OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
02/23/2022 2:54 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends drug storage requirements for pharmacies

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/29/2022 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 03/29/2022
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 414 724 81# for audio only.

You may file written comments before 4:30PM on March 29, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

The proposed rules amend pharmacy requirements for drug storage, drug storage monitoring, and response to drug storage excursion. In addition, the proposed rules clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019). Proper drug storage is essential to maintain medication purity, potency and safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021): https://www.uspnf.com/
National Institute of Standards and Technology (NIST): Optimizing Data Logger Setup and Use for Refrigerated Vaccine Tempera
https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=916348
Thermal Analysis of Refrigeration Systems Used for Vaccine Storage: Report on Pharmaceutical Grade Refrigerator and Household
https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=907377
Accurate Cold Chain Temperature Monitoring Using Digital Data Logger Thermometers (2012) https://www.nist.gov/system/file
Accurate-Cold-Chain-Temperature-Monitoring-Using-Digital-Data-Logger-Thermometers.pdf
Oregon: VFC Vaccine Management Guide
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOUR
CDC: Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.p

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Since the proposed rules provide clarity, transparency and promote patient safety by ensuring drugs are properly stored, no effects on racial equity are anticipated. Ensuring proper drug storage positively impacts all Oregonians in all communities.

FISCAL AND ECONOMIC IMPACT:

On September 24, 2021 the agency sent out a fiscal impact request to approximately 678 email addresses which included board meeting and rulemaking interested parties. OBOP received 1 response with the following estimates:

In 2019, the respondent received a quote of $10,000 for continuous temperature monitors to be installed at seven pharmacies ($1,429 for one outlet) which included one year of service. This vendor also charges for ongoing annual fees; however, that information was not provided.

Thus, it is estimated that for a licensed outlet to comply with the proposed rules, it could potentially cost $2,858 ($1,429 x 2 thermometers) for procurement and 1 year of service plus additional annual service fees. As of 12/2/2021 there are currently 1,898 registered outlets.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

It is anticipated that state agencies, units of local government and the public will not be financially impacted by the proposed rules. We do anticipate that licensed drug outlets may be financially impacted to comply with the proposed rules. There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of the proposed rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Rule amendments are necessary to incorporate standards of reference per the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

RULES PROPOSED:
855-041-1036, 855-139-0125

AMEND: 855-041-1036

RULE SUMMARY: Clarifies pharmacy requirements for proper drug storage including temperature monitoring, and response to temperature excursions; Incorporates standards by reference (e.g. USP).

CHANGES TO RULE:

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~~store each drug according to the manufacturer's ~~published or USP guidelines.~~¶
~~(b) All drugs must be stored in appropriate conditions of~~storage requirements for temperature, light, humidity, sanitation, ventilation, and space. ¶
(~~c~~2) ~~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~~If the drug's manufacturer does not include a storage requirement, the drug must be stored as required in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.¶
(~~2~~3) ~~A~~Each 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:~~¶
(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20 to 25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to 46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F); ~~or as specified by the manufacturer.~~¶
~~(B) Utilize a~~¶
(b) Utilize continuous temperature monitoring device(s) that:¶
(A) Have a buffered probe (glycol, glass beads, or similar) that is 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:~~located; ¶
(B) Records the temperature of each drug storage area at least every 15 minutes; and¶
¶
(C) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5 °C (0.9 °F) variance. A copy of the calibration certificate must be retained that includes:¶
(i) Model/device name or number;¶
(ii) Serial number;¶
(iii) Calibration date (report or issue date); and ¶
(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).¶
(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented; ¶
(~~A~~d) ~~Documentation of training of all personnel~~Utilize a system that notifies a pharmacist of each temperature excursion in real-time;¶
(~~B~~e) ~~Maintenance of manufacture~~Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or fre~~commended calibration of thermometers;~~ezer compartments with its

own exterior door and independent thermostat control; ¶
(~~C~~f) ~~Maintenance of records of temperature logs f~~Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, 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 respons~~nd door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves; ¶
(~~E~~g) ~~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~~Maintain proper drug storage conditions during transfers between facilities and delivery to patients; ¶
(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (i.e. shortened expiration date), needs to be returned to the supplier, or destroyed;¶
(~~F~~i) ~~A written emergency action plan; and~~Ensure that the following is completed at a minimum of every 3 months:¶
(~~G~~A) ~~Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equip~~Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;¶
(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be docu~~.~~ment~~.~~ed;¶
(~~3~~j) ~~Vaccine Drug Storage:¶~~
~~(a) A pharmacy that stores vaccines must comply with secti~~Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond two ~~of this rule and the following:¶~~
~~(A) Vaccines must be~~temperature excursions;¶
(k) Establish, maintain, and enforce a written action plan to ensure proper drug stor~~ag~~ed ~~in the temperature stable sec~~event of an emergency (i.e. power outage or natural disaster) that includes identifica~~tion~~s ~~of the refrigerator~~backup storage and a procedure for transfer of product between units or facilities;¶
(~~B~~l) ~~A centr~~Document the training of all~~y 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~~harmacy personnel on use of temperature monitoring system(s), quality assurance plan and written action plan to ensure proper drug storage in the event of an emergency;¶
(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer specifications, whichever is more frequent;¶
(~~C~~n) ~~Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;~~Document the following for each temperature excursion:¶
(A) Date of temperature excursion;¶
(B) Start and end time; ¶
(C) Minimum and maximum temperatures reached;¶
(D) List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experienced by the drug(s); ¶
(~~D~~E) ~~A system of continuous temperature monitoring with automated data logging and physical conf~~Each drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expir~~m~~ation ~~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~~date if determined by the manufacturer; and¶
(F) Name of person(s) involved in responding to the temperature excursion event discovery and response;¶
(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:¶
(A) Drug manufacturer information utilized indicating each drug is safe for use;¶
(B) Name of the representative providing the information;¶
(C) Manufacturer contact information; ¶
(D) Copy of information and case number if provided by manufacturer; ¶
(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 requirement~~Date and time information was obtained from manufacturer; ¶
(F) Reference number associated with manufacturer contact; ¶
(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for

continued use; and¶
(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion, documentation of this reference must be maintained; and ¶
(p) Have at least one accurate and calibrated back-up buffered temperature probe.¶
(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature.¶
(r) Maintain all records required by OAR 855-041-1036 for a minimum of three years.
Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0125

RULE SUMMARY: Clarifies pharmacy requirements for proper drug storage including temperature monitoring, and response to temperature excursions; Incorporates standards by reference (e.g. USP).

CHANGES TO RULE:

855-139-0125
Drug: Storage
(1) A ~~RDSP must maintain proper storage of all drugs. This includes, but is not limited to the following:~~¶
~~(a) All drugs must be stored~~pharmacy must store each drug according to the manufacturer's ~~published or USP guidelines.~~¶
~~(b) All drugs must be stored in appropriate conditions of~~storage requirements for temperature, light, humidity, sanitation, ventilation, and space. ¶
(~~c~~2) ~~Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.~~¶
~~(d) A RDSP must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.~~¶
~~(2) A RDSP 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~~If the drug's manufacturer does not include a storage requirement, the drug must be stored as required in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.¶
(3) Each pharmacy must:¶
(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20 to 25 ⍰C (68 to 77 ⍰F); refrigerated products between 2 to 8 ⍰C (35.6 to 46.4 ⍰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;~~¶
~~(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 RDSP must adhere to a monitoring plan, which includes, but is not limited to:~~¶
~~(A) Documentation of training of all personnel~~¶
(b) Utilize continuous temperature monitoring device(s) that:¶
(A) Has a buffered probe (glycol, glass beads, or similar) that is centrally located;¶
(B) Records the temperature of each drug storage area at least every 15 minutes; and¶
¶
(C) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5⍰C (0.9 ⍰F) variance. A copy of the calibration certificate must be retained that includes:¶
(i) Model/device name or number;¶
(ii) Serial number;¶
(iii) Calibration date (report or issue date); and ¶
(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).¶
(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented; ¶
(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;¶
(~~B~~e) ~~Maintenance of manufacture~~Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or fr~~ecommended calibration of thermometers;~~ezer compartments with its own exterior door and independent thermostat control; ¶
(~~C~~f) ~~Maintenance of records of temperature logs f~~Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, 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 respons~~nd door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves; ¶
(~~E~~g) ~~Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source~~Maintain proper drug storage conditions during transfers between facilities and delivery to

patients; ¶
(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (ie. shortened expiration date), needs to be returned to the supplier, or destroyed;¶
(~~F~~i) ~~A written emergency action plan;~~ Ensure that the following is completed at a minimum of every 3 months:¶
(~~G~~A) ~~Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and~~¶
~~(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.¶~~
~~(3) Vaccine D~~Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;¶
(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be documented;¶
(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond to temperature excursions;¶
(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of an emergency (i.e. power outage or natural disaster) that includes identification of backup storage and a procedure for transfer of product between units or facilities;¶
(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s), quality assurance plan and written emergency action plan to ensure proper drug ~~S~~storage~~:~~ in the event of an emergency;¶
(~~a~~m) ~~A RDSP that stores vaccines must comply with~~Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer spec~~tion two of this rule and the following:¶~~
~~(A) Vaccines must be stored in the temperature stable sections of the refrigerator~~ifications, whichever is more frequent;¶
(n) Document the following for each temperature excursion:¶
(A) Date of temperature excursion;¶
(B) Start and end time; ¶
(C) Minimum and maximum temperatures reached;¶
(~~B~~D) ~~A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C va~~List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experi~~a~~ence ~~must be utilized;~~d by the drug(s); ¶
(~~C~~E) Each ~~freezer and refrigerator compartment must have its own exterior door and independent thermostat control;~~drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expiration date if determined by the manufacturer; and¶
(~~D~~F) ~~A system of c~~Name of person(s) involved in respon~~t~~din~~uous~~g to the 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~~excursion event discovery and response;¶
(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:¶
(A) Drug manufacturer information utilized indicating each drug is safe for use;¶
(B) Name of the representative providing the information;¶
(D) Copy of information and case number if provided by manufacturer; ¶
(E) Date and time information was obtained from manufacturer; ¶
(F) Reference number associated with manufacturer contact; ¶
(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use; and¶
(~~E~~H) ~~Must adhere to a written quality assurance process to avoid~~In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion~~s~~.¶
~~(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 requirement~~, documentation of this reference must be maintained; and ¶
(p) Have at least one accurate and calibrated back-up buffered temperature probe.¶
(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature¶
(r) Maintain all records required by OAR 855-139-0032 for a minimum of three years.
Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155