

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: This regulation is being promulgated in accordance with R.I. General Laws 5-19.1 and 5-19.2 to create a standing order section and details procedures for such, creation of an administration of medication section and details procedures for such and rewording of Collaborative Practice Agreement. It also adds “hormones and hormone analogs” to section § 1.11.3(E)(2).

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

TESTIMONY AND COMMENTS:

No public comments were received in opposition to the proposed regulations. Public comment was received that the proposed regulation should add the following words “and hormones” to Section 1.11.3, Administration of Medications, to read E. Pharmacists shall not administer the following drugs or drug classes: 1. Chemotherapy agents, and 2. Controlled substances, except those used for addiction treatment and hormones. Public comment noted that this change would permit pharmacist administration of testosterone products and potentially increase access to this medication class.

Public comment also noted the medication administration section of the regulations in 1.11.3B.9 lists “Hormones and Hormone Analogs” as a drug class that pharmacists can already administer.

Public comment further noted that, in 2022, use of testosterone products used by transmasculine people results in improved quality of life and lowers the prevalence of anxiety and depression. It was noted that the initiation and maintenance of testosterone is already difficult because of misinformation, unnecessary counseling requirements, discrimination, and drug shortages.

The Rhode Island Department of Health agrees with this recommendation. Hormone replacements are legal prescription drugs used to treat conditions such as low testosterone levels or for the purposes of providing evidence-based gender affirming healthcare for gender diverse individuals.

CHANGES TO THE TEXT OF THE RULE:

§ 1.11.3(E)(2) adds the phrase “and hormones and hormone analogs.”

“Hormone analogs” was added for consistency with the regulations in section 1.11.3. Administration of Medications, under (B), which states that “A pharmacist is authorized to administer medications in the following drug classes:

(9) Hormones and hormone analogs”.

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.