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 <u>Cannabis</u> or the resinous extractives thereof; and
 - (c) Contains not more than 0.1 percent residual THC by weight.