are prescribed or dispensed opioids or other controlled substances for chronic pain resulting from non-malignant conditions
- The facility meets any other identifying criteria established by rule
- Pain management clinic does not include the following:
  - Facility associated with an accredited medical school at which training is provided for medical or osteopathic students, residents or fellows, podiatrists, dentists, nurses, physician assistants, veterinarians, or any affiliated facility to the extent that it participates in the provision of the instruction
  - Facility that does not prescribe or dispense controlled substances for the treatment of pain
  - A hospital licensed in West Virginia, a facility located on the campus of a licensed hospital that is owned, operated, or controlled by that licensed hospital, and an ambulatory health care facility that is owned, operated, or controlled by a licensed hospital
  - A physician practice owned or controlled, in whole or in part, by a licensed hospital or by an entity that owns or controls, in whole or in part, one or more licensed hospitals
  - A hospice program licensed in West Virginia
  - A nursing home licensed in West Virginia
  - An ambulatory surgical facility
  - A facility conducting clinical research that may use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs

Pain Clinic/Pain Management Regulations, cont'd.

No partnership, person, association, or corporation may operate a pain management clinic without first obtaining a license from the secretary

- Licenses are valid for one year
- At least one owner of the clinic must be a physician actively licensed in West Virginia
- Each clinic must designate a physician owner who shall practice at the clinic and who will be responsible for the operation of the clinic and who shall:
  - Have an active, unencumbered license to practice medicine, surgery, or osteopathic medicine or surgery in this state
  - Meeting one of the following requirements:
    - Complete a pain medicine fellowship
    - Hold current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology or such other board certification as may be approved by the secretary
  - Practice at the licensed clinic location for which the physician has assumed responsibility
  - Be responsible for complying with all requirements related to the licensing and operation of the clinic
  - Supervise, control, and direct the activities of each individual working or operating at the facility, including any employee, volunteer, or individual under contract, who provides treatment of chronic pain at the clinic or is associated with the provision of that treatment
  - All persons employed by the clinic shall comply with the requirements for the operation of the clinic
- No person may own or be employed by or associated with a pain management clinic who has previously been convicted of, or pleaded guilty to, any felony in this or another state
- A person may not dispense any medication, including a controlled substance, on the premises of a pain management clinic unless s/he is a physician or pharmacist licensed in West Virginia
  - Prior to dispensing, the physician must check the PMP and at every patient examination thereafter or a minimum of every 90 days
- Clinics may not dispense to any patient more than a 72-hour supply of a controlled substance
- Clinic shall develop patient protocols, treatment plans and profiles, and which shall include, but not be limited to, the following guidelines:
  - When a physician diagnoses an individual as having chronic pain, the physician may treat the pain by managing it with medications in amounts or combinations that may not be appropriate when treating other medical conditions
    - The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived to be the source of the pain unless the individual has already been diagnosed as having chronic pain and is referred to the clinic by such diagnosing physician
  - Physician shall maintain a record of the following:
    - Medical history and physical exam
    - Diagnosis of chronic pain, including signs, symptoms, and causes
    - Plan of treatment proposed, the patient's response to treatment, and any modification of the plan of treatment
    - The dates on which any medications were prescribed, dispensed, or administered
    - A copy of the report made by the physician to whom referral for evaluation was made

Pain Clinic/Pain Management Regulations, cont'd.

- A physician, physician assistant, certified registered nurse anesthetist, or advanced nurse practitioner shall perform a physical examination of the patient on the same day the physician initially prescribes, dispenses, or administers a controlled substance to the patient and at least four times a year thereafter

Physician is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for prescribing, administering, or dispensing pain-relieving controlled substances for the purpose of alleviating or controlling pain if the physician practices in accordance with established guidelines

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

Unless a physician has completed and timely provided to the Board a Board-developed certification form and waiver request attesting that he or she has not prescribed, administered, or dispensed a controlled substance during the entire previous reporting period, every physician as a prerequisite to license renewal shall complete a minimum of three hours of drug diversion training and best practice prescribing of controlled substances training

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

This section deals only with the conditions that qualify a patient for the use of medical marijuana or a therapeutic research program and the attendant physician responsibilities. For complete information on state medical marijuana and therapeutic research programs, please visit the NAMSDL website at www.namsdl.org.

Controlled substances therapeutic research program

- Established for the benefit of cancer chemotherapy patients who are certified to the patient qualification board by a qualified practitioner as being involved in a life-threatening or sense-threatening situation and who are not responding to conventional controlled substances or where the conventional controlled substances administered have proven to be effective, but where the patient has incurred severe side effects

Physician is eligible to prescribe marijuana if he meets the following criteria:

- Patient qualification review board will review and certify each physician for participation in the controlled substances therapeutic research program
  - Physicians shall apply to the board for approval
- Physician shall document experience in cancer therapy
- Physician shall have a current DEA number
- Physician shall register with a registered pharmacy as hereinafter described and the National Cancer Institute
- Physician shall affirm that the patient has signed an informed consent form
- Physician shall limit drug usage to the purposes herein
- Physician shall report adverse drug reactions to the Investigational Drug Bank, National Cancer Institute, and the patient qualification review board

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions, cont'd.

Once certified, registered, and approved, the prescribing physician shall complete a "Research Order for Medication" which shall be presented to a registered pharmacy by the patient

- Standard prescription order may be used but it must contain a statement that informed patient consent has been obtained

Quantity of marijuana dispensed is limited to 25 capsules (5mg strength) for each single prescription

Director shall apply to NIDA or any federally registered distributor or manufacturer for receipt of marijuana

- Director may cause such marijuana to be transferred to a certified licensed pharmacy for distribution to a certified patient upon the written prescription of a certified practitioner

Physician shall advise the patient of the effects and possible side effects of the drug prior to the initial administration thereof

PMP Requirements for Mandatory Registration and Access

Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner or dentist to be suffering from a terminal illness, a practitioner or dentist shall:

- Apply for and receive capability to access the PMP
- Access the PMP to determine whether the patient has obtained any controlled substance from any source other than the current practitioner within the 12 month period immediately preceding the visit of the patient to the current practitioner
    - Date of access and any controlled substance reported to the PMP within the 12 month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record with rationale for the provision of the pain-relieving controlled substance by the current practitioner
- If the patient continues to be treated by the practitioner or dentist with pain-relieving controlled substances, the practitioner shall access the PMP at least annually
    - Date of access and any controlled substances from any other source than the current practitioner shall then be promptly documented in the patient's medical chart by the current practitioner, with the rationale for continuing provision of the pain-relieving controlled substance

Physicians in opioid treatment programs shall query the PMP:

- At the patient's intake
- Before the administration of methadone or other treatment
- After the initial 30 days of treatment
- Prior to any take-home medication being granted
- After any positive drug test
- At each 90-day treatment review

Prior to dispensing or prescribing controlled substances in a pain management clinic, the treating physician must access the PMP to ensure the patient is not seeking controlled substances from multiple sources

- If the patient receives ongoing treatment, the physician shall also review the PMP at each patient examination or at least every 90 days

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, Board of Medicine (July 2013)

Responsibility for appropriate pain management

- All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain
- Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient
  - Legitimate physician-patient relationship must exist
  - The prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed
- Medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and non-pharmacologic modalities, including the use of opioid analgesics and non-opioid therapies

Guidelines

- Patient evaluation and risk stratification
  - The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic and reflect an appropriately detailed patient evaluation
    - Evaluation should be completed before the decision to prescribe opioids is made
    - Nature and extent of the evaluation depends on the type of pain and the context in which it occurs
      - Assessment typically includes the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning
  - Initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated
  - Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be a part of the initial evaluation
  - All patients should be screened for depression and other mental health disorders as part of risk evaluation
    - Patients with untreated depression and other mental health problems are at an increased risk for misuse or abuse of controlled medications, including addiction and overdose
  - Treatment of a patient with a history of substance abuse should involve consultation with an addiction specialist before opioid therapy initiated if possible
  - Patients with an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional

Board Guidelines, cont'd.

- Development of treatment plan and goals
  - Goals of pain treatment include reasonably attainable improvement in pain and function
    - Improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety and avoidance of unnecessary or excessive use of medications
  - Treatment plan and goals should be established as early as possible in the treatment process and revisited regularly
    - Treatment plan should include information supporting the selection of therapies, both pharmacologic and non-pharmacologic
    - Treatment plan should specify objectives that will be used to evaluate treatment progress, such as pain relief and improved physical and psychosocial function
  - Treatment plan should document any further diagnostic evaluation, consultations or referrals, or additional therapies that have been conducted
- Informed consent and treatment agreements
  - The decision to initiate opioid treatment should be a shared decision between physician and patient
  - Physician should discuss the risks and benefits with the patient
  - Use of written informed consent and treatment agreement is recommended
  - Informed consent documents typically address:
    - The potential risks and anticipated benefits of chronic opioid therapy
    - Potential side effects of the medication
    - The likelihood that tolerance to and physical dependence on the medication will develop
    - The risk of drug interactions and over-sedation
    - The risk of impaired motor skills
    - The risk of opioid misuse, dependence, addiction, and overdose
    - The limited evidence as to the benefit of long-term opioid therapy
    - The physician's prescribing policies and expectations, including the number and frequency of refills, as well as the physician's policy on early refills and replacement of lost or stolen medications
    - Specific reasons for which drug therapy may be changed or discontinued
  - Treatment agreements outline the joint responsibilities of physician and patient and are indicated for opioid or other abusable medications and typically discuss:
    - The goals of treatment in terms of pain management, restoration of function, and safety
    - Patient's responsibility for safe medication use
    - Patient's responsibility to obtain opioids from only one physician or practice
    - Patient's agreement to be periodically drug tested
    - Physician's responsibility to be available or have a covering physician available to care for unforeseen problems or to prescribe scheduled refills
- Initiating an opioid trial
  - Safer alternative treatments should be considered before initiating opioid therapy for chronic pain
  - Should be presented to the patient as a therapeutic trial or test for a defined period of time, usually no more than 90 days, and with specified evaluation points
  - The lowest dose possible should be given to an opioid naïve patient and titrate after
  - Decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits vs. adverse events and/or potential risks

Board Guidelines, cont'd.

- Ongoing monitoring and adapting the treatment plan
  - Physician should regularly review the patient's progress, including new information about the etiology of the pain or the patient's overall health and level of function
  - As the patient is stabilized in the treatment regimen, follow up visits may be scheduled less frequently
  - At each visit, the results of opioid therapy should be monitoring by assessing the 5 A's of pain management:
    - Analgesia – whether the patient is experiencing a reduction in pain
    - Activity – has demonstrated an improvement in level of function
    - Adverse – whether there are any adverse effects
    - Aberrant – whether there is evidence of aberrant substance-related behaviors
    - Affect – mood of the patient
  - Continuation, modification, or termination of opioid therapy should be contingent on the physician's evaluation of evidence of the patient's progress toward treatment objectives and the absence of substantial risks or adverse events, such as overdose or diversion
  - Satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life
- Periodic drug testing
  - Periodic drug testing may be useful in monitoring adherence to treatment plans as well as detecting the use of non-prescribed drugs
- Consultation and referrals
  - Physician should seek consultation with or refer the patient to a pain, psychiatry, addiction, or mental health specialist as needed
- Discontinuing opioid therapy
  - The physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate
  - Reasons for discontinuing opioid therapy include resolution of the underlying condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use
    - If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen
- Medical records
  - Every physician who treats patients for chronic pain must maintain accurate and complete medical records that include the following:
    - Copies of the signed informed consent and treatment agreement
    - Patient's medical history
    - Results of the physical exam and all laboratory tests
    - Results of the risk assessment
    - Description of treatments provided, including all medications prescribed or administered
    - Instructions to the patient, including discussion of the risks and benefits
    - Results of ongoing monitoring of patient progress or lack of progress in terms of pain management and functional improvement
    - Notes on evaluations by and consultations with specialists
    - Any other information to support the initiation, continuation, revisions, or termination of treatment and steps taken in response to any aberrant medication use behaviors
    - Authorization for release of information to other providers
    - Must include all prescriptions for opioids and other controlled substances