## PROPOSED REGULATION OF THE

## STATE BOARD OF PHARMACY

## LCB File No. R045-17

September 1, 2017

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

AUTHORITY: §§1-3, 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. 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) Section 1 of 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. Sections 2 and 3 of this regulation provide that, beginning January 1, 2018, or upon the effective date of this regulation, whichever occurs later, 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. Sections 2 and 3 similarly provide a definition for the term "Days Supply."

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

NEW FIRST PARALLEL SECTION 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 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 \$875 for nonmembers.
- 3. 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. 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.
  - **Sec. 2.** NAC 639.926 is hereby amended to read as follows:

NEW SECOND PARALLEL SECTION 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, 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 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;

(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 \$875 for nonmembers.
- 3. 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. 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.
  - 5. 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

  <u>Diseases, Tenth Revision, Clinical Modification</u>, 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.
- **Sec. 3.** 1. This section and section 1 of this regulation become effective upon filing with the Secretary of State.
- 2. Section 2 of this regulation becomes effective on January 1, 2018, or upon filing with the Secretary of State, whichever occurs later.