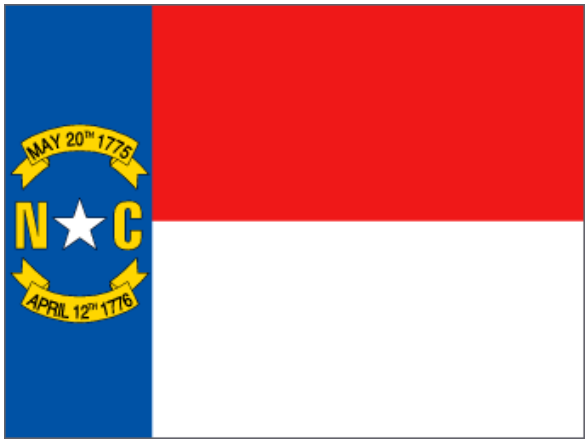
Prescribing and Dispensing Profile

North Carolina



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NAMSDL
National Alliance for Model State Drug Laws

Schedule II Prescribing Limitations (not related to pain clinics)

Schedule II prescriptions 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
  - Must be reduced promptly to writing

Schedule II prescriptions must be dispensed within six months of being issued

Schedule II prescriptions may not be refilled

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

Schedule III – IV prescriptions may only be dispensed on the written or oral prescription of a practitioner

- Oral prescriptions must be promptly reduced to writing

Pharmacist may dispense a one-time emergency refill of a prescription of up to a 30 or 90 day supply, as long as:

- The prescription is not for a Schedule II substance
- The medicine is essential to the maintenance of life or to the continuation of therapy in a chronic condition
- The interruption of therapy might reasonably produce undesirable health consequences
- The dispenser makes a good faith attempt to notify the prescriber or the prescriber's office of the emergency dispensing within 72 hours of the dispensing

Schedule III – IV prescriptions may not be filled or refilled more than six months after originally issued or refilled more than five times

Schedule V substances may not be distributed or dispensed for other than a medical purpose

Miscellaneous Prescribing/Dispensing Requirements

Prescriptions shall contain the following information:

- Date of issuance
- Name and address of patient
- Name, address, and telephone number of prescriber
- DEA number of prescriber
- Name, strength, dosage form, and quantity of drug prescribed
- Refills authorized
- Route of administration of drug prescribed
- Directions for use

Prescribing/Dispensing Limitations for Dentists

The practice of dentistry includes the prescribing drugs for the treatment of dental diseases and conditions

Prescribing/Dispensing Limitations for Optometrists

Optometrist may prescribe and use pharmaceutical agents so long as s/he meets the educational requirements and has been certified by the board

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

No specific statutes or regulations identified.

Medical Marijuana or Controlled Substances Therapeutic Research Program Provisions

No specific statutes or regulations identified.

PMP Requirements for Mandatory Registration and Access

Medical director of an opioid treatment program is required to access the PMP upon admission of a new patient and at least annually thereafter

Patient Referral to Treatment

No specific statutes or regulations identified.

Board Guidelines

Medical Board Policy for the Use of Opiates for the Treatment of Pain, Jan. 2015

Board believes that a fundamental component of good medical practice includes the appropriate evaluation and management of pain

- Responsibly prescribed opiate medications may help North Carolina physicians treat their patients' pain safely and effectively and improve their quality of life
- Board is aware that undertreatment of pain is recognized as a serious health problem that compromises patients' function and quality of life
- Must be understood that chronic pain is often intractable and that complete elimination of chronic pain may not be achieved, even with modern medical knowledge and medical therapies
- Chronic pain is managed optimally with a bio-psychosocial model and not with opio-centric practices of the past
    - Data suggests that patients on chronic high-dose opioids may fare worse over time than those on lower doses or none at all
        - Quality of life measures were lower than those on a low-dose regimen and patients were four times less likely to recover significantly during five years of study
- Board's goal is to provide guidelines that may help to improve the quality of life for those North Carolinians who suffer from pain and reduce the morbidity and mortality associated with inappropriate use of opiates and other controlled substances to treat pain

Evaluation and management of pain is integral to the practice of medicine

- Physicians should be knowledgeable about the process of evaluating their patients' pain and function and be familiar with methods of managing pain safely and effectively
    - Process should be based on an established physician-patient relationship
    - Patients should be assessed for the potential for substance abuse and coexistent mental health conditions
    - Objective and verifiable goals that incorporate physical, functional, and social domains should be prominent components of a patient's treatment plan
    - Non-pharmacologic treatment interventions and use of non-opiate pain medications should be explored before beginning opioid medications
    - When controlled substances are used to treat chronic pain, their use should be accompanied by informed consent and treatment agreements
    - When opioid medications are part of a treatment plan, they should be prescribed or administered in response to an identified medical condition that qualifies for treatment with a controlled substance
    - Physicians should be aware that there is very little data to support the use of long term opioid therapy for common causes of chronic pain such as fibromyalgia, low back pain, pelvic pain, functional bowel disorders, and chronic headache
    - Follow up monitoring should include the patient's progress in achieving objective and verifiable goals and should insure the patient is using prescribed medications safely
    - Opioids should be tapered or discontinued when a patient's pain is poorly controlled on appropriate doses of medication or if there is no physical, functional, or psychosocial improvement

Board Guidelines, cont'd.

- Medical record should provide documentation of:
    - Diagnoses and treatment plans
    - Periodic assessment of patient's progress toward identified goals
    - Medications prescribed and results of medication monitoring
    - Evidence of compliance with treatment agreements
    - Pertinent results of laboratory, radiographic, and ancillary services, including consultations and referrals

The Board recommends the following as best practices behavior when using opiates to treat pain:

- Patient evaluation and assessment of pain
    - Assessment should include the nature and intensity of the pain, past and current treatments, any underlying or co-occurring disorders or conditions, effect of the pain on the patient's physical, function and psychosocial activities
    - Initial work-up should include a systems review and relevant physical examination and laboratory investigations as indicated
    - Social and vocational assessment can be helpful
    - Assessment of patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse should be part of initial evaluation
        - Whenever possible, treatment of a patient with a history of substance use disorder, including alcohol, should involve consultation with an addiction specialist prior to initiating therapy with opiates
        - People who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives, such as co-management with an addiction professional are established
        - Physicians who treat patients with chronic pain are strongly encouraged to be knowledgeable about addiction, including recognizing behaviors that indicate addiction, and how and when to refer patients for addiction evaluation and treatment
        - Physicians should register with the PMP and use information from the PMP to confirm each patient's compliance with treatments plans and opiate medication agreements
        - Obtaining a toxicology screen is a useful tool in setting of risk assessment prior to prescribing opioids
- Development of treatment plan and goals
    - Goals of treatment include reasonably attainable improvement in pain and activity; improvement in pain-associated problems such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications
    - Early treatment with non-pharmacologic interventions including physical therapy, exercise, and cognitive behavioral techniques should be employed whenever possible
        - First line pharmaco-therapy should be the appropriate use of non-opioid analgesics, including over the counter medications, non-steroidal anti-inflammatory drugs, and acetaminophen
        - Other treatment modalities including anesthetic and joint injections, cutaneous stimulators, topical anesthetics, and local therapies employing heat, massage, and manipulations should be considered before using opiates

Board Guidelines, cont'd.

- 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 and should specify the objectives that will be used to evaluate the control of pain and achievement of specific physical, functional, and psychosocial activity goals
- Treatment plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered

- When treating chronic pain, use of a written informed consent and a treatment agreement are recommended, which may be combined into one document for convenience
  - Informed consent documents typically address the following:
    - Potential risks and benefits of chronic opioid therapy
    - Potential side effects, both long and short term, of the medication
    - The risk of tolerance to and dependence on the medication
    - The risk of drug interactions and over-sedation, including the increased risk of using opiates in diseases and conditions such as obesity and sleep apnea
    - Risk of impaired motor skills
    - 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 patient and physician in the management of chronic pain and are indicated when opiates or other abusable medications are prescribed and typically include:
    - The goals of treatment, in terms of pain management, restoration of activities, and safety
    - The patient's responsibility for using medication safely
    - The patient's responsibility to obtain prescribed opioids from only one physician or practice
    - The patient's agreement to periodic drug testing
    - The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills
- When the decision has been made to initiate opioid therapy, it should be presented as a therapeutic trial or test for a defined period of time, usually no more than 90 days, and with specified evaluation points
  - When initiating therapy, the lowest possible dose should be given to an opioid naïve patient and titrated to affect while monitoring for complications
- Physician should regularly review the patient's progress, including any new information about the etiology of the pain and the patient's overall health and level of activities
  - Physician should regularly review the PMP
  - Continuation, modification, or termination of opioid therapy for pain should be contingent on the physician's evaluation of the patient's progress toward treatment goals and assessment of substantial risks or adverse events

Board Guidelines, cont'd.

- At each visit, the results of chronic opioid therapy should be assessed using the 5 A's of chronic pain management
  - Analgesia – reduction in pain
  - Activity – improved physical, functional and psychosocial activity
  - Adverse – the presence of adverse effects
  - Aberrant – evidence of aberrant substance-related behaviors
  - Affect – any change in affect
- Physician should avoid increasing the dosage without adequate attention to risks or alternative treatments

- Periodic drug testing should be used to monitor adherence to treatment plan
- If the physician believes a patient is diverting medication, s/he should conduct a pill count
  - If a drug screen is negative for the prescribed medication, it is an indication that the patient is diverting
  - If a drug screen is positive for the prescribed medication, but the pill count is short, it might be an indication that the patient is diverting
  - Things the physician may look for to ascertain if a patient is seeking prescriptions for other than a legitimate medical purpose:
    - Suspicious history including the patient referred is already taking controlled substances, soft diagnosis, multiple doctors and pain physicians in the past, patient travelled out of the way to see physician, no past medical records, patient brings records that look old, patient asks for a specific controlled substance
    - Suspicious physical exam including no abnormal findings, abnormal findings inconsistent with witnessed behavior (normal gait outside office, limps upon entering facility), exaggerated behaviors, unimpressive imaging, presence of injecting behavior (old or recent track marks or multiple healed or current abscesses), patient smells like marijuana smoke
    - Equivocal compliance including PMP report that shows multiple providers, multiple pharmacies, prescriptions for multiple types of medications, out of the area doctors, etc.; drug screen is refused or abnormal, patient offers multiple excuses, or illegal substances are detected; inconsistent results over time; patient seeks recurrent early refills for lost or stolen prescriptions or for increased opioid use without consultation with prescriber; patient has excuses for lost pills
    - No or equivocal clinical improvement
  - What you should do if you suspect misuse, abuse, or addiction:
    - Request picture ID or other ID and social security number, make photocopy and keep in patient record
    - Call previous practitioner, pharmacist, or hospital to confirm the patient's story
    - Confirm telephone number, if provided by the patient
    - Confirm the current address at each visit
    - Investigate by presenting and discussing specific concerns with the patient, re-checking PMP, increase the use of drug screens, talk with family members
    - Write prescriptions for limited quantities until concerns are resolved and it is safe to do so, and increase frequency of visits and drug screens

Board Guidelines, cont'd.

- Physician should seek consultation with or refer the patient to a pain, psychiatry, addiction, or mental health specialist as needed
- Throughout treatment, physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate
  - Opioids should be discontinued or tapered when a patient's pain is poorly controlled on appropriate doses of medication or if there is no improvement in physical, functional, or psychosocial activity with opioid treatment
- Physicians must maintain complete and accurate records that include the following:
  - Copies of the signed informed consent and treatment agreement
  - Patient's medical history
  - Results of physical exam and laboratory testing
  - Results of the risk assessment, including results of any screening instruments used
  - Description of treatments provided, including all medications prescribed or administered
  - Instructions to the patient, including discussions of risks and benefits with the patient and any significant others
  - Results of ongoing monitoring of patient progress
  - Notes on evaluations by and consultations with specialists
  - Any other information used to support the initiation, continuation, revision, or termination of treatment
  - Authorization for release of information to other providers
  - All prescription orders for opioid analgesics and other controlled substances
- Recommendations for emergency departments:
  - ER physicians should not provide replacement prescriptions for controlled substances that were lost, destroyed, or stolen
  - Long-acting or controlled-release opioids should not be prescribed by ER physicians
  - ER physicians are encouraged to use the PMP before prescribing opioids
  - Physicians who treat chronic pain should send patient pain agreements to local emergency departments for reference
  - Whenever possible, when evaluating a patient with an exacerbation of chronic pain, the ER physician should contact the patient's primary opioid prescriber and access the PMP
    - If analgesics are to be provided, the quantity should be limited to an amount sufficient to tide the patient over until the primary physician's office opens
  - Prescriptions for opioids from ER departments should not exceed 30 pills
  - When appropriate, patients should be screened for substance abuse prior to prescribing opioid medication for acute pain