# SMALL BUSINESS IMPACT STATEMENT AS REQUIRED BY NRS 233B.0608 LCB File No. R058-16

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 proposed amendment establishes standardized procedures or protocols for the furnishing of opioid antagonists.

The Board of Pharmacy (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 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.

The Board received written comment from Mary Staples, National Association of Chain Drug Stores (NACDS) regarding the renewal process of the written protocol between physicians and pharmacists. NACDS also commented on the reporting and recordkeeping requirements.

Liz MacMenamin, Retail Association of Nevada (RAN) commented on the reporting and recordkeeping requirements. RAN stated no objection to the regulation after hearing Board Staff's explanation.

Heidi Gustafson, Foundation for Recovery, commented in support of the regulation.

Scott Stolte, Dean, College of Pharmacy, Roseman University, commented that he did not support the reporting of the patient's name that is receiving the opioid antagonist. Board Staff clarified the reporting requirements. Mr. Stolte stated no objection to the regulation after hearing the explanation.

Trey Delap, Group Six Partners, commented in support of the regulation.

Parties interested in obtaining a summary, or a copy, of that comment from the affected businesses, 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.

#### 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. It conducted that analysis by discussing the possible impact of the amendment on small businesses among its staff and knowledgeable experts in the relevant industry. It determined that there would be no impact so long as the potentially affected businesses comply with the statutory requirements of SB 459.

### 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

The Board anticipates no significant adverse or beneficial economic impact from R058-16 on legitimate Nevada small businesses.

#### (b) Both direct and indirect effects.

The Board anticipates no direct or indirect effect on legitimate small businesses from R058-16.

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 R058-16 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.

None.

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.

Not Applicable.

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

### 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, and received none.

## 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 its 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 a summary of the proposed amendment on the Board's website (bop.nv.gov), with a link to the full text of the proposed amendment, (2) soliciting comment from Nevada dispensers who receive Board of Pharmacy notifications using a facsimile notice directed to each, and (3) contacting a representative of each relevant industry association Board Staff deemed likely to have an interest in the proposed amendment. The Board also allowed the opportunity for public comment at the workshop(s) concerning the regulation, and opened the floor for public comment at the public hearing on the regulation. It took into thoughtful consideration the comments it received, if any. No public comment was submitted related to this regulation.

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. Absent any evidence, the Board concluded that no such impacts are likely to exist.

Signature of director, executive head or other person who is responsible for the agency certifying that, to the best of his or her knowledge or belief, the information contained in the statement was prepared properly and is accurate.

Leo Basch President

Nevada State Board of Pharmacy