## PROPOSED REGULATION OF

## THE STATE BOARD OF PHARMACY

## LCB File No. R118-98

July 24, 1998

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

AUTHORITY: NRS 639.070.

**Section 1.** NAC 639.709 is hereby amended to read as follows:

639.709 1. A pharmacy may furnish drugs, controlled substances, poisons, [medicines, chemicals or], *chemicals*, devices or appliances restricted by federal law to sale by or on the order of a physician only to:

- (a) The ultimate user;
- (b) A licensed practitioner;
- (c) Another pharmacy [in order] to alleviate a temporary shortage; or
- (d) A wholesaler or manufacturer licensed pursuant to NRS 639.233 to engage in the business of wholesale distribution or furnishing *of drugs*, controlled substances, poisons, [drugs,] *chemicals*, devices or appliances that are restricted by federal law to sale by or on the order of a physician.
- 2. [If] Except as otherwise provided in this subsection, a pharmacy shall not sell in any calendar year more than [5] 10 percent of the [gross sales of a] total amount of drugs, controlled substances, poisons, chemicals, devices or appliances purchased by the pharmacy in the immediately preceding calendar year [were from the sale of prescription drugs] to wholesalers or manufacturers pursuant to paragraph (d) of subsection 1 . [,] If a pharmacy is in operation less

than 2 calendar years, the pharmacy shall not sell during the period the pharmacy is in operation more than 10 percent of the total amount of drugs, controlled substances, poisons, chemicals, devices or appliances purchased by the pharmacy to wholesalers or manufacturers pursuant to paragraph (d) of subsection 1. Drugs, controlled substances, poisons, chemicals, devices or appliances that are returned by a pharmacy for credit to the wholesaler or manufacturer from which those products were purchased are not subject to the provisions of this subsection.

- 3. For each sale made by the pharmacy pursuant to paragraph (d) of subsection 1, the pharmacy shall provide to each wholesaler or manufacturer to whom a [prescription] drug, controlled substance, poison, chemical, device or appliance is sold during the current year a statement identifying each such sale.
  - [3.] 4. The statement required pursuant to subsection [2] 3 must:
- (a) Be in writing and bear the title "Statement Identifying Sales of [Prescription] Drugs, Controlled Substances, Poisons, Chemicals, Devices or Appliances by Pharmacists to Wholesalers or Manufacturers";
- (b) [Include] *Set forth* all necessary identifying information concerning each sale in the chain of distribution of the product from the wholesaler or manufacturer;
- (c) [Include] *Set forth* the business name and address of the person from whom the [drug] *product* was purchased;
  - (d) [Include] Set forth the date of sale; and
  - (e) [Include] Set forth the:
    - (1) Name of the [drug;] *product*;
    - (2) Strength of the [drug;] product, if applicable;

- (3) Size of the container [;], if applicable;
- (4) Number of containers [;], if applicable;
- (5) Lot number of the [drug;] product, if applicable; and
- (6) Name of the manufacturer of the finished dosage form [.
- 4. Each], if applicable.
- 5. The statement required pursuant to subsection 3 must be:
- (a) Maintained by the buyer and pharmacist for 3 years after the [expiration]:
- (1) Expiration date of the [drug;] product, if the product is a drug, controlled substance, poison or chemical; or
  - (2) Date of sale, if the product is a device or appliance;
- (b) Available for copying or inspection upon a request by an authorized representative of any federal, state or local agency, a manufacturer of [prescription] drugs, controlled substances, poisons, chemicals, devices or appliances or a pharmacist or practitioner who purchases [prescription] drugs, controlled substances, poisons, chemicals, devices or appliances from the pharmacy; and
  - (c) Maintained by the pharmacy at its place of business.
- [5.] 6. As used in this section, "ultimate user" means a person who lawfully possesses a drug, controlled substance, poison, [medicine, chemical or], *chemical*, device or appliance restricted by federal law to sale by or on the order of a physician for his own use, the use of a member of his household or the use of any person for whom he is caring, or for administering to any animal owned by him or by a member of his household.