SMALL BUSINESS IMPACT STATEMENT AS REQUIRED BY NRS 233B.0608

LCB File No. R085-24

1. A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

The amendment will ensure that patients are receiving counseling on their prescription medication(s) and that accurate patient counseling records are maintained by both the pharmacist that counseled the patient and the pharmacy.

The Board, through its executive staff and legal counsel, have carefully examined the proposed amendment and have determined that it is not likely to (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses."

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

- Liz MacMenamin
  Retail Association of Nevada
  Contact Number: 775-882-1700

  Liz MacMenamin requested clarification from the Board on the proposed language for Section 2, Paragraph 8 and if this paragraph will bring discipline against the pharmacy if they are not properly staffed.

- Scott Young
  Animal Pharmacy Group
  Contact Email: scott@animalpolicygroup.com

  Scott Young submitted written public comment requesting that mail-order prescriptions are excluded from Section 2, 1(d) since the information is provided in written format and counseling is only provided if the individual contacts the pharmacy.

- Loren Breen
  Animal Pharmacy Group
  Contact Email: loren@animalpolicygroup.com

  Loren Breen submitted written public comment and requested clarity from the Board regarding this rule being applied in a veterinary space. She requested that the Board define what client consulation needs to look like and specify "animal owners" along with "person caring for the patient" to include veterinarians if that is the intention. She commented that implementing pharmacy regulations can be a bit more challenging as they do not have the same resources as human medicine, so she wants to make sure veterinarians are clear about what compliance looks like.

Parties interested in obtaining a copy of the summary of the comments solicited should contact Board Coordination at teamBC@pharmacy.nv.gov or call Darlene Nases at (775) 850-1440 ext. 120.

2. The manner in which the analysis was conducted.

Board Staff analyzed the regulation to determine whether it could perceive a direct and significant economic burden on pharmacies, which are the businesses most likely to be affected by the regulation. It also analyzed whether the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis. The comments received could not be perceived or analyzed to have direct and/or significant economic burden on pharmacies.

3. The estimated economic effect of the proposed regulation on the small businesses which it is to regulate, including, without limitation:

(a) Both adverse and beneficial effects; and

There should be no adverse economic impact from this regulation amendment on the regulated entities or on the public. The regulation amendment will have a beneficial effect on the regulated entities and on the public by ensuring patients are being counseled on their prescription medication(s) and accurate counseling records are maintained at the pharmacy.

(b) Both direct and indirect effects.

Both the direct and indirect economic effects on regulated entities and on the public will be beneficial by ensuring patients are being counseled on their prescription medication and that accurate counseling records are maintained at the pharmacy.

4. A description of the methods that the agency considered to reduce the impact of the proposed regulation on small businesses and a statement regarding whether the agency actually used any of those methods.

The Board anticipates no significant adverse economic impact from R085-24 on legitimate

Nevada businesses, so no alternative methods of regulation are deemed necessary.

5. 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.

6. If the proposed 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.

7. If the proposed regulation includes provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity, an explanation of why such duplicative or more stringent provisions are necessary.

The regulation does not include provisions which duplicate or are more stringent than federal, state or local standards regulating the same activity.

8. The reasons for the conclusion of the agency regarding the impact of a regulation on small businesses.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small businesses. It also found no evidence that the proposed regulation would restrict the formation, operation or expansion of such small businesses. Board Staff solicited public and industry comment as described in Question #1 above to inform its analysis. The comments received could not be perceived or analyzed to have direct and/or significant economic burden on pharmacies.

9. The methods used by the agency in determining the impact of the regulation on small business and the reasons for the agency's conclusions.

The Board, through it executive staff and legal counsel, carefully examined the regulation and determined that it is not likely to (1) "impose a direct and significant economic burden upon small business," or (2) "[d]irectly restrict the formation, operation or expansion of small businesses."

In reaching that conclusion, the Board solicited comment on the regulation by (1) posting notice, with a link 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.

In its analysis of the regulation, the Board did not perceive, and found no evidence of, a direct and significant economic burden on small business. It also found no evidence that the proposed

regulation would restrict the formation, operation or expansion of such small businesses. Absent any evidence, the Board concluded that no such impacts are likely to exist.

I hereby certify that to the best of my knowledge or belief a concerted effort was made to determine the impact of this proposed regulation on small businesses and that the information contained in the statement was prepared properly and is accurate.

J. David Wuest, R.Ph.
Executive Secretary
Nevada State Board of Pharmacy