VERMONT SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
WHOLESALE IMPORTATION PROGRAM FOR PRESCRIPTION DRUGS:
BOARD OF PHARMACY LICENSE CATEGORIES

This report by the Office of Professional Regulation concludes that, to facilitate a prescription drug importation program, the General Assembly should assign the Vermont Board of Pharmacy express, statutory authority to create two novel categories of wholesale drug distributor.

Introduction

The General Assembly has directed the Agency of Human Services, in consultation with relevant stakeholders, to "design a wholesale prescription drug importation program that complies with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings." 18 V.S.A. § 4651(a). Further to this goal, Act 72 (2019), Sec. E.300.7 directs that "The Board of Pharmacy in the Office of Professional Regulation,[1] in consultation with the Agency of Human Services, shall explore whether any new prescription drug wholesaler license categories would be necessary in order to operate a wholesale prescription drug importation program in this State." The elements of such a program are set out in the *Wholesale Importation Program for Prescription Drugs Legislative Report* submitted to committees of jurisdiction December 31, 2018 by the Agency of Human Services.[2]

Analysis

The Vermont Board of Pharmacy is charged with supervising the practice of pharmacy within the State, including by issuing certificates of registration and licenses to drug outlets. 26 V.S.A. § 2032. A "drug outlet" includes "wholesalers" and "other entities that are engaged in the … delivery or distribution of prescription drugs." *Id*. § 2022(7). "Wholesale distributor[s]" are among the enumerated classifications of "drug outlet" to which the Board issues licenses." *Id*. § 2061.

The Board's regulation of wholesale distributors conforms to Federal, *Guidelines for State Licensing of Wholesale Prescription Drug Distributors*, 21 CFR 205.1 *et seq*. 26 V.S.A. § 2071. "Wholesale distribution" is synonymous with "distribution of prescription drugs to persons other than a consumer or patient," such as to a retail pharmacy or health care entity. 21 CFR 205.3(f).

Federal Guidelines also require that conforming state laws "provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations," and "where appropriate," for violations of the licensing law. 21 CFR 205.8.

[1] The Office provides administrative and legal support to the Board, pursuant to 3 V.S.A. § 123, and has prepared this analysis incident to that responsibility. The Board has not been asked to take any official action.
[2] Hereinafter, *Importation Report*. Available at: https://legislature.vermont.gov/assets/Legislative-Reports/AHS-12-31-2018-Wholesale-Importation-of-Drugs.pdf.

Entities distributing imported Canadian drugs into Vermont, as well as recipient entities in Vermont, which would not act as final pharmacy destinations, would be engaged in the delivery and distribution of prescription drugs other than to consumers and patients, and would therefore need to obtain a Board wholesaler license. *Accord*, 26 V.S.A. § 2022(7), *supra*.

Consistent with the *Importation Report*, pp. 5-6, the Board of Pharmacy could meet its mandate to supervise prescription drug distribution, while facilitating importation, by establishing two subtypes of the existing wholesale distributor license:

1. "Canadian Prescription Drug Supplier," an entity registered with FDA as a Foreign prescription drug seller, which exports Canadian drugs to a recipient-wholesaler in the United States, and
2. "Prescription Drug Importer-Wholesaler," that recipient-wholesaler.

For example, the General Assembly could amend 26 V.S.A. § 2061 as follows:

Subchapter 5: Registration Of Facilities

§ 2061. Registration and licensure

(a) All drug outlets shall biennially register with the Board of Pharmacy.

(b) Each drug outlet shall apply for a license in one or more of the following classifications:

(1) Retail.
(2) Institutional.
(3) Manufacturer.
(4) Wholesale distributor.
(5) Investigative and research projects.
(6) Compounding.
(7) Outsourcing.
(8) Home infusion.
(9) Nuclear.
(10) Third-party logistics provider.

(c) No individual who is employed by a corporation that is licensed under any classification listed in subsection (b) of this section need obtain a license under the provisions of this subchapter.

(d) The Board shall establish by rule under the powers granted to it under section 2032 of this title and 3 V.S.A. chapter 25, the criteria that each drug outlet that has employees or personnel engaged in the practice of pharmacy must meet to qualify for licensure in each classification designated in subsection (b) of this section. The Board may issue various types of licenses with varying restrictions to such outlets referred to in this subsection where the Board deems it necessary by reason of the type drug outlet requesting a license. <u>The Board may, with or without the adoption of rules, issue wholesale-distributor-exporter and wholesale-distributor-importer licenses to drug outlets that comply with Federal, State, and Board requirements to import prescription drugs through a program approved by the Secretary of Human Services.</u>

(e) Retail and institutional drug outlets shall be managed by licensed pharmacists who have held an unrestricted license in this or another ~~state~~ <u>jurisdiction</u> for at least one year. A pharmacist who holds a

restricted license may petition the Board for permission to be a pharmacist manager, which may be granted by the Board for good cause shown.

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Should the U.S. Department of Health and Human Services certify the State's wholesale prescription drug importation program, the application for which is to be submitted by the Agency of Human Services by July 1, 2020, the Office of Professional Regulation would be able to create the applications and associated administrative outreach for the two new license categories within ninety days.

Respectfully submitted to the House Committees on Government Operations and on Health Care and the Senate Committees on Government Operations and on Health and Welfare.

STATE OF VERMONT
SECRETARY OF STATE
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