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
04/16/2021 1:46 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Clarifies requirements for pharmacies related to Drug Take Back Programs

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/26/2021 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@oregon.gov

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

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

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

DATE: 05/26/2021
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 via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. Email written comment to pharmacy.rulemaking@oregon.gov by 4:30PM on 5/26/2021. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

To address directives of 2019 HB 3273 which directs Department of Environmental Quality (DEQ) to adopt any rules necessary for the effective administration of ORS 459A.200 to 459A.266. DEQ requested OBOP to assist DEQ in adopting rules under ORS 459A.200 to 459A.266.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 HB 3273 https://olis.leg.state.or.us/liz/2019r1/Downloads/MeasureDocument/HB3273 , ORS 459A.200 to 459A.266 https://www.oregonlegislature.gov/bills_laws/ors/ors459a.html

FISCAL AND ECONOMIC IMPACT:

None anticipated.

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).

There are no known economic impacts to the Oregon Board of Pharmacy, small businesses or members of the public.

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

Small businesses were not involved in the development of the proposed rules; revisions are legislatively required.

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

Revisions are legislatively required.

RULES PROPOSED:
855-041-1045, 855-041-1046

AMEND: 855-041-1045

RULE SUMMARY: Amends rules related to returned drugs and devices and secure and responsible drug disposal to align with the directives of 2019 HB 3273.

CHANGES TO RULE:

855-041-1045
Returned Drugs and Devices ¶

(1) Pharmacists, ~~pharmacies,~~ pharmacy technicians, ~~and~~ certified Oregon pharmacy technicians ~~may only~~and interns may not accept the return of controlled substances ~~upon receiving a waiver from the Board of Pharmacy~~.¶
(2) Pharmacists, pharmacies, pharmacy technicians, ~~and~~ certified Oregon pharmacy technicians and interns may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;¶
(a) The drugs or devices are accepted for destruction or disposal and;¶
(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or¶
(c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.¶
(3) Not withstanding ~~section 2~~(2) of this rule, drugs or devices previously dispensed or distributed may be returned and redispensed or redistributed provided all the following conditions are met:¶
(a) The drug is in an unopened, tamper-evident unit;¶
(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;¶
(c) The drug or device has not been adulterated or misbranded and has been stored ~~under conditions meeting United States Pharmacopeia standards.¶~~
~~(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective~~

~~when it is issued by the Board in writing~~according to the manufacturer recommendations.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

AMEND: 855-041-1046

RULE SUMMARY: Amends rules related to returned drugs and devices and secure and responsible drug disposal to align with the directives of 2019 HB 3273.

CHANGES TO RULE:

855-041-1046
Secure and Responsible Drug Disposal ¶

(1) A pharmacy that operates a drug take back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector ~~may~~to collect controlled and non-controlled drugs for destruction ~~in accordance with all applicable federal laws.~~¶
~~(2) A pharmacy that operates a drug take-back collection program shall.~~¶
(2) A pharmacy that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the ~~B~~board ~~in writing prior to initi~~within 30 days of initiating or terminating the program and ~~shall~~must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which ~~must be~~is accessible to the public ~~and can~~, within view of the pharmacy counter and must not be ~~plac~~located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation and key accountability; and¶
(c) Personnel training and accountability.¶
(3) ~~P~~A pharmacy ~~personnel shall not count, sort, inventory, or otherwise handle drugs collected.~~¶
~~(4) A pharmacy shall not dispose of quarantined, recalled or outdated drugs from pharmacy stock in a collection receptacle~~must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A pharmacy must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to be transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx or USPS) or a reverse wholesaler registered with the DEA and the board.¶
(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.¶
(~~5~~8) A pharmacy ~~shall~~must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws: ¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85 (04/01/2020);

and¶
(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218