R009-20
June 15, 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 proposed amendment will authorize the delivery of a prescription drug to a practitioner for administration to the ultimate user if the FDA has made a determination that the drug is dangerous for the ultimate user to possess or administer. The regulation is necessary for the protection, health and safety of the public.

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 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 further 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 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.

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: -32
The number of persons who testified at the hearing was: -3-
The number of agency submitted statements was: -0-
The name of persons who testified at the hearing:

Lauren Paul, Senior Director
Pharmacy Regulatory Affairs - CVS Health
1 CVS Drive, Mail Code 2325
Woonsocket, RI 02895 (540-604-3661)
Lauren.Paul@CVSHealth.com
Ms. Paul commented that CVS Health has concerns only allowing the dispensing of the prescription drugs to practitioners if the FDA has adopted the Risk Evaluation Mitigation Strategy (REMS) for the drugs. Some prescription drugs that are not subject to a REMS program may require special administration, handling and/or storage. She requested removing the REMS language and allow the practitioner or ultimate user the choice to have the medication dispensed to the practitioner on behalf of the ultimate user.

Lorri Walmsley, Director
Pharmacy Affairs – Walgreen Co.
5330 E. Washington D-105
Phoenix, AZ 85034 – (602-214-6618)
Lorri.Walmsley@walgreens.com
Ms. Walmsley commented that it is too restrictive to limit the types of drugs to only REMS drugs. Ms. Walmsley noted circumstances where the drug may not be able to be administered to the patient within the proposed 14 day requirement and requested the rule be amended to 30 days. She requested modification of the amendment to allow the return of the drug that has not been administered to the patient within 30 days to the pharmacy adhering to the pharmacy's policies and procedures for the return or destruction of the prescription drug.

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 amendment with the changes proposed by Walgreens.

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

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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 R009-20 with non-substantive amendments to Section 2(c) extending the time to administer the drug to the patient from 14 days to 30 days; and Section 3, adding the option to return the drug to the pharmacy. A drug returned to the dispensing pharmacy may not be dispensed to another patient. Amendments to "LCB Draft of Proposed Regulation R009-20" are highlighted in green text (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. This amendment will have a beneficial economic effect on regulated entities and the public by ensuring the delivery of safe and reliable pharmaceutical care. The regulation amendment will benefit public health, safety and welfare.

   B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

   The immediate and long-term economic effect on regulated entities will be to improve the delivery of safe and reliable pharmaceutical care in Nevada. The regulation amendment will benefit public health, safety and welfare.

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 this regulation amendment.

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 any other state or local governmental agency that the proposed regulation amendment 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.

This regulation amendment does not provide a new or increase of fees.