Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	On-hold prescriptions
Document preparation date	3/9/2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

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

Regulations of the Board of Pharmacy address requirements for filing prescriptions and pharmacist verification of data entry into an automated data processing system, when pharmacies make use of such a system. While the regulations satisfy the handling of prescriptions intended to be dispensed that day, pharmacists are experiencing increased requests from patients to place prescriptions for routine medications "on-hold" until the patient is in need of the prescribed drug.

Because regulations do not specifically address when the data entry of these prescriptions must be performed, some pharmacies store this prescriptions in a single file until needed. Others perform data entry of the prescription and file by the date of entry into the computer which is non-compliant with the current regulation, but find it burdensome to retrieve and move the prescription to the file associated with the date of initial dispensing. Additionally, when the data entry is performed on a separate date than the date of initial dispensing a pharmacist may not be verifying the accuracy of the data entered at the time of entry.

The lack of regulation on this issue may contribute to misplacing of the prescription which may impede patients from obtaining their medication when needed, the dispensing of prescriptions fraudulently due to improper handling of the prescriptions, and possibly dispensing errors

resulting from data entry being performed on a separate date from the date of initial dispensing without pharmacist verification of the accuracy of the data. Therefore, the Board will consider the promulgation of amendments to regulation to address concerns regarding on-hold prescriptions.

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.

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

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The following sections of the regulations have been identified as having issues that may need to be addressed in the promulgation of amended regulations:

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records.

The current requirement that all prescriptions shall be filed chronologically by date of initial dispensing is problematic when filing on-hold prescriptions which are prescriptions presented by

the patient to the pharmacist and maintained by the pharmacist for days or weeks until the patient is in need for the prescription to be dispensed. As written, the regulation currently requires a pharmacist to physically retrieve and relocate the prescription from the file that it was originally maintained in on the date of receipt to the file associated with the date of initial dispensing. This appears to be creating an undue burden on practicing pharmacists, particularly in community pharmacies where on-hold prescriptions are more frequently received. Therefore, this regulation may be amended to create a less burdensome filing requirement for on-hold prescriptions.

Additionally, current regulations do not specifically address when data entry of the on-hold prescription must be performed and how the prescription must be maintained prior to the initial dispensing, therefore, the following concerns may exist: if data entry and proper filing for the on-hold prescription is not performed on or about the date of receipt, then the prescription may be misplaced which may impede a patient from readily obtaining the drug when needed, or it may increase the possibility for it being diverted and dispensed fraudulently either at the receiving pharmacy or another pharmacy. Thus, regulations may be promulgated that specifically address data entry requirements and maintaining of on-hold prescriptions.

18VAC110-20-250. Automated data processing records of prescriptions.
The current regulation requires pharmacists making use of an automated data processing system to document on a daily printout or logbook that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct. Because the Board may promulgate regulations requiring the data entry of an on-hold prescription prior to the initial dispensing of the drug, this regulation may be amended to require a pharmacist to document the fact that the information entered into the computer that day is correct, regardless of whether the prescription is dispensed that day.

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.

In September 2010, the Board reviewed and denied a petition for rulemaking to amend the filing requirements in Regulation 18VAC110-20-240 to allow prescriptions to be filed by date of initial dispensing or date of initial entry into the pharmacy's electronic record keeping system if such a system is employed by the pharmacy. The petition was submitted based on a perceived burden in filing on-hold prescriptions under current filing requirements. Though the petition was denied, the Board agreed to research other states' requirements for filing on-hold prescriptions. At the request of Board staff, the National Association of Boards of Pharmacy surveyed all states on current requirements for processing and filing on-hold prescriptions. Fourteen states responded to the survey and the results of the survey were reviewed at the December 2010 board meeting. Two states currently have rules addressing on-hold prescriptions and other states commented in the survey that rules on this subject may be warranted due to concerns for diversion resulting from improper handling of these prescriptions or dispensing errors resulting from data entry being performed on a separate date from the date of initial dispensing without pharmacist verification of the accuracy of the data. In December, the Board assigned members

to an Ad Hoc committee to review the possibility for needed regulations. This committee was unable to meet prior to the March 2011 full board meeting due to a shortage in board staff and activities associated with the General Assembly. Therefore, the full Board discussed the possible need for regulations at the March 2011 full Board meeting and determined that the Board must proceed with a Notice of Intended Regulatory Action to potentially alleviate concerns associated with the improper handling of on-hold prescriptions and the undue burden with current filing requirements.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

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