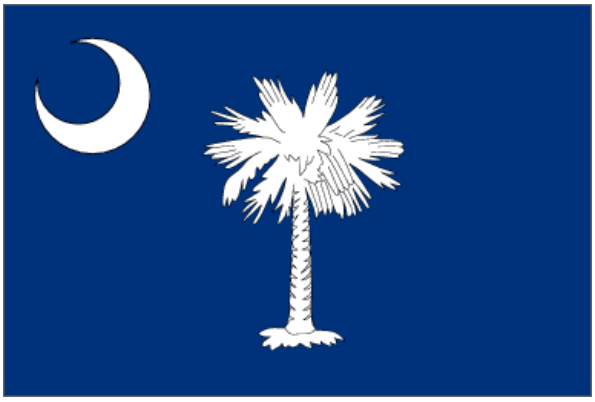
Prescribing and Dispensing Profile

South Carolina



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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 prescription of a practitioner

- May be dispensed on the oral prescription of a practitioner in an emergency situation
  - The quantity dispensed must be limited to an amount sufficient to treat the patient during the emergency period
  - Must immediately be reduced to writing
  - If the prescriber is not known to the pharmacist, s/he shall make a good faith effort to determine that oral authorization came from a registered practitioner, which may include a callback to the prescriber at his or her phone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity
  - Prescriber must deliver a written prescription to the pharmacy within 72 hours
- May be dispensed on the faxed prescription of a practitioner in the following circumstances:
  - A Schedule II narcotic substance to be compounded for direct administration to a patient via certain methods
  - For patients in a long term care facility or hospice program

Prior to the issuance of a prescription for a Schedule II substance, the prescriber shall have a valid practitioner-patient relationship established with the recipient of the prescription, including:

- A sufficient knowledge of the medical need of the patient for a Schedule II substance
- Determination of the risk-benefit ratio
- Good faith determination of the identity of the patient
- Determination of the physical condition of the patient
- Practitioner must be in personal attendance at the time of issuance of the prescription

Schedule II prescriptions may not exceed a 30 day supply

Schedule II prescriptions must be dispensed within 90 days of the date originally issued

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

Schedule II prescriptions may not be refilled

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

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

Prior to the issuance of a prescription for a Schedule III – V substance, the prescriber shall have a valid practitioner-patient relationship established with the recipient of the prescription, including:

- A sufficient knowledge of the medical need of the patient for a Schedule III – V substance
- Determination of the risk-benefit ratio
- Good faith determination of the identity of the patient
- Determination of the physical condition of the patient
- Practitioner must be in personal attendance at the time of issuance of the prescription

Schedule III, IV and V Prescribing Limitations (not related to pain clinics), cont'd.

No prescription shall be refilled sooner than 48 hours prior to the time that the prescription should be consumed if the prescribed daily dosage is divided into the total prescribed amount

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

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

Miscellaneous Prescribing/Dispensing Requirements

It is unprofessional conduct for a physician to initially prescribe drugs to an individual without first establishing a proper physician-patient relationship

- Proper relationship, at a minimum, requires that the physician make an informed medical judgment based on the circumstances of the situation and on the physician's training and experience and that the physician:
  - Personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan
- May prescribe for a patient whom the physician has not personally examined under certain circumstances, including:
  - Writing admission orders for a newly hospitalized patient
  - Prescribing for a patient of another physician for whom the physician is taking call
  - Prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender
  - Continuing medication on a short-term basis for a new patient prior to the patient's first appointment
- Prescribing drugs to an individual the physician has never personally examined based solely on the answers to a set of questions is unprofessional

An individual practitioner may dispense a controlled substance listed in Schedule II - V in the course of his or her professional practice

Prescriptions must contain the following information:

- Full name and address of the patient
- Name, address, telephone number, degree classification of prescriber, license number, and DEA registration number of prescriber
- Date of issuance
- Name, strength, dosage form, and quantity prescribed
- Directions for use
- Number of refills
- Signature of prescriber

Prescribing/Dispensing Limitations for Dentists

Dentists may prescribe controlled substances

Prescribing/Dispensing Limitations for Optometrists

Optometrists may administer, supply, and prescribe pharmaceutical agents, including oral and topically applied medications other than Schedule I and II controlled substances

Pain Clinic/Pain Management Regulations

No specific statutes or regulations identified.

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

Physicians must complete two hours of continuing education related to approved procedures of prescribing and monitoring controlled substances

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.

Program shall distribute marijuana to cancer chemotherapy and radiology patients and to glaucoma patients who are certified as being in a life-threatening or sense-threatening situation and who are not responding to conventional drug therapies or where conventional therapies have proven to be effective but where the patient has incurred severe side effects

Julian's Law

- Qualifying patient means anyone who suffers from Lennox-Gastaut Syndrome, Dravet Syndrome, also known as severe myoclonic epilepsy of infancy, or any other form of refractory epilepsy that is not adequately treated by traditional medical therapies
- A statewide investigational new drug application may be established in this state, if approved by the FDA, to conduct expanded access clinical trials using cannabidiol on qualifying patients with severe forms of epilepsy
- Any physician who is board certified and practicing in an academic medical center in South Carolina and treating patients with severe forms of epilepsy may serve as the principal investigator for such clinical trials if such physician:
  - Applies to and is approved by the FDA as the principal investigator in a statewide investigational new drug application
  - Receives a license from the DEA
- Expanded access clinical trials shall use cannabidiol which is:
  - From an approved source
  - Approved by the FDA to be used for treatment of a condition specified in an investigational new drug application
- A person acting in conformity with the provisions of this law must not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical cannabis

PMP Requirements for Mandatory Registration and Access

No specific statutes or regulations identified.

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Joint Revised Pain Management Guidelines, Board of Medical Examiners, November 2014

Principles of quality medical practice dictate that South Carolinians have access to appropriate and effective pain relief

Persistent, intractable pain is best treated with a bio-psychosocial model and not with opio-centric practices of the past

- Continuum of care choosing possible opioid and non-opioid alternatives is preferred

General principles on the standard of care

- Physicians must assess and evaluate the current status of pain treatment prior to initiating new treatment or adjusting current treatment
- Registering for and using the PMP is considered mandatory for prescribers to provide safe, adequate pain treatment
- All prescribing for pain must be based on clear documentation of unrelieved pain
- To be within the usual course of professional practice, a practitioner-patient relationship must exist
- Prescribers should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction

Guidelines for the treatment of pain

- Prescribers who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including behaviors that indicate addiction and circumstances under which it is appropriate to refer a patient for addiction evaluation and treatment
- Essential elements of appropriate pain management include:
    - Patient evaluation
        - Medical history and physical examination must be obtained, evaluated, and documented in the record
            - Medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases and conditions, the effect of the pain on physical and psychological function, and history of substance abuse as well as the presence of one or more medical indications for the use of controlled substances
        - Use of the PMP should be a part of every patient's initial evaluation and subsequent monitoring and is considered the standard of care
            - Failure to use the PMP could be considered a sign of misconduct by the appropriate licensing board, depending on the clinical situation

Board Guidelines, cont'd.

- Consideration of alternate treatments to opioid therapy
  - Prescriber treating a patient seeking care for pain should have knowledge of all available treatment options including, but not limited to: physical therapy; non-opioid medications; injections; surgical options; cognitive and behavioral methods; rehabilitation approaches; and complementary treatments
  - First line pharmacotherapy should be the appropriate use of non-opioid analgesics, including over the counter medications, non-steroidal anti-inflammatory drugs, and acetaminophen
- Development of a treatment plan and goals
  - Decision to treat pain with opioid therapy should be a joint one between patient and practitioner
  - Prescriber should discuss the risks and benefits of the treatment plan, including any proposed use of opioid analgesics, and should discuss safe storage and disposal of said opioids
  - Appropriate goals of pain treatment include:
    - Reasonably attainable improvement in pain and activity
    - Improvement in pain-associated problems, such as sleep disturbance, depression, and anxiety
    - Avoidance of unnecessary and excessive use of medications
  - Plan should document any further diagnostic evaluations, consultations, or referrals, and/or additional therapies that have been considered, including any follow up plans
- Informed consent documents and treatment agreements are the standard of care, which may be combined into one document for convenience
  - Informed consent documents typically address the following:
    - Potential risks and anticipated benefits of chronic opioid therapy
    - Potential short and long term effects of the medication
    - Risk of drug interactions and over-sedation, including the increased risk of using opiates in disease and conditions such as obesity and sleep apnea
    - Risk of impaired motor skills affecting driving and other tasks
    - Risk of opioid misuse, dependence, addiction, and overdose
    - Limited evidence of the benefit of long term opioid therapy
    - Prescriber's policies and expectations, including the number and frequency of prescription refills, 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 the prescriber and the patient in the management of chronic pain and typically discuss the following:
    - Treatment goals for pain management, restoration of activities, and safety
    - Patient's responsibility for using medications safely, including not using more medication than prescribed, not using an opioid in combination with alcohol or other potentially dangerous substances, storing medications in a secure location, and safely disposing of unused medications
    - Patient's responsibility to obtain opioids from only one prescriber or practice and to fill prescriptions at an in-state pharmacy or one that participates in the South Carolina PMP
    - Patient's agreement to submit to periodic drug testing
    - Prescriber's responsibility to be available or to have a covering prescriber be available to care for unforeseen problems and to prescribe scheduled refills
    - Prescriber's responsibility to provide referrals to substance abuse counseling when abuse potential is present and for failed drug screens

Board Guidelines, cont'd.

- Safer alternative treatments should be considered before initiating opioid therapy
    - Opioid therapy should be presented as a therapeutic trial or test for a defined period of time, usually no more than 90 days, with specified evaluation points
    - Lowest possible dose should be given to an opioid naïve patient at the beginning of opioid therapy and titrated to effect while monitoring for complication
- Prescriber should regularly review the patient's progress with treatment, including any new information about the etiology of the pain or the patient's overall health and level of activities
    - Prescriber should regularly review the PMP
    - Patient should be seen more frequently while the treatment plan is being initiated and when the opioid dose is being adjusted
    - Continuation, modification, or termination of opioid therapy for pain should be contingent on the prescriber's evaluation of the patient's progress toward treatment goals and assessments of substantial risks or adverse events
    - When a patient is prescribed 80 morphine equivalent dose for longer than three continuous months, it is recommended that the prescriber:
        - Re-establish informed consent
        - Review the patient's functional status, including daily activities, analgesia, aberrant behavior, and adverse effects
        - Consult the PMP
        - Re-establish office visit intervals
        - Review frequency of drug screens
        - Review and execute a new treatment agreement
    - Clinicians should avoid over-reliance on opioids as the primary or only treatment modality, including using opioid dose escalation as the only response to a complaint of inadequate pain relief
    - Clinicians should reconsider referral to one or more other providers specializing in the treatment of the area, system, or organ of the body perceived to be the source of the patient's pain
- Periodic drug testing may be useful in monitoring adherence to the treatment plan
- Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require an immediate response
    - Prescribers should be knowledgeable about substance use disorders and be able to distinguish substance use disorder from physical dependence on opiates
    - Combination of periodic, unscheduled, and random pill counting and a concomitant UDS with a confirmation is effective in detecting diversion

Board Guidelines, cont'd.

- Warning signs that a patient may be seeking opioid medications for reasons other than legitimate pain relief include:
  - Suspicious history:
    - Patient referred is already taking controlled substances, especially a combination of narcotics, muscle relaxants, and sedative/hypnotics
    - Self-diagnosis, perhaps based solely on chief complaint
    - Multiple doctors and pain physicians in the past
    - Patient travelled out of the way to come to your clinic
    - Solicitous behavior
    - No past medical records are provided and patient states he is unable to obtain records from "referring doctor"
    - Patient brings records that look tattered, old, or suspicious in some other way
    - Patient asks for specific controlled substance
  - Suspicious physical exam:
    - No abnormal findings
    - Abnormal findings in exam room inconsistent with witnessed behavior (ex., patient has normal gait from car to office door, but limps once inside)
    - Exaggerated behaviors, pain is always a 10 on a scale of 1 to 10
    - Unimpressive imaging
    - Presence of injective behavior or marked nasal erythema from insufflation
    - Patient smells like marijuana smoke
  - No or equivocal clinical improvement
    - Subjective improvement alone does not count
    - Lack of evidence of objective improvement in physical, functional, and psychosocial activities
    - Lack of evidence of decreasing use of opioid medications, decreasing visits to ERs, etc.
  - What to do if clinician suspects misuse, abuse, or addiction:
    - Photocopy patient's ID and social security card
    - Call previous practitioner, pharmacist, or hospital to confirm patient's story
    - Confirm telephone number, if provided by the patient
    - Confirm the address at each visit
    - Investigate suspicions by presenting and discussing specific concerns with the patient, re-checking PMP data, increasing the use of drug screens, and talking with family members
    - Write prescriptions for limited quantities until conflicts are resolved and it is safe to do so
    - Increase frequency of visits and drug screens
    - Document all activities in support of mitigating potential misuse, abuse, or addiction
- Prescriber should seek consultation with or refer the patient to a pain, psychiatric, addiction, or other mental health specialist as needed

Board Guidelines, cont'd.

- Prescriber and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate
    - Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication or if when opioid treatment produces no improvement in physical, functional, or psychosocial activity
    - Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, deteriorating physical, functional, or psychosocial activities or significant aberrant medication use
- Every prescriber who treats patients for pain must maintain accurate and complete medical records that include the following:
    - Copies of the signed consent and/or treatment agreement as appropriate
    - Patient's medical history
    - Results of physical exam and all laboratory test
    - Results of the risk assessment, including results of any screening instruments used
    - Description of the treatment provided, including all medications prescribed or administered
    - PMP data
    - Instructions to patient, including discussion of risks and benefits
    - Results of ongoing monitoring of patient progress in terms of pain management and physical, functional, and psychosocial improvement
    - Notes on evaluations by and consultations with specialists
    - Any other information used to support the initiation, continuation, revision or termination of treatment and the steps taken in response to any aberrant medication use behaviors
    - Authorization for release of medical information to other treatment providers
    - All prescription orders for analgesics and other controlled substances

Actions outside the scope of appropriate pain management include:

- Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine the risks associated with their use in a particular individual with pain
- Inadequate monitoring during the use of potentially abusable medications
- Inadequate attention to patient education and informed consent
- Unjustified dose escalation without adequate attention to risks or alternative treatments
- Excessive reliance on opioids, particularly high dose opioids for chronic pain management
- Not making use of available tools for risk mitigations