

July 21, 2020

INFORMATIONAL STATEMENT

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

The proposed regulation amendments establish enhanced oversight of the licensing and regulation of wholesalers consistent with recommendations by the Executive Branch Audit Committee, Division of Internal Audit Report No. 20-05. The proposed regulations allow for wholesaler applicants to be sufficiently evaluated for licensure to protect the health, safety and welfare of the public.

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 Hearing 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 dispensing practitioners, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. The Board further provided time for public comment at the workshop(s) concerning the proposed amendment. The Board received no public response.

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: 6

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: N/A

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.

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 Hearing 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 dispensing practitioners, and from representatives of relevant industry associations that Board Staff deemed likely to have an interest in the proposed amendment. Further, the Board provided time for public comment at the workshop(s) concerning the proposed amendment. The Board received no response from affected businesses.

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.

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 Board received no comments from industry or the public requesting any changes.

The Board adopted LCB File R040-20 with a change at Section 9.7 (page 11, line 2), to read as follows:

...and the wholesaler shall cease conducting business in Nevada...

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.

There should be no adverse economic impact from this regulation amendment on wholesalers or on the public. The regulation amendment has beneficial impact by decreasing the potential for counterfeit or adulterated drugs to be introduced into market.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

Immediate or long-term economic effect on wholesalers and public will be negligible. Impact on industry and public is safer pharmaceuticals provided to patients.

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 of Pharmacy for enforcement of this regulation amendment.

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.

There are no similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

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 proposed regulation amendments are not more stringent than the requirements of federal law but rather conform to the requirements of 21 CFR 205.

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.