**New Mexico board of pharmacy drug storage/temperature monitoring regulations 2016**

**NMAC 16.19.6.11:** Minimum equipment and accessory standards. The pharmacy shall have the **necessary equipment** for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of drugs and parenteral products appropriate to the scope of pharmaceutical services provided. The following items shall be in the pharmacy; an **updated reference source,** appropriate to each practice site, either electronic or paper version; and one copy of the most recently published *New Mexico pharmacy laws, rules and regulations* and available revisions, either electronic or paper version.

**NMAC 16.19.6.10:** Minimum standards. ***

F. The restricted area shall contain an **adequate sink with hot and cold water.**

G. The restricted area shall contain a **refrigerator capable of maintaining the adequate temperature.**

**NMAC 16.19.30.9:** Operational standards. ***

C. Equipment and Supplies. The pharmacy shall:

1. have a **class A prescription balance,** or **analytical balance and weights** when necessary which shall be properly maintained and subject to inspection by the New Mexico board of pharmacy and;

2. have **equipment and utensils necessary for the proper compounding** of prescription or medication drug orders; such equipment and utensils used in the compounding process shall be:
(a) of appropriate design and capacity, and be operated within designated operational limits;

(b) of suitable composition so that surfaces that contact components, in-process material or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond the desired result;

(c) cleaned and sanitized appropriately prior to each use and;

(d) routinely inspected, calibrated when necessary or checked to ensure proper performance. * * *

Oregon Regulations: Proper Storage of Drugs:
Section 855-041-1036

855-041-1036
Proper Storage of Drugs
(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:
(a) All drugs must be stored according to manufacturer’s published or USP guidelines.
(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.
(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.
(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect.
Cold Storage and Monitoring:
(2) A pharmacy must store all drugs at the proper temperature according to manufacturer’s published guidelines (pursuant to FDA
package insert or USP guidelines).
(a) All drug refrigeration systems must:
(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.
(B) Utilize a centrally placed, accurate, and calibrated thermometer;
(C) Be dedicated to pharmaceuticals only; and
(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.
(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:
(A) Documentation of training of all personnel;
(B) Maintenance of manufacturer recommended calibration of thermometers;
(C) Maintenance of records of temperature logs for a minimum of three years;
(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;
(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;
(F) A written emergency action plan; and
(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.
(3) Vaccine Drug Storage:
(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:
(A) Vaccines must be stored in the temperature stable sections of
the refrigerator;
(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;
(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;
(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and
(E) Must adhere to a written quality assurance process to avoid temperature excursions.
Stat. Auth.: ORS 689.205, 689.325
Stats. Implemented: ORS 689.155
Hist.: BP 3-2015, f. 7-1-15, cert. ef. 1-1-16
Proposed Temperature Monitoring and Drug Storage Language 2016

Proposed Automated Environmental Monitoring and Drug Storage Language 2016

A pharmacy must store all drugs at the proper temperature according to manufacturer’s published guidelines (pursuant to FDA package insert or USP guidelines). A system of continuous temperature monitoring with automated data logging must be utilized for ambient, refrigerator and freezer storage units. Each sensor shall be NIST calibrated annually and include a certificate of traceability. All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space. Appropriate storage conditions must be provided for, including during transfers between facilities and to patients. Documentation of the temperature of each active storage unit(s) must be measured continuously and documented via an automated system capable of producing a historic report of temperature readings, to include minimum, maximum and current temperatures. The system must also include a method for tracking excursion details. The sensor must be centrally placed and include an accurate buffered system, such as glycol, glass beads, or simulated software buffer, which is calibrated within a plus or minus 0.5 °C variance. The refrigerator unit must also have an uninterrupted seal to maintain refrigerator integrity and be dedicated to pharmaceuticals only.

System validations must be conducted quarterly to assure out of range temperatures are appropriately triggering alerts, e.g. audible device alarms, phone, text, and email.

Insert after Section G: **NMAC 16.19.6.10**: Minimum standards