Nevada State Board of Pharmacy

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May 4, 2021

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 conduct a Public Hearing on Thursday, June 3, 2021, at 9:00 a.m. at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 044, the meeting can be listened to or viewed live over Zoom remotely or at the following location:

Home2 Suites Las Vegas Strip South
7740 Las Vegas Blvd. South
Las Vegas, NV 89123

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

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 (NAC) Chapter 639. The proposed amendment authorizes the dispensing of a prescription drug to a practitioner instead of the ultimate user of the drug in certain circumstances.
(LCB File No. R009-20)

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

The proposed amendment will authorize the delivery of a prescription drug to a practitioner for administration to the ultimate user if the FDA has made a determination that the drug is dangerous for the ultimate user to possess or administer. The regulation is necessary for the protection, health and safety of the public.

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.

There should be no adverse economic impact from this regulation amendment on the regulated entities or on the public. This amendment will have a beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care. The regulation amendment will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

The immediate and long-term economic effect on regulated entities will be to improve the delivery of safe and reliable pharmaceutical care in Nevada. The regulation amendment will benefit public health, safety and welfare.

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 amendment.

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 amendment 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 amendments 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 Board at pharmacy@pharmacy.nv.gov or to the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521. Written submissions must be received by the Board on or before June 3, 2021. 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.

Pursuant to NRS 233B.064(1), upon adoption of any regulation, the Board, 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.

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 www.notice.nv.gov and www.bop.nv.gov and 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. R009-20

February 25, 2020

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

AUTHORITY: §1, NRS 639.070.

A REGULATION relating to prescription drugs; authorizing the dispensing of a prescription drug to a practitioner instead of the ultimate user of the drug in certain circumstances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations governing the dispensing of poisons, drugs, chemicals and medicines. (NRS 639.070) Existing federal law authorizes the United States Food and Drug Administration to require the adoption of a risk evaluation and mitigation strategy for certain drugs. (21 U.S.C. § 355-1) This regulation authorizes the dispensing of a prescribed drug to a practitioner instead of the ultimate user if: (1) such a risk evaluation and mitigation strategy requires the drug to be administered only under the direct supervision of a provider of health care; and (2) the practitioner is authorized to possess the drug. This regulation also prescribes requirements governing the storage, administration and disposal of a drug that is dispensed to a practitioner under such circumstances.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. A prescription for the dispensing of a drug to the ultimate user may instead be dispensed to a practitioner if:

(a) The United States Food and Drug Administration has adopted a risk evaluation and mitigation strategy for the drug pursuant to 21 U.S.C. § 355-1 that requires the drug to be administered only under the direct supervision of a provider of health care; and

(b) The practitioner is authorized by federal and state law to possess the drug.

2. A practitioner to whom a drug is dispensed pursuant to subsection 1 shall:

(a) Comply with any federal and state law or regulation that addresses the handling of the drug;

(b) Store the drug separately from any other drug in the possession of the practitioner; and

(c) Except as otherwise provided in subsection 3, administer the drug only to the patient named in the prescription not later than 14 days after receiving the drug.

3. If a drug dispensed to a practitioner pursuant to subsection 1 is not administered within the time prescribed by paragraph (c) of subsection 2, the practitioner must:

(a) Destroy the drug; or

(b) Donate the drug to the Prescription Drug Donation Program established pursuant to NRS 453B.080.