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BOARD OF PHARMACY

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FILING CAPTION: Updates prescription transfer requirements; Creates pharmacy permanent closure requirements; Requires patient access to pharmacy records

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RULES:

855-041-1090, 855-041-1092, 855-041-1167, 855-041-2115, 855-139-0025, 855-139-0145, 855-139-0325, 855-139-0560

AMEND: 855-041-1090

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: Amendments require pharmacies notify the board a minimum of 15 days prior to any change of business name of a pharmacy; Removes information related to pharmacy closures. Pharmacy closure information and requirements are available in OAR 855-041-1092.

CHANGES TO RULE:

855-041-1090

Registration: Change of Business Name, Closure (Both Retail and Institutional Drug Outlets) ¶

~~(1) Any change of business name of a pharmacy must be reported to notify the Board within 15 days by filing a new application for which no fee is required.¶~~

~~(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs a minimum of 15 days prior to any change of business name of a pharmacy. The change must be reported by filing a new application for which no fee is required.~~

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.205

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: During the COVID-19 pandemic, there has been an increase in permanent pharmacy closures. Registrants need clear direction on orderly disposition of pharmacy records and drugs when a pharmacy permanently closes. The patients and the public need advance notice of the pharmacy closure to determine where they would like their pharmacy records sent. The proposed rules require pharmacies to respond to transfer requests in a timely manner, to notify the public and patients in the event of a permanent closure, to complete a list of items prior to, within 24 hours, and within 30 days of a permanent pharmacy closure, and to make protected health information in the pharmacy record available to the patient or the patient's representative upon their request.

CHANGES TO RULE:

855-041-1092

Retail Drug Outlet Pharmacy Closures: Temporary, Permanent or Emergency

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

(a) Post notification of closure on 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)d~~ Federal and state holidays are exempt from the requirements of (1).

(2) Permanent Closing. If a Retail Drug Outlet pharmacy is permanently closing to the public, the pharmacy must:

(a) Prior to closing, the pharmacy must comply with the following:

(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail or written notice with each prescription dispensed;

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the pharmacy; and

(iii) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.

(C) Provide any new patients filling prescriptions during the 15 calendar day period prior to the pharmacy closing with written notification that includes:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the Pharmacist-in-charge must comply with the following:¶

(A) Complete and document an inventory of all controlled substances.¶

(B) If the pharmacy dispenses prescriptions:¶

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;¶

(ii) Update the pharmacy operating status with each electronic prescribing vendor; and¶

(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).¶

(c) After closing. Within 30 calendar days after the closing of the pharmacy, the Pharmacist-in-charge must:¶

(A) Complete and document an inventory of all non-controlled drugs and devices.¶

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:¶

(i) Return to manufacturer or supplier (credit or disposal);¶

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2021), 21 CFR 1304.22 (4/1/2021), 21 CFR 1317.05 (4/1/2021), 21 CFR 1317.90 (4/1/2021) and 21 CFR 1317.95 (4/1/2021).¶

(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶

(i) Date of closing to the public and discontinuance of the business;¶

(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;¶

(iv) If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;¶

(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021) for discontinuing operation as a pharmacy that dispenses controlled substances.¶

(vi) The name, address and phone number of the pharmacy that took possession of the pharmacy records or the Oregon licensed Pharmacist who is serve as the custodian of pharmacy records which must be maintained according to OAR 855-041-1160;¶

(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;¶

(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶

(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶

(D) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.¶

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶

(3) Emergency closing. If a Retail Drug Outlet pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, 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.¶

(4) Non-resident Retail Drug Outlet pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 30 calendar days on a form prescribed by the board which includes the following information:¶

(a) Date of closing to the public and discontinuance of the business;¶

(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed Pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and¶

(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.¶

(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.

Statutory/Other Authority: ORS 689.205, ORS 475.035

Statutes/Other Implemented: ORS 689.205

ADOPT: 855-041-1167

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: New rules require a licensees and registrants of the board to make protected health information in the pharmacy record available to the patient or the patient's representative upon their request.

CHANGES TO RULE:

855-041-1167

Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make protected health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of protected health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566

AMEND: 855-041-2115

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: Amended rules permit a pharmacy to transfer a prescription for the purpose of an initial fill and require pharmacies to respond to transfer requests by another pharmacy on behalf of the patient or patient's agent in a timely manner.

CHANGES TO RULE:

855-041-2115

Transfer of Prescription Information Between Pharmacies ¶¶

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or refill dispensing provided that:¶¶

(a) The prescription is invalidated at the sending pharmacy; and¶¶

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.¶¶

(2) Prescriptions for controlled substances can only be transferred one time.¶¶

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.¶¶

(4) An Oregon registered pharmacy must transfer a prescription:¶¶

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and¶¶

(b) By the end of the next business day of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0025

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: Amendments remove information related to pharmacy closures. Pharmacy closure information and requirements for Remote Dispensing Site Pharmacies is available in OAR 855-139-0145.

CHANGES TO RULE:

855-139-0025

Registration: Change of Business Name ~~or Closure~~

~~(1) A RDSP Affiliated Pharmacy must notify the board a minimum of 15 days prior to any change of business name of a Retail Drug Outlet RDSP. The change must be reported by filing a new application for which no fee is required.~~

~~(2) A RDSP Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet RDSP. Notification must include the:~~

~~(a) Final disposition of drugs stored in the Retail Drug Outlet RDSP including:~~

~~(A) Name and location where the drugs are transferred; and~~

~~(B) Name and location where destruction occurred; and~~

~~(C) Name and location of the site that will store all records; and~~

~~(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice; and~~

~~(d) Provide the board with:~~

~~(A) Oregon Board of Pharmacy state license(s); and~~

~~(B) Signed statement giving the effective date of closure; and~~

~~(e) Comply with the requirements of 21 CFR 1301.52 (04/01/2021).~~

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0145

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: Amendments provide a list of items that must be completed prior to, on the date of or within 24 hours and within 30 calendar days of the permanent Remote Dispensing Site Pharmacy closure.

CHANGES TO RULE:

855-139-0145

Outlet: Closure- ~~Temporary~~, Permanent and 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 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.[¶]

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

(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:[¶]

(a) Prior to closing, the RDSP must comply with the following:[¶]

(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:[¶]

(i) The last day the RDSP will be open;[¶]

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;[¶]

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and[¶]

(iv) The last day a transfer may be initiated.[¶]

(B) The notification must be made via:[¶]

(i) Distribution by direct mail or written notification with each prescription dispensed;[¶]

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the RDSP; and[¶]

(iii) Posting a closing notice at each building and each RDSP entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).[¶]

(iv) In addition to (i), (ii) and (iii), the RDSP may also provide notification via email or text.[¶]

(C) Provide any new patients filling prescriptions during the 15-calendar day period prior to the RDSP closing with written notification that includes:[¶]

(i) The last day the RDSP will be open;[¶]

(ii) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;[¶]

(iii) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and[¶]

(iv) The last day a transfer may be initiated.[¶]

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021).[¶]

(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:[¶]

(A) Complete and document an inventory of all controlled substances.[¶]

(B) If the RDSP dispenses prescriptions:[¶]

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records;[¶]

(ii) Update the RDSP operating status with each electronic prescribing vendor; and[¶]

(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).¶

(c) After closing. Within 30 calendar days after the closing of the RDSP, the pharmacist-in-charge must:¶

(A) Complete and document an inventory of all non-controlled drugs and devices.¶

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the RDSP by one or a combination of the following methods:¶

(i) Return to manufacturer or supplier (credit or disposal);¶

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or¶

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2021), 21 CFR 1304.22 (4/1/2021), 21 CFR 1317.05 (4/1/2021), 21 CFR 1317.90 (4/1/2021) and 21 CFR 1317.95 (4/1/2021).¶

(C) Provide the board a written notice of the closing on a board prescribed form which includes the following information:¶

(i) Date of closing to the public and discontinuance of the business;¶

(ii) Date and time the inventory of all prescription drugs and devices was conducted;¶

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the RDSP were transferred or disposed;¶

(iv) If drugs were destroyed, name and license numbers of individuals who witnessed the destruction;¶

(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021) for discontinuing operation as a RDSP that dispenses controlled substances.¶

(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP or Oregon licensed Pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;¶

(vii) Confirmation all RDSP labels and blank prescriptions were destroyed;¶

(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and¶

(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.¶

(D) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-139-0015.¶

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.¶

(3) Emergency closing. If the RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, 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.¶

(4) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ~~2021 SB 629~~ ORS 689.700

Statutes/Other Implemented: ORS 689.155, ~~2021 SB 629~~ ORS 689.700

AMEND: 855-139-0325

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: Amended rules permit a RDSP to transfer a prescription for the purpose of an initial fill and require RDSP Affiliated Pharmacies to respond to transfer requests by another pharmacy on behalf of the patient or patient's agent in a timely manner.

CHANGES TO RULE:

855-139-0325

Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or refill dispensing provided that:¶

(a) The prescription is invalidated at the sending pharmacy; and¶

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.¶

(2) Prescriptions for controlled substances can only be transferred one time.¶

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.¶

(4) An Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy must transfer a prescription:¶

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and¶

(b) By the end of the next business day of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0560

NOTICE FILED DATE: 04/27/2022

RULE SUMMARY: New rules require a licensees and registrants of the board to make protected health information in the pharmacy record available to the patient or the patient's representative upon their request.

CHANGES TO RULE:

855-139-0560

Patients Access to Pharmacy Records

(1) Licensees and registrants of the board must make protected health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of protected health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566, ORS 689.155