ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R045-17

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

AUTHORITY: §1, NRS 453.221 and 639.070.

A REGULATION relating to controlled substances; 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 not later than the next business day after dispensing the controlled substance. The required information consists of certain segments and data elements set forth in a document concerning prescription monitoring programs that was published by the American Society for Automation in Pharmacy in 2011 and which the Board has adopted by reference. Existing regulations also require such a pharmacy 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. (NAC 639.926) Certain practitioners who dispense controlled substances are deemed to be pharmacies for the purposes of being subject to those requirements. (NAC 639.745) This regulation adds controlled substances that are listed in schedule V to the controlled substances for which such pharmacies and practitioners are required to transmit the required information to the Board or its agent. This regulation also provides that such a pharmacy or practitioner is required to include in the information transmitted to the Board, the code number adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services that corresponds to the diagnosis for which the controlled substance was prescribed. Finally, this regulation adopts by reference the most recent edition of the document published by the American Society for Automation in Pharmacy and establishes a procedure for the adoption of subsequent editions.

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 *or V* 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]~~ ***Implementation Guide –*** *ASAP* ~~[Version 4.2]~~ *Standard for Prescription* ***Drug*** *Monitoring Programs* ***in the form most recently*** published by the American Society for Automation in Pharmacy ~~[.]~~ ***, unless the Board disapproves the most recently published version pursuant to subsection 3.*** The following Segments and the accompanying Data Elements ~~[of the Implementation Guide for the 2011]~~ ***set forth in Implementation Guide –*** *ASAP* ~~[Version 4.2]~~ *Standard for Prescription* ***Drug*** *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; ***and***

(14) ICD-10 Code;

(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 *adopted by reference in subsection 1* 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 $875 for nonmembers.

3. ***The Board will periodically review the publication adopted by reference in subsection 1, and determine, within 30 days after the review, whether any change made to the publication is appropriate for application in this State. If the Board does not disapprove a change to the publication within 30 days after the review, the change is deemed to be approved by the Board.***

4. 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 not later than 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.]~~ *5.* The information required pursuant to this section or a zero report must be transmitted by means of:

(a) A secure file transfer protocol;

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

(c) A manual entry.

6. For the purposes of this section:

(a) "Days Supply" means the fewest number of days necessary to consume the quantity of a controlled substance dispensed to a patient if the patient consumes the maximum dose of the controlled substance authorized by the prescribing practitioner.

(b) "ICD-10 Code" means the code established in the International Classification of Diseases, Tenth Revision, Clinical Modification, adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, or the code used in any successor classification system adopted by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services, that corresponds to the diagnosis for which the controlled substance was prescribed.

R045-17
NAC Chapter 639.926
Transmission of Information Regarding
Controlled Substances

December 8, 2017

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

New language to be added to NAC 639.926 pursuant to Assembly Bill 474 from the 2017 Legislative Session which amended the laws for prescribing controlled substances in Nevada. The proposed amendment adds controlled substances listed in Schedule V drugs to the list of controlled substances that need to be reported to the Prescription Monitoring Program. The proposed amendment also requires that a pharmacy or practitioner transmit the International Classification of Diseases Tenth Revision (ICD-10) diagnosis code for the disease being treated with the controlled substance. The proposed amendment also defines the term "days' supply."

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.

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: 24
The number of persons who testified at the hearing was: -0-
The number of agency submitted statements was: -1-

The name of persons who testified at the hearing:
Not Applicable

The names of the agencies that submitted statements:
-Mike Podgurski, Rite Aid Corporation – P.O. Box 3165, Harrisburg, PA 17105

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

Mike Podgurski, Rite Aid Corporation, submitted written comment that Nevada's PMP reporting format will require an update to version ASAP 4.2A, which includes a field for ICD-10 codes. Mr. Podgurski recommended that prescribers be required to put the ICD-10 code on the prescription.

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.

The Board adopted LCB File R045-17 with a non-substantive change at Section 1.1, page 2 to read as follows:

Sec. 1. NAC 639.7105 is hereby amended to read as follows:

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 *or V* 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 *most current version of* [~~*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:

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 on businesses or 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 business or the public, or any such effects will be negligible.

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.

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

LCB File No. R045-17

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 Board of Pharmacy (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.

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

Mike Podgurski, Rite Aid Corporation, submitted written comment that Nevada's PMP reporting format will require an update to version ASAP 4.2A, which includes a field for ICD-10 codes. Mr. Podgurski recommended that prescribers be required to put the ICD-10 code on the prescription.

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.

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

The Board anticipates no significant adverse or beneficial economic impact from R045-17 on Nevada small businesses.

(b) Both direct and indirect effects.

The Board anticipates no direct or indirect effect on small businesses from R045-17.

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 R045-17 on Nevada businesses, so no alternative methods of regulation are deemed necessary.

5. The estimated cost to the agency for enforcement of the proposed regulation.

No additional cost to enforce.

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.

Not Applicable.

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 Board of Pharmacy is not aware of any similar federal regulation of the same activity in which the state regulation is more stringent.

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 its 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.

Larry Pinson, Pharm.D.
Executive Secretary
Nevada State Board of Pharmacy