Virginia Regulatory Town Hall

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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	18VAC110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	"Run dry" requirement for automated counting devices
Date this document prepared	12/27/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the proposed regulatory action is modification or elimination of the current requirement in 18VAC110-20-355 regarding the requirement for bulk bins in an automated counting device to be "run dry" every 60 days. Comment on the requirement indicates that the 60-day requirement may be unnecessary and could be extended to six months or longer, or the "run dry" could be eliminated if concerns about expired or recalled drugs in the bins can be appropriately addressed. The goal of the amended regulation would be a requirement that protects the safety and efficacy of the drugs to be dispensed to patients in a manner that is reasonable and the least burdensome to pharmacies that use such devices.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

The specific authority to control the sale and dispensing of prescription drugs 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

Need

Please detail 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, delineate any potential issues that may need to be addressed as the regulation is developed.

The proposed regulation would be less burdensome and less costly for pharmacies that utilize automated counting devices. Most such devices are used for "fast-moving" drugs, so the requirement to allow the bins to "run dry" every 60 days to prevent expired drugs from being dispensed is probably not necessary in order to protect public health and safety. Some states do not allow multiple lots to be placed in one bin, but the majority of states have no such requirement and no "run dry" requirement.

In modifying regulation 18VAC110-20-355, the Board will consider safeguards that would ensure expired or recalled drugs are not being dispensed to patients. If the technology of the device can ensure drugs in a particular lot have been cleared out of the machine, it might not be necessary to dispose of all drugs in a bin to which a recalled lot has been added. If not, and if multiple lots are in a bin, the drugs may have to be removed and not used for patient care if there is a recall on any of the lots. Additionally, the regulation may require regular emptying and cleaning of the device to avoid an accumulation of drug residue that might affect the efficacy of the drugs or the accuracy of the dispensing.

In considering modification to or elimination of the "run-dry" regulation, the Board will include requirements in the best interest of public health and safety in prescription medications.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

There is a public safety concern with the use of automated counting devices if there is a recall on a lot number among the drugs that have been placed in a bulk bin. Therefore, the revised regulation may specify emptying and disposal of drugs if one of multiple lots have been placed in the bin or cell in the last three or four months. Exceptions to the requirement for disposal could be included if there is a reliable means of proving that the drugs included in the recall are no longer in the bin or if the bin has been allowed to run dry since the recalled lot was placed in the bin. The intent of the regulation is to protect the public without unnecessarily requiring drugs to be disposed of and wasted. Additionally, if the run dry requirement is eliminated, there may need to be a provision in the revised regulation requiring emptying and cleaning of the bins in accordance with manufacturer's specifications in order to alleviate any concerns about drug residue affecting functionality and quality assurance.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

At the Board of Pharmacy meeting held on September 20, 2011, the Executive Director reported that a pharmacist had expressed concern that the current "run drug" requirement for automated counting devices may overly burdensome. The pharmacist noted that there is an increasing trend to use the devices to more securely store certain slow-moving drugs that do not inherently empty from the bin every sixty days, as required by 18VAC110-20-355. The Board voted to refer the review of the regulation to the Regulation Committee for discussion and to collect further information for consideration by the Board.

On November 29, 2011, the Executive Director reported to the Regulation Committee that other states do not have a "run dry" requirement; however some states do not allow multiple lots of drugs to be placed in a bin. She also surveyed pharmacy inspectors for the Department to determine the different types of devices typically used by pharmacies in Virginia. She then surveyed those manufacturers to determine whether current technology could assure that the first drugs in the devices would be the first drugs out. No manufacturer could offer a guarantee of "first in, first out", although most current devices are designed for that to occur. The Committee's primary concern was assurance that recalled drugs could be identified and removed from a device to protect patients. To that end, the Committee's recommendation was a regulation that stated: "In the event of a drug recall involving one of multiple lots placed in a cell of an automated counting device in the last four months, all drugs shall be removed from the cell and not used for patient care."

At its meeting on December 14, 2011, the Board heard testimony from Kaiser-Permanente requesting an opportunity to present further research on the technological capability of the devices. Other issues were raised about a provision for periodic cleaning of the device, about the four-month time frame recommended by the Committee and about the need to remove drugs from the cell if the cell had been allowed to run dry within that four-month time.

Consequently, the Board is seeking comment on the proposal and accepting recommendations for changes that would make the requirements less onerous and still protect public health.

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 on this notice.

Please also indicate, to the extent known, if standing or ad hoc advisory panels (also known as regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate whether 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Board will utilize the participatory approach as members of the Regulation Committee has reviewed the regulations requiring a dry run of automated counting devices with the participation of representatives of health care systems that employ such devices. Public participation was encouraged and evident in discussions of the requirement and issues surrounding its modification during the Committee and Board meetings at which this item was on the agenda. Public comment was encouraged as the Board considers necessary and appropriate changes to the regulation.

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) 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 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) 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 to Elaine Yeatts at 9960 Mayland Drive, Henrico, VA 23233; by fax to (804) 527-4434 or by email to 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 (**http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi**). Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed 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 family.