Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Continuous quality improvement programs for pharmacies
Date this document prepared	9/21/11

Preamble

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

1) Please explain why this is an emergency situation as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing 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 requires that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, there is an "emergency situation" as defined in § 2.2-4011 of the Administrative Process Act. The statutory deadline for regulations to be in effect is December 20, 2011.

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; 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.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary. Please include a citation to the emergency language.

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 33:

§ 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 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 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.

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.

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.

The Board is not aware of potential issues that may be addressed as the permanent regulation is developed.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

Current section number	Current requirement	Proposed change and rationale
10	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.*
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.*
418 B	New regulations for individual continuous	B. Pharmacies not actively reporting to patient safety organizations, consistent with §54.1-3434.03 and

	quality improvement programs in pharmacies	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.*

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 describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

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 is now mandated to promulgate regulations for CQI programs within 280 days or by December 20, 2011.

A third enactment on HB2220 requires 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.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include 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 meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action to replace the emergency regulations with permanent regulations, including but not limited to 1) ideas to assist in the development of a 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/board 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) 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 send them to Elaine Yeatts at the 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 or by posting on the Regulatory Townhall at www.townhall.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period on the Notice of Intended Regulatory Action.

At the conclusion of the NOIRA comment, the Board will adopt proposed regulations to replace the emergency regulation. A public meeting will be held and notice of the meeting will be found in the Calendar of Events section of the Virginia Register of Regulations after Executive Branch review and approval to open the regulation for 60 days of public comment. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate the extent to which an ad hoc advisory group or regulatory advisory panel will be used in the development of the proposed regulation. Indicate that 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.

In the development of proposed regulations for continuous quality improvement programs in pharmacy, the Board used the participatory approach by inviting 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. (see discussion of Ad Hoc Committee under "Alternatives")

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 potential impact on the institution of the family and family stability.