Nevada State Board of Pharmacy

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September 16, 2014

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, October 16, 2014, at the Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada. 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 639 of the Nevada Administrative Code.

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

Amendment of Nevada Administrative Code 453.540 Schedule IV

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

   On July 2, 2014, the Federal Drug Enforcement Agency (DEA) published a final ruling in the Federal Register placing tramadol into Schedule IV of the Controlled Substances Act. The rule became effective August 18, 2014.

   The proposed amendment to NAC 453.540 will add tramadol to Nevada's Schedule IV, consistent with the new federal regulation.

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

   A copy of the proposed regulation amendment 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 adverse economic impact from this regulation on businesses or the public (see attached "Small Business Impact Statement"). The amendment will create continuity between existing federal regulations and closely related Nevada regulations.

(b) Both immediate and long-term effects.

There will be no immediate or long-term negative economic impact on businesses or the public (see attached "Small Business Impact Statement").

4. The estimated cost to the agency for enforcement of the proposed regulation.

There will be no cost incurred by the Board for enforcement of this regulation.

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 other Nevada state or local government agencies that the proposed regulation overlaps or duplicates. The amended regulation will mirror 21 C.F.R. §1308.14.

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

The amended NAC 453.540 will be consistent with 21 C.F.R. §1308.14.

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 regulations 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.

SMALL BUSINESS IMPACT STATEMENT AS REQUIRED BY NRS 233B.0608

LCB File No. R133-14

1. A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

On July 2, 2014, the DEA published the final ruling in the Federal Register placing tramadol into Schedule IV of the Controlled Substances Act. The rule became effective August 18, 2014. The proposed amendment to NAC 453.540 will add tramadol to Nevada's Schedule IV.

The Board of Pharmacy (Board), through its executive staff and legal counsel, have carefully examined the proposed amendment and have determined that it will not likely (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses."

The Board solicited comment on the proposed amendment by posting a summary of the proposed amendment on the Board's website (bop.nv.gov), and by posting hard copies of its agenda at various public locations. The Board also provided time for public comment at the workshop(s) concerning the proposed amendment.

Parties interested in obtaining a copy of the summary of the proposed amendment, or that wish to view the text of the proposed amendment, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

2. The manner in which the analysis was conducted.

Board Staff analyzed the regulation to determine whether it could perceive a direct and significant economic burden on pharmacies, which are the businesses most likely to be affected by the regulation. It also analyzed whether the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis, but received none.

3. The estimated economic effect of the proposed regulation on the small businesses which it is to regulate, including, without limitation:

(a) Both adverse and beneficial effects; and

The Board anticipates no significant adverse or beneficial economic impact from R133-14 on legitimate Nevada small businesses. The proposed amendment may, however, adversely impact Nevada businesses that deal in illicit drugs.

(b) Both direct and indirect effects.

The Board anticipates no direct or indirect effect on legitimate small businesses from R133-14.

4. A description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Board anticipates no significant adverse economic impact from R133-14 on legitimate Nevada businesses, so no alternative methods of regulation are deemed necessary.

5. The estimated cost to the agency for enforcement of the proposed regulation.

None.

6. If the proposed regulation provides a new fee or increases an existing fee, the total annual amount the agency expects to collect and the manner in which the money will be used.

Not Applicable.

7. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

The Federal Drug Enforcement Administration maintains its own schedules of controlled substances, which schedules closely parallel the schedules found in NAC Chapter 453. Nevada has no control over the substances the DEA schedules, however, it is beneficial for the Board to add illicit substances to its own schedules from time to time in response to trends in illicit substance abuse that appear in Nevada.

8. The reasons for the conclusion of the agency regarding the impact of a regulation on small businesses.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small businesses. It also found no evidence that the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis, and received none.

9. The methods used by the agency in determining the impact of the regulation on small business and the reasons for the agency's conclusions.

The Board, through its executive staff and legal counsel, carefully examined the regulation and determined that it is not likely to (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses." It is designed to bring Nevada law in line with existing federal law. The Board allowed the opportunity for public comment at the workshop concerning the regulation, and opened the floor for public comment at the public hearing on the regulation. It took into thoughtful consideration the comments it received, if any. No public comment was submitted related to this regulation.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small businesses. It also found no evidence that the proposed regulation would restrict the formation, operation or expansion of such small businesses. Absent any evidence, the Board concluded that no such impacts are likely to exist.

I hereby certify that to the best of my knowledge or belief a concerted effort was made to determine the impact of this proposed regulation on small businesses and that the information contained in the statement was prepared properly and is accurate.

S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R133-14

August 19, 2014

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

AUTHORITY: §1, NRS 453.146 and 639.070.

A REGULATION relating to controlled substances; designating tramadol as a schedule IV controlled substance; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law establishes five schedules of controlled substances. Substances are categorized based on: (1) the potential for abuse of the substance; (2) whether there is an accepted medical use for the substance; and (3) the potential for physical and psychological dependence on the substance. (NRS 453.166-453.206) Under existing law, the State Board of Pharmacy is authorized to add, delete or reschedule substances listed as controlled substances in each schedule. (NRS 453.146) The Board is required to place a substance in schedule IV if it finds that: (1) the substance has a low potential for abuse relative to substances in schedule III; (2) the substance has currently accepted medical use in treatment in the United States; and (3) abuse of the substance may lead to limited physical or psychological dependence relative to the substances in schedule III. (NRS 453.196) This regulation adds tramadol to the list of substances in schedule IV.

Section 1. NAC 453.540 is hereby amended to read as follows:

453.540 1. Schedule IV consists of the drugs and other substances 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 material, compound, mixture or preparation containing any of the following narcotic drugs, including,

without limitation, their salts, calculated as the free anhydrous base of alkaloid, is hereby enumerated on schedule IV, in quantities:

(a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; or

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy-butane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alprazolam;

Barbital;

Bromazepam;

Butorphanol;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Meprobamate;

Methohexital;

Methylphenobarbital (mephobarbital);

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Tramadol (2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol);

Triazolam;

Zaleplon;

Zolpidem; or

Zopiclone.

4. Any material, compound, mixture or preparation which contains any quantity of fenfluramine, including, without limitation, its salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible, is hereby enumerated on schedule IV. For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

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 stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV:

Cathine ((+)-norpseudoephedrine);

Diethylpropion;

Fencamfamin;

Fenproporex;

Mazindol;

Mefenorex;

Modafinil;

Pemoline (including organometallic complexes and chelates thereof);

Phentermine;

Pipradrol;

Sibutramine; or

SPA ((-)-dimethylamino-1,2,diphenylethane).

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including, without limitation, its salts, is hereby enumerated on schedule IV.