



PERMANENT ADMINISTRATIVE ORDER

BP 17-2021
CHAPTER 855
BOARD OF PHARMACY

FILED
06/15/2021 3:07 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

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

EFFECTIVE DATE: 06/15/2021

AGENCY APPROVED DATE: 06/09/2021

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RULES:

855-041-1045, 855-041-1046

AMEND: 855-041-1045

NOTICE FILED DATE: 04/16/2021

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) Notwithstanding ~~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

NOTICE FILED DATE: 04/16/2021

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 Board in writing prior to ~~init~~ 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) ~~A pharmacy must inform consumers to directly deposit drugs into the collection receptacle.~~ Pharmacy personnel ~~shall~~ must 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 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 being 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.~~¶

(58) ~~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