

CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-40-15-1

RULE TITLE: Pharmacists, Pharmacies, and Manufacturers, Wholesalers and Distributors

REASON FOR RULEMAKING: The purposes of this regulation are as follows: to create definitions for “active ingredient,” “auto substitute,” “COVID-19” and “dispense as written;” to permit prescription drugs to be returned to a pharmacy in the event of a recall or medication error and require the pharmacy to maintain a record of returned medications and make the record available to the Department upon request; to allow pharmacists to dispense an amount of non-controlled substance medication beyond the original prescription amount, as written by the prescriber, not to exceed the total amount of authorized refills; to allow for a one-time emergency refill for up to 90 days, excluding schedule II, III, and IV drugs; to allow pharmacists and pharmacy technicians to work remotely as operationally feasible; to allow hospitals to direct that patients’ personal medications be stored in their rooms, instead of the hospital pharmacy; and to permit certain pharmacy procedures in the event of a state of emergency.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

A written comment was received requesting that the provisions permitting auto-substitutions of medications during a state of emergency be expanded to permit auto-substitutions in scenarios such as being unable to reach a provider and natural disasters. While these are emergencies, there are other solutions to these problems that could be used prior to the use of auto-substitutions, which are intended to be used only in extreme circumstances. This comment will not be accepted at this time.

A written comment was received requesting immediate notification to the prescriber in the event of an auto-substitution. The authority to auto-substitute is dependent on the approval of the Director during a declared State of Emergency, with the goal of leveraging the professional knowledge of pharmacists to provide alternatives in the absence or shortage of the prescribed medication. Pharmacists will exercise their

professional judgment in determining whether to auto-substitute. Requiring immediate notification to the prescriber is inefficient and contrary to the goals of the provision. This comment will not be accepted at this time.

A written comment was received requesting that any auto-substitutions must be done within the coverage rules of the insurer. Consideration of coverage rules is outside the scope of the practice of pharmacy. More importantly, the authority to auto-substitute is dependent on the approval of the Director during a declared State of Emergency, with the goal of providing pharmacists with alternatives in the absence or shortage of the prescribed medication. Pharmacists will exercise their professional judgment in determining whether to auto-substitute. This comment will not be accepted at this time.

A comment was received requesting that any auto-substitution not adversely impact a patient's out of pocket costs. Consideration of out-of-pocket costs is outside the scope of the practice of pharmacy. More importantly, the authority to auto-substitute is dependent on the approval of the Director during a declared State of Emergency, with the goal of providing pharmacists with alternatives in the absence or shortage of the prescribed medication. Pharmacists will exercise their professional judgment in determining whether to auto-substitute. This comment will not be accepted at this time.

A comment was received regarding expansion of emergency, in § 1.15, to include other types of emergencies, such as snowstorms, hurricanes, and power outages. The intent, however, was that the emergency provisions be narrow in scope and only used in extreme circumstances. This comment will not be accepted at this time.

A comment was received regarding the definition of "auto-substitution;" the comment requested that the definition be separated into two separate definitions: "auto-substitution" and "therapeutic substitution." Additionally, the comment requested removal of the pharmacist's ability to auto-substitute even with a dispense as written directive. The current definition addresses both auto-substitution and therapeutic substitution and is only permitted in emergencies when access to medication may be limited. Changing the definition would expand the practices of pharmacy, which expansion would require further investigation by the Department relative to its impact. This comment will not be accepted at this time.

A comment was received expressing concern over pharmacists being permitted to dispense non-controlled substance medication beyond the prescription amount, not to exceed total amount of authorized refills. Many prescriptions are maintenance drugs, and prescribing larger quantities improves medication adherence for patients. Pharmacists will exercise their professional judgment in determining whether to dispense beyond the prescription amount, and any risk of prescribing excess medication can be controlled by the physician by not permitting refills. This comment will not be accepted at this time.

A comment was received regarding concerns over the pharmacist's ability to dispense medication for up to ninety days in the event of an emergency and suggested amending the regulation to allow for an emergency supply of no more than 30 days, once , annually. The Department's position is that the 90-day supply limit is a cap, only. Pharmacists are not obligated to dispense a 90-day supply and will exercise their professional judgement, dispensing less than the allowable 90-day amount as appropriate. On the other hand, permitting an emergency supply once annually on the same prescription is overly broad. This comment will not be accepted at this time.

A comment was received regarding the automatic termination of the pharmacy licenses for an alternate hospital site (AHS) at the conclusion of a state of emergency. The comment requested this language be removed because there could be a gap between the termination of the state of emergency and the closing of the AHS. The Department agrees that such a gap could occur; however, complete removal of the language would allow the pharmacy in the AHS to remain open indefinitely. Notably, with respect to the present state of emergency, which is ongoing as of March 18, 2021, the AHSs have already transitioned to "warm" status and are effectively closed. Accordingly, this comment will not be accepted at this time.

A comment was received requesting the amendment of language in various licensing sections in accordance with recently effective legislation, R.I. Gen Laws § 28-5.1-14. Unfortunately, RIDOH cannot accept this comment at this time as the regulation had no proposed amendments in any of the licensing areas; any amendments to these areas would violate R.I. Gen Laws § 42-35-6.1.

CHANGES TO THE TEXT OF THE RULE:

§ 1.2(A)(3) Creates a definition for "Active ingredient".

§ 1.2(A)(9) Creates a definition for "Auto substitute".

§ 1.2(A)(39) Creates a definition for "COVID-19".

§ 1.2(A)(49) Creates a definition for "Dispense as written".

§ 1.2(A)(63) Removes the definition for "Executive Order" as it no longer appears in the regulation.

§ 1.4.20(B)(1) Permits prescription drugs to be returned to a pharmacy in the event there is a recall or medication error.

§ 1.4.20(B)(3) Requires records of returned drugs to be made available to the Department upon request.

§ 1.4.22(B) Adds a provision noting that dispensing additional prescription refills beyond what is prescribed may constitute unprofessional conduct.

§ 1.4.22(C) Permits pharmacists to dispense drug quantities in excess of the face amount of prescriptions for non-controlled substances, not to exceed the total amount of authorized refills.

§ 1.4.24(A) Allows pharmacists to dispense a one-time emergency refill for up to 90 days.

§ 1.4.24 (A)(1) Prohibits drugs in schedules II, III, and IV from being dispensed for a one-time emergency 90-day refill.

§ 1.5.5(B)(5) Allows pharmacists to work remotely as operationally feasible.

§ 1.5.15 Allows prescriptions to be transferred an unlimited amount of times.

§ 1.5.27(C)(5)(a) Allows hospitals to direct that patients' personal medication be stored in their rooms, instead of the hospital pharmacy.

§ 1.12.1(A)(8) Allows pharmacy technicians to work remotely as operationally feasible.

§ 1.15 Permits certain pharmacy procedures in the event of a state of emergency declared by the governor pursuant to R.I. Gen. Laws § 30-15-9.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

- 1) Alternative approaches;
- 2) Overlap or duplication with other statutory and regulatory provisions; and
- 3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.