INFORMATIONAL STATEMENT LCB File No. R137-14

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1 EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION

NAC 453.520 currently lists products containing <u>high</u> percentages of hydrocodone as Schedule II controlled substances. However, NAC 453.530 contains certain provisions that allow products containing a <u>small</u> percentage of hydrocodone to be listed as Schedule III controlled substances. NAC 453.520 and .530 were consistent with similar federal controlled substance regulations until August 22, 2014, when the Federal Drug Enforcement Administration (DEA) amended its regulations, effective October 6, 2014, and placed all hydrocodone containing products on Schedule II. Consistent with the new and current DEA regulations, this proposed amendment to NAC 453.520 specifies that all hydrocodone containing products will now be listed as Schedule II controlled substances, and the exceptions in NRS 453.530 will be eliminated. This proposed amendment will bring Nevada's controlled substance regulations back in line with their federal counterparts.

2. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

The Board solicited comment on the proposed amendment by (1) posting notice, with links to the full text of the proposed amendment, to the LCB Administrative Regulation Notices webpage, (2) posting a copy of the full text of the proposed changes to the Board's website as part of the Board Meeting materials, (3) posting notice to the Nevada Public Notice website, operated by the Department of Administration, with a link back to a full text of the proposed amendment on the Board's website, and (4) posting notices and agendas in numerous public locations per NRS Chapter 233B.

The Board also solicited comment from Nevada dispensers, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. 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.

3. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was 21.

The number of persons who testified at the hearing was __-0-_. The number of agency submitted statements was __-0-_. The name of persons who testified at the hearing:

4. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

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5. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without changes because the amendments were drafted consistent with the language in the Federal Register the proposed amendments are designed to follow. Additionally, the Board received no comments from industry or the public requesting any changes.

- 6. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:
 - A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no adverse or beneficial economic effect on businesses or on the public. Businesses and the public may feel some short-term adverse impact in the process of obtaining hydrocodone containing products due to the heightened level of regulation and additional rules associated with Schedule II controlled substances. That impact is primarily due,

however, to the already effective change in DEA regulations, which preceded these proposed amendments

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that this regulation will have no immediate or long-term economic effects on business or the public.

7. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the board for enforcement of this regulation.

8. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

These proposed regulations overlap or duplicate 21 C.F.R. § 1308, the DEA's regulation that now lists all hydrocodone containing products to Schedule II.

9. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

10. IF THE 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.

This regulation does not provide a new or increase of fees.