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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Standards for entities serving as collection sites for unused drugs
Date this document prepared	3/25/15

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.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

As of October 2014, the Drug Enforcement Administration (DEA) has adopted 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." In order for the Virginia Board to inspect for and enforce standards for collection on controlled substances, they must be set in regulations adopted by the Board. 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. However, the collection must be handled in a manner that protects the drugs until destruction in compliance with local, state, and federal laws.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency'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 describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

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.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

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.

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.

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.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held

to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time. A regulatory panel will not be used as the amendments will be drafted by the Regulation Committee of the Board in an open meeting.