ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R047-15

Effective April 4, 2016

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

AUTHORITY: §1, NRS 639.070.

A REGULATION relating to pharmacy; revising provisions relating to the transmission of information regarding the dispensing of controlled substances to certain persons; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Under existing regulations, the State Board of Pharmacy requires each pharmacy that uses a computerized system to record information concerning prescriptions and that dispenses to certain persons a controlled substance that is listed in schedule II, III or IV to transmit certain information concerning the controlled substance to the Board or its agent on a weekly basis. (NAC 639.926) Certain practitioners who dispense controlled substances are also subject to those requirements. (NAC 639.745) This regulation requires such a pharmacy or practitioner to transmit that information not later than the next business day after dispensing the controlled substance. This regulation also requires such a pharmacy or practitioner that does not dispense such a controlled substance to transmit to the Board or its agent a zero report stating that the pharmacy or practitioner did not dispense such a controlled substance on the immediately preceding business day. Finally, this regulation revises the methods that a pharmacy or practitioner is required to use to transmit the information or zero report.

Section 1. NAC 639.926 is hereby amended to read as follows:

639.926 1. Each pharmacy that uses a computerized system to record information concerning prescriptions and that dispenses a controlled substance that is listed in schedule II, III or IV to a person who is not an inpatient of a hospital, correctional institution or nursing facility shall transmit to the Board or its agent the following information, as applicable, set forth in the *2011 ASAP Version 4.2 Standard for Prescription Monitoring Programs* published by the American Society for Automation in Pharmacy. The following Segments and the accompanying

Data Elements of the Implementation Guide for the *2011 ASAP Version 4.2 Standard for Prescription Monitoring Programs* are hereby adopted by reference:

(a) The Segment entitled "TH Transaction Header" and the following Data Elements:

(1) Version/Release Number;

(2) Transaction Control Number;

(3) Transaction Type;

(4) Response ID;

(5) Creation Date;

(6) Creation Time;

(7) File Type; and

(8) Segment Terminator Character;

(b) The Segment entitled "IS Information Source" and the following Data Elements:

(1) Unique Information Source ID;

(2) Information Source Entity Name; and

(3) Message;

(c) The Segment entitled "PHA Pharmacy Header" and the following Data Elements:

(1) National Provider Identifier (NPI);

(2) DEA Number;

(3) Pharmacy or Dispensing Prescriber Name;

(4) Phone Number;

(5) Contact Name; and

(6) Chain Site ID;

(d) The Segment entitled "PAT Patient Information" and the following Data Elements:

(1) Last Name;

(2) First Name;

(3) Address Information - 1;

(4) City Address;

(5) State Address;

(6) ZIP Code Address;

(7) Phone Number;

(8) Date of Birth; and

(9) Gender Code;

(e) The Segment entitled "DSP Dispensing Record" and the following Data Elements:

(1) Reporting Status;

(2) Prescription Number;

(3) Date Written;

(4) Refills Authorized;

(5) Date Filled;

(6) Refill Number;

(7) Product ID Qualifier;

(8) Product ID;

(9) Quantity Dispensed;

(10) Days Supply;

(11) Transmission Form of Rx Origin Code;

(12) Classification Code for Payment Type; and

(13) Date Sold;

(f) The Segment entitled "PRE Prescriber Information" and the following Data Elements:

(1) National Provider Identifier (NPI);

(2) DEA Number;

(3) DEA Number Suffix;

(4) Last Name;

(5) First Name; and

(6) Phone Number;

(g) The Segment entitled "CDI Compound Drug Ingredient Detail" and the following Data Elements:

(1) Compound Drug Ingredient Sequence Number;

(2) Product ID Qualifier;

(3) Product ID;

(4) Component Ingredient Quantity; and

(5) Compound Drug Dosage Units Code;

(h) The Segment entitled "TP Pharmacy Trailer" and the Data Element Detail Segment Count; and

(i) The Segment entitled "TT Transaction Trailer" and the following Data Elements:

(1) Transaction Control Number; and

(2) Segment Count.

2. A copy of the publication may be obtained from the American Society for Automation in Pharmacy at the Internet address **http://www.asapnet.org**, or by telephone at (610) 825-7783, for the price of $175 for members and ~~[$770]~~ ***$875*** for nonmembers.

3. ~~[The]~~ ***A*** pharmacy ***that dispenses a controlled substance and is required to transmit information to the Board or its agent pursuant to subsection 1*** shall transmit the information ~~[required pursuant to this section]~~ not later than ~~[each Wednesday for the prescriptions filled from the immediately preceding Sunday through Saturday. If a Wednesday falls on a legal holiday, then the information must be reported on the next business day that is not a legal holiday.]~~ ***the end of the next business day after dispensing the controlled substance. A pharmacy that does not dispense a controlled substance as specified in subsection 1 shall transmit to the Board or its agent a zero report stating that the pharmacy did not dispense such a controlled substance on the immediately preceding business day.***

4. The information ***required pursuant to this section or a zero report*** must be transmitted by means of ~~[a form of electronic data transmission approved by the Board, including, without limitation, a computer modem that can transmit information at the rate of 2400 baud or more.]~~ ***:***

(a) A secure file transfer protocol;

(b) An upload from an Internet web portal; or

(c) A manual entry.

R047-15
NAC Chapter 639.926
Transmission of Information Regarding the Dispensing of Controlled Substances to Certain Persons

January 27, 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

As required by SB459, this proposed amendment amends the rule that presently establishes the frequency of the controlled substance information transmitted to the Board and the Prescription Monitoring Program (PMP). The amendment will improve the timeliness and quality of the data provided to practitioners and pharmacies through the PMP pursuant to NRS 453.1545 and SB459.

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.

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: 30
The number of persons who testified at the hearing was: -0-
The number of agency submitted statements was: -0-
The name of persons who testified at the hearing: N/A

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.

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.

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.