ADOPTED REGULATION OF

THE STATE BOARD OF PHARMACY

LCB File No. R036-16

Effective June 28, 2016

EXPLANATION – Matter in *italics* is new; matter in brackets [omitted material] is material to be omitted.

AUTHORITY: §1, NRS 453.1545, as amended by Senate Bill No. 459, chapter 26, Statutes of Nevada 2015 at page 114, and NRS 639.070.

A REGULATION relating to pharmacy; providing a penalty for the failure to transmit to the State Board of Pharmacy certain information concerning the dispensing of certain controlled substances; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing regulations set forth certain fines which the State Board of Pharmacy may impose against a pharmacist or pharmacy for certain violations of statute or regulation. (NAC 639.955) This regulation establishes a fine of \$100 per day for the failure to transmit to the Board certain information concerning the dispensing of certain controlled substances.

- **Section 1.** NAC 639.955 is hereby amended to read as follows:
- 639.955 1. Except as otherwise provided in this section, the Board may impose a fine against a pharmacist or pharmacy pursuant to paragraph (f) of subsection 1 of NRS 639.255 according to the following schedule:
- (c) For an error in a prescription that resulted in a negative outcome to

treatment by a medical facility or a physician
(d) For an error in a prescription that resulted in a significant negative
outcome to the patient or required intervention or treatment by a medical
facility or a physician
(e) For an error in a prescription that resulted in or contributed to a
patient's death
(f) Working as a pharmacist or employing a pharmacist to work in a
pharmacy without a certificate of registration
(g) Working as a pharmaceutical technician or employing a
pharmaceutical technician to work in a pharmacy without a certificate of
registration
(h) For failing to make or maintain a biennial inventory of controlled
substances
(i) For failing to transmit the information required pursuant to NAC
639.926

- 2. The Board may impose a fine for a violation listed in subsection 1 that is less than or greater than the amount set forth in that subsection for that violation after giving consideration to any aggravating and mitigating factors that relate to the violator's role in and responsibility for the conduct for which the fine is being imposed, and the unique circumstances of each case.
- 3. If a pharmacy or pharmacist commits a violation listed in subsection 1 more than once during any 36-month period, the Board may impose a fine for any subsequent violation in an amount that is greater than the amount set forth in subsection 1 for that violation.

- 4. If a pharmacy under common ownership with one or more pharmacies commits a violation listed in subsection 1, and any pharmacy under that common ownership thereafter commits the same violation within any 36-month period, the Board may impose a fine for those subsequent violations in an amount that is greater than the amount set forth in subsection 1 for that violation.
- 5. The Board may, as it deems appropriate, impose a fine for a violation not listed in subsection 1 that is commensurate with the severity of the violation.
 - 6. No fine imposed by the Board will exceed \$10,000.
- 7. If, within an accusation, a member of the Board's staff groups similar violations into one cause of action, that grouping is for administrative convenience only and does not affect the authority of the Board to take disciplinary action for each separate violation.
- 8. This section will be construed and applied so as to preserve the discretion of the Board to take any disciplinary action authorized by NRS 639.255.

R036-16 NAC Chapter 639.955 Penalty for Failure to Transmit Controlled Substance Information June 16, 2016

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

SB 459 (2015) directed that the "Board shall establish by regulation and impose administrative penalties for the failure to upload information [to the Prescription Monitoring Program Database] pursuant to this subsection [Section 13, subsection 2]". The proposed amendment (R036-16) establishes that penalty as required by the Legislature.

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 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 further provided time for public comment at the workshop(s) concerning the proposed amendment.

The Board received comment from the Retail Association of Nevada (RAN)(Liz MacMenamin) regarding the procedure through which this penalty could be imposed. It seemed satisfied with Board Staff's explanation of the due process to which a licensee would be entitled before the penalty is imposed. RAN stated no objection to the regulation after hearing the explanation.

Parties interested in obtaining a summary, or a full copy, of the public comment, 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: 61
The number of persons who testified at the hearing was: -1The number of agency submitted statements was: -0The name of persons who testified at the hearing: Liz MacMenamin, RAN

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.

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

The Board received comment from the Retail Association of Nevada (RAN)(Liz MacMenamin) regarding the procedure through which this penalty could be imposed. It seemed satisfied with Board Staff's explanation of the due process to which a licensee would be entitled before the penalty is imposed. RAN stated no objection to the regulation after hearing the explanation.

Parties interested in obtaining a summary, or a full copy, of the public comment, 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 received no comments from industry or the public requesting any changes.

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.

This regulation should have no adverse or beneficial economic effect on legitimate businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that this regulation will have no immediate or long-term economic effects on legitimate business or the public.

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 for enforcement of this regulation.

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.

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