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Fast-Track Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq. 18VAC110-50-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousers
Action title	Regulations for collection sites for unused drugs
Date this document prepared	10/9/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

As of October 2014, the Drug Enforcement Administration (DEA) has new federal regulations to allow entities authorized to possess controlled substances, such as pharmacies and wholesale distributors, to collect unused drugs from a consumer (ultimate user) to deliver for appropriate disposal in a safe and effective manner consistent with effective controls against diversion.

The intent of this regulatory action is to establish standards for collection sites similar to those required by the DEA in order to register as an "authorized collector."

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

DEA = Drug Enforcement Administration

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On September 29, 2015, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards, including the Board of Pharmacy, the responsibility to promulgate regulations and establish renewal schedules:

> *§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:*
>
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 and Chapter 25 of this title…*

The specific authority to control prescription drugs in the Commonwealth is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this regulatory action is to establish regulations that will authorize the Virginia Board to inspect for and enforce standards for collection on controlled substances. If requirements for collection and destruction are not followed, there may be opportunity for diversion of donated drugs or adulteration of controlled substances if there is risk of co-mingling with existing stocks. Designation of authorized collection sites will facilitate the disposal of unused prescription drugs, which in turn reduces the supply of such drugs for abuse and diversion and protects public health and safety. However, the collection must be handled in a manner that protects the drugs until destruction in compliance with local, state, and federal laws.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

This action was begun with a Notice of Intended Regulatory Action that was published on June 1, 2015 with comment until July 1, 2015. No comment was received, and no controversy is expected. The proposed regulation was unanimously recommended by the Regulation Committee and adopted by the Board. To facilitate the authorization for collection sites, the Board is promulgating the regulation under a fast-track action.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The new regulations will include requirements found in the DEA regulations such as registration with the DEA as an authorized collector to serve as a site for the collection of controlled substances from an ultimate user, who is defined as a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household. Manufacturers, wholesale distributors, reverse distributors, narcotic treatment programs, hospitals with an on-site pharmacy and retail pharmacies may become collectors by modifying their current DEA registration to be approved as authorized collectors.

Authorized collectors may maintain collection receptacles and then must dispose of collected drugs in accordance with DEA rules for destruction. Authorized collectors may conduct a mail-back program, but are not authorized to conduct take-back events. Registered collection sites may accept Schedule II through VI drugs in a single collection receptacle but may not accept illicit drugs (schedule I, heroin, etc.). Authorized hospitals with on-site pharmacies may maintain collection receptacles at long-term care facilities at which drugs may be disposed on behalf of an ultimate user who resides or has resided at the facility.

Drugs so collected by the authorized collector must be destroyed in a matter that makes the drugs non-retrievable, meaning they cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The advantage to the public is assurance that a facility that serves an authorized collector is not comingling donated intended for disposal with drug stocks and that the Board has some oversight authority. There are no disadvantages. If a facility meets the DEA requirements for an authorized collector, it will be able to comply with Board regulations.
2) The advantage to the Commonwealth is facilitation of authorized collector sites for disposal of unused medications to take those drugs out of circulation for abuse or diversion.
3) Since there was no comment on the NOIRA, the Board is promulgating a fast-track action.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

These regulations are consistent with DEA registration requirements for authorized collectors.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or

reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The only alternative to adoption of rules by the Board is reliance on the DEA for enforcement of its regulations for collection of controlled substances. The DEA typically relies on state boards to conduct inspections and to regulate the safety and integrity of prescription drugs in the Commonwealth, so regulation by the Virginia Board is the least burdensome alternative that meets the essential purpose of protection the public in the disposal of unused controlled substances.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The entities that would be affected pharmacies, restricted manufacturers, wholesale distributors and narcotic treatment programs that obtain a controlled substance registration.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are currently 1836 licensed pharmacies, 71 restricted manufacturers and 122 wholesale distributors. It is estimated that a very small number of those will choose to become authorized collectors.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential**	There would be some costs for destruction of the drugs collected and for recordkeeping as required by federal law and regulation. There would be no costs for notification to the Board that an entity had been registered as an authorized collector with the DEA. If a narcotic treatment program without an in-house pharmacy wants to become an authorized collector, it will need a controlled substance registration at a cost of $90.

purposes that are a consequence of the proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	Oversight by the Virginia Board of entities that collect unused drugs.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no less intrusive or less costly alternatives.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the institution of the family and family stability, except any effort to deter the proliferation of prescription drug abuse by removal and disposal of unused controlled substances is beneficial to families.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency

*regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Chapter 20: Regulations Governing the Practice of Pharmacy

10	Sets out definitions for words and terms used in regulations	Adds a definition for "authorized collector" and "ultimate user." Both definitions are taken from the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.
New 211	Sets out requirement for disposal of drugs by authorized collectors	New regulation: • Any narcotic treatment program, hospital/clinic with an on-site pharmacy, or pharmacy wishing to accept for return a previously dispensed drug for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility must first be authorized by DEA as a collector. • The process used to collect and destroy drugs, along with any required recordkeeping, must comply with applicable federal and state law. *The provisions for an entity to accept unused drugs from an ultimate user are consistent with the federal Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.* • Prior to collecting drugs, an authorized collector is required to submit in writing to the board: a. The name, address, and license number, if applicable, of the facility; b. The intended method(s) of collection (i.e., collection receptacle and/or mail-back program); and, c. Signature of PIC or medical director of a narcotic treatment program. *Notification is required in order for the Board of Pharmacy to have oversight responsibility and to know whether an entity is serving as an authorized collector, so compliance with state and federal law can be included in an inspection of the facility. The Board will also be able to list names of collectors on its website to inform the public of where to take their unwanted drugs for destruction.* • If an entity chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days. *Likewise, the Board must be notified if the entity chooses to cease collection.* • A narcotic treatment program that does not have an in-house pharmacy has to obtain a controlled substance registration. *A program without an in-house pharmacy would have no authority to possess unused drugs unless it is issued a CSR (controlled substance registration). Such registration is necessary for Board inspection and oversight.*

Chapter 50: Regulations Governing Wholesale Distributors, Manufacturers and Warehousers

10	Sets out definitions for words and terms used in regulations	Adds a definition for "authorized collector" and "ultimate user." Both definitions are taken from the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.
New 51		New regulation: • Any manufacturer, wholesale distributor, or reverse distributor wishing to accept for return a previously dispensed drug in Schedules II-V for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property must first be authorized by DEA as a collector. • The process used to collect and destroy drugs, along with any required recordkeeping, must comply with applicable federal and state law. *The provisions for an entity to accept unused drugs from an ultimate user are consistent with the federal Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.* • Prior to collecting drugs, the manufacturer, wholesale distributor, or reverse distributor shall submit in writing to the board: a. The name, address, and license number, if applicable, of the facility; b. The intended method(s) of collection (i.e., collection receptacle and/or mail-back program); and, c. Signature of the responsible party. *Notification is required in order for the Board of Pharmacy to have oversight responsibility and to know whether an entity is serving as an authorized collector, so compliance with state and federal law can be included in an inspection of the facility. The Board will also be able to list names of collectors on its website to inform the public of where to take their unwanted drugs for destruction.* • If an entity chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.