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	18 VAC 110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Limitation on refills of prescriptions for Schedule VI drugs to one year
Document preparation date	12/13/04

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

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The Board of Pharmacy is resubmitting its proposed amendment to section 320, which currently limits the time period on refills for Schedule VI drugs to two years from date of issuance. The original proposal was to limit the time for dispensing or refilling to one year from date of issuance of a prescription. At its meeting on December 10, 2004, the Board proposed to change the amended regulation to limit the time for dispensing or refilling to one year from date of issuance, *unless the prescriber specifies a longer period, not to exceed two years*.

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.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy are promulgated under the general authority of Title 54.1, Chapter 24 of the Code of Virginia. Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations in accordance with the Administrative Process Act.

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 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 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 would 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" 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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so 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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, 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 approximately $2,000 for promulgation of the amended rule. A public hearing would be heard in conjunction with a regularly scheduled board meeting, and to the extent possible, all notifications would be done electronically to minimize the cost. There would be no on-going expenditures.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	Consumers who do not have prescription coverage by a third-party payer would continue to be able to get S VI prescriptions refilled for two years without having to see the doctor or have the refill authorized by the prescriber – if the prescriber so indicates on the prescription. Those practitioners

	who are authorized to prescribe Schedule VI drugs would be affected, including: doctors of medicine or osteopathy, podiatrists, physician assistants, nurse practitioners, dentists and veterinarians, and the pharmacists licensed to refill and dispense prescriptions. The businesses affected would be pharmacies.
Agency's best estimate of the number of such entities that will be affected	There are approximately 7675 pharmacists with active licenses, and approximately 1517 permitted pharmacies. Prescribers include: Doctors of Medicine 29,106 Doctors of Osteopathic Medicine 1085 Doctors of Podiatry 488 Interns & Residents 2750 Physician Assistants 885 Nurse Practitioners 4825 Dentists 5320 Veterinarians 2185
Projected cost of the regulation for affected individuals, businesses, or other entities	For those consumers who have prescriptions covered by third-party payers, there would be no additional cost, since the amended rule would not effectively change the refill procedures that occur with virtually all prescriptions. Since costs for the vast majority of S VI prescriptions are reimbursed by third party payers, pharmacies currently are required to call the prescriber to get authorization for a new prescription if the patient has not seen the physician in over a year. Likewise, physicians should not be impacted differently from what occurs now. If the prescriber will not authorize a refill without seeing the patient, there may be an additional cost for an office visit for those consumers who do not have prescription coverage. A few practices are also charging patients for refill authorizations, so some consumers may incur that cost.

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.

The Board of Pharmacy is responding to a petition for rule-making filed by a pharmacist in Northern Virginia and concurs that a change in the regulation would be less burdensome for pharmacists and patients. There is no alternative to the proposed regulatory action to achieve the essential purpose of the action requested by the petitioner. Under current regulations, no refills

are permitted for Schedule II drugs, which are those with potential for abuse or addiction. Schedule III, IV, or V cannot be dispensed or refilled more than six months after the date on which such prescription was issued, so the amendment to limit refills of Schedule VI drugs to one year would be a logical policy change consistent with neighboring states. According to statistics provided by the National Association of Boards of Pharmacy, 38 states currently place a one-year time limit on refill of Schedule VI prescriptions. All states in this area, including North Carolina, Maryland, Kentucky, West Virginia, Tennessee, and Delaware, have the one-year rule.

To maintain a rule that is inconsistent with other states and with current practice does not appear to be in the best interest of the public or the regulated entities. In addition, the board believes that a two-year refill rule is inconsistent with the standard of care for patients, who should be seen by the prescriber at least once a year to determine whether continuation of drug therapy is necessary, and if so, whether the prescribed drug at the prescribed dosage continues to be the best available therapy. In reality, pharmacists currently have to call for re-authorization of a prescription beyond one year, and if the prescriber has not seen a patient in over a year, the prescription is typically authorized for a single refill with instruction from the prescriber to tell the patient to make an appointment to see the doctor. Since the prescription can only be refilled once, the patient must then come back to the pharmacy or replace an order after seeing his prescriber and having the prescription written for additional refills. An amendment to the refill rule would be not only less confusing for patients but also less cumbersome.

In its economic impact analysis of the amendment proposed by the Board in June of 2004, the Department of Planning and Budget (DPB) stated that the proposal would deprive prescribers of the opportunity to write a prescription lasting for more than one year if they believed that was appropriate for their patients and patients would lose the opportunity to have a prescription written for more than one year. The Department also noted that the Board of Medicine had expressed opposition to the regulation change as an inconvenience to patients.

The suggestion to have insurance expiration information printed on the label was not a reasonable alternative to the proposed regulation. There is so much information currently required for a prescription label that there simply isn't room for that much additional information, and it would necessitate costly reprogramming in every pharmacy data system.

To address the concerns of DPB and in response to objections from the Board of Medicine, the Regulation Committee of the Board of Pharmacy approved compromise language that would continue to give prescribers the opportunity to elect a longer time frame for refills on Schedule VI drugs. The draft language was reviewed with the Board of Medicine at its meeting on November 19, 2004 and approved by that body. Accordingly, the full Board of Pharmacy accepted the recommended change and agreed to withdraw the original proposal and resubmit the proposed amendment.

Public comment

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

Commenter	Comment	Agency response
Board of Medicine	Opposes the amendment. It accommodates policies set by third party payers but would not be in the best interest of patients. It is inconvenient and takes away from time physicians have to spend with patients.	The Board of Pharmacy does not agree that the amended regulation would be inconvenient to patients or more time-consuming for prescribers, since currently pharmacies must get a prescription re-authorized if it is more that one year old and if the cost is to be borne by a third-party payer.
National Association of Chain Drug Stores	Supports the amendment. The proposed amended rule is consistent with the realities of day-to-day pharmacy practice and supports good medical and pharmacy practice. It will reduce confusion for patients. NACDS urges the board to adopt the amended rule.	The Board considered the comment and voted to move forward with the amendment.

Family impact

Please assess the 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.

Detail of changes

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

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

For changes to existing regulations, use this chart:

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

			<u>specifically authorized dispensing or refilling for a longer period of time not to exceed two years.</u> *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.*