R001-15
NAC 639.620, NAC 639.6282, NAC 639.6305
Third-Party Logistics Providers
July 29, 2016

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 regulation amends the definition of third-party logistics providers (3PLs) to be more consistent with the Federal Drug Quality and Security Act (DQSA). The amendment requires that a 3PL obtain a license as an *authorized warehouse*, rather than being licensed as a *wholesaler*, as the Board has historically licensed them.

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 further provided time for public comment at the workshop(s) concerning the proposed amendment.

The Board received positive comments regarding the proposed amendments from the 3PL industry and the public. The majority of the comments indicate broad *support* for the changes. The Board also received comments in opposition to the proposed amendments from one large out-of-state 3PL. At that party's request, the Board delayed action on the proposed amendment anticipating that the Food and Drug Administration (FDA) would meet its November 2015 deadline for providing guidance on the DQSA. The FDA has not provided that guidance. Additionally, during that delay, Board Staff and the opposing party met to discuss the proposed amendments and any possible changes that might satisfy that party, but those negotiations were not successful. Board Staff presented this information to the Board over the course of several meetings, and after substantial deliberation, the Board passed the amendments based on (1) Board Staff's and the Board Members' reading and understanding of the DQSA and Nevada law,

which support continuing to license out-of-state 3PLs, and (2) support for the proposed amendment from the majority of the interested parties in the industry.

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: 14
The number of persons who testified at the hearing was: -1-
The number of agency submitted statements was: -2-
The name of persons who testified at the hearing:

Paul Enos, CEO – The Nevada Trucking Association

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 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. Further, the Board provided time for public comment at the workshop(s) concerning the proposed amendment.

As indicated above, the Board received positive comments regarding the proposed amendments from the 3PL industry and the public. The majority of the comments indicate broad *support* for the changes. The Board also received comments in opposition to the proposed amendments from one large out-of-state 3PL. At that party's request, the Board delayed action on the proposed amendment anticipating that the Food and Drug Administration (FDA) would meet its November 2015 deadline for providing guidance on the DQSA. The FDA has not provided that guidance. Additionally, during that delay, Board Staff and the opposing party met to discuss the proposed amendments and any possible changes that might satisfy that party, but those negotiations were not successful. Board Staff presented this information to the Board over the course of several meetings, and after substantial deliberation, the Board passed the amendments based on (1) Board Staff's and the Board Members' reading and understanding of the DQSA and Nevada law, which support continuing to license out-of-state 3PLs, and (2) support for the proposed amendment from the majority of the interested parties in the industry.

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 proposed amendment will not significantly change the way that Third-Party Logistics Providers (3PLs) are licensed in Nevada. Historically, Nevada has licensed 3PLs as wholesalers. Like wholesalers, 3PLs are required to obtain a Wholesalers License before they may ship and store prescription medications in the State. Congress, however, recently enacted the Federal Drug Quality and Security Act (DQSA), which allows states to continue to license 3PLs, but not as wholesalers. As a result, the Board, like other states' licensing boards, acted to amend its regulations to distinguish between wholesalers and 3PLs. The licensing process will be the same process that 3PLs are already accustomed to, and the licensing fee is the same. The most significant change that 3PLs will notice is that their Nevada licenses will now be issued as a Third-Party Logistics License, rather than as a Wholesalers License.

The Board received comments from industry and the public both in support of, and, to a lesser extent, in opposition to, the proposed amendment. At the request of one interested party, the Board even delayed action on the proposed amendment in anticipation of guidance from the Food and Drug Administration (FDA) related to that party's argument that Nevada should cease to license 3PLs. That FDA guidance never came. That delay also allowed the Board and interested parties additional time to meet and discuss the proposed amendments, which they did. The Board ultimately passed the proposed amendment based on (1) Board Staff's and the Board Members' reading and understanding of the DQSA, which they do not see as supporting the argument for non-licensure of 3PLs, and (2) stronger support for the proposed amendment from other interested parties in the industry.

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 3PLs or the public since it will allow the Board to continue to license 3PLs as it has done historically.

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 because it only amends the regulation to comply with the DQSA and allows the Board to continue to license 3PLs in a matter that is similar to the way it has historically licensed those entities.

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.

The Board is not aware of any 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 amendment relates to the federal DQSA, but the Board 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.