

LCB File No. R162-99

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

Section 1. NAC ch. 639 shall be amended to add the following new language:

1. Every pharmacy shall be inspected:

(a) Before it may conduct business on a new pharmacy license;

(b) Once annually; and

(c) At any time deemed necessary by board staff.

2. Before any annual inspection, the board shall provide to a pharmacy a self-assessment form. The self-assessment form shall be in a form prescribed by the board and shall be comprised of two parts:

(a) A statutory and regulatory compliance questionnaire by which the pharmacy can assess its physical plant and operations to assure that it complies with all applicable statutes and regulations. The questionnaire shall be a public document.

(b) A workplace assessment tool by which the pharmacy can assess its work and prescription volume, personnel, work flow, and technological assistive devices. The workplace assessment tool shall also be accompanied by documentation prescribed in the form. The workplace assessment tool and the accompanying documentation is confidential and will be destroyed within six months of the board's receipt of the workplace assessment tool and the accompanying documentation. The board staff may compile and analyze the data provided in the workplace assessment tools as the board deems appropriate, but any compilation or analysis may not be provided to board members or published unless the compilation or analysis has had removed from it any information by which an individual pharmacy could be identified. The data provided in the workplace assessment tools may not be used for disciplinary purposes.

3. The managing pharmacist or designee for the pharmacy shall fully complete the self-assessment form provided by the board. The managing pharmacist may also request from the board a self-assessment form at any time and may complete such a self-assessment form solely for the managing pharmacist's convenience.

4. The managing pharmacist shall make notes and comments on the self-assessment form to explain his answers and to make suggestions for compliance or improvement. If the managing pharmacist makes suggestions for compliance or improvement, he shall transmit a copy of the self-assessment form to his superior in accordance with his company's policies and procedures. Should the managing pharmacist feel his suggestions, which he deems are necessary for patient care, have not been appropriately responded to by his superiors, he may contact the Board of Pharmacy which may take action as it deems appropriate.

5. Whenever a member of board staff conducts an annual inspection, he shall review the most recently provided self-assessment form with the managing pharmacist or a pharmacist on duty to verify that all of the information on the self-assessment form is true and complete. If the member of board staff notices discrepancies between the self-assessment form and the actual state of the pharmacy, or if the member of board staff notices deficiencies in the pharmacy or its operation that are not in compliance with statute or regulation, he shall so note in his inspection.

(a) Deficiencies noted by the member of board staff shall be corrected within a reasonable time period as stated by the member of board staff.

(b) A failure to timely correct a deficiency noted by the member of board staff shall be deemed unprofessional conduct pursuant to NRS 639.210(4) that may serve as the basis for disciplinary action against the managing pharmacist and the owner of the pharmacy as the board staff deems appropriate in its discretion.

6. No employee of a pharmacy may be terminated or otherwise have his employment affected in any way by his superiors for:

(a) Providing in good faith truthful answers, information, or suggestions for compliance or improvement in the preparation or completion of a self-assessment form;

(b) Transmitting a copy of the self-assessment form to his superior or the board staff pursuant to this section; or

(c) Providing truthful information in good faith to a member of board staff as part of an investigation incident to this section.

7. The board shall review this section, its operation, and its utility at its next regularly scheduled meeting following July 1 of each year. During such review, the board may consider and suggest amendments and deletions to this section, including deletion of this entire section, in the board's discretion.