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Final Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Unprofessional conduct to induce or incentivize a patient to transfer prescriptions
Date this document prepared	3/21/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 purpose of the regulatory action is to amend section 25, which sets out the practices that constitute unprofessional conduct and may be grounds for disciplinary action pursuant to § 54.1-3316. The new provision would prohibit advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing a patient to transfer a prescription absent professional rationale by use of coupons, rebates, etc. The action responds to a petition for rulemaking from a Virginia pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews.

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.

N/A

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 March 21, 2017, the Board of Pharmacy adopted 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 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 of the Board to regulate the practice of pharmacy is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. 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 that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
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. Describe the specific reasons the regulation 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.

In 2012, the U. S. Department of Justice resolved allegations against Walgreens Pharmacy with a $7.9 million payment because the chain offered beneficiaries of government health care programs (Medicare, Medicaid, TRICARE, etc.) inducements that are prohibited by law to transfer prescriptions to Walgreen pharmacies. Quotes from federal law enforcement illustrate the need to enact such a prohibition in Virginia. The U. S. Attorney for the Eastern District of Michigan said, “Continuity with a pharmacist is important to detect problems with dosages and drugs interactions. Patients should make decisions based on legitimate health care needs, not on inducements like gift cards.” The Inspector General for the U. S. Department of Health and Human Services, said, “Violating Federal health care laws, as Walgreens allegedly did by offering incentives for new business, cannot be tolerated.”

As the Virginia Pharmacists Association stated in its letter of support for a regulatory change, “Transfer coupons and other transfer incentives fragment the medication records of patients which leads to inaccuracies in the mediation records and is detrimental to patient care.” The Board has determined that there is a need to propose a regulation to protect the health, safety and

welfare of the citizens who count on Virginia pharmacies for accuracy and integrity in filling prescriptions.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

The proposed regulation would make it unprofessional conduct to offer inducements or incentives, such as coupons or gift cards, for a patient to transfer a prescription, absent any professional rationale for such transfer. Customer rewards or affinity cards that encourage loyalty to a pharmacy would not be considered unprofessional.

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.

) The primary advantage to the public is improvement in the continuity of care in delivery of pharmaceutical services. There is a disadvantage for customers who use prescription transfer just as a means of obtaining gift cards and incentives;
2) There are no advantages or disadvantages to the agency; and
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under 54.1-2400 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.*"
Additionally, the Code of Virginia requires:
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered…
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.

As stated in the "Purpose" section of this document, quotes from federal law enforcement illustrate the need to enact such a prohibition in Virginia. The U. S. Attorney for the Eastern District of Michigan said, "Continuity with a pharmacist is important to detect problems with dosages and drugs interactions. Patients should make decisions based on legitimate health care needs, not on inducements like gift cards." The Inspector General for the U. S. Department of Health and Human Services, said, "Violating Federal health care laws, as Walgreens allegedly did by offering incentives for new business, cannot be tolerated."

Therefore, the prohibition against use of coupon or other incentives for a patient to transfer a prescription, absent a professional rationale, is a foreseeable result of the statute requiring the Board to protect the safety and efficacy of prescription drugs in the Commonwealth. Any restraint on competition that results from this regulation is in accord with the General Assembly's policy as articulated in § 54.1-100 and is necessary for the preservation of the health, safety, and welfare of the public and will further the public's need for assurances of prescription drug safety.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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.

In 2012, the U. S. Department of Justice resolved allegations against Walgreens Pharmacy with a $7.9 million payment because the chain offered beneficiaries of government health care programs (Medicare, Medicaid, TRICARE, etc.) inducements that are prohibited by law to transfer prescriptions to Walgreen pharmacies.

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.

Family impact

Please assess the impact of this 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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There are no changes since 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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Robert Sedaker	There should be no prohibition of Pharmacy incentives to switch pharmacies. There is no causal effect of such practice leading to mistakes by pharmacies.	The Board has promulgated the regulation in order to detect problems with dosages and drugs interactions to protect patients, not to avoid mistakes made by pharmacists.

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. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Current requirement	Proposed change, intent, and likely impact of proposed requirements
25	Sets out the practices that would constitute unprofessional conduct within the meaning of 54.1-3316 and authorize disciplinary action by the Board.	The section is amended to add to unprofessional conduct practices: *Advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing the transfer a prescription absent professional rationale by use of coupons, rebates, or similar offerings.* The Board has determined that the practice of incentivizing patients to transfer prescription is potentially dangerous and may lead to medication errors, unnecessary proliferation of antibiotics or other drugs, and drug interactions. In its statutory responsibility to protect the efficacy and safety of prescription drugs, the Board has acted to prohibit the practice.