Nevada State Board of Pharmacy

985 DAMONTE RANCH PARKWAY • SUITE 206 • RENO, NEVADA 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov

January 31, 2019

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, March 7, 2019, at the Hyatt Place, 1790 East Plumb Lane, Reno, 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/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 Chapter 453 to add certain products to the controlled substances listed in schedule V in conformity with federal regulations.
(LCB File No. R198-18)

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

The Drug Enforcement Administration (DEA) has added certain drug products which are approved by the U.S. Food and Drug Administration (FDA) and contain cannabidiol to the list of controlled substances in schedule V of the Federal Controlled Substances Act. The proposed amendment adds such drug products to the list of controlled substances in schedule V in conformity with federal regulations of the Uniform Controlled Substances Act.

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.

This regulation adds certain FDA-approved drug products that contain cannabidiol to the list of controlled substances in schedule V of the Federal Controlled Substances Act in conformance with federal regulations. There should be no adverse economic impact from this regulation on the public.

(b) Both immediate and long-term effects.

The Board anticipates that there will be no immediate or long-term economic effect on the public, or that any such effects will be negligible.

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

There will be no additional or special costs incurred by the Board of Pharmacy 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 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 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 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.

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 Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521, or at e-mail address: shunting@pharmacy.nv.gov. Written submissions must be received by the Board at least fourteen days before the scheduled public hearing. 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.

A copy of this notice and the regulation to be adopted and amended will be on file at the State Library, 100 Stewart Street, Carson City, Nevada, for inspection by members of the public during business hours. Additional copies of the notice and the regulation to be adopted and amended will be available in all counties in which an office of the agency is not maintained, at the main public library, for inspection and copying by members of the public during business hours. The text of each regulation will include the entire text of any section of the Nevada Administrative Code which is proposed for amendment or repeal. 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. A reasonable fee may be charged for copies if it is deemed necessary.

Upon adoption of any regulation, the agency, 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 of hearing has been posted at the following locations:

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

Washoe County Courthouse
Reno, Nevada

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R198-18

December 26, 2018

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; adding certain drug products to the controlled substances listed in schedule V in conformity with federal regulations; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to adopt regulations to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act. (NRS 453.146) Existing law also provides that if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law, the Board is required, with certain limited exceptions, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) The Drug Enforcement Administration of the United States Department of Justice has added certain drug products which are approved by the United States Food and Drug Administration and contain cannabidiol to the list of controlled substances in schedule V of the federal Controlled Substances Act. (83 Fed. Reg. 48,950-48,953 (Sep. 28,, 2018)) This regulation brings the treatment of such drug products into conformity with federal regulations by adding such drug products to the list of controlled substances in schedule V of the Uniform Controlled Substances Act.

Section 1. NAC 453.550 is hereby amended to read as follows:

453.550 1. Schedule V consists of the drugs and other substances listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base alkaloid, containing one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone, in quantities:

(a) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(b) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(c) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(d) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(e) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; or

(f) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

3. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pyrovalerone having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers.

4. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pregabalin having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers.

5. Lacosamide.

6. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight.