

LCB File No. R160-99

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Notice of Hearing for the Amendment of and Addition to Regulations of the Nevada State Board of Pharmacy

The Nevada State Board of Pharmacy will hold a public hearing at 9:30 a.m., on Thursday, November 4, 1999, at the Nevada State Board of Pharmacy office, 4220 South Maryland Parkway, Suite 314, Las Vegas, Nevada. The purpose of the hearing is to receive comments from all interested persons regarding the amendment of and addition to regulations. If no such person appears to make an oral presentation, the Nevada State Board of Pharmacy may proceed immediately to act upon any written submissions. Comments will be received regarding the following:

1. Amendment of Nevada Administrative Code 453.520 Schedule II

A. Statement of the need for and purpose of the proposed regulation
Remove Marinol from schedule II.

B. Economic effect of the regulation on the business it is to regulate
There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public
There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.
There will be no additional expenses for enforcement of this regulation.

2. Amendment of Nevada Administrative Code 453.530 Schedule III

A. Statement of the need for and purpose of the proposed regulation
Add Marinol to schedule III.

B. Economic effect of the regulation on the business it is to regulate
There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public
There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.
There will be no additional expenses for enforcement of this regulation.

3. Amendment of Nevada Administrative Code 639.220 Schedule of fees; penalties; applicability.

A. Statement of the need for and purpose of the proposed regulation

This amendment will increase the pharmaceutical technician in training and the pharmaceutical technician registration fees and renewals from \$20 to \$40.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

4. Amendment of Nevada Administrative Code 639.485 Maintenance of records for controlled substances.

A. Statement of the need for and purpose of the proposed regulation

Records of the distribution of controlled substances listed in schedule II, III and IV must include....(f) A record of any waste of a controlled substance, witnessed and cosigned by another medically licensed person.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

5. Amendment of Nevada Administrative Code 639.486 Maintenance of records of controlled substances administered from floor stock.

A. Statement of the need for and purpose of the proposed regulation

Controlled substances administered by a practitioner authorized to administer anesthesia need not be witnessed and cosigned if other current, complete and accurate records of each substance administered and wasted is maintained.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

6. Amendment of Nevada Administrative Code 639.503 Maintenance in pharmacy of current statutes, regulations and reference material.

A. Statement of the need for and purpose of the proposed regulation

This amendment will allow pharmacies to maintain reference materials as computer data providing it is readily retrievable and includes information equivalent to the volumes currently required to be kept in a pharmacy.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

7. Amendment of Nevada Administrative Code 639.510 Maintenance and storage of pharmaceutical stock.

A. Statement of the need for and purpose of the proposed regulation

The managing pharmacist is responsible for and must have knowledge and control of all acquisition and disposition of stock by the pharmacy and is responsible for the retention of all records of stock acquisition or disposition required by law.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

8. Amendment of Nevada Administrative Code 639.520 Security of prescription departments.

A. Statement of the need for and purpose of the proposed regulation

A pharmacy must maintain a duplicate key in a lock box in a secure place not accessible to the general public.

The registered pharmacist on duty is responsible to assure all dangerous drugs, controlled substances and devices delivered to the premises of a store or business in which there is a pharmacy, are immediately placed in the pharmacy in the physical control of the pharmacist.

The audible alarm must be of sufficient decibels to alert more than one person in the building that entry into the pharmacy has been made and the system must be devised to provide notice to the managing pharmacist or his designee that entry has occurred.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

9. Amendment of Nevada Administrative Code 639.760 Return of unused drugs packaged in unit doses.

A. Statement of the need for and purpose of the proposed regulation

Dangerous drugs and controlled substance prescriptions dispensed by a pharmacy and removed from the pharmacy may not be returned to the pharmacy for purposes of destruction or return of drugs to a stock of drugs in a pharmacy. Drugs dispensed for a patient may be returned to the pharmacy for repackaging or relabeling for purposes of dispensing to the same patient. This does not establish any conditions of reimbursement, credit or refunds of prescriptions purchased in a pharmacy.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

10. Amendment of Nevada Administrative Code 639 NEW LANGUAGE

A. Statement of the need for and purpose of the proposed regulation

The Board of Pharmacy developed statistical data to analyze work volume, type, and environment and its evaluation to assess potential prescription errors. Objection by industry was made regarding the measurement device used as well as the corrective mandates drafted in proposed regulation. The proposed regulation is drafted reflecting recommendations by a board sub-committee comprised of industry, pharmacist and board representation to proactively develop a self assessment and workplace appraisal reporting mechanism.

B. Economic effect of the regulation on the business it is to regulate

The economic effect will be limited to pharmacy staff twice reporting of one weeks staffing patterns, prescription category and volume, and extent of automated equipment. The fiscal impact estimate should be no more than one and one half hours annually to pharmacist staff time. The proposal will have such minimal impact it will not cause an increase of staff employment or be detrimental to the expansion of retail drug business in Nevada.

C. Economic effect on the public

There will be no economic effect on the public, however it is acknowledged that multiple regulatory mandates of insignificant impact can be accumulative.

D. Estimated cost to the agency for enforcement.

Additional expenses for the Board of Pharmacy will include personnel costs associated with regulation promulgation, publication and distribution of surveys, data analysis and reporting, and response to components of reporting elements of the process.

11. Amendment of Nevada Administrative Code 639 NEW LANGUAGE

A. Statement of the need for and purpose of the proposed regulation

No organization or agency through a mechanism of reimbursement denial for a prescription benefit can require a pharmacy to dispense a prescription requiring a solid oral dose form of medication to be divided in two or more parts if the equivalent strength is readily available.

B. Economic effect of the regulation on the business it is to regulate

There will be no economic effect on the regulation on businesses that do not follow this practice.

C. Economic effect on the public

There will be no economic effect on the public.

D. Estimated cost to the agency for enforcement.

There will be no additional expenses for enforcement of this regulation.

Upon adoption of any regulation, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall 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.

Persons wishing to comment upon the proposed action of the Nevada State Board of Pharmacy 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, 555 Double Eagle Court, Suite 1100, Reno, Nevada 89511-8991. Written submissions must be received by the Nevada State Board of Pharmacy at least five days before the scheduled public hearing.

A copy of the amendments and additions to the regulations will be on file at all county libraries within the state for inspection by members of the public during business hours. This notice and copies of the proposed regulations have been posted at the following additional locations for inspection and copying by the members of the public during business hours. Copies will also be mailed to members of the public upon request. A reasonable fee may be charged for copies if it is deemed necessary.

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

Carson City Courthouse
Carson City, Nevada

Washoe County Courthouse
Reno, Nevada

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

639.520 Security of prescription departments.

1. The prescription department of every pharmacy must be separated from the merchandising or public areas of the premises by a barrier of sufficient height and width to make dangerous drugs, controlled substances, narcotics, poisons or restricted devices inaccessible to unauthorized persons. The barrier must be constructed of solid material and contain gates permitting access by the pharmacist. The gates or doors must be secured by a deadbolt lock that can be opened from the outside only by a key. The door may be secured by a combination lock during the hours of business.

2. The registered pharmacist on duty:

(a) Must possess the key to the prescription department~~[-; and]~~. *Any other key must be maintained in a locked box operated by a lock accessible only to licensed pharmacists. The box may be maintained in any secure place not accessible to the general public.*

(b) Is responsible for securing the prescription department at all times when he is not personally present in the department except when he is in the immediate area and can observe and exercise control over the prescription department.

(c) Is responsible to assure all dangerous drugs, controlled substances, and devices delivered to the premises of a store or business in which there is a pharmacy, are immediately placed in the pharmacy in the physical control of the pharmacist.

3. The secretary of the board may permit an alternative type of physical security if, in his opinion, the alternative type will be sufficient to make the drugs, controlled substances, narcotics, poisons and restricted devices inaccessible to any unauthorized person.

4. Other than as permitted by law or regulation, no person other than a registered pharmacist may enter the prescription department of a pharmacy unless he is on business directly concerning the operation, maintenance or repair of the prescription department and a pharmacist employed in the prescription department is physically present at the same time.

5. The pharmacy must have an operating alarm system monitored by a UL approved central station facility. Any pharmacy that is located within a building in which employees of the pharmacy's ownership are on site 24 hours per day, may maintain an alarm system that has an audible alarm in lieu of a UL approved central station facility. *The audible alarm must be of sufficient decibels to alert more than one person in the building that entry into the pharmacy has been made and the system must be devised to provide notice to the managing pharmacist or his designee that entry has occurred.* Any pharmacy that is staffed 24 hours a day is exempt from this paragraph.

Workshop 8/5/99

Workshop 9/23/99

Public Hearing 9/23/99

Public Hearing 11/4/99