LCB File No. T048-01

ADOPTED TEMPORARY REGULATION OF THE STATE BOARD OF PHARMACY

(Effective May 9, 2001)

NAC 639.512 Class A and B packaging: Label; expiration date; log.

1. This section only applies to Class A and B packaging as defined in the *United States Pharmacopoeia*.

2. Each unit dose of a controlled substance or dangerous drug packaged or repackaged by a pharmacy must contain a label which specifies:

(a) The generic or trade name;

(b) The strength;

(c) The expiration date; and

(d) Where applicable, an internal control number or the lot number of the bulk package.

3. A unit dose of a controlled substance or dangerous drug packaged or repackaged by a pharmacy, including a hospital pharmacy, must be dispensed before the expiration date thereof. For the purposes of this section, "expiration date" means the date ~~[6]~~ ***12*** months after the date of the packaging or repackaging of the substance or dangerous drug ~~[unless a stability study acceptable to the board justifies an expiration date greater than the 6-month period]~~. No expiration date may exceed the original manufacturer's expiration date.

4. Each pharmacy must maintain a log containing with respect to each controlled substance or dangerous drug packaged or repackaged by the pharmacy:

(a) The generic name, trade name and manufacturer;

(b) The strength;

(c) The manufacturer's expiration date;

(d) Where applicable, an internal control number;

(e) The lot number of the bulk packaging;

(f) The date of packaging or repackaging;

(g) The number of doses packaged or repackaged; and

(h) The initials of the pharmacist.

(Added to NAC by Bd. of Pharmacy, eff. 12-3-84)

Workshop 1/25/01
Public Hearing 4/26/01

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INFORMATIONAL STATEMENT

639.512

May 7, 2001

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 adopted without change as no testimony was offered.

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.