

Rhode Island Department of Health

Cost-Benefit Analysis

Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors

216-RICR-40-15-1

June 2022

Background

In the 2021 legislative season, the general assembly passed legislation to expand the practice of pharmacy to permit pharmacists to administer medications. Such medications must be developed by the Rhode Island Department of Health (RIDOH) and the Board of Pharmacy (BOP).

Proposed Regulation

While there are various changes being proposed in the Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors Regulation, the following are the key substantive changes which will be the focus of this analysis:

1. Permitting Pharmacists to Engage in a Standing Order
2. Permitting Pharmacists to Administer Medications
3. Revising the Collaborative Practice Agreements

Benefits and Costs

Key Change 1: Standing Orders

As defined in the proposed regulation, standing orders are medications that can be dispensed by a pharmacist to an individual who does not have an individual prescription. This prewritten prescription is written by a qualified provider for the purpose of treating conditions without having to obtain prior authorization and thus improves efficiency of healthcare by allowing providers to focus on other types of care. This tactic is used in half of the United States, including Rhode Island, to allow pharmacists to dispense an opioid antagonist such as Naloxone (Narcan) without a prescription (1). This mechanism eliminates barriers to receiving treatment for individuals with opioid use disorder.

The Department is proposing expanding standing orders beyond opioid antagonist to other diseases with common accepted forms of treatment, such as vaccines or oral contraception. As proposed in the regulation standing orders, such standing orders must have a detailed set of criteria for what disease is being treated and that the patient

meets the criteria prior to the medication being dispensed. Additionally, before the patient can even take advantage of the standing order, the standing order must be approved by the Rhode Island Board of Pharmacy, the Board of Medical Licensure and Discipline and approved by the Director of the Department.

With extensive review by qualified providers, standing orders are not expected to increase risk to patients. And a pharmacist is still able to refer a patient to a provider if he or she is uncomfortable with dispensing a standing order. If implemented, standing orders can reduce healthcare costs by eliminating a patients' need to see a physician, or other provider, before obtaining a prescription and allows for a patient to be treated faster.

Standing orders also benefit the providers by allowing physicians or other providers to redistribute the prescriber workload to pharmacists. It is estimated that for a standard patient panel of 2,500 it would take 21.7 hours for a physician to provide all the necessary care (2). This number does not account for any quality reporting (2). By developing standing orders, the physicians can shift the workload of less complex or routine patients to other, qualified members of the care team – like pharmacists (3). Thus, allowing for physicians to focus on patients with more complex medical needs.

Key Change 2: Administration of Medication

Pharmacists are the most accessible healthcare provider and most visited member of the healthcare team (4). As a result, their scope of practice has been expanding for a number of years. For example, in 2007 the R.I. General Assembly permitted pharmacists to administer vaccines, becoming the 46th state (at the time) to permit such practice. Now with all 50 states permitting pharmacists to administer vaccines, pharmacists have administered 1/3 of the total immunizations in the United States (5). With the recent COVID-19 pandemic, pharmacists were instrumental in the administering millions of COVID vaccinations.

In the R.I. 2021 legislative session, the General Assembly looked to expand the scope of pharmacists again by permitting pharmacists to administer additional medications that are prescribed by a licensed physician or other prescriber and that the Board of Pharmacy approves and deems appropriate for a pharmacist to administer. This expansion of practice scope is not intended to increase risk, as in many hospital settings pharmacists are asked to advise nursing staff on the appropriate ways to administer medications (e.g., route of administrations, dilution of medication prior to injection, time to push an injection over, types of needles to be used etc.). Additionally, pharmacists are highly educated on the appropriateness of all medications for various conditions and evaluate all pertinent clinical markers prior to administration of the medication.

The Board of Pharmacy proposes a pharmacist to administer the following medications should a physician or other provider prescribe it:

1. Anti-infectives

2. Anti-HIV

- | | |
|---------------------------------|--------------------------------|
| 3. Purified Protein Derivative | 15. Interferons |
| 4. Vaccines | 16. Calcium Regulating Agents |
| 5. Antipsychotics | 17. Immunologic Agents |
| 6. Epinephrine | 18. Hematopoietic Agents |
| 7. Buprenorphine | 19. Dermatologic Agents |
| 8. Vitamins | 20. Colony Stimulating Factors |
| 9. Hormones and Hormone Analogs | 21. Antirheumatic Agents |
| 10. Fertility Agents | 22. Anticoagulants |
| 11. Contraceptives | 23. Steroids |
| 12. Androgens | 24. Opioid Antagonists |
| 13. Biologics | 25. Topicals |
| 14. Monoclonal Antibodies | |

Anti-infectives, Anti-HIV, Epinephrine, Fertility agents, Monoclonal antibodies, Opioid Antagonists: Patients **benefit** by the availability of many accessible pharmacists especially for time sensitive administration such as for prophylactic medications needed for post sexual assault or post needle stick, Lyme disease, shingles, covid-19 as a few examples. Rescue drugs like epinephrine may need timely and appropriate administration especially in hospital settings as allowed by hospital policies/procedures, pharmacists are well trained for assistance in hospital codes. None of these activities by a pharmacist in a hospital adds to the expense of the patient or cost of healthcare. Fertility drugs need to be administered appropriately and timely for optimal effectiveness, accessible pharmacists can do this for patients who are timid or afraid to inject themselves. Risks to patients are decreased by pharmacist involvement in the proper administration of medications. Pharmacists are well trained in all aspects of technique and safety in administration of medications. Patients would not be subject to increased **costs** as pharmacists would be billing for equal reimbursement as other healthcare providers.

Patients **benefit** not only by the incredible access of pharmacists but the assurance the medication is being administered correctly. Many medications can be self-administered by patients after a healthcare professional teaches the patient, yet there are many safety concerns with patients self-administration of medications. Having a pharmacist administer guarantees safety and proper dosing which is especially critical in medications like androgens, hormones, hormone replacements, and steroids in which

these drugs can be abused or cause serious unwanted side effects if overdosed. This is also the case with biologics for rare diseases, certain injectable forms of buprenorphine/naloxone (long-acting opioid antagonists/MAT combos), anti-psychotics, interferons, Calcium regulating agents, anticoagulants, immunologic agents, hematopoietic agents, colony stimulating factors, and anti-rheumatic agents. Improper administration can be fatal and have the potential to mortally wound patients of not administered properly. Pharmacist administration **reduces these risks**. Pharmacist administration of other drug classes such as purified protein derivative for the diagnosis of the presence of tuberculosis **benefits** public health by pharmacist being able to refer patients for prophylactic treatment immediately. Optimization of treatment is also improved by pharmacist administration of topicals since pharmacists are trained to properly apply creams/ointments based on the drug. Some topicals should be applied heavily and some very thinly. Some topicals cannot be applied in such a way to spread to other body parts or to other humans upon contact (i.e., topical hormones) – pharmacists can instruct on these important factors when administering the drug. This expertise reduces the risk of harm when drugs are applied by a professional. This also enhances the training of patients to self-administer if applicable. Patients would not be subject to increased **costs** as pharmacists would be billing for equal reimbursement as other healthcare providers.

Pharmacist administration could contribute to overall healthcare **cost savings** by enhancing patient compliance in receiving their medication, leading to decreased hospital admissions or additional treatment if condition worsens due to non-compliance.

Key Change 3: Collaborative Practice Agreements

The regulation proposes amendments to section 1.13 regarding collaborative practice agreements, a partnership between a pharmacist(s) and physician(s) to provide coordinated care with patients. This concept is permitted by R.I. Gen. Laws § 5-19.2-3 and is permitted in the current pharmacy regulations. The revisions are being updated to align with the new process recently adopted in the Department's Licensure and Discipline of Physician regulation (216-RICR-40-05-1).

Per the statute, collaborative practice agreements must include the setting where the collaborative practice is to take place, informed consent procedures, qualifications of participants, scope of practice protocols and risk management activities, outcome measurements and that the agreement must be renewed on a biennial basis. These statute requirements are currently in the effective pharmacy regulations and have been revised to be identical to the collaborative practice language in the physician regulations.

In addition to the revisions, some new requirements are proposed. The first new requirement is to receive prior authorization from the Board of Pharmacy, Board of Medical Licensure and Discipline, and the Department's Director prior to the collaborative practice commencing. This is to ensure that the collaborative practice

agreement is fully reviewed by a collaborative and comprehensive group of healthcare professionals to maximize public health and safety.

The agreement also requires procedures for cross coverage and continuity of care. This would ensure patient care is not disrupted during provider leave of absence. These new requirements of collaborative practice agreements are not intended to increase costs and have the benefit of ensuring patient needs are met and care is not interrupted.

Determination

Based on the above analysis, RIDOH has determined that the current proposed regulation provides Rhode Islanders with additional access to healthcare.

Pursuant to R.I. Gen. Laws § 42-35-2.8, RIDOH has determined:

1. The benefits of the proposed rule justify the costs of the proposed rule; and
2. The proposed rule will achieve the objectives of the authorizing statute in a more cost-effective manner or with greater net benefits than other regulatory alternatives.

Therefore, RIDOH's proposed regulation is the most cost-effective solution as benefits outweigh the costs.

References

1. Singer, J. A. (2021, January 22). *Governors' Standing Orders Can Lower Healthcare Costs*. Cato Institute. Retrieved June 6, 2022, from <https://www.cato.org/commentary/governors-standing-orders-can-lower-healthcare-costs>
2. Yarnall KS, Østbye T, Krause KM, Pollak KI, Gradison M, Michener JL. Family physicians as team leaders: "time" to share the care. *Prev Chronic Dis*. 2009 Apr;6(2):A59. Epub 2009 Mar 16. PMID: 19289002; PMCID: PMC2687865.
3. Leubner, J. (2018, April 30). *Developing Standing Orders to Help Your Team Work to the Highest Level*. American Academy of Family Physicians. <https://www.aafp.org/pubs/fpm/issues/2018/0500/p13.html#fpm20180500p13-b1>
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/#:~:text=Pharmacists%20are%20the%20most%20accessible,and%20preventive%20care%20to%20patients>.
5. Popovian, R., Winegarden, W., Rivera, E., & Gavigan, K. (2022). Accessibility of adult immunizations in pharmacies compared to physician offices in low-income communities. *Journal of the American Pharmacists Association*. <https://doi.org/10.1016/j.japh.2022.03.021>