

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

LCB File No. R004-15

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 to NAC 453.540 will add Suvorexant to the list of Schedule IV substances.

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.

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.

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, but received none.

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 R004-15 on legitimate Nevada small businesses.

(b) Both direct and indirect effects.

The Board anticipates no direct or indirect effect on legitimate small businesses from R004-15.

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 R004-15 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 Federal Drug Enforcement Administration maintains its own schedules of controlled substances, which schedules closely parallel the schedules found in NRS Chapter 453. Nevada has no control over the substances on the federal schedules.

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 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.

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.

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



S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy