Virginia

Regulatory Town Hall
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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Continuous quality improvement programs for pharmacies
Date this document prepared	June 5, 2014

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

Chapter 124 (HB2220) of the 2011 General Assembly mandates that the Board of Pharmacy promulgate regulations to specify the elements of a continuous quality improvement program that provides "*a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors.*" The legislation further required that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, the final regulations replace emergency regulations that were in effect from October 1, 2012 to September 30, 2013.

The key provisions of the regulations are: 1) definitions for terms used in regulation, such as "actively reports," "analysis" and "dispensing error;" 2) provision for pharmacies actively reporting to a patient safety organization; and 3) provisions for a continuous quality improvement program in a pharmacy, to include notification responsibilities, documentation

requirements, remediation of systems or procedures, and maintenance of a record of the analysis of the error.

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 or board taking the action, and (3) the title of the regulation.

On June 4, 2014, the Board of Pharmacy adopted final regulations for the establishment of continuous quality improvement programs in 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.

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 issue licenses and permits to pharmacists and pharmacies and 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

The specific requirement for regulations is found in a new section of Chapter 34:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to

develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

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 it 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 intent of the regulatory action in the adoption of emergency regulations is compliance with the statutory mandate of Chapter 124 of the 2011 Acts of the Assembly to promulgate regulations to specify the elements of a continuous quality improvement program that provides "*a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors.*"

The goal of the regulations is to provide a framework for a continuous quality improvement (CQI) program that can identify, analyze and reduce risks and errors associated with dispensing of drugs to patients. An analysis of an error is required to identify systems failures and personnel deficiencies, and to review any gaps in the efficiency and effectiveness of policies and processes that might result in dispensing errors. Oversight of CQI programs by the Board can be accomplished through routine inspections or investigations initiated by a complaint, so documentation of an analysis is required to be maintained for at least 12 months from the date of the analysis.

To protect the health and safety of patients who receive drugs dispensed by pharmacies to Virginia residents, legislation was introduced to require continuous quality improvement programs in every licensed pharmacy (resident and non-resident). Quality improvement programs can result in the identification of root causes for errors in the systems and workflow processes in order to prevent or reduce future errors.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The key provisions of the regulations are: 1) definitions for terms used in regulation, such as "actively reports," "analysis" and "dispensing error;" 2) provision for pharmacies actively

reporting to a patient safety organization; and 3) provisions for a continuous quality improvement program in a pharmacy, to include notification responsibilities, documentation requirements, remediation of systems or procedures, and maintenance of a record of the analysis of the error.

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 pharmacy is recording and analyzing errors in dispensing of prescriptions in order to identify problems that led to a prescription error that could cause harm to a patient. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) This action is in response to a mandate in the Code of Virginia.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	Defined "dispensing error"	Definition was expanded to include "regardless of whether the patient received the drug."	The definition sets out the items on incidents that would be considered a "dispensing error." The addition of the phrase will clarify that one of the described incidents would be considered an error regardless of whether the patient actually received the drug. The intent of a CQI program is identification of systems errors that could lead to patient harm, so the fact that a patient never actually took possession of the drug does not negate the need to report an error for the purpose

			of quality control.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
Va. Hospital & Healthcare Association	Requested that the definition of "actively reports" be amended to mean "documented as collected for" reporting. The VHHA stated that the Agency for Healthcare Research and Quality does not require information to be actually reported to a patient safety organization to qualify for protections under the Patient Safety and Quality Improvement Act of 2005.	The Board reviewed the provisions of § 54.1-3434.03 as enacted by the 2011 General Assembly in which the law states: *Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.* The Board does not agree that documenting dispensing errors as collected would fit the statutory requirement for "actively reports" to a PSO.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.

Current section number	Proposed new section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	n/a	Establishes definitions for words and terms used in regulations	Definitions are added for words and terms used in regulations for continuous quality improvement programs. "Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error. "Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors. *In §54.1-3434.03, each pharmacy is required to have a program for a systematic, ongoing process of*

			analysis of dispensing errors. Pharmacies that actively report to a patient safety organization are deemed to be in compliance. *To implement the provisions of the Act, the Board has defined "actively reports" to include an analysis of an error and has defined an "analysis." Active reporting must include reporting the error and the analysis of the error within 30 days of identifying the error. Patient safety organizations aggregate the analyses to develop and disseminate recommendations, protocols and information on best practices to foster avoidance or elimination of errors. Timely reporting is necessary for trending purposes.* Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug: 1. Variation from the prescriber's prescription drug order, including, but not limited to: a. Incorrect drug; b. Incorrect drug strength; c. Incorrect dosage form; d. Incorrect patient; or e. Inadequate or incorrect packaging, labeling, or directions. 2. Failure to exercise professional judgment in identifying and managing: a. Therapeutic duplication; b. Drug-disease contraindications, if known; c. Drug-drug interactions, if known; d. Incorrect drug dosage or duration of drug treatment; e. Drug-allergy interactions; f. A clinically significant, avoidable delay in therapy; or g. Any other significant, actual or potential problem with a patient's drug therapy. 3. Delivery of a drug to the incorrect patient. 4. Variation in bulk repackaging or filling of automated devices, including, but not limited to: a. Incorrect drug; b. Incorrect drug strength; c. Incorrect dosage form; or d. Inadequate or incorrect packaging or labeling.

			The definition of a dispensing error is essential to implementation of a CQI program that requires reporting of errors. What constitutes an error is describes in the components and timing outlined in the definition. An error should be reported if any of the events in the definition is discovered after the pharmacist has made his final verification or check of the drug, and it is ready for delivery to the patient. Even if the error is discovered by the clerk, the patient or someone caring for the patient before the drug is administered, it still constitutes an error if the pharmacist has verified its correctness. The proposed definition is taken from the definition of a "quality-related event" in Model Rules of the National Association of Boards of Pharmacy (NABP) "Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality (AHRQ). *A patient safety organization (PSO) must be compliant with the Patient Safety and Quality Improvement Act of 2005 and be credentialed by the Agency charged with implementing the Act and responsible for listing PSO's that meet certain criteria. While PSO's are listed primarily on the basis of self-attestation to AHRQ, the federal rule authorizes AHRQ to conduct reviews, including site visits, to assess PSO compliance. Since pharmacies that participate in a PSO are deemed in compliance with Virginia requirement for a CQI program, verification that a PSO meets the criteria of the federal law and regulation is essential.*
n/a	418 A	New regulations for pharmacies that participate in patient safety organizations	A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a patient safety organization consistent with §54.1-3434.03 and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record. *Subsection A allows a pharmacy that actively reports dispensing errors and its analysis in a patient safety organization (all terms defined in section 10) as meeting the requirements for a CQI program. In*

			order to have verification that the pharmacy is actively reporting, reports must be maintained for 12 months. Since "actively reports" requires reporting of any errors and analyses within 30 days, a pharmacy can document evidence of compliance by recording a zero report, if no errors were found within the past 30 days.
n/a	418B	New regulations for individual continuous quality improvement programs in pharmacies	B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section. 1. Notification requirements: a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error. b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient. c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified. *Notification requirements are similar to those in the Model Rules and other states. The pharmacist on duty has an obligation to take whatever steps necessary for patient health and safety, including notification of the error to the patient (or responsible party) and, if the drug has been administered, notification to the patient's prescriber.* 2. Documentation and record requirements; remedial action: a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further

			investigation, categorization and analysis of the event. b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18 VAC 110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error. c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis. d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly. e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information: (1) Dates the analysis was initiated and completed; (2) Names of the participants in the analysis; (3) General description of remedial action taken to prevent or reduce future errors; and (4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. *Documentation requirements are necessary to ensure that there is sufficient information about the event to perform an analysis of the circumstances and failures that led up to commission of a dispensing error. Documenting the dispensing error must occur as soon as possible, but at least within 3 days of identification of the error. Then the analysis of the error must be conducted within 30 days of identification. It then becomes the responsibility of the pharmacist-in-charge to inform (educate) all pharmacy personnel of changes to policies and procedures that will be made as a result of the analysis.* *All documentation of the error (specific information about who committed the error, patient related information, etc.) must only be maintained until the analysis is performed and then the analysis must be maintained for at least 12 months and available for inspection. As with pharmacies reporting to a PSO,*

			pharmacies with their own CQI program must record a "zero report" if no errors were identified within the past 30 days.