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

LCB File No. R038-26

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 453.510 will add adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I in conformity with federal regulations of the Uniform Controlled Substances Act.

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.

Furthermore, the Board also 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 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, 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

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 since the drugs proposed for addition to the Schedule I controlled substances category have a high potential for abuse and no accepted medical use. By placing these drugs into the Schedule I category in NAC 453, Nevada will be in conformance with the federal Controlled Substances Act, which will benefit the health, safety and welfare of the regulated entities and the public.

(b) Both direct and indirect effects.

Both the direct and indirect economic effects on regulated entities and on the public will be beneficial since the drugs proposed for addition to the Schedule I controlled substances category have a high potential for abuse and no accepted medical use. By placing these drugs into the Schedule I category in NAC 453, Nevada will be in conformance with the federal Controlled Substances Act, which will benefit the health, safety and welfare of the regulated entities and the public.

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 R038-26 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 proposed regulation will add N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to NAC 453.510, the controlled substances listed in Schedule I in Nevada, to conform with and duplicate the controlled substances listed in Schedule I of the federal Controlled Substances Act (CSA). The CSA places all substances which arein some manner regulated under existing federal law into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. The Drug

Enforcement Administration (DEA) issued a temporary order to schedule two schedule N-pyrrolidino metonitazene and N-pyrrolidino protonitazene in schedule I of the CSA. DEA based this action on a finding that placing these substances in schedule I is necessary to avoid imminent hazard to public safety. The temporary order was effective August 15, 2025, until August 15, 2027. On January 12, 2026, the DEA issued a final order effective on February 11, 2026, permanently placing N-pyrrolidino metonitazene and N-pyrrolidino protonitazene in schedule I of the CSA.

NRS 453.211 requires the Board to maintain a list of current schedules and NRS 453.2182 requires the Board, if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law to similarly treat the substance pursuant to the provisions of NRS 453.011 to 453.552,

The purpose of the Uniform Controlled Substances Act is to align state-level regulation with the CSA to create a consistent, uniform structure for drug laws across different states that mirror federal legislation. Additionally, it ensures that state laws are consistent with federal law to prevent conflicts and ensure consistent enforcement. The proposed regulation is necessary to carry out the intent of the Uniform Controlled Substances Act and to ensure Nevada's Schedule I controlled substance list is in-line with the CSA so that enforcement as it relates to these drugs in Nevada is consistent with federal law.

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 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