

Proposed Revision to Med 501.02 (i)

I. Purpose

This rule has been adopted to enable the Board to best protect public health and safety while providing a framework for licensees to effectively treat and manage pain. A licensee's failure to comply with this rule shall constitute unprofessional conduct within the meaning of RSA 329:17, VI (c) and Med 501.01 (a).

This rule is not intended to be used as the standard of care for purposes of any legal claim for civil damages.

This rule is applicable to the prescribing of opioids for the treatment or management of chronic pain and acute pain, as specified.

This rule is not applicable to the prescribing of opioids for the chronic pain management for: (a) patients with cancer pain; (b) patients with a terminal condition; (c) current long-term, non-rehabilitation, residents of a nursing home facility; (d) patients in a hospice program; or (e) patients in a hospital based palliative care program.

II. Definitions

For the purposes of this rule, the following definitions shall apply:

“*Aberrant drug behavior*” means any drug-related behavior that departs from strict adherence to the prescribed therapeutic plan of care.

“*Acute pain*” means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited, often less than three months in duration, and usually less than six months.

“*Addiction*” means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Addiction is characterized by behaviors that include:

- (a) Impaired control over drug use;
- (b) Craving;
- (c) Compulsive use; or
- (d) Continued use despite harm.

“*Chronic pain*” means a state in which non-cancer pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

“*Controlled drug health and safety program*” means the State of New Hampshire’s prescription drug monitoring program which monitors controlled drug prescriptions for DEA scheduled drugs II through IV through the use of an entry driven database accessible to those who prescribe or dispense controlled substances.

“*Controlled substance*” is defined as a drug or other substance, or immediate precursor, included in schedules set forth in the federal Controlled Substances Act.

“*Comorbidity*” means the presence and effect of two illnesses occurring in the same person simultaneously or sequentially. For example, there is significant comorbidity in persons with substance dependence. That is, many individuals who abuse or depend on drugs or alcohol may have an underlying psychiatric condition such as depression, bipolar disorder, post-traumatic stress disorder (PTSD), anxiety disorder, obsessive-compulsive disorder (OCD), etc. Other non-psychiatric comorbidities such as respiratory, cardiac, renal or hepatic disease, sleep apnea, or seizures are also important in the consideration of chronic opiate therapy.

“*Dependence*” means a state of adaptation that is manifested by drug-class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of drug, and/or administration of an antagonist.

“*Episodic care*” means medical care provided by a practitioner other than the designated primary care practitioner in the acute care setting, such as an urgent care facility or emergency department.

“*Long-acting opioids*” are defined as sustained release, controlled release or extended release medications with a longer duration of analgesic action than a short-acting opioid.

“*Maintenance treatment*” means dispensing or administering an opioid medication at a stable dose over 21 days or more for the treatment of opioid addiction.

“*Medication-assisted treatment*” means any treatment of opioid addiction that includes a medication (i.e. methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment.

“*Morphine equivalent dose (MED)*” means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.

“*Opioid abuse*” means the repeated use of a drug while producing problems in three or more areas over a 12-month period. Areas include tolerance, withdrawal, overdose and use despite impending adverse consequences.

“*Opioid*” means any compound that binds to the opioid receptor in the central nervous system. For purposes of this rule, an opioid is any prescription synthetic, or semi-synthetic, medication not derived from the opium plant.

“*Opioid misuse*” means all uses of a prescription medication other than those as directed by a prescriber and used by a patient within the law and requirements of good medical practice.

“*Pain management specialist*” is a licensee or a New Hampshire licensed Advanced Practice Registered Nurse (APRN) who meets one or more of the following qualifications:

If a physician or osteopathic physician:

- i. Is board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or
- ii. Has a subspecialty certificate in pain medicine by an ABMS-approved board; or
- iii. Has a certification of added qualification in pain management by the AOA; or
- iv. Has a minimum of three years of clinical experience in a chronic pain management care setting and:
 - a. Is credentialed in pain management by an entity approved by the Board; and
 - b. Has successfully completed a minimum of at least eighteen continuing education hours in pain management during the past two years for physicians or three years for osteopathic physicians; and
 - c. At least thirty percent of his or her current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.

If an APRN:

- i. Has a minimum of three years of clinical experience in a chronic pain management care setting; and
- ii. Is credentialed in pain management by the New Hampshire state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity; and
- iii. Has successfully completed a minimum of at least eighteen continuing education hours in pain management during the past two years.

“*Short-acting opioids*” are defined as immediate-release medications with a short duration of analgesic activity.

“*Substance dependence*” is defined as exhibition of any three of the following seven criteria during a 12-month period: (1) tolerance; (2) withdrawal; (3) substance often taken in larger amounts or over longer period than intended; (4) persistent desire or unsuccessful efforts to cut down or control use; (5) great deal of time spent in activities necessary to obtain, use, or recover from the substance; (6) important social, occupational, or recreational activities given up or reduced; (7) continued use despite knowledge of having persistent or recurrent physical or psychological problem likely to have been caused or exacerbated by the substance.

“*Toxicology drug screen*” means a test used to check for drugs or other chemicals in a patient’s blood, urine, or saliva specimen that was obtained in the presence of a witness.

“*Transmucosal immediate-release fentanyl (TIRF) drug*” is defined as a highly regulated drug containing fentanyl with a restricted use of managing breakthrough pain in adults with cancer who are routinely taking other opioid pain medicines around-the-clock for pain.

III. *Prescribing Protocols*

When prescribing any opioid to a patient for use in the management or treatment of chronic pain or acute pain, when indicated, all licensees of the Board shall comply with the following:

(1) *Compliance with laws.* To prescribe an opioid to manage or treat any pain in the State of New Hampshire, a licensee shall comply with applicable federal and state statutes, rules and regulations related to the prescribing of controlled substances.

(2) *Continuing Medical Education.*

(A) A licensee authorized to prescribe controlled substances in the State of New Hampshire shall complete at least four (4) hours of continuing medical education every two (2) years in the areas of pain management and the prescribing of controlled substances (opioids).

(B) A licensee authorized to prescribe methadone to manage or treat addiction in the State of New Hampshire shall complete four (4) continuing medical education hours in the area of prescribing methadone to manage or treat addiction. These hours will be good for as long as the licensee holds an active license with the Board.

(3) *Evaluation of the Patient.* Prior to prescribing an opioid to a patient for the management or treatment of acute pain or chronic pain, a licensee shall conduct a complete patient evaluation and risk stratification in order to determine whether or not the patient is an appropriate candidate for an opioid prescription.

(A) A licensee is responsible for obtaining, evaluating and documenting a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of his or her patient.

(B) The medical record shall document the medical history and physical examination. In the case of acute pain or chronic pain, the medical record shall document:

- i. The licensee's personal participation in the evaluation process;
- ii. The nature and intensity of the pain;
- iii. Current and past treatments for pain and reports of previous evaluations and treatments received directly from other providers;
- iv. Medications, including indication(s) and the date, type, dosage, and quantity of all medications prescribed;
- v. Underlying or coexisting disorders and conditions;
- vi. The effect of the pain on physical, functional and psychosocial functions;
- vii. Any personal, and family, history of substance abuse and diversion;
- viii. A review by the licensee, or his or her delegate, of the New Hampshire Controlled Drug Prescription Health and Safety Program, with the results obtained documented in the medical record. The effective date of this mandatory requirement is January 1, 2017;
- ix. Use of a opioid risk-assessment screening tool, which shall generate a risk assessment (low, moderate, or high) by addressing:
 - a. History of addiction;
 - b. Abuse or aberrant drug behavior regarding opioids;
 - c. Psychiatric conditions;
 - d. Regular concomitant use of benzodiazepines, alcohol, or other central nervous system medications;
 - e. Depression or anxiety;
 - f. Evidence, or the risk, of significant adverse events, including falls or fractures;
 - g. Receipt of opioids from more than one prescribing practitioner or practitioner group;
 - h. Repeated visits to urgent care facilities and/or emergency departments seeking opioids;
 - i. History of sleep apnea or other respiratory risk factors;

- j. Possible or current pregnancy; and
 - k. History of allergies or intolerances.
- x. The presence of one or more recognized medical indications for the use of an opioid;
 - xi. Social and vocational assessment; and
 - xii. Systems review, a relevant physical examination and laboratory investigations, as indicated.
- (C) A licensee shall only prescribe an opioid for the management or treatment of acute pain or chronic pain when the evaluation of the patient has revealed the following considerations that shall be documented in the medical record:
- i. That other physical, behavioral and non-opioid medication measures have not resolved the patient's pain,
 - ii. The potential benefits of opioid therapy are likely to outweigh the potential harm associated with it, and
 - iii. Any contraindication to the use of an opioid for pain (e.g. substance abuse/substance abuse disorder) has been evaluated and discussed with the patient.
- (D) A licensee shall consider prescribing nalaxone, as a preventative rescue medication in the event of an opioid-related overdose, if the licensee prescribes an opioid. The consideration of the prescribing of nalaxone shall be documented in the medical record.

(4) Prescribing Limitations. If a patient is determined to be a candidate for an opioid prescription to manage or treat acute pain or chronic pain, the licensee writing the opioid prescription shall adhere to the following restrictions:

- (A) Prior to issuing an initial prescription for an opioid for the treatment of acute pain or chronic pain, the licensee shall review prescription data and history, if any, related to the patient, contained in the New Hampshire Controlled Drug Prescription Health and Safety Program database. The effective date of this mandatory requirement is January 1, 2017.
- (B) The licensee shall use caution prior to issuing an opioid prescription to a patient when the licensee's review of the Controlled Drug Prescription Health and Safety Program database indicates that the patient:

- i. Has been untruthful to the licensee, or his or her staff, about his or her current prescriptions; or
 - ii. Has received prescriptions for opioids from two or more prescribers and/or has had opioids dispensed to him or her from two or more pharmacies.
- (C) A licensee shall not prescribe more than a five day supply of an opioid to a patient who presents for episodic care of acute pain or chronic pain.
- (D) A licensee shall not prescribe any Transmucosal Immediate-Release Fentanyl (TIRF) drug to any non-cancer patient, including patients whose cancer is in remission.
- (E) When prescribing an opioid for the treatment of acute pain or chronic pain, a licensee shall not combine an opioid with sedative-hypnotics, benzodiazepines, or barbiturates unless such co-prescribing is medically indicated and documented as such in the medical record along with documentation of the licensee discussing the risks associated by such co-prescribing with the patient.
- (F) For an initial dosage of any opioid prescription written for the management or treatment of acute pain or chronic pain in opioid-naïve patients and patients at high risk for substance abuse, misuse or addiction, a licensee shall only prescribe the opioid at the lowest possible effective dosage and titrate slowly.
- (G) In the management or treatment of acute pain: A licensee shall only prescribe long-acting opioids after the use of short-acting opioids has been attempted or considered and documented in the medical record. When use of short-acting opioids has only been considered, and not attempted, the licensee must document the rationale for providing long-acting opioids instead of short-acting opioids.
- (H) In the management or treatment of chronic pain: Long-acting opioids, including methadone, should only be prescribed by a licensee who is familiar with its risks and use, and who is prepared to conduct the necessary careful monitoring. Special attention should be given to patients who are initiating such treatment.
- (I) When prescribing an opioid for the management or treatment of chronic pain, a licensee shall only write such a prescription in multiples of a seven day supply.

(5) Treatment Plan for Chronic Pain. A licensee is responsible for creating and maintaining a current, complete, and accurate treatment plan for the prescribing of any opioid to his or her chronic pain patients. The treatment plan shall be documented in the medical record and include the following:

- (A) How the opioid(s) relate(s) to the chief presenting complaint of chronic pain;
- (B) The type, dosage, quantity, date and frequency of any opioid prescribed;

- (C) Further laboratory testing and diagnostic evaluations to be ordered, if medically indicated, as well as the results of such tests and evaluations;
- (D) Other treatments that are planned or considered;
- (E) Periodic reviews planned; and
- (F) Objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(6) Informed Consent and Treatment Agreements.

- (A) It is the responsibility of the licensee issuing an opioid prescription to discuss the risks and benefits of the use of opioids for the management or treatment of acute pain or chronic pain, with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.
- (B) This discussion, including the informed consent, shall be documented by both a written signed document maintained in the medical record and contemporaneous notations in the medical record for each change in the type, dosage and quantity of the opioid(s) being prescribed.
- (C) Discussion of the risks and benefits shall include an explanation of the:
 - i. Diagnosis;
 - ii. Treatment plan and the rationale for the plan, including any opioid being prescribed;
 - iii. Anticipated therapeutic results, including the realistic expectations for sustained pain relief and improved functioning and possibilities for lack of pain relief;
 - iv. Therapies in addition to, or instead of, drug therapy, including physical therapy or psychological techniques;
 - v. Potential side effects and how to manage them;
 - vi. Adverse effects, including the potential for addiction, tolerance, and withdrawal; and
 - vii. Potential for impairment of judgment and motor skills.

- (D) If a licensee prescribes an opioid for the treatment of acute pain or chronic pain to a patient with a prescription for a sedative-hypnotics benzodiazepines or barbiturates because it is deemed by the licensee to be medically indicated, the licensee shall discuss the risks associated by such co-prescribing with the patient and shall document the discussion, including the informed consent, in the medical record.
- (E) When prescribing an opioid to a chronic pain patient or patient at high risk for medication abuse, misuse or addiction, including a patient with, but not limited to, psychiatric comorbidities or a history of substance abuse, the licensee shall use a written agreement for treatment with the patient. The written agreement for treatment shall include:
- i. The patient's agreement to provide biological samples for urine/serum medical level screening when requested by the licensee. The agreement shall note that the licensee may make the request randomly;
 - ii. The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
 - iii. Reasons for which drug therapy may be discontinued (e.g., violation of the agreement);
 - iv. The requirement that all chronic pain management prescriptions are provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system unless the designated pharmacy under the agreement is out of stock of the drug prescribed at the time that the prescription is communicated by the physician to the pharmacy or patient presents to have the drug dispensed;
 - v. The patient's agreement to not abuse alcohol or use other medically unauthorized substances;
 - vi. A written authorization for:
 - a. The licensee to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and
 - b. Other practitioners to report violations of the agreement back to the licensee;
 - vii. An acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;
 - viii. An acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and
 - ix. An acknowledgment that if the patient violates the terms of the agreement, the violation and the physician's response to the violation will be

documented, as well as the rationale for changes in the treatment plan if applicable.

(7) Consultations and Referrals.

(A) The licensee shall consider referring a patient being prescribed opioids for the management or treatment of pain for additional evaluation and treatment as needed to achieve treatment objectives. Such consideration shall be documented in the medical record. Special attention should be given to those chronic pain patients who are under eighteen years of age, or who are at risk for medication abuse, misuse, or addiction. The treatment or management of pain in patients with a history of substance abuse or with comorbid psychiatric disorders may require extra care, monitoring, documentation, and consultation with, or referral to, an expert in the management of such patients.

(B) The consultation consideration threshold for adults is one hundred milligrams per day morphine equivalent dose (orally) or prescribed opioids for ninety days or more. In the event a licensee prescribes a dosage amount that causes a patient to meet or exceed the consultation threshold of one hundred milligrams per day morphine equivalent dose (orally) or prescribes opioids to a patient for ninety days or more, a consultation with a pain management specialist shall be considered.

(C) A licensee shall document in the medical record when the consultation consideration threshold is met. If the consultation consideration threshold is met, and the licensee determines to waive consultation with a pain management specialist, the licensee shall document the rationale in the medical record.

(D) Any consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides documentation of the consultation to the licensee, the licensee shall maintain such documentation as part of the medical record.

(E) A licensee who suspects that his or her patient has become addicted to an opioid shall explain to the patient the option of buprenorphine detoxification and maintenance and refer the patient to an addiction specialist, buprenorphine provider, or methadone maintenance treatment program. Such explanation or referral shall be documented in the medical record.

(8) Periodic Review of the Treatment of Chronic Pain.

(A) A licensee prescribing opioids to a chronic pain patient shall see the patient for periodic reviews at reasonable intervals in view of the patient's risk level of substance abuse, misuse, or addiction. Low risk patients shall be seen at a minimum of every six to eight months; moderate risk patients shall be seen at a minimum of every three to five months; and high risk patients or those patients who are on a one hundred milligrams per day morphine equivalent dose (orally) or greater shall be seen at a minimum of every one to two months.

(B) Each periodic review shall assess progress toward reaching treatment objectives, taking into consideration the history of medication usage, as well as any new information about the etiology of the pain.

(C) Each visit for a periodic review shall include an evaluation of the patient and shall be documented in the medical record.

(D) Contemporaneous to the periodic reviews, the licensee shall note in the medical record any adjustment in the treatment plan based on the individual medical needs of the patient.

(E) A licensee shall base any continuation or modification of the use of opioids for pain management on an evaluation of the following considerations that are to be documented in the patient's medical record:

- i. Progress or the lack of progress in relieving pain as indicated by the patient's decreased pain and increased level of function.
- ii. Objective evidence of improved or diminished function, which shall be monitored.
- iii. If the patient's progress is unsatisfactory or treatment goals are not being achieved (despite medication adjustments), the licensee shall reassess the current treatment plan and consider the use of other therapeutic modalities or a physical rehabilitation program instead of continued treatment with opioids.
- iv. The licensee shall periodically review the patient's compliance with the prescribed treatment plan and reevaluate for any potential for substance abuse, misuse, addiction, or diversion. In doing so, the licensee shall periodically review prescription data and history related to the patient, if any, contained in the Controlled Drug Health and Safety Program database. The licensee shall document his or her review of the Controlled Drug Health and Safety Program database in the medical record.
- v. A licensee shall obtain toxicology drug screen(s) to determine the presence of drugs, if any, in the patient. Such drug screen(s) shall be obtained at a minimum of once a year for low risk patients, twice a year for moderate risk patients and at a minimum of one to two months for patients determined to be at high risk for substance abuse, misuse, or addiction. The licensee shall discuss any drug screen result with the patient at his or her next office visit. The occurrence and details of such a discussion shall be documented in the medical record.
- vi. A licensee shall document any non-adherence to the treatment plan and any evidence of opioid abuse, misuse, addiction, or diversion.

(F) A licensee shall taper or wean a pain patient off opioids if the patient engages in repeated aberrant drug related behaviors, experiences no progress toward treatment objectives, or experiences intolerable adverse effects.

(G) When prescribing an opioid to a pain patient whose drug screen is negative for the opioid that has been prescribed to him or her and the patient claims to have taken the opioid as prescribed, the licensee shall document the rationale for continuing to prescribe the opioid.

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