

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 2:59 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Requires pharmacies to post accurate hours of operation and to update due to closure

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)

Moves temporary rule for accurate pharmacy hours from pharmacy operations to minimum equipment rules; Permanently adopts temporary rule language concerning temporary & emergency pharmacy closures; Adds requirements for accurate hours and temporary & emergency pharmacy closures to Remote Dispensing Site Pharmacy rules.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Other State Regulations: ME 392-13-2 Hours of Operation; Posting of Hours

<https://www.maine.gov/sos/cec/rules/02/392/392-all.doc>

Surescripts: Emergency Response Action Plans <https://surescripts.com/action-plans-disaster-response>

NCPDP: Emergency Preparedness Guidance (v.1.9)

<https://www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation.pdf>

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

The proposed rule will positively impact people in both urban and rural areas of Oregon by mitigating multiple issues identified via complaints received by the agency. All communities regardless of race have been negatively impacted statewide due to issues such as pharmacies closing without notification or not having an alternate process in place for patients to access medication from another source. The proposed rule will allow patients from all communities to be informed in a timely manner and make alternative arrangements to access medication if the pharmacy they utilize closes temporarily.

FISCAL AND ECONOMIC IMPACT:

On 1/4/2022 the agency sent out a fiscal impact request to 1,261 interested party email addresses, and 17,645 licensee/registant email addresses. We asked for an estimate of costs associated with compliance, implementation and operation related to both temporary and permanent closure for items such as: displaying accurate hours, updating telephone greeting or website, etc. We received 2 responses; one registrant estimated costs for some items to be \$0 or no additional cost while another licensee estimated each of the costs ranging from \$800,000 to \$1,000,000 but did not provide an explanation on how costs were calculated. A detailed breakdown is shown below:

- Estimate of fiscal impact associated with compliance implementation & operation related to:
- Displaying accurate hours of operation at each building and pharmacy entrance = \$0 "Internal process, supported locally. A change can be made and uploaded within minutes, provided the owners of this work are available." = \$800 no explanation provided.
- Indicating accurate hours of operation on each pharmacy telephone greeting = \$0 no additional cost, and = \$3500 "time and paying someone to re-record voicemail due to changing seasonal hours etc."
- Indicating accurate hours of operation on pharmacy-operated internet (e.g. website, social media, mobile applications) = \$0 "No additional cost, this is internal and supported at the national level (weekdays/regular business hours). A change can be made within 1-2 days of request." = \$100,000 "develop and maintain website, social media, mobile app that would otherwise be unnecessary for pharmacy operations"
- Fiscal impact associated with notifying patients with of a temporary pharmacy closure by:
- Displaying accurate hours of operation at each building and pharmacy entrance that provides:
- The estimated period of time the pharmacy will be closed = \$2800 no explanation provided.
- Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = \$9500 "waiting on hold with pharmacies that may also be closed, waiting on hold with prescribers' offices, having to hire pharmacists to come onsite so prescriptions can be reversed etc."
- Updating each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) with:
- The estimated period of time the pharmacy will be closed = \$7500 no explanation provided.
- Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = \$0 "No additional cost, IVR phone broadcast messaging (telephone greeting) can be made and uploaded within minutes, provided the owners of this work are available, informing phone-in members of closure(s) as well as other pharmacy options." = \$0 "No additional cost, Website/Social Media/Apps is internal and supported at the national level (weekdays/regular business hours). A message can be added within 1-2 days of request. Depending on

the type of message to be conveyed via this means, what is included may be limited by space available." = \$12,500 no explanation provided.

- Indicate if additional fees would be incurred if the above must be completed within 2, 4, 8, 12 or 24 hours = N/A and = 2-24 hours: \$155,000 "hiring pharmacist to be on call all year to make sure employees can access pharmacy at will based on closure".

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).

May have a fiscal impact for all Oregon pharmacies. Because all Oregon pharmacies are required to comply with these rules, small businesses are impacted including independently owned pharmacies; however, no fiscal impact was received from these outlets or licensees upon request.

- Number/Type: 113 independently owned pharmacies.

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

Small businesses were not involved with the development of proposed rule amendments.

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

Rules are straightforward and necessary to provide the public with accurate information of pharmacy hours of operation to allow access to medication.

RULES PROPOSED:

855-041-1015, 855-041-1035, 855-041-1092, 855-139-0145, 855-139-0155

AMEND: 855-041-1015

RULE SUMMARY: Proposed rule amendments remove language related to displaying accurate hours at each pharmacy entrance, each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) from OAR 855-041-1015 and move these requirements into OAR 855-041-1035 (1)(g)(E) and (1)(h).

CHANGES TO RULE:

855-041-1015

Operation of Pharmacy (Both Retail and Institutional Drug Outlets) ¶¶

(1) Supervision. A pharmacy may only be operated when a pharmacist licensed to practice in this state is present. This means that the pharmacist must be physically present in the pharmacy or institutional facility.¶¶

(2) Sanitation:¶¶

(a) Pharmacies shall be kept clean.¶¶

(b) Persons working in a pharmacy shall practice appropriate infection control.

Statutory/Other Authority: ORS 689.305

Statutes/Other Implemented: ORS 689.305

AMEND: 855-041-1035

RULE SUMMARY: Proposed amendments add accurate pharmacy hours information and requirements to (1)(g)(E) and (1)(h).

CHANGES TO RULE:

855-041-1035

Minimum Equipment Requirements ¶¶

(1) Each retail drug outlet and institutional drug outlet must have the following:¶¶

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) based on services offered by the outlet; ¶¶

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;¶¶

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEEx, OHA ALERT-IIS) based on the services offered by the outlet;¶¶

(d) Appropriate equipment to maintain the proper storage of drugs;¶¶

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;¶¶

(f) A sink with running hot and cold water;¶¶

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶¶

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height. ¶¶

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;¶¶

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; and¶¶

(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-041-2340.¶¶

~~(H); and¶¶~~

(E) Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance: and¶¶

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).¶¶

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.¶¶

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a);

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.515, ORS 689.564, ORS 689.686

ADOPT: 855-041-1092

RULE SUMMARY: Adds requirements for pharmacy to notify the public of a temporary or emergency pharmacy closure.

CHANGES TO RULE:

855-041-1092

Pharmacy Closures: Temporary or Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a pharmacy is temporarily closed to the public the pharmacy must: ¶

(a) Post notification of closure on each building entrance and each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include: ¶

(A) Estimated period of time the pharmacy will be closed; and ¶

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). ¶

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include: ¶

(A) Estimated period of time the pharmacy will be closed; and ¶

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). ¶

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure. ¶

(2) Federal and state holidays are exempt from the requirements of (1). ¶

(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

Statutory/Other Authority: ORS 689.205, ORS 475.035

Statutes/Other Implemented: ORS 689.205

ADOPT: 855-139-0145

RULE SUMMARY: Adds requirements for pharmacy to notify the public of a temporary or emergency pharmacy closure.

CHANGES TO RULE:

855-139-0145

Outlet: Closure- Temporary or Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each building entrance and each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(3) Emergency closing. If RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

Statutory/Other Authority: ORS 475.035, ORS 689.205, 2021 SB 629

Statutes/Other Implemented: ORS 689.205, ORS 689.155, 2021 SB 629

AMEND: 855-139-0155

RULE SUMMARY: Proposed amendments add accurate pharmacy hours information and requirements to (1)(g)(E) and (1)(h).

CHANGES TO RULE:

855-139-0155

Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet RDSP must have the following:¶¶

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) services offered by the outlet;¶¶

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;¶¶

(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;¶¶

(d) Appropriate equipment to maintain the proper storage of drugs;¶¶

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;¶¶

(f) A sink with running hot and cold water;¶¶

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶¶

(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height. ¶¶

(B) Providing notification in each of the languages required in OAR 855-139-0062410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;¶¶

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and 720; ¶¶

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of RDSP Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and ¶¶

~~(E)~~ Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance; and ¶¶

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications). ¶¶

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge. ¶¶

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205, ORS 689.686, ORS 689.515, 2021 SB 629

Statutes/Other Implemented: ORS 689.155, 2021 SB 629