R008-21
October 21, 2021

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 Board administers the PMP database, which maintains a records of all transactions for schedule II, III, IV and V controlled substances prescribed and dispensed in Nevada. *See* NRS 453.162 through 453.165, *inclusive*. The PMP database contains Protected Health Information (PHI) as defined in 45 C.F.R. § 160.103 that is protected from unauthorized use or disclosure under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. 45 CFR Part 160 and Part 164, Subparts A and E. Patient utilization reports in the PMP are also confidential and protected from unauthorized use or disclosure under State law. The proposed regulations will better protect PHI in the PMP database from the unauthorized use and disclosure.

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 amendments 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 amendments. The Board further provided time for public comment at the workshop(s) concerning the proposed amendments.

Elizabeth MacMenamin, VP, Government Affairs
Retail Association of Nevada
410 S. Mountain Street
Carson City, NV 89703 – (775-882-1700)
LizM@rannv.org
Ms. MacMenamin spoke in support of the amendments, including the deletion of proposed Section 5 based on Board Staff's explanation that both federal and State law already prohibit the unauthorized use and disclosure of PHI contained in the PMP database.

Parties interested in obtaining a copy of the summary of the proposed amendments, or that wish to view the text of the proposed amendments, may access that information on the Board's website at bop.nv.gov, or by contacting the Board's office at (775) 850-1440.

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: -48-
The number of persons who testified at the hearing was: -1-
The number of agency submitted statements was: -0-
The name of persons who testified at the hearing:

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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.

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

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already prohibit the unauthorized use and disclosure of PHI contained in the PMP database.

Parties interested in obtaining a copy of the summary of the proposed amendments, or that wish to view the text of the proposed amendments, 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 Board adopted LCB File R008-21 with a non-substantive amendment, the deletion of Section 5. The deletion to Section 5 of the LCB draft of proposed regulation R008-21 is struck through in red (see attached).

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.

   There should be no adverse economic impact from this regulation amendment on the regulated entities or on the public. The proposed amendment will benefit the the regulated entities and the public by improving the delivery of pharmaceutical care in Nevada and ensuring that the PMP database is only used to coordinate patient care and to prevent diversion, abuse and overdoses involving controlled substances.

   B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

   Both immediate and long-term economic effects on regulated entities and the public will be to improve the safe and efficient delivery of pharmaceutical care and reduce diversion, abuse and overdoses involving controlled substances.

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 of Pharmacy for enforcement of these regulation amendments.

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 of Pharmacy 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 Board of Pharmacy 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.

These regulation amendments do not provide a new or increase of fees.