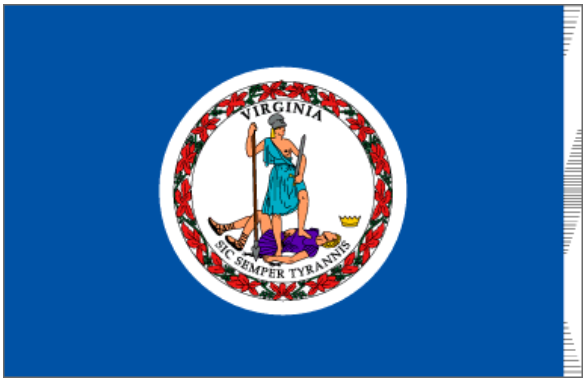
Prescribing and Dispensing Profile

Virginia



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

A prescription for a Schedule II substance shall not be dispensed more than six months after originally issued

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

- May be dispensed on the oral prescription of a practitioner provided that:
  - The quantity prescribed and dispensed is limited to an amount adequate to treat the patient during the emergency period
  - The prescription shall be immediately reduced to writing by the pharmacist
  - If the prescriber is unknown to the pharmacist, s/he shall make a reasonable effort to determine that the oral authorization came from a practitioner using his phone number as listed in the telephone directory or other good faith efforts to ensure his identity
  - The prescriber shall cause a written prescription to be delivered to the pharmacist within seven days
- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - For patients in long term care facilities
  - For home infusion patients
  - For Schedule II narcotic substances for patients residing in a hospice

Schedule II prescriptions shall be maintained in a separate file

Schedule II prescriptions shall not be refilled

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

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

Schedule III – V prescriptions shall either be maintained in a separate file or in such form that they are readily retrievable from other prescriptions of the pharmacy

Schedule III – V prescriptions shall not be dispensed or refilled more than six months after the date on which such prescription was issued and no prescription may be refilled more than five times unless renewed by the practitioner

Schedule V prescriptions may be dispensed without a prescription if:

- The preparation is dispensed only by a pharmacist directly to the patient requesting the preparation
- The preparation is dispensed only to a person who is at least 18 years of age
- The pharmacist requires the person requesting the preparation to furnish suitable identification including proof of age when appropriate
- The pharmacist does not dispense to any one person, or for the use of any one person or animal, any narcotic drug preparation when he knows, or can by reasonable diligence ascertain, that such dispensing will provide the person to whom or for whose use such preparation is dispensed, within 48 consecutive hours, with more than specified amounts of certain drugs

Miscellaneous Prescribing/Dispensing Requirements

Physicians shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of professional practice

- Physician shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled
- The physician shall advise the patient of the right to obtain a controlled substance from him or a pharmacy
  - If the patient chooses to obtain the controlled substance from a pharmacy, the practitioner shall either provide the patient with a written prescription or transmit the prescription orally, electronically, or by fax to the pharmacy of the patient's choice
  - If the patient chooses to purchase the controlled substance from the licensee, the practitioner shall either:
    - Have the patient sign the written prescription and return it to the physician
    - In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years with the dispensing records according to the date of dispensing
      - Form may not be kept in patient's chart

Prescriptions must contain the following information:

- Date of issuance and signature of prescriber
- Full name and address of patient
- Full name, address, telephone number, and registry number of prescriber

Prescribing/Dispensing Limitations for Dentists

Dentists shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of professional practice

Prescribing/Dispensing Limitations for Optometrists

Optometrists shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of professional practice

A TPA-certified optometrist may procure, administer, and prescribe medically appropriate therapeutic pharmaceutical agents to treat diseases and abnormal conditions of the human eye in the following categories:

- Oral analgesics – Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV, and VI narcotic and non-narcotic agents
- Topically administered Schedule VI agents
- Orally administered Schedule VI agents
- Schedule I, II, and V drugs are excluded from the list of therapeutic pharmaceutical agents

Pain Clinic/Pain Management Regulations

In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record

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

No specific statutes or regulations identified.

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.

A practitioner of medicine or osteopathy licensed by the Board of Medicine in the course of his professional practice may issue a written certification for the use of cannabidiol or THC-A oil for treatment or to alleviate the symptoms of a patient's intractable epilepsy

- Written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court in consultation with the Board of Medicine
- Written certification shall contain the name, address, and telephone number of the practitioner; the name and address of the patient; the date on which the certification was made; and the signature of the practitioner
- Written certification expires one year after issuance unless the practitioner provides for an earlier expiration
- No practitioner shall be prosecuted for dispensing or distributing cannabidiol oil or THC-A oil

No medical doctor shall be prosecuted for dispensing or distributing marijuana or THC for medical purposes when such action occurs in the course of his professional practice for treatment of cancer or glaucoma

PMP Requirements for Mandatory Registration and Access

All prescribers licensed in the Commonwealth to treat human patients and who are authorized to issue prescriptions for a covered substance must register with the PMP

Prescribers shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of a benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request PMP information on the patient

Prescribers authorized to prescribe controlled substances for use in the treatment of opioid addiction shall, prior to or as part of execution of a treatment agreement, request a PMP report

The department shall register every dispenser licensed by the Board of Pharmacy with the PMP

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Guidance on the Use of Opioid Analgesics in the Treatment of Chronic Pain, Board of Medicine (October 24, 2013)

Adopted the FSMB Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

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

Board Guidelines, cont'd.

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
- 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

Board Guidelines, cont'd.

- 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
- 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

Board Guidelines, cont'd.

- 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