Nevada State Board of Pharmacy

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October 7, 2020

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 November 10, 2020, at 1:30 p.m. at the following location:

Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.

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 Codes (NAC) 639 and 453: Proposed amendment relating to the manner in which a prescription must be given to pharmacies. (LCB File No. R083-20)

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

The proposed amendment will add a new section in conformity with AB310 providing for the exemption of a practitioner pursuant to 639.23535(2) from the requirement that a prescription for a controlled substance must be given to a pharmacy by electronic transmission in certain circumstances. The proposed amendment provides certain exemptions; authorizes discipline and penalty against a practitioner who violates that requirement.

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 Either the terms or the substance of the regulations to be adopted, amended or repealed.

A copy of the proposed regulation is attached to this notice; however, please note that the proposed regulation posted at www.bop.nv.gov 3 working days before the hearing will be the regulation considered.

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 proposed regulation on the regulated entities or on the public. The proposed regulation will benefit public health, safety and welfare.

(b) Both immediate and long-term effects.

Immediate and long-term economic effects on regulated entities will be negligible. The immediate and long-term economic effects will be improved pharmaceutical care for the public.

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 proposed 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 proposed 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 proposed state regulation is more stringent.

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

This proposed 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 November 10, 2020. 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.

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.

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.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to Governor's Declaration of Emergency Directive 006.

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R083-20

October 13, 2020

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

AUTHORITY: §§1-3, NRS 639.070, 639.23535.

A REGULATION relating to pharmacy; requiring completion of a form to be exempted from certain requirements; revising provisions relating to certain controlled substances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the practice of pharmacy. (NRS 639.070) Beginning January 1, 2021, existing law requires that a prescription for a controlled substance be given to a pharmacy by electronic transmission, with limited exceptions. Existing law authorizes the Board to grant an exemption to the requirement to transfer a prescription for a controlled substance electronically for up to 1 year if the Board determines the practitioner is unable to transmit a prescription electronically for certain reasons. (NRS 639.23535) **Section 1** of this regulation requires a practitioner who is exempted from the electronic transmission requirements to complete a form certifying that the practitioner is exempt from such requirements and to maintain the form in a manner that makes the form available to the Board upon request.

Existing regulations authorize a prescription for a dangerous drug or certain controlled substances to be transmitted to a pharmacy electronically in certain circumstances. (NAC 639.7105) **Section 2** of this regulation removes the authorization to transmit prescriptions for certain controlled substances to a pharmacy electronically. Existing regulations authorize a prescription for certain controlled substances to be transmitted to a pharmacy by a facsimile machine. (NAC 453.430) **Section 3** of this regulation removes this authorization.

Section 4 of this regulation sets the effective date of this regulation to be January 1, 2021 or the date the regulation is filed with the Secretary of State, whichever occurs later. **Section 4** also expires by limitation **section 1** on December 31, 2021.

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

1. A practitioner who is exempted from the requirements of subsection 1 of NRS 639.23535 by the Board must complete a form furnished by the Board certifying that the practitioner is exempt from such requirements pursuant to subsection 2 of NRS 639.23535.

2. The certification form required pursuant to subsection 1 must be maintained by the practitioner in a form and manner that is readily retrievable by the practitioner and made available to the Board upon request.

Sec. 2. NAC 639.7105 is hereby amended to read as follows:

639.7105 Except as otherwise provided in NAC 639.648 and 639.711:

1. A prescription for a dangerous drug ~~[or a controlled substance listed in schedule II, III, IV or V]~~ may be transmitted to a pharmacy electronically by a practitioner or, if the prescription is for a dangerous drug, the designated agent of the practitioner, if the patient:

(a) Consents to the transmission of the prescription electronically; and

(b) Approves the pharmacy where the prescription will be transmitted.

2. A practitioner shall not transmit a prescription for a controlled substance to a pharmacy electronically unless:

(a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy; and

(b) All requirements of 21 C.F.R. Part 1311 are satisfied.

3. The designated agent of a practitioner shall not transmit a prescription for a dangerous drug to a pharmacy electronically unless:

(a) The practitioner prescribes the dangerous drug;

(b) The designated agent receives training from the practitioner regarding the electronic transmission of prescriptions and the practitioner keeps written documentation of such training at his or her office; and

(c) The practitioner documents in the medical record of the patient for whom the prescription is being transmitted electronically the intention of the practitioner to prescribe the dangerous drug and to have his or her designated agent transmit the prescription electronically.

4. If the designated agent of a practitioner transmits a prescription electronically to a pharmacy, the practitioner shall review the electronic prescription file not later than 24 hours after the electronic transmission.

5. In addition to the requirements set forth in NRS 639.2353 , *639.23535* and 639.2589, a prescription that is transmitted electronically to a pharmacy must include:

(a) The telephone number of the prescribing practitioner;

(b) The time and date of the transmission; and

(c) The name of the pharmacy to which the prescription is sent.

6. In addition to the requirements set forth in subsection 5 and NRS 639.2353 , *639.23535* and 639.2589, a prescription for a controlled substance that is transmitted electronically to a pharmacy must include:

(a) The registration number from the Drug Enforcement Administration of the prescribing practitioner; and

(b) If the technological capability exists to require such information to be transmitted electronically:

(1) The Nevada controlled substance registration number of the prescribing practitioner;

(2) The indication for use or the diagnosis code; and

(3) The date of the last physical examination of the patient.

7. A pharmacist who receives a prescription that is transmitted electronically shall keep a paper or electronic copy of the prescription for at least 2 years after the pharmacist receives the prescription. The copy of the prescription that is kept must be readily accessible to:

(a) Personnel of the pharmacy who are authorized to access records of prescriptions kept by the pharmacy; and

(b) Members, employees, agents and designees of the Board.

8. A pharmacist shall not dispense a prescription that is transmitted electronically until the pharmacist determines that the prescription complies with the requirements of state and federal law.

9. A prescription that is transmitted and complies with the provisions of this section shall be deemed an original prescription.

10. The Board may suspend the privilege of a practitioner to transmit prescriptions electronically or take any other appropriate action if the Board reasonably suspects that the practitioner or the designated agent of the practitioner has transmitted a prescription electronically that is:

(a) Unlawful;

(b) Fraudulent; or

(c) Not for a legitimate medical purpose.

Sec. 3. NAC 453.430 is hereby amended to read as follows:

453.430 1. An individual practitioner may not issue a prescription in order to obtain controlled substances for the purpose of general dispensing to patients.

2. A prescription may not be issued for dispensing any narcotic drug to a person dependent on a narcotic drug for the purpose of continuing the person's dependence upon the drug except in the course of an authorized clinical investigation in the development of a program for rehabilitating narcotic addicts.

3. The administering or dispensing directly, but not the prescribing, of any narcotic drugs to a person dependent on a narcotic drug for the purpose of continuing the person's dependence upon the drug is permissible in the course of conducting a federally authorized clinical investigation in the development of a program for rehabilitating narcotic addicts if the activity is within the course of professional practice or research.

~~[4. A prescription for a controlled substance listed in schedule III, IV or V may be transmitted by a practitioner or his or her agent by a facsimile machine to a pharmacy pursuant to the provisions of NAC 639.711.]~~

Sec. 4. 1. This regulation becomes effective upon the later of:

(a) January 1, 2021; or

(b) The date this regulation is filed with the Secretary of State.

2. Section 1 of this regulation expires by limitation on December 31, 2021.