JOE LOMBARDO Governor



HELEN PARK
President

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985 Damonte Ranch Pkwy, Ste 206 Reno, NV 89521

Posted: July 19, 2024

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, September 5, 2024.

Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn 7830 S. Las Vegas Boulevard Las Vegas, NV

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 Chapter 639 and/or 453 of the Nevada Administrative Code.

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

Amendment to Nevada Administrative Code (NAC) 639.708. The proposed amendments clarifies record keeping requirements of counseling by a pharmacy. (LCB File No. R085-24)

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

The amendment will ensure that patients are receiving counseling on their prescription medication(s) and that accurate patient counseling records are maintained by both the pharmacist that counseled the patient and the pharmacy.

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

A copy of the proposed regulation 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 economic impact from this regulation amendment on the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public by ensuring patients are being counseled on their prescription medication(s) and accurate counseling records are maintained at the pharmacy.

(b) Both immediate and long-term effects.

Both the immediate and long-term economic effects on regulated entities and on the public will be beneficial by ensuring patients are being counseled on their prescription medication and that accurate counseling records are maintained at the pharmacy.

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.

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

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 Board at teambc@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 September 5, 2024. 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.

Members of the public who are disabled and require special accommodations or assistance at the meeting are requested to notify the Nevada State Board of Pharmacy in writing at 985 Damonte Ranch Pkwy., #206, Reno, Nevada 89521, or by calling (775) 850-1440. Please notify us at least one (1) week prior to the scheduled meeting date to allow time to secure any necessary equipment or provisions prior to the meeting.

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 of hearing has been posted at:

www.notice.nv.gov www.bop.nv.gov www.leg.state.nv.us.

Nevada State Board of Pharmacy Reno, Nevada

Nevada State Board of Pharmacy Las Vegas, Nevada

Nevada State Library 100 N. Stewart St. Carson City, NV 89701

REVISED PROPOSED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R085-24

June 25, 2024

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

AUTHORITY: §§ 1 and 2, NRS 639.070 and 639.266.

A REGULATION relating to pharmacy; revising requirements concerning the documentation of the counseling of a patient by a pharmacist, intern pharmacist or dispensing practitioner; requiring a pharmacy or dispensing practitioner to have certain staff; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires a pharmacist, upon receiving a prescription and after reviewing the record of the patient, to communicate with the patient or a person caring for the patient matters which will enhance therapy through drugs. Existing law requires such communication to include appropriate elements of counseling, as prescribed by regulations of the State Board of Pharmacy. (NRS 639.266) **Section 2** of this regulation requires a pharmacy or dispensing practitioner to ensure that the pharmacy or dispensing practitioner, as applicable, has adequate staff to comply with all legal requirements governing the counseling of patients.

Existing regulations require a pharmacy or dispensing practitioner to maintain a record of medication for each person to whom a prescription has been dispensed by the pharmacy or dispensing practitioner, as applicable. (NAC 639.708) **Section 2** requires such a record to include: (1) the prescription number; (2) the date and time that the prescription was dispensed; and (3) certain information about counseling provided to the patient or the refusal of the patient to accept such counseling. **Section 1** of this regulation requires a pharmacist, intern pharmacist or dispensing practitioner who dispenses a prescription to: (1) create or update, as applicable, the record of medication; and (2) include the record of medication in the computerized system or files of the pharmacy. **Section 1** also removes an existing requirement that is partially duplicative of the requirements being added by **section 2**.

Section 1. NAC 639.707 is hereby amended to read as follows:

639.707 1. Except as otherwise provided in this section, a pharmacist, an intern pharmacist under the supervision of a pharmacist or a dispensing practitioner shall verbally

provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient that:

- (a) Has not been previously dispensed to the patient from that pharmacy or dispensing practitioner, as applicable; or
- (b) Has been previously dispensed to the patient from that pharmacy or dispensing practitioner, as applicable, including, without limitation, a prescription drug or a device that is being refilled, if, in the professional judgment of the pharmacist, intern pharmacist or dispensing practitioner:
 - (1) The information would further or improve the drug therapy of the patient; or
- (2) A reasonable concern relating to the safety or efficacy of the drug therapy of the patient was raised by the review of the patient's record that the pharmacist, intern pharmacist or dispensing practitioner conducted pursuant to subsection 4.
- 2. The information provided by the pharmacist, intern pharmacist or dispensing practitioner pursuant to subsection 1 may include, without limitation:
 - (a) The name and a description of the drug;
 - (b) The form of dosage, dose, route of administration and duration of drug therapy;
 - (c) The intended use of the drug or device and expected responses from that use;
- (d) Any special directions and precautions for the preparation, administration and use of the drug or device by the patient;
- (e) Any common severe side effects, interactions and contraindications that may occur, recommendations to avoid these side effects, interactions or contraindications, and the action required if they occur;
 - (f) Techniques for the patient or the person caring for the patient to monitor the drug therapy;

- (g) Proper storage of the drug or device;
- (h) Information about refilling the prescription;
- (i) Actions to be taken in the event of a missed dose;
- (j) Any relevant information contained in the record of medication of the patient; and
- (k) Any other information which, in the professional judgment of the pharmacist, intern pharmacist or dispensing practitioner, is necessary to ensure the safe and effective use of the drug or device by the patient.
- 3. The pharmacist or intern pharmacist shall provide the information required pursuant to subsections 1 and 2 in written form to the patient if a drug or device will be distributed to the patient outside the confines of the pharmacy by mail or any other delivery service. A pharmacist or intern pharmacist is not required to provide written information pursuant to this subsection if the drug or device is being delivered to a patient who is in a licensed medical facility where other licensed health care professionals are authorized to administer drugs.
- 4. The pharmacist, intern pharmacist or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation:
 - (a) Overutilization of the drug and drug misuse;
 - (b) Underutilization of the drug;
- (c) Therapeutic duplications, contraindications and any warning labels or other information included with the drug;
 - (d) Interactions between the drug and any:
 - (1) Other drugs which the patient is taking or has recently taken;
 - (2) Diseases which the patient has, including any stages of that disease; and

- (3) Allergies that the patient may have; and
- (e) Incorrect dosage or duration of treatment.
- 5. A pharmacist, intern pharmacist or dispensing practitioner is not required to counsel a patient pursuant to this section if the patient or a person caring for the patient refuses to accept the counseling.
- 6. [Except as otherwise provided in subsection 7, the] A pharmacist, intern pharmacist or dispensing practitioner who dispenses a prescription shall [, at the time that counseling is provided or refused:
- (a) Initial a written document that is maintained at the pharmacy or at the primary place of business of the dispensing practitioner to record whether counseling was provided to or refused by a patient or the person caring for the patient; or
- (b) Enter, pursuant to NAC 639.751, initials onto a record in a computerized system used by the pharmacy or dispensing practitioner, as applicable, for recording information concerning prescriptions to indicate whether counseling was provided to or refused by a patient or the person earing for the patient.
- 7. The pharmacist, intern pharmacist or dispensing practitioner is not required to comply with the provisions of subsection 6 if the prescription drug or device dispensed to the patient is being refilled.]:
- (a) Create or update, as applicable, the record of medication described in subsection 1 of NAC 639.708; and
- (b) Include the record of medication, and any updates to the record of medication, in the computerized system or files, as applicable, of the pharmacy where the prescription is dispensed.

- **Sec. 2.** NAC 639.708 is hereby amended to read as follows:
- 639.708 To facilitate counseling regarding a prescription, a pharmacy or dispensing practitioner shall:
- 1. Maintain a record of medication for each patient to whom a prescription has been dispensed by that pharmacy or dispensing practitioner, as applicable. The record must:
 - (a) Be retrievable for use by the pharmacist or dispensing practitioner;
 - (b) Be maintained for at least 2 years after the most recent entry;
- (c) List all prescriptions dispensed to the patient at that pharmacy or by the dispensing practitioner; and
- (d) Include [all] for each prescription dispensed at the pharmacy or by the dispensing practitioner:
 - (1) All data required to be placed on the prescription [...];
 - (2) The prescription number;
 - (3) The date and time on which the prescription was dispensed; and
 - (4) If counseling is required by NAC 639.707:
- (I) A notation of whether such counseling was provided by a pharmacist, intern pharmacist or dispensing practitioner or refused by the patient or a person caring for the patient that is made at the time the counseling was provided or refused and initialed by the pharmacist, intern pharmacist or dispensing practitioner who provided or offered to provide the counseling; and
 - (II) The date on which the counseling was provided or refused, as applicable.
 - 2. Make a reasonable effort to obtain and retain in the record of medication the:
 - (a) Telephone number or numbers, if any, of the patient;

- (b) Gender of the patient;
- (c) Age or date of birth of the patient;
- (d) History of the patient, including allergies, reactions to particular drugs and any medications or medical devices used by the patient; and
- (e) Any comments relevant to the drug therapy of the patient, including any other information which is specific to the patient or drug.
- 3. Ensure that a pharmacist or dispensing practitioner who has access to the medical records of the patient is available by telephone during business hours and, for a pharmacy that routinely delivers prescriptions outside of the trade area covered by local telephone service, provide a toll-free telephone number.
- 4. Include with each prescription container of a pharmacy that is delivered or distributed by a public carrier:
 - (a) The local, and if applicable toll-free, telephone numbers of the pharmacy;
 - (b) The hours during which the patient may contact the pharmacy by telephone; and
 - (c) A written notice in substantially the following form:

Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available between the hours of and to answer your questions.

5. Maintain the confidentiality of each patient's records, including prescriptions, pursuant to NRS 449A.112 or 639.238, as applicable. A pharmacist or dispensing practitioner shall not

divulge the contents of a patient's records, except as authorized by NRS 639.238 or any other applicable provision of law.

- 6. Make available to a practitioner, upon request, all information relating to a prescription that is provided to a patient of that practitioner by the pharmacist, an intern pharmacist or a dispensing practitioner.
- 7. Ensure that counseling is conducted in a confidential manner to prevent disclosure of information to any person other than the patient or the person caring for the patient.
- 8. Ensure that the pharmacy or dispensing practitioner has adequate staff to comply with the requirements of this section, NAC 639.707 and any other requirements of federal or state law or the regulations of the Board regarding the counseling of patients.