ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R157-04

§§1, 3 and 4 effective October 22, 2004

§2 effective January 1, 2005

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

AUTHORITY: §§1-4, NRS 639.070.

A REGULATION relating to controlled substances; requiring a registered practitioner who dispenses a controlled substance that is listed in schedule II, III or IV under certain circumstances to transmit certain information to the State Board of Pharmacy or its agent; requiring a pharmacy that dispenses such a controlled substance and records certain information under certain circumstances to transmit that information to the Board or its agent; and providing other matters properly relating thereto.

Section 1. NAC 639.745 is hereby amended to read as follows:

639.745 1. Each practitioner who is registered with the Board to dispense controlled substances and dangerous drugs and dispenses such products for use by his patients outside his presence **[**~~,~~**]** shall:

(a) Keep complete, accurate and readily retrievable records of each controlled substance and dangerous drug purchased and dispensed. The record for each such product dispensed to a patient must include:

(1) The name of the patient and, if not readily available from the practitioner's records, the patient's address;

(2) The name, strength and quantity of the prescribed controlled substance or dangerous drug;

(3) The directions for use;

(4) The date the prescription was issued; and

(5) A unique identifying number.

(b) Maintain a separate file for the records concerning the purchase of each controlled substance listed in schedule II and a separate file for the records concerning the dispensing of each controlled substance listed in schedule II. Each prescription for a controlled substance or dangerous drug must be maintained in a separate file pursuant to the requirements set forth in NAC 453.480.

(c) Keep all controlled substances and dangerous drugs in a locked storage area. Access to the storage area must be restricted to the persons described in NRS 453.375.

(d) Ensure that each package or container in which a controlled substance is dispensed, except samples in the manufacturer's packages, is clearly labeled pursuant to the requirements set forth in NRS 639.2801.

(e) Ensure that the package or container in which a controlled substance or dangerous drug is dispensed complies with all state and federal packaging requirements.

(f) Be deemed to be a pharmacy as that term is used in NAC 639.926 and shall comply with that section.

2. A practitioner may dispense dangerous drugs or controlled substances only after the patient has been informed by the practitioner that the patient may request a written prescription and have it filled at another location of the patient's choosing.

3. A record regarding the dispensing of a controlled substance or dangerous drug made and kept pursuant to this section must be maintained on paper or in a computer. If the record is:

(a) Maintained on paper, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Set forth on the front of the prescription a certification initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be serially numbered and kept in numerical order in a single file for all dispensing practitioners, including, without limitation, physician assistants and advanced practitioners of nursing, practicing at the same location.

(b) Maintained in a computer, the record must:

(1) Include all the information required to be on the prescription pursuant to NRS 639.2353 and NAC 453.440;

(2) Contain a certification, either in the computer or a separate paper document, initialed and dated by the patient that the patient has been informed by the practitioner in accordance with subsection 2 and that the patient has agreed to have the practitioner dispense the controlled substance or dangerous drug; and

(3) Be searchable for any item required by paragraph (a) of subsection 1 to be included in the record.

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 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 information set forth in the *ASAP Telecommunications*

Format for Controlled Substances, May 1995 edition, published by the American Society for Automation in Pharmacy, which is hereby adopted by reference, except the information relating to the following field names:

(a) Identifier;

(b) Bin;

(c) Version Number;

(d) Transaction Code;

(e) Compound Code;

(f) DEA Suffix;

(g) Date RX Written;

(h) Number Refills Authorized;

(i) RX Origin Code;

(j) Customer Location;

(k) Diagnosis Code;

(l) Alternate Prescriber Number;

(m) State;

(n) Zip Code (Extended);

(o) Triplicate Serial Number; and

(p) Filler.

2. A copy of the publication may be obtained from the American Society for Automation in Pharmacy, ~~[~~482~~]~~ ***492*** Norristown Road, Suite ~~[~~112,~~]~~ ***160,*** Blue Bell, Pennsylvania 19422, at no charge.

3. ***If the pharmacy records in its computerized system, in addition to the information required pursuant to subsection 1, the:***

(a) Prescription type;

(b) Payment type; or

(c) Identity of the person picking up the prescription,

➥ and its computerized system is capable of transmitting this information, the pharmacy shall include this information in its transmittal.

4. The pharmacy shall ~~[ensure that,]~~ ***transmit the information required pursuant to this section*** not later than ~~[the 15th day of the month immediately following the month in which the prescription was dispensed, the information required pursuant to subsection 1 is transmitted to the Board or its agent by a:~~

~~(a) Computer]~~ ***:***

(a) The 20th day of a month for all prescriptions dispensed on and between the 1st and 15th days of that month; and

(b) For all prescriptions dispensed on and between the 16th day and the last day of a month, the 5th day of the following month.

5. The information must be transmitted by means of a:

(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;

(b) Computer disc; or

(c) ~~[Cassette containing magnetic tape which is 1/4 of an inch wide and is]~~ ***Magnetic tape of the kind that is*** used to transmit information between computerized systems.

~~[4. Upon a showing of good cause, the Board may, for a period of 90 days, waive the requirements set forth in this section for a pharmacy that cannot transmit the information required pursuant to subsection 1 before January 1, 1997. The Board may renew the waiver.]~~

Sec. 3. The Board may, upon written application and a showing of good cause, grant an extension of time for a pharmacy to comply with the requirements set forth in NAC 639.926. An application for an extension must be received by the Board no later than November 30, 2004.

Sec. 4. 1. This section and sections 1 and 3 of this regulation become effective on October 22, 2004.

2. Section 2 of this regulation becomes effective on January 1, 2005.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R157-04

The State Board of Pharmacy adopted regulations assigned LCB File No. R157-04 which pertain to chapter 639 of the Nevada Administrative Code on September 2, 2004.

Notice date: 7/27/2004 **Date of adoption by agency:** 9/2/2004
Hearing date: 9/2/2004 **Filing date:** 10/22/2004

INFORMATIONAL STATEMENT

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. 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.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

There was no public response expressed relative to this proposed regulation.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

There was no public response expressed relative to this proposed regulation.

3. 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.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

There was no response from affected businesses relative to this proposed regulation.

4. 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 proposed regulation was amended slightly as reflected in section 2.

5. 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 economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. 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.

7. 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.

8. 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.

9. 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.