PROPOSED REGULATION OF THE

STATE BOARD OF OSTEOPATHIC MEDICINE

LCB File No. R069-16

June 3, 2016

EXPLANATION - Matter in *italics* is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §§1-11, NRS 633.131 and 633.291.

A REGULATION relating to osteopathic medicine; prescribing requirements relating to the treatment of pain; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Osteopathic Medicine to adopt and enforce regulations necessary to carry out its statutory duties, including regulations which establish the principles of medical ethics to be used as the basis for determining whether conduct which does not constitute malpractice is unethical. (NRS 633.291) **Section 6** of this regulation: (1) authorizes an osteopathic physician or physician assistant to prescribe, order, administer or dispense an opioid only based on accepted scientific knowledge or a sound clinical basis; and (2) requires an osteopathic physician or physician assistant to document certain actions in the medical record of the patient. **Section 7** of this regulation prescribes conditions under which an osteopathic physician or physician assistant may prescribe an opioid to treat acute pain. **Section 8** of this regulation requires an osteopathic physician or physician assistant to take certain actions in conjunction with treating a patient for chronic pain or intractable pain, including developing a treatment plan for the patient. **Section 9** of this regulation requires an osteopathic physician or physician assistant to take certain actions if he or she prescribes an opioid to treat chronic pain or intractable pain.

Existing regulations provide that an osteopathic physician or physician assistant engages in unethical conduct if he or she prescribes a controlled substance in an amount that the Board determines is excessive. (NAC 633.350) **Section 11** of this regulation removes this provision and instead provides that an osteopathic physician or physician assistant engages in unethical conduct if he or she prescribes an opioid and fails to comply with the requirements of **sections 3-9** of this regulation.

Section 1. Chapter 633 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 9, inclusive, of this regulation.

- Sec. 2. "Opioid" means any controlled substance that binds to an opioid receptor in the central nervous system. The term includes, without limitation, any naturally occurring, synthetic or semisynthetic medication or endogenous opioid peptide.
- Sec. 3. As used in sections 3 to 9, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 4 and 5 of this regulation have the meanings ascribed to them in those sections.
- Sec. 4. "Chronic pain" means pain suffered by a patient that lasts more than 90 days or longer than the time of normal healing from the condition suffered by the patient, whichever period is shorter. The term does not include pain occurring and being treated at an inpatient acute care facility or pain resulting from cancer or the treatment of cancer.
 - Sec. 5. "Intractable pain" has the meaning ascribed to it in NAC 630.255.
 - Sec. 6. An osteopathic physician or physician assistant:
- 1. May prescribe, order, administer or dispense an opioid to treat acute pain, chronic pain or intractable pain only for a legitimate medical purpose based on accepted scientific knowledge of the treatment of such pain or sound clinical grounds relating to the unique condition and circumstances of the patient.
- 2. Shall document in the medical record of the patient all actions taken by the osteopathic physician or physician assistant to comply with the requirements of sections 3 to 9, inclusive, of this regulation, insofar as those requirements are applicable to the treatment rendered.
- Sec. 7. 1. Except as otherwise provided in this section, an osteopathic physician or physician assistant treating a patient for acute pain shall consider and discuss with the patient all non-opioid treatments that could, in the professional judgment of the osteopathic physician or physician assistant, possibly be used to treat the acute pain. If, in the professional judgment

of the osteopathic physician or physician assistant, an opioid is appropriate to treat the acute pain of a patient, the osteopathic physician or physician assistant shall prescribe the opioid at the lowest effective dose and for not longer than the expected duration of the acute pain.

- 2. Except as otherwise provided in this section, an osteopathic physician or physician assistant shall not prescribe a long-lasting or extended-release opioid to treat acute pain unless the osteopathic physician or physician assistant determines, based on the needs of the particular patient, that there is a clinical reason that a long-lasting or extended-release opioid is necessary to treat the acute pain. If the osteopathic physician or physician assistant makes such a determination, he or she shall document the clinical reason in the medical record of the patient.
 - 3. The provisions of subsections 1 and 2 do not apply to treatment rendered:
 - (a) At an inpatient acute care facility; or
 - (b) In the course of palliative care or end-of-life care.
 - 4. As used in this section:
- (a) "Acute pain" means pain that is the normal, predictable response to a noxious chemical, thermal or mechanical stimulus that is typically associated with an invasive procedure, trauma or disease and limited in duration. The term does not include pain resulting from cancer or the treatment of cancer.
 - (b) "End-of-life care" means care:
- (1) For a patient with a terminal illness or who is at high risk of dying in the near future; and
 - (2) That is provided in a hospice, hospital, long-term care facility or home.
 - (c) "Long-term care facility" has the meaning ascribed to it in NAC 449.638.

- (d) "Palliative care" means care that provides relief from pain and other symptoms, supports quality of life and is focused on the advanced illness of a patient.
- Sec. 8. 1. Before treating the chronic pain or intractable pain of a patient, an osteopathic physician or physician assistant must have:
- (a) Conducted a medical history, a physical examination and diagnostic testing that is appropriate based on the symptoms and medical history of the patient;
 - (b) Diagnosed the patient as suffering from chronic pain or intractable pain; and
 - (c) Developed a written treatment plan that includes:
- (1) Information supporting all of the pharmacologic and nonpharmacologic treatment that the osteopathic physician or physician assistant plans to use to treat the chronic pain or intractable pain;
- (2) The specific goals of the treatment that the osteopathic physician or physician assistant will use to evaluate the progress and success of the treatment, such as the relief of pain and improved physical, psychological and social functions; and
- (3) Documentation of the ordering, consideration or analysis of diagnostic evaluations, consultations and referrals and any additional therapies that the osteopathic physician or physician assistant considered.
- 2. While treating a patient for chronic pain or intractable pain, an osteopathic physician or physician assistant shall:
- (a) Refer or consider referring the patient to or consult or consider consulting with other appropriate providers of health care, including, without limitation, specialists in pain medicine, psychiatrists, psychologists, neurologists and addiction specialists if necessary to further the goals of the treatment; and

- (b) Conduct an assessment of the patient at each patient visit to monitor the treatment plan and modify that plan if the osteopathic physician or physician assistant determines that modification is necessary as a result of the assessment.
- Sec. 9. 1. If an osteopathic physician or physician assistant prescribes an opioid to treat chronic pain or intractable pain:
 - (a) The osteopathic physician or physician assistant shall, before prescribing the opioid:
- (1) Obtain and analyze a patient utilization report regarding the patient for the immediately preceding 12 months from the computerized program established by the State Board of Pharmacy and the Investigation Division of the Department of Public Safety pursuant to NRS 453.162; and
- (2) Obtain the informed written consent of the patient to opioid treatment on a form signed by the patient.
- (b) The treatment plan established pursuant to section 8 of this regulation must include a trial period for the opioid treatment, which must include:
- (1) Specified points at which the progress and success of the treatment will be evaluated;
- (2) Initiation of the treatment at the lowest possible dosage and increasing the dosage as necessary until the treatment is effective;
- (3) Periodic and regular monitoring of the benefit and harm caused by the treatment in relation to the patient's level of pain, physical, psychological and social functions and quality of life; and
- (4) Evaluation of the benefit and harm caused by the treatment and the potential risk of continuing the treatment beyond the trial period.

- 2. After the trial period described in subsection 1, the osteopathic physician or physician assistant shall evaluate all relevant information and determine whether to continue, discontinue or modify the opioid treatment.
- 3. During the course of using an opioid to treat the chronic pain or intractable pain of a patient, an osteopathic physician or physician assistant shall:
- (a) Obtain and analyze drug screens of the patient at the frequency warranted by the risk or evidence of aberrant behavior or as prescribed in the treatment plan established pursuant to section 8 of this regulation;
- (b) Periodically obtain and analyze a patient utilization report regarding the patient from the computerized program established by the State Board of Pharmacy and the Investigation Division pursuant to NRS 453.162 to ensure that the patient is compliant with the treatment plan established pursuant to section 8 of this regulation and is not misusing, abusing or diverting opioids; and
- (c) Terminate, modify or place additional conditions on continued opioid treatment if there is evidence or reason to suspect that the patient is misusing, abusing or diverting opioids.
 - **Sec. 10.** NAC 633.005 is hereby amended to read as follows:
- 633.005 As used in this chapter, unless the context otherwise requires, the words and terms defined in NAC 633.020 to 633.065, inclusive, *and section 2 of this regulation* have the meanings ascribed to them in those sections.
 - **Sec. 11.** NAC 633.350 is hereby amended to read as follows:
- 633.350 1. For the purposes of this chapter and chapter 633 of NRS, an osteopathic physician engages in unethical conduct if he or she:
 - (a) Engages in sexual misconduct with a patient;

- (b) Abandons a patient;
- (c) Willfully makes and files false reports, records or claims in the osteopathic physician's practice;
- (d) Willfully fails to file or record a medical report required by law, willfully impedes or obstructs the filing or recording of such a report, or willfully induces another person to fail to file or record such a report;
- (e) Fails to generate or create medical records relating to the diagnosis, treatment and care of a patient;
- (f) Prescribes [a controlled substance in a manner or an amount that the Board determines is excessive;] an opioid and fails to comply with the requirements of sections 3 to 9, inclusive, of this regulation;
- (g) Fails to comply with the terms of an agreement with a diversion program approved by the Board;
 - (h) Fails to comply with an order of the Board;
- (i) Violates the provisions of NRS [633.505] 633.750 concerning retaliation or discrimination against an employee;
- (j) Violates the provisions of NRS 629.061 concerning making the health care records of a patient available for physical inspection and furnishing a copy of the health care records;
- (k) Fails to provide adequate supervision of a medical assistant who is employed or supervised by the osteopathic physician; or
- (l) Engages in any other conduct that the Board determines constitutes unfitness to practice osteopathic medicine.

- 2. For the purposes of this chapter and chapter 633 of NRS, a physician assistant engages in unethical conduct if the physician assistant engages in any conduct which constitutes unethical conduct by an osteopathic physician pursuant to paragraphs (a) to (i), inclusive, of subsection 1.
 - 3. As used in this section, "medical assistant" means any person who:
 - (a) Is employed by an osteopathic physician;
 - (b) Is under the direction and supervision of the osteopathic physician;
 - (c) Assists in the care of a patient; and
- (d) Is not required to be certified or licensed by an administrative agency to provide that assistance.