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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
08/27/2018 3:24 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Auto Refill corrected rule

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/27/2018 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.

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Filed By:
Karen MacLean
Rules Coordinator

HEARING(S)

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

DATE: 09/27/2018
TIME: 9:30 AM
OFFICER: Staff
ADDRESS: Portland State Office Building
800 NE Oregon St. Conf. Rm. 1E
Portland, OR 97232

NEED FOR THE RULE(S):

Needed to correct a 2017 rule filing error. Language that should have been deleted June 2018 was retained in error. This rulemaking serves to make a current temporary rule permanent.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

OAR 855-041-1120 filed 6/30/17 and Temporary Rule filed July 16, 2018.

FISCAL AND ECONOMIC IMPACT:

A fiscal or economic impact is dependent on whether or not a company elects to provide an auto-refill service. If a company decides to provide this service, these rules must be followed and there will likely be adjustments to technology, however the 2017 Work Group did not identify a fiscal or that this would result in a significant economic impact.

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).

1. State agencies or local government are not expected to be impacted as the proposed revisions are specific to retail pharmacy outlets. The public may need to have conversations with their pharmacist regarding the automatic refilling of their prescriptions.

2. a. All retail pharmacies registered in Oregon are subject to this rule. Of the 1356 registered retail pharmacies, approximately 450 are out of state and there are between 50 to 100 small retail pharmacies in the state. It is unknown how many small businesses this may impact that are out of state.

2.b. Unless they provide auto refill services, there is no additional cost. No formal reporting is required for compliance. Otherwise, they must comply with their own company's policies and procedures within the limitations of this proposed rule.

2.c. No special equipment is required, as this rule covers an activity that an outlet can choose to participate in or not. If they do participate, the method, equipment they use, will be of their choosing.

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

Small businesses were not involved in the development of this rule.

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

The Board convened a legislatively required Stakeholders Work Group in 2017 to evaluate, discuss and achieve consensus to address this safety issue. Multiple meetings were held over a two year period. This is simply a correction to the 2017 filing error.

AMEND: 855-041-1120

RULE SUMMARY: Permanently corrects rule filing of June 2017 to reflect the Board's adopted rule.

CHANGES TO RULE:

855-041-1120
Prescription Refills ¶

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.¶
(2) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.¶
(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;¶
(a) The identity of the responsible pharmacist;¶
(b) Name of the patient;¶
(c) Name of the medication;¶

(d) Date of refill; and¶
(e) Quantity dispensed.¶
(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.¶
(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.¶
(6) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:¶
(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program; and¶
(b) The prescription is not a controlled substance; and¶
(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent; and¶
(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and¶
(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.¶
~~(7) An automated reminder cannot be used to generate a prescription refill unless the patient or patient's agent provides authorization for each individual prescription refill. The content of each reminder must include:¶~~
~~(a) Drug name and strength; and¶~~
~~(b) Date of last fill.¶~~
~~(8) Pick-up notification to a patient or patient's agent may only be generated upon full completion of the prescription refill.~~
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515~~, 2013 OL Ch. 342~~