Virginia Regulatory Town Hall

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Proposed 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	December 27, 2012

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

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 proposed regulations replace emergency regulations in effect since October 1, 2012.

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.

Acronyms and Definitions

CQI= Continuous Quality Improvement
NACDS = National Association of Chain Drug Stores

Legal basis

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

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

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

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.

Requirements more restrictive than federal

The proposed regulations are not more restrictive than federal requirements since "*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."*

Localities particularly affected

There are no localities particularly affected by the proposed regulation.

Public participation

In addition to any other comments, the board is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

Economic impact

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, 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	The businesses that may be affected would be 1764

other entities likely to be affected by the *new regulations or changes to existing regulations*.	resident pharmacies and 511 non-resident pharmacies permitted to dispense drugs in Virginia.
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 pharmacies are not licensed by category or ownership, it is not possible to identify those that are small businesses. The vast majority of pharmacies in the market today are part of national chain or large health care system. There will be some independently owned pharmacies that do not currently report to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act that will be affected.
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 projected costs of establishing a continuous quality improvement program may be minimal, depending on the methodology used and the extent of the errors to be reported. A pharmacy may be in compliance by educating staff to manually record any error with an analysis of all errors performed by the pharmacist in charge who must respond appropriately to prevent patient harm and inform staff of any changes necessary to prevent repeat errors. If there are no dispensing errors within a 30 day period, all that is required is a "zero" report. While there is some additional time required to complete a report and analysis, it is not anticipated that additional staff will be needed nor is an additional data program required for recording.
Beneficial impact the regulation is designed to produce.	The beneficial impact is identification of the causes for prescription errors that may be remedied to avoid or mitigate the potential harm to the public. For example, the remedy may be as simple as moving medications with similar names on the stock shelf to avoid picking the wrong drug.

Alternatives

Continuous quality improvement programs are increasingly important in health care organizations as a means of identifying systems and processes that may lead to errors. The Board of Pharmacy has supported the institution of CQI programs for a number of years. With the passage of HB2220, the Board was mandated to promulgate emergency regulations for CQI programs.

A third enactment on HB2220 required that the Board of Pharmacy "work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act." To that end, an Ad Hoc Committee representing various fields of pharmacy practice reviewed the legislation and other information on CQI programs and concluded the law requires the drafting of regulations for pharmacies to either implement a continuous quality improvement program or actively report to a patient safety organization. At the meeting on May 18, 2011,

discussion primarily focused on possible subject matter for inclusion in the regulations. Documents reviewed by the Committee included the Virginia legislation, background information from the Agency for Healthcare Research and Quality (the federal agency that implements the Patient Safety Act), Model Rules from the National Association of Boards of Pharmacy, and laws and regulations from other states.

Based on the subject matter for regulations identified by the Committee, the Board determined that it was necessary to publish a Notice of Intended Regulatory Action to allow for public comment prior to the adoption of emergency regulations. Comment was requested from August 1, 2011 to August 31, 2011. There was one question about the regulation posted on Townhall, but no other public comment received.

At the meeting on August 25, 2011, the Committee reviewed a draft of emergency regulations prepared by staff based on the recommendations from the earlier meeting. Edits and changes were made by members, and attendees at the meeting were invited to comment and participate.

Following publication of the emergency regulations, the Board made an edit to the definition of a "dispensing error" but made no further changes to the emergency regulations currently in effect.

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.

In the development of proposed regulations for continuous quality improvement programs in pharmacy, the Board invited affected parties from various types of pharmacy practice to participate in an Ad Hoc Committee and by asking for comment and recommendations on language. Serving on the Ad Hoc Committee were members representing the Virginia Pharmacist Association (which supported the CQI legislation), hospital pharmacies, long-term care pharmacies and retail pharmacies.

There were no alternative regulatory methods identified; the Code of Virginia requires regulations: "*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.*"

Small business impact review result

1) The regulation is required by § 54.1-3434.03.of the Code of Virginia, so there is a continued need for the regulation.
2) Since evidence of a CQI program will not be required for a pharmacy inspection until April of 2013, there have been no complaints about the regulation to date.
3) There were no comments about the complexity of the emergency regulation; it was developed by an Ad Hoc Committee of persons representing various types of pharmacies.
4) There is no overlap with federal or state law or regulation.
5) The regulation is new and will not be enforced for six months from the effective date of the emergency regulation.
The objectives of the applicable law (to establish a continuous quality improvement program in each pharmacy to reduce the incidences of prescription errors) were considered and minimal standards adopted. A pharmacy that already reports to a CQI program is deemed in compliance and will only have to provide documentation of such participation.

Public comment

Commenter	Comment	Agency response
Kurt Bell, RPh	Concern about the demands on pharmacists and pharmacies that induce them to use resources outside the realm of their immediate control.	Commenter was primarily concerned about the pressure to supply medication "ready for administration" that led to ordering products from outside pharmacies so a pharmacist cannot ensure the quality and pedigree of the product. The Board concurred with the commenter concern about the safe delivery of pharmaceutical care to patients.
NACDS (Jill McCormack)	1) Requested consistency with other state programs. 2) Requested legal protection for participation and peer review. 3) Suggested an error be identified only after the drug has been received by the patient. 4) Requested a definition of "systematic ongoing analysis." 5) Requested a 90-day aggregate record of errors.	1) Pharmacies already participating in patient safety organizations that have as their primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act are deemed in compliance with the Virginia statutory mandate. National chain pharmacies are already participants in such organizations. 2) Legal protection from civil liability can only be granted under the law in the Code of Virginia and is not a regulatory issue. 3) The regulation provides that the error is identifiable only *after* the pharmacist has checked it for accuracy. Therefore, it is ready to be given to the patient. 4) The Board has defined "analysis" and set forth in regulation the scheduled requirement for reporting and analysis. 5) The Board requires an analysis of the error within 30 days of reporting. It was uncertain about the NACDS comment about an aggregate record and believes the 30-day requirement for an analysis of

	6) Requested elimination of the zero report if there were no errors within the past 30 days.	the error is necessary for public safety. 6) The Board determined that the zero report required very little effort and was necessary to indicate to inspectors that reporting is actively occurring. If there was no entry for the past 30 days, there would be no documentation of participation in a CQI program.

Family impact

There is no impact on the institution of the family and family stability.

Detail of changes

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: 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.*

Changes made since publication of the emergency regulations

Current section number	Emergency regulation	Change in proposed regulation
10	Dispensing error" means one or more of the following discovered after the final verification by the pharmacist: 2. Failure to exercise professional judgment in identifying and managing: a. Therapeutic duplication; b.Drug-disease contraindications,	Dispensing error" means one or more of the following discovered after the final verification by the pharmacist: 2. Failure to exercise professional judgment in identifying and managing: a. Known therapeutic duplication; b. Known drug-disease contraindications~~, if~~

	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.	~~known~~; c. Known drug-drug interactions~~, if known~~; d. Incorrect drug dosage or duration of drug treatment; e. Known 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. *There was concern expressed that a pharmacist or technician would be responsible for reporting a dispensing error for a interaction or contraindication that was not known at the time of dispensing. Therefore, the word "known" was added to a and e and changed in b and c from the end to the beginning of the phrase.*