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	18 VAC 110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Limitation on refills of prescriptions for Schedule VI drugs
Document preparation date	9/13/05

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.*

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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

The Board of Pharmacy proposes to amend its regulations to limit the time for dispensing or refilling of Schedule VI drugs to one year from date of issuance, *unless the prescriber specifies a longer period, not to exceed two years* (which is the current limitation on refills for Schedule VI drugs).

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 taking the action, and (3) the title of the regulation.

On September 13, 2005, the Board of Pharmacy adopted final amended regulations for 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy to limit the time for dispensing or refilling of Schedule VI drugs.

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 numbers, 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 Governing the Practice of Pharmacy, 18VAC110-20-10 et seq., are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6), 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 statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including the dispensing of controlled substances 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.

The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

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.

The Board is amending regulations because the current rule is in conflict with the policy of all third-party insurance companies that require prescriptions to be renewed annually in order to be reimbursed and with the rules of all surrounding states. Approximately 85% of all prescriptions are covered by Medicaid or some other third-party payer. The disparity in requirements causes confusion on the part of patients who believe they have refills remaining, but the pharmacy cannot refill the prescription if third-party reimbursement is involved.

In addition, the pharmacist has no assurance that a prescription written more than one year ago continues to be valid based on a bona fide practitioner-patient-pharmacist relationship as required in § 54.1-3303 of the Code of Virginia. Continuity of care is necessary for patient health and safety, including at least a yearly re-examination of the prescription options for treatment of a particular disease or condition.

Pharmacists attempting to verify with the prescriber that the prescription is still valid after a year or more often find an invalid practitioner-patient relationship due to relocations, changes in primary care physicians and other reasons. Transfers of prescriptions from state to state are also confusing, since Virginia's rule is inconsistent with many other states.

The amended regulation will provide that the "default" limit would be one year if a prescriber indicates PRN on the prescription. However, if, in the judgment of a prescriber, a prescription

could safely be written for a period longer than one year, he can indicate the number of refills to cover a time not to exceed a two-year limitation for dispensing or refilling.

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 proposed amendment to 18VAC110-20-320 (Refilling of Schedule III through VI prescriptions) is as follows: "A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than ~~two years~~ one year after the date on which it was issued, unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years. "

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 primary advantage to the public is consistency in the refill requirements, so prescriptions can be filled and dispensed without undue confusion and delay. As private businesses, pharmacies may have fewer prescriptions that exceed the one year for refilling and necessitate contact with the prescriber, who may not have seen the patient in recent months and be reluctant to grant a refill request over the phone.

For consumers that do not have prescription coverage by a third-party payer, the additional amendment proposed by the Board will allow a prescription to continue to be valid for two years, if a prescriber does not believe it is necessary for a patient to be seen during that period for the disease or condition being treated by the drug. While the pharmacy can usually get authorization to refill an expired prescription without the patient being seen by the prescriber, some are reluctant to continue a patient on a medication without a reevaluation of the condition for which the prescription was written.

2) There are no disadvantages to the agency. There may be a slight advantage in having a regulation that is consistent with the vast majority of other states and all third-party payers, in that there would be less confusion.

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 to the text of the proposed regulation since it was published at the proposed stage.

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.

Proposed regulations were published on May 30, 2005 with a comment period that closed on July 29, 2005. A public hearing on the proposed regulation was held on June 7, 2005. There was no public comment.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
320	n/a	Limitation of two years from date of issuance for dispensing of a Schedule VI drug or device	Limitation changed to one year from date of issuance for dispensing of a Schedule VI drug or device, unless the prescriber specifically authorized dispensing or refilling for a longer period of time not to exceed two years. *Amendment would make refills less confusing to patients, be more consistent with the standard of care for patients on maintenance medications, be consistent with all neighboring states and with the policies of all third-party payers.* *If it is unnecessary to see a patient on a maintenance drug at least once a year, the prescriber could indicate at least two years worth of refills.*

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

In its analysis of the final regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability.