ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R035-09

Effective August 13, 2010

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

AUTHORITY: §1, NRS 639.070 and 639.0745.

A REGULATION relating to pharmacies; revising provisions governing the filling and refilling of prescriptions by a fulfillment pharmacy for a dispensing pharmacy; and providing other matters properly relating thereto.

Section 1. NAC 639.7125 is hereby amended to read as follows:

- 639.7125 1. [A] Except as otherwise provided in subsection 2, a prescription may be filled or refilled by a fulfillment pharmacy for a dispensing pharmacy if:
- (a) The *fulfillment pharmacy enters the data concerning the prescription into its computer system directly or the* dispensing pharmacy enters the data concerning the prescription into its computer system and transfers that data to the computer system of the fulfillment pharmacy in a secure and confidential manner;
 - (b) The computer system of the dispensing pharmacy:
- (1) Transmits to the computer system of the fulfillment pharmacy the National Drug Code number of [a generic] the drug [in stock] that the [dispensing] fulfillment pharmacy [would have used] must use to fill or refill the prescription; [if the prescription had not been transmitted to the fulfillment pharmacy;]
- (2) Makes and retains a record documenting the date and time that the prescription is transmitted to the fulfillment pharmacy and the identity of the fulfillment pharmacy; and

- (3) If applicable, automatically reduces the number of refills of the prescription;
- (c) The computer systems of the dispensing pharmacy and the fulfillment pharmacy are operated in compliance with the applicable provisions of this chapter and chapter 639 of NRS;
- (d) The fulfillment pharmacy labels the container in which the prescription will be dispensed in compliance with NRS 639.2801 using a label from the dispensing pharmacy or a label that contains the same information as the dispensing pharmacy would have been required to place on the label if the dispensing pharmacy had filled or refilled the prescription;
- (e) For each prescription that is being filled for the first time [by the fulfillment pharmacy, a]
- (1) A pharmacist employed by the dispensing pharmacy or a pharmacist employed by the fulfillment pharmacy [:
- (1) Verifies] *verifies* the correctness of the data in the computer system of the dispensing pharmacy concerning the prescription before the prescription is [transmitted to] *filled by* the fulfillment pharmacy [to be filled, if:], and:
- (I) [The] If the computer system of the dispensing pharmacy is capable of recording the identification of the pharmacist and the date and time when the pharmacist performed the verification [; and
- (II) The], *the* pharmacist properly records in the computer system of the dispensing pharmacy [his] *the* verification of the data; or
- (II) Makes a written notation of the verification of the data directly on the prescription; or
- (2) [Verifies] If the dispensing pharmacy receives the prescription drug from the fulfillment pharmacy, a pharmacist employed by the dispensing pharmacy verifies the

correctness of the prescription drug ordered by the prescription when it is received from the fulfillment pharmacy and the pharmacist makes a written notation on the prescription or in the record of the prescription in the computer system of the dispensing pharmacy that includes [his] the name of the pharmacist and the date on which [he] the pharmacist performed the verification; [and]

- (f) For each prescription that is being refilled by the fulfillment pharmacy, a pharmacist *or*any other person employed by the dispensing pharmacy ::
- (1) Makes] *makes* a record, by hand on a written document or in the record of the prescription in the computer system of the dispensing pharmacy, that includes:
- [(1)] (1) The date that the request to refill the prescription was sent to the fulfillment pharmacy;

[(II)] and

- (2) The date that the prescription drug ordered to refill the prescription was received by the dispensing pharmacy from the fulfillment pharmacy; and
- [(III) The date that the prescription drug was dispensed to the patient or an agent of the patient; and
- (2) Verifies]
- (g) A pharmacist employed by the dispensing pharmacy verifies the correctness of the prescription drug ordered to refill the prescription [when] if the prescription drug is received from the fulfillment pharmacy and if, in his or her professional judgment, the pharmacist determines such verification is necessary.
- 2. If [a fulfillment pharmacy fills or refills a prescription pursuant to this section with a generic drug that is manufactured by a different manufacturer than the manufacturer used by the

dispensing pharmacy, the fulfillment pharmacy shall show on the label of the container in which the prescription will be dispensed the name of the manufacturer of the generic drug used to fill or refill the prescription and the computer system of the fulfillment pharmacy must transmit to the computer system of the dispensing pharmacy] the drug identified by the National Drug Code number [and the price of that generic drug. If the computer system of] which is transmitted to a fulfillment pharmacy pursuant to subparagraph (1) of paragraph (b) of subsection 1 is not available to the fulfillment pharmacy, the fulfillment pharmacy shall not fill or refill the prescription and shall notify the dispensing pharmacy that the fulfillment pharmacy cannot]:

- (a) Shall not fill or refill the prescription []; and
- (b) Shall transmit the prescription back to the dispensing pharmacy to be filled or refilled.
- 3. If a dispensing pharmacy:
- (a) Does not include prescription drugs ordered by prescriptions that are filled or refilled by a fulfillment pharmacy in the inventory of the dispensing pharmacy, the dispensing pharmacy shall, not later than 30 days after receipt of a prescription drug ordered by a prescription that was filled or refilled by a fulfillment pharmacy:
- (1) Return the prescription drug to the fulfillment pharmacy that filled or refilled the prescription if the prescription drug has not been dispensed to a patient or an agent of a patient; and
- (2) Ensure that a pharmacist employed by the dispensing pharmacy records the date that the prescription drug was returned to the fulfillment pharmacy on a written document that is maintained at the dispensing pharmacy or in the record of the prescription in the computer system of the dispensing pharmacy.

- (b) Includes prescription drugs ordered by prescriptions that are filled or refilled by a fulfillment pharmacy in the inventory of the dispensing pharmacy, the dispensing pharmacy shall:
- (1) Not take possession of a prescription drug ordered by a prescription that was filled or refilled by a fulfillment pharmacy unless the prescription drug is accompanied by [an invoice;] a written or electronic record;
- (2) File and process an invoice for each prescription drug that it receives from a fulfillment pharmacy in the same manner as the dispensing pharmacy files and processes invoices for prescription drugs that it receives from a wholesaler; and
- (3) Process and treat each prescription drug ordered by a prescription that is filled or refilled by a fulfillment pharmacy in the same manner as the dispensing pharmacy processes and treats prescription drugs that originate from the inventory of the dispensing pharmacy.
- 4. The transmission of a prescription by a dispensing pharmacy to a fulfillment pharmacy pursuant to this section is not a transfer of a prescription.
 - 5. A dispensing pharmacy shall ensure that [:
- (a) A] a patient has been counseled in compliance with NRS 639.266 and NAC 639.707 and 639.708. [; and
- (b) All communications with the patient are made by and through the dispensing pharmacy.]
- 6. If a prescription is transmitted to and filled or refilled by a fulfillment pharmacy pursuant to this section, both the dispensing pharmacy and the fulfillment pharmacy are individually responsible for ensuring that *their respective portions of* the prescription [has] *have* been filled or refilled correctly.

- 7. A dispensing pharmacy shall not transmit, and a fulfillment pharmacy shall not fill or refill, a prescription pursuant to this section for any controlled substance listed in schedule II.
- 8. This section does not prohibit a fulfillment pharmacy from communicating with a patient concerning a prescription which is filled or refilled by the fulfillment pharmacy.
 - **9.** As used in this section:
 - (a) "Dispensing pharmacy" means a pharmacy licensed by the Board that [:
- (1) Sends] sends a prescription to a fulfillment pharmacy to be filled or refilled by the fulfillment pharmacy. [; and
- (2) Dispenses the prescription drug ordered by the prescription and filled or refilled by the fulfillment pharmacy to the ultimate user.]
- (b) "Fulfillment pharmacy" means a pharmacy licensed by the Board that fills or refills prescriptions on behalf of a dispensing pharmacy.
 - (c) "Wholesaler" has the meaning ascribed to it in NRS 639.016.

LCB File No. R035-09 NAC 639.7125 Fulfillment/Central Fill Pharmacy

July 29, 2010

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.

The number of persons who attended the hearing was _	<u>30</u>
The number of persons who testified at the hearing was	<u>3</u> .
The number of agency submitted statements was <u>0</u>	•

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 adopted with amendments or changes suggested through comments received from the public.

- 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.