LCB File No. R016-01

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

(This proposed regulation was previously adopted as LCB File No. T048-01)

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)