Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20
Regulation title	Regulations of the Board of Pharmacy
Action title	"Run dry" requirement for automated counting devices
Date this document prepared	10/12/12

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.*

Brief summary

Please provide a brief summary (no more than 2 short 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The purpose of the proposed regulatory action is 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 eliminated if concerns about expired or recalled drugs in the bins can be appropriately addressed. Therefore, only if there is a drug recall within the last three months or if it is known that a recalled drug is in the device will it be required that drugs be removed. If the device has technology that ensures a particular lot has been cleared or if the bin has been allowed to "run dry" since the addition of the recalled lot, it will not be necessary to remove all drugs in the bin in the event of a recall.

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 October 1, 2012, the Board of Pharmacy adopted amendments to 18VAC110-20, Virginia Board of Pharmacy Regulations.

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

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail 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 goal of the amended regulation is 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.

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 not necessary in order to protect public health and safety unless there is a risk of a drug that has been recalled remaining in a bin and being dispensed to patients. 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 considered safeguards that would ensure 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 is 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 within the last three months. Additionally, the regulation requires 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.

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?

Please note: 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 (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The Board has opted to use the fast-track process for two reasons: 1) the action is consistent with the Governor's project to reform regulations that are unnecessarily burdensome; and 2) there was no objection voiced during the NOIRA comment period.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

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 specifies emptying and disposal of drugs if one of multiple lots have been placed in the bin or cell in the last three months or if it is known that a recalled lot remains in the bin. 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. Since the run dry requirement is eliminated, there is need for a provision 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.

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 primary advantage of the regulatory action is cost and time savings to pharmacies that are currently required to "run dry" cells or bins in automated counting devices. The purposes for the requirement can be accomplished with a less burdensome and costly regulation that assures recalled lots of drugs do not remain the cell for dispensing. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) There are no other pertinent matters of interest.

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.

There are no applicable federal requirements.

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.

The proposed regulation does not affect any locality.

Regulatory flexibility analysis

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.

Since the intent is to promulgate a less burdensome and costly regulation, there are no alternative methods for accomplishing the objective other than elimination of the current requirement for automated counting devices to run-dry every 60 days.

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. There would be little or no additional expense for promulgation of the amended rule. Consideration of the proposed rule has been during a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There are no on-going expenditures for the agency related to amendments to regulations.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There are no costs to localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The businesses that would be affected would be pharmacies with counting devices that are typically used for filling fast-moving prescriptions for institutions (hospitals/nursing homes).
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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Since the Board does not issue pharmacy permits by category, there is no estimate of the number of small businesses that may be affected. There are 1760 pharmacies in Virginia that have a current license (permit). Those such as Kaiser-Permanente would not qualify as "small businesses," but the pharmacy owned by a Delegate in the General Assembly who initially raised the issue would qualify.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	The changes to regulations eliminating the "run dry" requirement will result in cost-savings – both in staff time consumed with meeting the current 60-day run-dry requirement and in the unnecessary loss of drugs that are removed every 60 days when the bin must be "run dry."
Beneficial impact the regulation is designed	Savings in staff time consumed with meeting the

to produce.	current 60-day run-dry requirement and in the unnecessary loss of drugs that are removed every 60 days.

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.

At the Board of Pharmacy meeting held on September 20, 2011, the Executive Director reported that a pharmacist who is a member of the General Assembly 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.

In response, the Board published a Notice of Intended Regulatory Action on March 26, 2012 with comment accepted until April 26, 2012. Kaiser-Permanente provided the only comment on the NOIRA and recommended the changes that were subsequently adopted by the Board.

Family impact

Please assess the 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.

The proposed regulatory action does not affect the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. 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.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
355	The current requirement for use of an automated counting devices allowed more than one lot to be added to a bin of drugs but the machine must be "run dry" every 60 days to ensure that all lots have cleared the device. *If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates.*	The proposed change eliminates the run-dry requirement with provisions to ensure that any recalled lot of drugs does not remain in a bin for filling patient prescriptions. In the event of a recall, drugs don't have to be removed if the device has technology to indicate that a particular lot has cleared or if the device has be allowed to run dry after the time when the recalled drug would have placed in the bin. *If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed~~,~~ and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot~~, and the bin shall be allowed to "run dry" where all product is completely removed prior to filling at least once every 60 days with a record made of the run dry dates~~.* *5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:* *a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or* *b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.* *6. An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.*