The rule amendments to Div 007 Public Health Emergency and 041 Operation of Pharmacies update rules related to the registration and regulation of Drug Rooms.

The rule (1) describes oversight of long-term storage of state and federal emergency medications in a Drug Room (2) clarifies that secondary storage areas related to Retail Pharmacies can register as a Drug Room; and (3) allows a Drug Room to be affiliated with an Institutional Pharmacy.

855-007-0060
SNS and State Stockpile Emergency Drugs
(1) General: When drugs from the Strategic National Stockpile (SNS) are delivered to the state, the drugs may be delivered to a state Receipt, Staging and Storage center (RSS) for further distribution to Points of Dispensing (PODs) selected by OSPHD. State drugs (state stockpile) may also be delivered to the RSS.
(2) Temporary storage of drugs from SNS or state stockpile:
(a) The RSS, PODs and local health departments (LHD) are authorized to store any drugs from the SNS or state stockpile prior to and during an emergency without any registration from the Board.
(b) All such drugs must be stored in accordance with manufacturers’ guidelines.
(c) This authority to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.
(3) A long-term drug storage area for state and federal emergency medications not otherwise registered as a drug outlet must be approved by the Board, comply with storage and security requirements, and register as a Drug Room.
Stat. Auth.: ORS 401.065, 433.441, 689.305, 689.205
Stats. Implemented: ORS 689.155

855-041-1001
Definitions
(1) “Biological product” means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.
(3) “Drug room” is a drug storage area registered with the Board which is secure and lockable.
(4) “Interchangeable” means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).
(5) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C.
262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.
Stat. Auth.: ORS 689.205 & ORS 689.522
Stats. Implemented: ORS 689.155 & 342, ORS 689.522

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 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.  
(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.  
Stat. Auth.: ORS 689.205, 689.325  
Stats. Implemented: ORS 689.155  

855-041-5005  
Definitions  
For purposes of these rules, OAR 855-041-5000 through 855-041-9999 the following definitions apply:  
(1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient care facilities, and such facility is licensed by the appropriate state agency. For the purpose of this rule, an Institutional Facility is a Residential Drug Outlet.  
(2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an institutional facility, and which is:  
(a) Located within the institutional facility;  
(b) Located outside the facility but provides pharmaceutical services to institutionalized patients; and  
(c) For the purpose of this rule, an Institutional Pharmacy is a Residential Pharmacy.  
(3) "Drug Room" means a secure and lockable location within a facility that does not have a pharmacy and is a Board approved location associated with a licensed institutional pharmacy.