LCB File No. R153-99

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, comlete and accurate records of each substance administered and wasted is mintained.
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

NAC 453.520 Schedule II.

1. Schedule II consists of the drugs listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(a) Opium and opiate, and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone and naltrexone, and their respective salts, but including:

Codeine;
Ethylmorphine;
Granulated opium;
Hydrocodone;
Metopon;
Morphine;
Opium extracts;
Opium fluid;
Powdered opium;
Raw opium;
Oxycodone;
Oxymorphone;
Thebaine; and
Tincture of opium.

(b) Any salt, compound, isomer, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (a) if they do not include the isoquinoline alkaloids of opium.

(c) Opium poppy and poppy straw.

(d) Cocaine hydrochloride salt prepared by a registered chemical or pharmaceutical manufacturer or the Drug Enforcement Administration of the Department of Justice which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration.

(e) Benzolyecgonine or ecgonine.

(f) Concentrate of poppy straw (meaning the crude extract of poppy straw in either liquid, solid or powder form and containing the phenanthrene alkaloids of opium poppy).

3. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (dextrorphan and levopropoxyphene excepted):

Alfentanil;
Alphaprodine;

Anileridine;
Bezitramide;
Bulk dextropropoxyphene (in nondosage forms);
Carfentanil;
Dihydrocodeine;
Diphenoxylate;
Fentanyl;
Isomethadone;
Levo-alphacetylmethadol (some trade or other names: levo-alpha-acetylmethadol; levomethadyl acetate; (LAAM);
Levomethorphan;
Levorphanol;
Metazocine;
Methadone;
Methadone-Intermediate, 4-cyano-2dimethylamino-4, 4-diphenylbutane;
Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
Pethidine (meperidine);
Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
Pethidine-Intermediate-B, ethyl-4-phenylpiperdine-4-carboxylate;
Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
Phenazocine;
Piminodine;
Racemethorphan;
Racemorphan; or
Sufentanil.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(a) Amphetamine, its salts, optical isomers and salts of optical isomers;

(b) Phenmetrazine and its salts;

(c) Unless specifically excepted, any preparation which contains any quantity of methamphetamine, including its salts, isomers and salts of isomers, prepared by a registered chemical or pharmaceutical manufacturer of the Drug Enforcement Administration of the Department of Justice, which is properly labeled, including lot numbers, and is available for medicinal purposes through a distribution system approved by the Drug Enforcement Administration; or

(d) Methylphenidate.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Amobarbital;
Glutethimide;
Pentobarbital; or

Secobarbital.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances:

(a) Immediate precursors to phencyclidine (PCP):

1-Phenylcyclohexylamine; or

1-piperidinocyclohexanecarbonitrile (PCC).

(b) Immediate precursors to amphetamine and methamphetamine:

Phenylacetone (some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone).

7. Any material, compound, mixture or preparation which contains any quantity of:

~~[Synthetic Dronabinol in sesame oil encapsulated in a soft gelatin capsule in a drug product approved the United States Food and Drug Administration (some trade or other names: (6aR-trans)-6a,7,8,10a-tetrahydro-6; 6,9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran-1-ol; (-)-delta-9-(trans)-tetrahydrocannabinol);]~~

Nabilone (commonly referred to as: (+)-trans-3-(1,1-dimethylheptyl)-6, 6a, 7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzol[b,d]pyran-9-one).

Workshop 8/5/99
Public Hearing 9/23/99
Public Hearing 11/4/99