LCB File No. T024-03

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

Filed with the Secretary of State on March 28, 2003

AMENDMENT TO THE PHARMACY COMPUTER REGULATIONS

Section 1. NAC 639.914 is hereby amended as follows:

NAC 639.914 Maintenance and availability of information relating to operation; entrance of each prescription into system required; issuance of consecutive numbers for prescriptions. Each pharmacy that uses a computerized system to record information concerning prescriptions must:

1. Maintain and make available, upon request, the information relating to the operation of the computerized system to:

(a) A pharmacist employed by the pharmacy; or

(b) The board or any of its agents or investigators.

2. Enter into the system each prescription filled at the pharmacy.

3. Ensure, for the maintenance of files of prescriptions required by NAC 453.480, that the numbers assigned to the prescriptions are issued consecutively and that each number is recorded in a manner that ensures that each number is assigned to a prescription or is otherwise accounted for by the pharmacy.

Section 2. NAC 639.930 is hereby amended as follows:

NAC 639.930 Safeguards against access to and manipulation of information. The system must have adequate safeguards to:

1. Prevent access by a person who is not authorized to obtain information ***and to a person who is not authorized to modify or manipulate information*** from the system; and

2. Identify ***regarding*** any modification or manipulation of information concerning a prescription~~[.]~~***:***

(a) That a modification or manipulation was made;

(b) The date the modification or manipulation was made;

(c) The person who made the manipulation; and

(d) The substance of the manipulation.

3. Prevent the removal of any prescription record once the pharmacy's computer system has assigned the prescription record a unique number.

Section 3. NAC 639.935 is hereby amended as follows:

NAC 639.935 Printed record of contents.

1. The computerized system must be able to produce a printed record of its contents in a manner that permits an audit of each prescription.

2. The printed record must be provided to the person who requests the record pursuant to NRS 639.238 ~~[within 7 business days after he requests the record]~~ ***immediately or at a later time agreed to by the person requesting the record and the pharmacist***.

3. The computerized system must be able to produce a printed record of:

(a) All prescriptions for controlled substances or dangerous drugs filled by the pharmacy on a particular day;

(b) All prescriptions filled by the pharmacy for a particular controlled substance or dangerous drug within the period specified by the person who requests the record pursuant to NRS 639.238;

(c) All prescriptions filled by the pharmacy which are prescribed by a particular practitioner;

(d) All prescriptions filled by the pharmacy for a particular patient; ~~[and]~~

(e) All patients for whom prescriptions for a particular controlled substance or dangerous drug are filled by the pharmacy~~[.]~~ ***;***

(f) The history of a prescription at the pharmacy, including a record of all refills, returns to stock, modifications or manipulations regarding the prescription, and any other acts related to the processing, filling, or dispensing of the prescription.

4. The computerized system may print a record for a patient that does not contain all of the information that must be maintained pursuant to NAC 639.930(2), but the computerized system must be able to print a record that contains all of the information that must be maintained pursuant to NAC 639.930(2) upon the request of a board member, the board's investigator, or the board's inspector.

NOTICE OF ADOPTION OF TEMPORARY REGULATION
LCB File No. T024-03

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 in opposition 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 __1__.
The number of persons who testified at the hearing was __1__.
The number of agency submitted statements was __0__.

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.

One oral response from affected businesses relative to this proposed regulation expressed support for the amendment.

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 a result of testimony offered at the hearing.

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 cost 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.