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	Allowing on-hold prescriptions to be entered by date prescription is received rather than dispensed
Date this document prepared	September 11, 2013

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

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.

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 September 10, 2013, the Board of Pharmacy adopted final amendments to 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:

§ 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 statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including regulations pertaining to the safety and integrity of drugs is found in § 54.1-3307 of the Code of Virginia.

§ 54.1-3307. Specific powers and duties of Board.

The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices which do not conform to the requirements of law. In so regulating the Board shall consider any of the following criteria as they are applicable:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

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.

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 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 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

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 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.

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.

There were no changes made to the text of the proposed regulation.

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
John Lubkowski	No disadvantages to the change – will increase the security of the hard copy prescription and avoid misplacement; fully supports the amendments	The Board appreciates the comment.
Kathryn Weakley	Fully supports the changes; will eliminate excessive steps that could lead to an increase in filing errors.	The Board appreciates the comment.
Travis Hale	Changes will preview filing errors or misplacement of an actual prescription and will allow remote dispensing to determine if prescriptions are on file at the pharmacy. Will make workflow simpler and cleaner.	The Board appreciates the comment.
Jim Perkinson	When data entry of on-hold prescription is performed, it's	The Virginia Board and other state boards of pharmacy are aware of dispensing errors

	entered with same accuracy as when dispensing any prescription. No advantage, but many disadvantages, to "renewing" and assigning a different number to an on-hold prescription for sole purpose of placing prescription in chronological order.	resulting from incorrect data entry of an on-hold prescription. The errors occurred because the dispensing pharmacist assumed the data-entry had been previously verified by a pharmacist. Currently, there is no requirement for a pharmacist to verify the accuracy of the data entry when placing a prescription on-hold. "Renewing" and assigning a new number to an on-hold prescription just prior to dispensing is the act many pharmacists perform to comply with the current filing requirement. The Board believes the proposed regulation will alleviate that issue and improve patient safety, so no change was adopted.

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	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.*