# 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, [er] 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) Th	ne 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) Th	e 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:
- 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;		
(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
Elen	nents:
	(1) Compound Drug Ingredient Sequence Number;
8:	(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

  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.
- 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.

### REVISED PROPOSED REGULATION OF THE

### STATE BOARD OF PHARMACY

LCB File No. R046-17

October 24, 2017

EXPLANATION - Matter in italics is new, matter in brackets [omitted material is material to be omitted

AUTHORITY: §§1 and 2, NRS 453.221, 453.385 and 639.070.

A REGULATION relating to controlled substances; establishing the required contents of certain prescriptions; revising the required contents of certain prescriptions; revising provisions concerning the authority of a pharmacist and pharmaceutical technician to make changes to such prescriptions; providing other matters properly relating thereto.

## Legislative Counsel's Digest.

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the registration and control of the dispensing of controlled substances within this State and requires the Board to adopt regulation, that establish the requirements for the form and content of a prescription for a controlled substance (NRS 453.221, 453.385) Existing regulations require that certain information be contained in each written prescription for a controlled substance. Existing regulations also provide that, if certain required information is missing from such a prescription, a pharmacist of pharmaceutical technician may, before filling the prescription, add that information. (NAC 453.440) This regulation makes those requirements and provisions applicable to all prescriptions for controlled substances including oral and electronically transmitted prescriptions for controlled substances. This regulation requires that each such prescription include: (1) the patient's date of birth:/(2) the days' supply of the controlled substance; and (3) 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 is prescribed. This regulation also prohibits a pharmacist or pharmaceutical technician from adding or changing the registration number issued to a prescribing practitioner by the federal Drug Enforcement Administration on any prescription for a controlled substance.

**Section 1.** NAC 453.440 is hereby amended to read as follows:

- 453.440 1. Except as otherwise provided in subsection [2,] 3, each prescription for a controlled substance [, other than an oral or electronically transmitted prescription,] must contain:
  - (a) The name of the prescribing practitioner;
- (b) The address of the prescribing practitioner if not immediately available to the pharmacist or pharmaceutical technician;
  - (c) The handwritten signature of the prescribing practitioner in memorasable ink;
- —(d)] The date that the prescription was issued as expressed in the order of month, day and year;
  - (e) (d) The full name and date of birth of the patient;
- (f) (e) The address of the patient if not immediately available to the pharmacist or pharmaceutical technician;
  - (g) The name, strength and quantity of the drug or drugs prescribed;
  - {(h)} (g) The directions for use;
  - (h) The days' supply of the controlled substance;
- (i) The ICD-10 code that corresponds to the diagnosis for which the controlled substance is prescribed;
  - (j) The classification of the license of the prescribing practitioner; and
- (i) (k) The registration number from the Drug Enforcement Administration of the prescribing practitioner. If the prescription is written on a preprinted form that lists the names and registration numbers of more than one practitioner, the name and registration number of the prescribing practitioner must be clearly indicated by a mark.

- 2. Each written prescription for a controlled substance must include, in addition to the information required by subsection 1, the handwritten signature of the prescribing practitioner in nonerasable ink.
- 3. A prescription issued by a person who is authorized to prescribe controlled substances in the course of his or her official duties and who is exempted from registration pursuant to 21 C.F.R. § 1301.23 may be filled if, in lieu of the requirements set forth in paragraphs (a) and {(i)} (k) of subsection 1, it contains:
  - (a) The name of the person who issued the prescription stamped or printed on it;
- (b) The branch of military service or the agency pursuant to which the person who issued the prescription is authorized to prescribe controlled substances in the course of his or her official duties; and
- (c) The service identification number of the person who issued the prescription. Pursuant to 21 C.F.R. § 1301.23, the service identification number for an employee of the United States Public Health Service is his or her social security number.
- [3.] 4. Except as otherwise provided in this subsection and subsection [2,] 3, if the [registration number of the prescribing practitioner, the] address of the prescribing practitioner or the address of the patient is not on the prescription, before filling the prescription, the pharmacist or pharmaceutical technician shall write the missing [registration number,] address or addresses on the prescription or shall record the missing [registration number,] address or addresses in the record of the prescription in the computer system used by the pharmacy. If the address or addresses are immediately available to the pharmacist or pharmaceutical technician by an alphabetical card file, computer, patient profile system or any other system approved by the

Board, the pharmacist or pharmaceutical technician need not write the address or addresses on the prescription or record the address or addresses in the record of the prescription in the computer system used by the pharmacy but shall place on the prescription or in the record of the prescription his or her initials and a notation indicating the addresses are immediately available, including, without limitation, "RA," "readily available," "in files," "on computer" or any other similar notation.

- [4.] 5. Except as otherwise provided in subsection [2.] 3. if the registration number of the prescribing practitioner, the address of the prescribing practitioner or the address of the patient is not on the prescription and the address of the prescribing practitioner or the address of the patient are not immediately available to the pharmacist or pharmaceutical technician, or if the [registration number,] address or addresses have been added by the patient or a person other than the practitioner, before dispensing the prescription an employee of the pharmacy shall:
  - (a) If the address of the patient is missing or added obtain:
    - (1) Positive identification from the patient to verify his or her identity and address; or
- (2) Verification from the practitioner or his or her agent of the identity and address of the patient.
- (b) If the address of the practitioner is missing or added, obtain verification from the practitioner or his or her agent of the address of the practitioner.
- (c) If the registration number of the prescribing practitioner is missing or added, obtain verification from:
  - (1) The practitioner or his or her agent; or
- --- (2) The Board or its authorized agent.]

- An employee of the pharmacy shall place his or her initials and a notation indicating the person who provided the identification or verification to the pharmacist or pharmaceutical technician on the prescription or in the record of the prescription in the computer system used by the pharmacy.
- [5.] 6. A pharmacist [:] or pharmaceutical technician shall not add or change the registration number issued to a practitioner by the Drug Enforcement Administration on a prescription for a controlled substance.
  - 7. A pharmacist:
- (a) May, after obtaining approval of the practitioner who issued the prescription, add or change the following information on a prescription for a controlled substance listed in schedule II:
  - (1) The strength of the drug prescribed;
  - (2) The quantity of the drug prescribed;
  - (3) The directions for use; [and]
  - (4) The date that the prescription was issued [];
  - (5) The days supply of the drug prescribed; and
  - (6) The ICD-10 code that corresponds to the diagnosis for which the drug is prescribed.
- (b) May not add or change the following information on a prescription for a controlled substance listed in schedule II:
  - (1) The name of the patient;
- (2) The name of the controlled substance prescribed except that the pharmacist may change the name of the controlled substance to reflect the generic name of the controlled

substance if the pharmacist substituted a generic controlled substance for the controlled substance prescribed; or

- (3) [The] On a written prescription, the signature of the prescribing practitioner.
- (c) Shall:
- (1) Initial any addition or change made pursuant to paragraph (a) on the prescription or in the record of the prescription in the computer system used by the pharmacy; and
- (2) Make a notation on the prescription or in the record of the prescription in the computer system used by the pharmacy of:
- (I) The date and time that the prescribing practitioner approved the addition or change; and
  - (II) The reason for the addition or change
  - 8. For the purposes of this section:
- (a) "Days' supply" means the fewest number of days necessary to consume the quantity of the controlled substance dispensed to the 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.
- Sec. 2. This regulation becomes effective on January 1, 2018, or upon filing with the Secretary of State, whichever occurs later.