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	Allowing on-hold prescriptions to be entered by date prescription is received rather than dispensed
Date this document prepared	11/1/2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The amendments would allow a prescription to be filed either by the date of initial dispensing or by the date it is entered into an automated data processing system, if the prescription is "on-hold" until the patient needs the prescription. Verification of the accuracy of the prescription information entered into the data system would be done by the pharmacist who enters the on-hold prescription, and the prospective drug review would be performed by the pharmacist who subsequently dispenses the prescription.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

None

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., the 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

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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 these 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 has promulgated amendments to regulation regarding on-hold prescriptions in order to address issues of public health and safety.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The following sections of the regulations were identified as having issues 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 was 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 were 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. This regulation is 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.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.
This section was amended to ensure that the prospective drug review required of pharmacists prior to dispensing is conducted by the pharmacist at the time an on-hold prescription is filled.

Issues

1) The advantage to the public is assurance that prescriptions retained on-hold for patients have been reviewed for accuracy and reviewed for appropriateness and have been filed in a manner that facilitates retrieval. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) This action is in response to a petition for rulemaking.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

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

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 requirements create the anticipated 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 a one-time expense of less than $1,000 for promulgation of the amended rule. All notifications will be done electronically to minimize the cost. There are no on-going expenditures for the agency related to these amendments.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that would be affected retail pharmacies.
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.	The agency does not have an estimate of the number of licensed pharmacies (total of 1751) that are retail, dealing directly with a customer, because pharmacies are not licensed by type. It is likely that the vast majority of licensed pharmacies are retail; but among that group, only a small minority would be small businesses.
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	There are no costs; the regulation is permissive and does not require filing of on-hold prescriptions. For those who have an automated data system for filing prescriptions, entering on-hold prescriptions would be permissible at no additional cost to the pharmacy.

proposed regulatory changes or new regulations.	
Beneficial impact the regulation is designed to produce.	The regulation will facilitate less burdensome pharmacy practice, take advantage of available technology, and ensure more accuracy in filing and dispensing prescriptions.

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.

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 of 2010, 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.

Following receipt of comments on the NOIRA, all of which were highly supportive of a change in the regulations, the Board adopted proposed amendments at its meeting in September of 2011.

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 this action, the Board has adopted a less stringent requirement for compliance with rules for automated data processing of records of prescriptions and rules for dispensing.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
Angela Brittle	Allowing pharmacists to accept prescriptions from patients, enter them in the computer, and file them according to the date they were entered has advantages. An on-hold prescription should go through the same checks as a filled prescription does & a pharmacist should review the information to verify correctness. The current requirement for filing is out-dated and often requires redundant and burdensome work.	The Board concurred with the comment in amending the regulation.
William Wilkes	Regulation is unnecessary and redundant considering current technology. Making new numbers for on-hold prescriptions is archaic and unnecessary.	The Board concurred with the comment in amending the regulation.
Deanna Rotenberry	This regulation needs to be updated; it increases non-productive work for pharmacies and physicians.	The Board concurred with the comment in amending the regulation.
Winston Chapman	Placing prescriptions on-hold is better for patients and pharmacies; it is a more secure dependable method for tracking prescriptions that may be dispensed at a later date.	The Board concurred with the comment in amending the regulation.
Alan Friedman Kaiser Permanente	Supports allowing filing by date of initial dispensing or by date of initial entry into an electronic record keeping system.	The Board concurred with the comment in amending the regulation.

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.

There is no impact on 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 if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Current requirement	Proposed change, rationale, and consequences
10	Sets out definitions for words and terms used in regulation	Add a definition for an "on-hold" prescription as a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date. *The definition is necessary to understanding and compliance with regulations for such prescriptions.*
240	Sets requirements for the maintenance of records and prescriptions	Subsection B is amended to allow the alternative of filing a prescription by date of initial entry into an automated data system, if such a system is used by the pharmacy. *There appears to be an increase in the number of "on-hold" prescriptions received by pharmacists. Current filing requirements are overly burdensome. An alternative filing requirement will create more flexibility for pharmacists.*
250	Sets requirements for automated data processing records of prescriptions	Amendments revise the requirements for documenting correct information to allow for on-hold prescriptions that will not be filled until a later date. A pharmacist is responsible for checking the accuracy of the data entry of an on-hold prescription and for attesting to a review of information entered into the computer each day. Consistent with current requirements for producing a printout of dispensing data, the data systems must have the capacity to provide a printout of any data entry of on-hold

		prescriptions. *As one of the commenters stated, allowing pharmacists to accept prescriptions from patients, enter them in the computer, and file them according to the date they were entered has advantages. The pharmacist is still responsible for the accuracy of the data entry of on-hold prescriptions. It is safer and less burdensome for physicians and pharmacists to allow entry of a prescription that will be filled and dispensed at a later date, rather than relying on patients to keep up with the prescription until it is time to have it filled.*
270	Sets out requirements for dispensing of prescriptions	Subsection F is added to allow an on-hold prescription to be entered into the automated data processing system, if such system is employed by the pharmacy, and to require that the pharmacist on-duty must verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date must, at a minimum, conduct a prospective drug review consistent with the Drug Control Act. *The pharmacist on duty at the time the prescription is entered into the computer must check for accuracy of the information; then the pharmacist who fills the prescription and dispenses it to the patient must conduct the review at the time of dispensing because there may be contraindications for a drug at that time that were not present at the time the prescription was initially entered.* If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system. *If the patient decides later to retrieve the prescription to take it to another pharmacy, the data entry of that prescription must be deleted.*