Nevada State Board of Pharmacy

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December 15, 2020

AMENDED
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 Wednesday, January 13, 2021, at 1:00 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 Code (NAC) 639. The proposed amendment revises provisions relating to the operation of pharmacies in recovery centers and surgical centers for ambulatory patients. (LCB File No. R085-20)

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

The proposed amendment adds a new section regarding the licensing and regulation of a facility to dispense controlled substances and dangerous drugs if the facility is licensed by the State Board of Health pursuant to NRS 449.0303. The purpose of the proposed amendment is to define recovery centers and provides for their licensing and regulation to dispense controlled substances or dangerous drugs.

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 Either the terms or the substance of the regulations to be adopted, amended or repealed.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 regulation on the public. The proposed amendment provides for licensing and regulation of recovery centers to dispense controlled substances or dangerous drugs. The benefits of the proposed regulation will result from protecting the health, safety and welfare of the public.

Recovery centers that wish to dispense controlled substances or dangerous drugs must first apply to the Board of Pharmacy for a certificate of registration. The regulation will have an economic impact on those recovery centers that pay the $500 registration fee.

(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.

The revenue generated from the registration fee will partially offset the costs of enforcement of this new regulation incurred by the Board of Pharmacy.

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 December 3, 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. R085-20

September 17, 2020

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

AUTHORITY: §1, NRS 639.070 and 639.170, as amended by chapter 133, Statutes of Nevada 2019, at pages 723-25; §§2 and 6, NRS 639.070; §3, NRS 639.070, 639.071 and chapter 133, Statutes of Nevada 2019, at page 723 (NRS 639.2177); §§4 and 5, NRS 639.070 and 639.071.

A REGULATION relating to pharmacy; revising provisions relating to the operation of pharmacies in recovery centers and surgical centers for ambulatory patients; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Section 1 of this regulation establishes fees for the investigation or issuance of an original license and biennial renewal of a license to conduct a pharmacy in a recovery center or an ambulatory surgical center licensed by the State Board of Health.

Section 2 of this regulation revises the definition of the term "medical facility" to include a recovery center for the purposes of standards of operation and record-keeping of pharmacies in such facilities.

Existing regulations set forth certain requirements of state and federal registration for surgical centers for ambulatory patients, state and federal registration of certain practitioners at such centers and the licensure or certification of certain employees and contractors of such centers. (NAC 639.4992) **Section 3** of this regulation: (1) makes these requirements applicable to recovery centers; (2) requires licensure of each recovery center and surgical center for ambulatory patients by the State Board of Pharmacy; (3) eliminates the requirement that such centers register with the Board; and (4) requires such centers to ensure that each practitioner who dispenses dangerous drugs is registered with the Board and the Drug Enforcement Agency of the United States Department of Justice.

Existing regulations require a surgical center for ambulatory patients to employ or enter into a contract with a pharmacist to establish certain policies and procedures which satisfy certain requirements. (NAC 639.4996) Existing regulations also set forth the duties of such a pharmacist. (NAC 639.4998) **Sections 4 and 5** of this regulation make those provisions applicable to recovery centers and the pharmacists who are employed by or contract with those centers.

Existing regulations authorize a practitioner in charge of an emergency room of a hospital or a surgical center for ambulatory patients to dispense medication in a limited amount to treat patients in the emergency room or surgical center during the hours a local retail pharmacy is closed and its services are unavailable. (NAC 639.750) **Section 6** of this regulation makes these provisions applicable to recovery centers.

Section 1. NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist ..... Actual cost of the examination

For the investigation or registration of an applicant as a registered pharmacist.....$200

For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....200

For the investigation or issuance of an original license to conduct a retail pharmacy 500

For the biennial renewal of a license to conduct a retail pharmacy 500

For the investigation or issuance of an original license to conduct an institutional pharmacy 500

For the biennial renewal of a license to conduct an institutional pharmacy 500

For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution 500

For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303.....500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303.....500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist.....50

For the biennial renewal of registration as a registered pharmacist.....200

For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse).....100

For the initial registration of a pharmaceutical technician or pharmaceutical technician in training.....50

For the biennial renewal of registration of a pharmaceutical technician or pharmaceutical technician in training.....50

For the investigation or registration of an intern pharmacist.....40

For the biennial renewal of registration as an intern pharmacist.....40

For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....80

For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances.....80

For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, ***recovery center,*** facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ambulatory surgical center, ***recovery center,*** facility for treatment with narcotics, researcher, instructional user or any other authorized person to prescribe or possess controlled substances.....200

For the investigation or issuance of an original license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler 500

For the biennial renewal of a license to engage in business as an authorized warehouse, medical products provider or medical products wholesaler.....500

For the investigation or issuance of an original license to a manufacturer or wholesaler.....500

For the biennial renewal of a license for a manufacturer or wholesaler 500

For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....50

For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

➥ is not required to pay the fee for the collective certification of advanced practice registered nurses in the employ of a public or nonprofit agency as set forth in subsection 1.

6. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

➥ is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

7. A practitioner who is exempt from the payment of a fee pursuant to subsection 6 shall notify the Board in writing of each change of address or additional address, or both.

8. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay actual costs of inspection incurred by the Board.

Sec. 2. NAC 639.457 is hereby amended to read as follows:

639.457 "Medical facility" includes:

1. A surgical center for ambulatory patients;

2. An obstetric center;

3. An independent center for emergency medical care;

4. An agency to provide nursing in the home;

5. A facility for intermediate care;

6. A facility for skilled nursing;

7. A hospice;

8. A hospital;

9. A psychiatric hospital;

10. A facility for the treatment of irreversible renal disease; ~~[and]~~

11. A rural clinic ~~[.]~~ ***; and***

12. A recovery center.

Sec. 3. NAC 639.4992 is hereby amended to read as follows:

639.4992 Each ***recovery center and*** surgical center for ambulatory patients shall:

1. ***Apply to the Board for a license to dispense controlled substances or dangerous drugs by submitting an application on a form prescribed by the Board. A license to dispense controlled substances or dangerous drugs granted pursuant to this subsection is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.***

2. Register with ~~[the Board and]~~ the Drug Enforcement Administration of the United States Department of Justice to dispense controlled substances. ~~[;~~

~~2.]~~

3. Ensure that each practitioner who dispenses controlled substances ***or dangerous drugs*** in the ***recovery center or*** surgical center is registered with the Board and the Drug Enforcement Administration of the United States Department of Justice. ~~[; and~~

~~3.~~]

4. Require each person employed to work in a pharmacy of the ***recovery center or*** surgical center for ambulatory patients and any person with whom the ***recovery center or*** surgical center for ambulatory patients has entered into a contract to provide pharmaceutical services to possess a current state license or certificate to provide such services.

Sec. 4. NAC 639.4996 is hereby amended to read as follows:

639.4996 1. A ***recovery center or*** surgical center for ambulatory patients shall employ or enter into a contract with a pharmacist to establish policies and procedures which:

(a) Are consistent with the policies and procedures developed pursuant to NAC 639.477;

(b) Require the maintenance of records in accordance with the provisions of NAC 639.485 and 639.486;

(c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;

(d) Require maintenance of a perpetual inventory of all controlled substances;

(e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;

(f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;

(g) Ensure that the ***recovery center or*** surgical center dispenses drugs and investigational drugs ***pursuant to chart orders and*** in accordance with applicable state and federal laws; and

(h) Ensure that all compounding is:

(1) Performed by a registered pharmacist in accordance with the provisions of this chapter and chapter 639 of NRS; or

(2) If performed by an employee of the ***recovery center or*** surgical center, other than a registered pharmacist, performed:

(I) In accordance with the provisions of this chapter and chapter 639 of NRS;

(II) In a location designated for compounding that is clean and disinfected before each act of compounding; and

(III) By a person who has completed training for the type of compounding that will be performed.

2. The policies and procedures established pursuant to subsection 1 must be maintained, reviewed at least annually, and dated upon adoption and amendment.

3. The pharmacist employed by or contracted with a ***recovery center or*** surgical center for ambulatory patients pursuant to subsection 1 may establish the policies and procedures required pursuant to that subsection with the assistance of a practitioner or an employee or contractor of the ***recovery center or*** surgical center.

Sec. 5. NAC 639.4998 is hereby amended to read as follows:

639.4998 A pharmacist employed by or contracted with a ***recovery center or*** surgical center for ambulatory patients pursuant to NAC 639.4996 shall:

1. Visit the ***recovery center or*** surgical center at least once each month to:

(a) Evaluate the effectiveness of the policies and procedures established pursuant to NAC 639.4996; and

(b) Confirm that the ***recovery center or*** surgical center is complying with those policies and procedures, the provisions of this section and NAC 639.4996;

2. Maintain documentation of each visit that the pharmacist makes pursuant to subsection 1;

3. Conduct an audit at least once each month using a sufficient number of records of the ***recovery center or*** surgical center, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:

(a) The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;

(b) Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;

(c) The records demonstrate:

(1) That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and

(2) That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;

(d) The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;

(e) The employees of the ***recovery center or*** surgical center properly maintain accurate records relating to drugs and investigational drugs; and

(f) The employees of the ***recovery center or*** surgical center properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and

4. Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:

(a) The ***recovery center or*** surgical center is violating a state or federal law which affects the care and safety of a patient;

(b) There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ***recovery center or*** surgical center and the amount of the controlled substance that should be in the possession of the ***recovery center or*** surgical center according to the records of the ***recovery center or*** surgical center, including, without limitation:

(1) Purchase orders and invoices for the controlled substance;

(2) Records which indicate the removal of the controlled substance from the storage area;

(3) Patient records;

(4) Records which indicate the return of the controlled substance to the manufacturer;

(5) Records which indicate that the controlled substance was destroyed; and

(6) Any other record for the controlled substance;

(c) The ***recovery center or*** surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;

(d) The ***recovery center or*** surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or

(e) The ***recovery center or*** surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the ***recovery center or*** surgical center.

Sec. 6. NAC 639.750 is hereby amended to read as follows:

639.750 1. If the services of a local retail pharmacy are not available, the practitioner in charge of the emergency room of a hospital ***, of a recovery center*** or of a surgical center for ambulatory patients may dispense medication in an amount adequate to treat patients in the emergency room ***, recovery center*** or surgical center for ambulatory patients during the hours that the local retail pharmacy is closed.

2. If a practitioner dispenses medication at the emergency room of a hospital or at a ***recovery center or*** surgical center for ambulatory patients:

(a) The following information must be maintained for each medication dispensed:

(1) The name of the patient and, if not readily available from the records of the hospital, the address of the patient;

(2) The name, strength and quantity of the medication;

(3) The name of the prescribing practitioner and the classification of his or her license;

(4) The registration number of the prescribing practitioner that is issued by the Drug Enforcement Administration of the United States Department of Justice, if the medication is a controlled substance;

(5) The signature of the practitioner who dispenses the medication;

(6) The directions for using the medication;

(7) The date the medication is dispensed; and

(8) The signature of the prescribing practitioner.

(b) The medication must be dispensed in a container in accordance with NAC 639.740.

(c) A label that contains the following information must be affixed to the container:

(1) The date;

(2) The name of the prescribing practitioner;

(3) The name of the patient;

(4) The number of dosage units;

(5) Specific directions for use;

(6) The expiration date of the medication;

(7) The proprietary or generic name of the medication;

(8) The strength of the medication;

(9) The initials of the practitioner who dispenses the medication; and

(10) The following warning:

Caution: Do not use with alcohol or nonprescription drugs without consulting the prescribing practitioner.