

Neuada State Board of Pharmacy

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July 27, 2018

NOTICE OF INTENT TO ACT UPON A REGULATION

Notice of Hearing for the Adoption and Amendment of Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a Public Hearing at 1:30 p.m. on Wednesday, September 5, 2018, at the Hyatt Place, 1790 East Plumb Lane, Reno, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the adoption and amendment of regulations that pertain to Chapters 453 and/or 639 of the Nevada Administrative Code.

The following information is provided pursuant to the requirements of NRS 233B,060:

Amendment of Nevada Administrative Code Chapter 639 to add a new section thereto providing for the prescribing or dispensing of controlled substances for the treatment of pain in conformance with Assembly Bill 474 from the 2017 Nevada Legislative Session. (LCB File No. R144-18)

1. The need for and the purpose of the proposed regulation or amendment.

The proposed amendments relate to controlled substances. They clarify the requirements a practitioner must follow when obtaining informed written consent to prescribe a controlled substance, entering into prescription medication agreements concerning a class of certain controlled substances and establishing a manner for obtaining an assessment of a patient's risk for abuse, dependency and addiction; and providing other matters properly relating thereto.

2. Either the terms or the substance of the regulations to be adopted and amended.

A copy of the proposed regulation amendment is attached to this notice.

3. The estimated economic effect of the regulation on the business which it is to regulate and on the public:

(a) Both adverse and beneficial effects.

This regulation relates to the prescribing of controlled substances for the treatment of pain in conformance with Assembly Bill No. 474 of the 79th Legislative Session. There should be no adverse economic impact from this regulation on the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible.

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no additional or special costs incurred by the Board of Pharmacy for enforcement of this regulation.

5. A description of and citation to any regulations of other state or local governmental agencies which the proposed regulation overlaps or duplicates and a statement explaining why the duplication or overlapping is necessary. If the proposed regulation overlaps or duplicates a federal regulation, the notice must include the name of the regulating federal agency.

The Board of Pharmacy is not aware of any similar regulations of any other state or local governmental agency that the proposed regulation overlaps or duplicates.

6. If the regulation is required pursuant to federal law, a citation and description of the federal law.

The regulation is not required by federal law.

7. If the regulation includes provisions which are more stringent than a federal regulation that regulates the same activity, a summary of such provisions.

The Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

8. Whether the proposed regulation establishes a new fee or increases an existing fee.

This regulation does not provide a new or increase of fees.

Persons wishing to comment upon the proposed action of the Board may appear at the scheduled public hearing or may address their comments, data, views, or arguments in written form to the Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada 89509, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. If no person who is directly affected by the proposed action appears to request time to make an oral presentation, the Board may proceed immediately to act upon any written submissions.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. This notice and the text of the proposed regulation are also

available in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653, and on the Internet at http://www.leg.state.nv.us. Copies of this notice and the proposed regulation will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either before adoption or within 30 days thereafter, will issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

This notice of hearing has been posted at the following locations:

Nevada State Board of Pharmacy

Reno, Nevada

Nevada State Board of Pharmacy

Las Vegas, Nevada

Mineral County Courthouse

Hawthorne, Nevada

Elko County Courthouse

Elko, Nevada

Washoe County Courthouse Reno, Nevada

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R144-18

July 16, 2018

EXPLANATION - Matter in italies is new, matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §§1-4, NRS 639.070 and 639.23916.

A REGULATION relating to controlled substances; requiring a practitioner to take certain actions when obtaining informed written consent to and entering into a prescription medication agreement concerning a class of certain controlled substances; establishing a manner for obtaining an assessment of a patient's risk for abuse, dependency and addiction; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires a practitioner, other than a veterinarian, to obtain informed written consent from a patient before prescribing a controlled substance listed in schedule II, III or IV for the treatment of pain. (NRS 639.23911, 639.23912) Existing law also requires a practitioner, other than a veterinarian, who intends to prescribe a controlled substance listed in schedule II, III or IV for the treatment of pain to enter into a prescription medication agreement with the patient. (NRS 639.23914) Sections 2 and 4 of this regulation impose certain requirements on a practitioner when obtaining informed written consent and entering into a prescription medication agreement, respectively, concerning the use of a class of controlled substances listed in schedule II, III and IV. Sections 2 and 4 also require a practitioner who has obtained informed written consent to or entered into a prescription medication agreement concerning a class of controlled substances to take certain actions to ensure that the patient remains properly informed.

Existing law requires a practitioner, other than a veterinarian, to require a patient who has used a controlled substance listed in schedule II, III or IV for 90 consecutive days or more for the treatment of pain to complete an assessment of his or her risk for abuse, dependency and addiction before prescribing the controlled substance to continue the treatment. (NRS 639.23913) Section 3 of this regulation: (1) authorizes such an assessment to be conducted in verbal or written form; and (2) requires such an assessment to include at least one question concerning depression.

- **Section 1.** Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 and 3 of this regulation.
- Sec. 2. A practitioner who obtains informed written consent pursuant to NRS 639.23911 and 639.23912 to the use of a class of controlled substances listed in schedule II, III or IV, must, in addition to meeting the requirements for informed written consent set forth in NRS 639.23912:
- 1. Explain the nature and terms of the written consent to the person from whom informed written consent is obtained and answer any questions from the person concerning the written consent; and
- 2. Before issuing a prescription for a controlled substance in the class for which informed written consent was provided, inform the person that the medication is in the class of controlled substances for which he or she provided informed consent.
- Sec. 3. An assessment of risk for abuse, dependency and addiction completed pursuant to NRS 639.23913:
 - 1. May be completed in verbal or written form; and
 - 2. Must include, without limitation, at least one question concerning depression.
 - Sec. 4. Section 7 of LCB File No. R047-18 is hereby amended to read as follows:
- 1. A patient may enter into a prescription medication agreement in satisfaction of the requirements of [section 56 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4433 (NRS 639.23914),] NRS 639.23914 with a group of practitioners, including, without

limitation, by entering into such an agreement with a member or other agent of the group who has the authority to enter into the agreement on behalf of the group.

- 2. If a practitioner or group of practitioners enters into a prescription medication agreement with a patient before the issuance to the patient of a prescription for which such an agreement is required by the provisions of [section 56 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4433 (NRS 639.23914),] NRS 639.23914, the prescribing practitioner must review the agreement immediately before issuing the prescription, including, without limitation, by using a database maintained by the practitioner or group of practitioners, and update the agreement if necessary.
- 3. A practitioner who enters into a prescription medication agreement pursuant to NRS 639.23914 must:
 - (a) Answer any questions from the patient concerning the written consent; and
- (b) Before issuing a prescription for a controlled substance in the class for which informed written consent was provided, inform the patient that the medication is in the class of controlled substances for which he or she provided informed consent.