Nevada State Board of Pharmacy

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May 8, 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 9:00 a.m. on Thursday, June 7, 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. R047-18)

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

The proposed amendments further define "acute pain" and "course of treatment;" clarify "initial prescription" as defined in section 51 of AB 474; clarify "written informed consent" in sections 53 and 54 of AB 474 for practice groups; clarify "making a good faith effort to obtain and review the medical records of the patient" in paragraph (c) of subsection 1 of section 54 of AB 474; clarify the application of section 57 of AB 474 requiring a practitioner, other than a veterinarian, to consider certain factors before prescribing a controlled substance listed in schedule II, III or IV.
(LCB File No. R047-18)

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

REVISED PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R047-18

May 4, 2018

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

AUTHORITY: §§1-7, NRS 639.070 and section 58 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4434 (NRS 639.23916).

A REGULATION relating to controlled substances; defining certain terms for the purposes of provisions relating to the prescription of controlled substances; requiring a review of the medical history of a patient and physical examination of a patient conducted for certain purposes to be targeted to the condition causing the pain of the patient; specifying the conditions under which a practitioner will be determined to have made a good faith effort to obtain the medical records of the patient for certain purposes; specifying certain conditions under which a practitioner will be deemed to have obtained the informed written consent of a patient; clarifying that a practitioner may prescribe a controlled substance under certain conditions; clarifying that a patient may enter into a prescription medication agreement with a group of practitioners; requiring a practitioner to review and update a prescription medication agreement under certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law imposes certain requirements concerning the "initial prescription" of a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V, including limits on the prescription of a controlled substance listed in schedule II, III or IV issued for the treatment of "acute pain." (NRS 639.23507; sections 52-54 and 56 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at pages 4430, 4431 and 4433 (NRS 639.2391-639.23912, 639.23914)) For these purposes, "initial prescription" is defined to mean a prescription originated for a new patient or a new prescription to begin a new "course of treatment" for an existing patient of a practitioner, other than a veterinarian. (Section 51 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4430 (NRS 639.0082)) **Sections 2 and 3** of this regulation, respectively, define the terms "acute pain" and "course of treatment" for the purposes of these provisions.

Before issuing an initial prescription for a controlled substance listed in schedule II, III or IV for the treatment of pain, existing law requires a practitioner, other than a veterinarian, to: (1) obtain and review the medical history of the patient; (2) conduct a physical examination of the patient; (3) make a good faith effort to obtain and review the medical records of the patient from any other provider of health care who has provided care to the patient; and (4) obtain the informed written consent of the patient to the use of the controlled substance. (Sections 53 and 54 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4431 (NRS 639.23911, 639.23912)) **Section 5** of this regulation requires such a review or examination to be targeted to the condition causing the pain of the patient. **Section 5** also specifies the conditions under which a practitioner will be deemed to have made a good faith effort to obtain the medical records of the patient. **Section 4** of this regulation provides that a practitioner has obtained the informed written consent of a patient to the use of a controlled substance if the practitioner has: (1) viewed informed written consent previously given by the patient and stored on a database maintained by the practitioner or a group of practitioners with which the practitioner is associated; and (2) discussed the provisions of the informed written consent with the patient, allowed the patient to ask questions about those provisions and answered those questions.

Before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, a practitioner, other than a veterinarian, is required to obtain a patient utilization report regarding the patient from the computerized prescription monitoring program established by the State Board of Pharmacy and the Investigation Division of the Department of Public Safety. The practitioner is required to determine whether the patient has been issued another prescription for the same controlled substance that provides for ongoing treatment using the controlled substance. If the practitioner determines that the patient has been issued such a prescription, the practitioner is prohibited from prescribing the controlled substance. (NRS 639.23507) **Section 6** of this regulation clarifies that a practitioner is not prohibited from: (1) prescribing a controlled substance that is different from a controlled substance for which the patient has an existing prescription; (2) increasing the dosage of a controlled substance that has been prescribed to a patient; or (3) prescribing a controlled substance to continue an ongoing course of treatment or replace doses of a controlled substance that have been lost, stolen or destroyed.

Existing law requires a practitioner to enter into a prescription medication agreement with a patient not later than 30 days after issuing to the patient an initial prescription for a controlled substance listed in schedule II, III or IV for more than 30 days for the treatment of pain. (Section 56 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4433 (NRS 639.23914)) **Section 7** of this regulation clarifies that a patient can enter into such an agreement with a group of practitioners. **Section 7** also provides that, if such an agreement is entered into before a prescription is issued, the prescribing practitioner is required to review the agreement immediately before issuing the prescription and update the agreement if necessary.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 7, inclusive, of this regulation.

Sec. 2. ***As used in section 52 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4430 (NRS 639.2391), "acute pain" means pain that has an abrupt onset and is caused by injury or another cause that is not ongoing. The term does not include chronic pain or pain that is being treated as part of care for cancer, palliative care, hospice care or other end-of-life care.***

Sec. 3. ***As used in NRS 639.23507, sections 51 to 58, inclusive, of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at pages 4430-34 (NRS 639.0082, 639.2391 to 639.23916, inclusive), and sections 2 to 7, inclusive, of this regulation, "course of treatment" means all treatment of a patient for a particular disease or symptom of a disease, including, without limitation, a new treatment initiated by any practitioner for a disease or symptom for which the patient was previously receiving treatment.***

Sec. 4. ***As used in section 53 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4431 (NRS 639.23911), to "obtain informed written consent to the use of the controlled substance" includes, without limitation:***

1. Viewing informed written consent that meets the requirements of subsection 2 of section 54 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4431 (NRS 639.23912), previously given by the patient and stored on a database maintained by the practitioner or a group of practitioners with which the practitioner is associated; and

2. Immediately before prescribing the controlled substance, discussing the provisions of the informed written consent described in subsection 1 with the patient, allowing the patient to ask questions about those provisions and answering those questions.

Sec. 5. *1. A practitioner conducting a review of the medical history and physical examination of a patient pursuant to section 54 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4431 (NRS 639.23912), shall target the review and examination to the condition causing the pain of the patient.*

2. A practitioner makes a good faith effort to obtain and review the medical records of a patient, as required by section 54 of Assembly Bill No. 474, chapter 605, Statutes of Nevada 2017, at page 4431 (NRS 639.23912), if the practitioner makes an effort to obtain all medical records that, in the professional judgment of the practitioner, are necessary to determine whether to prescribe a controlled substance listed in schedule II, III or IV to the patient. In determining whether a medical record is necessary to make such a determination, a practitioner may consider:

(a) The time needed to provide care to the patient;

(b) The nature of the practice of the practitioner; and

(c) Whether the benefit of prescribing the controlled substance without obtaining the medical record outweighs the risk of doing so.

Sec. 6. *The Board does not construe NRS 639.23507 to prohibit a practitioner from:*

1. Prescribing a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V to a patient who has been issued another prescription

for a different controlled substance listed in schedule II, III or IV or opioid that is a controlled substance listed in schedule V;

2. Increasing the dosage of a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V that has been prescribed to a patient; or

3. Prescribing a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V for the purpose of:

(a) Continuing the same course of treatment for which the patient has previously been prescribed the same controlled substance; or

(b) Replacing doses of the controlled substance that have been lost, stolen or destroyed.

Sec. 7. *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), 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), 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.