

**PROPOSED REGULATION OF
THE STATE BOARD OF PHARMACY**

LCB File No. R128-10

August 18, 2010

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

AUTHORITY: §§1, 3 and 4, NRS 639.070; §2, NRS 639.070, 639.071 and 639.072.

A REGULATION relating to pharmacy; authorizing the prescription department of a pharmacy to have a freezer that is used to store medicine; establishing procedures concerning refrigerators and freezers used in pharmacies to store medicine; prohibiting the storage of any food or beverage in certain freezers used to store medicine in the prescription department of a pharmacy; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. The managing pharmacist of a pharmacy shall ensure that a record is made which documents, at least twice daily, the temperature in:

(a) A refrigerator that is used to store medicine in the prescription department of a pharmacy;

(b) The freezer section of such a refrigerator if the freezer section is used to store medicine; and

(c) A freezer that is used to store medicine in the prescription department of a pharmacy.

2. The temperature in a refrigerator described in subsection 1 must be maintained between 36 degrees Fahrenheit and 46 degrees Fahrenheit.

3. The temperature in:

(a) A freezer section described in subsection 1 must be maintained below 32 degrees Fahrenheit; and

(b) A freezer described in subsection 1 must be maintained below 32 degrees Fahrenheit.

4. If the temperature in a refrigerator, freezer section of a refrigerator, or freezer is outside of the range required by subsection 2 or 3, respectively:

(a) The person who documented the reading which is outside the range required by subsection 2 or 3 shall initial the record made pursuant to subsection 1 and inform the managing pharmacist of the temperature in the refrigerator, freezer section of the refrigerator, or freezer;

(b) The managing pharmacist shall ensure that action is taken to correct the temperature in the refrigerator, freezer section of the refrigerator, or freezer and, after verifying that such corrective action has been taken, shall initial the record made pursuant to subsection 1; and

(c) A pharmacist shall inspect the contents of the refrigerator, freezer section of the refrigerator, or freezer, as applicable, to determine whether the contents of the refrigerator, freezer section of the refrigerator, or freezer are safe to keep or should be discarded. If the pharmacist determines that those contents must be discarded, the pharmacist shall ensure that the contents are discarded.

Sec. 2. NAC 639.469 is hereby amended to read as follows:

639.469 1. A pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing, distribution and sterile preparation of drugs prepared in the pharmacy.

2. The pharmacy must be kept clean and arranged in an orderly manner. All required equipment must be clean and in good operating condition.

3. A sink with hot and cold running water must be available to all personnel of the pharmacy and must be maintained in a sanitary condition at all times.
4. The pharmacy must be well lighted and ventilated.
5. The temperature of the pharmacy must be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator must be maintained within ~~[a range compatible with the proper storage of drugs requiring refrigeration.]~~ *the range set forth in subsection 2 of section 1 of this regulation.*
6. The pharmacy must have a locked storage area for controlled substances listed in schedule II and other controlled substances requiring additional security.
7. Flammable materials must be stored in a designated area. The area must meet the requirements of local and state fire laws.

Sec. 3. NAC 639.525 is hereby amended to read as follows:

639.525 *1.* The prescription department in each licensed pharmacy must contain the following minimum work area and equipment for the compounding and dispensing of drugs:

~~[1.]~~ *(a)* A prescription counter on which to work, with a free working surface of not less than 3 feet in width and 2 feet in depth for each person who is compounding or dispensing drugs within the prescription department, including, without limitation, each registered pharmacist and pharmaceutical technician who is compounding or dispensing drugs within the prescription department. This working surface must be reserved for and restricted solely to the compounding and dispensing of drugs.

~~[2.]~~ *(b)* A free floor space behind the prescription counter that is not less than 8 feet in length and 4 feet in width.

~~{3.}~~ (c) A refrigerator that is equipped with a thermometer to ensure proper control of temperature, a sink that is suitable for cleaning the required pharmaceutical equipment and is supplied with hot and cold running water, soap and detergent, and a clean and sanitary disposal container for wastes.

~~{4.}~~ (d) If the pharmacy compounds prescriptions that require the measurement of weight, scales and balances for medium and light weighing, at least one of which must be sensitive to 1/2 grain, with weights, including, without limitation, apothecary and avoirdupois, from 1/2 grain to 4 ounces and from 0.02 gm to 100 gm.

~~{5.}~~ (e) If the pharmacy prepares sterile products, a laminar airflow hood that is certified at least annually.

~~{6.}~~ (f) Capsule and tablet counters and other devices and equipment necessary to compound and dispense drugs.

~~{7.}~~ (g) A facsimile machine that:

~~{(a)}~~ (1) Uses paper of such quality; and

~~{(b)}~~ (2) Prints in such a manner,

↳ that documents printed by the machine are usable and readable for at least 2 years. As used in this ~~{subsection,}~~ *paragraph*, “facsimile machine” includes, without limitation, a computer that has a facsimile modem through which documents can be sent and received.

2. In addition to the requirements of subsection 1, the prescription department in a licensed pharmacy may contain a freezer that is used to store medicine.

Sec. 4. NAC 639.528 is hereby amended to read as follows:

639.528 1. Food for consumption by the public must not be prepared in the prescription department of a pharmacy.

2. A pharmacist or a member of the staff of a pharmacy may prepare food in the prescription department of the pharmacy if the food is for his or her own personal consumption.

3. No food or beverage may be stored in ~~the~~:

(a) A refrigerator that is used to store medicine in the prescription department of a pharmacy ~~is~~;

(b) *The freezer section of such a refrigerator if the freezer section is used to store medicine; or*

(c) *A freezer that is used to store medicine in the prescription department of a pharmacy.*