Proposed 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	4/11/16

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 (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 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

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. A more detailed discussion is provided in the "Detail of changes" section below.

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.

1) 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.

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 of Pharmacy 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. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/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 requirement creates the anticipated economic impact.

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	a) 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 for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Chain drug stores that offer incentives for transferring prescriptions.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the number; the corporate advertising of incentives to transfer appears to have been lessened in recent years. None of these businesses would be small; they are the large pharmacy chains such as Walgreens and CVS.
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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	There are no costs.
Beneficial impact the regulation is designed to produce.	The benefit of this action is less fragmentation of the medication records of patients which leads to inaccuracies and incomplete information which

	can result in drug interactions and is detrimental to patient care

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.

At its meeting on March 26, 2014, the Board considered the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Several board members expressed concern for the practice and referenced the position of concern from the Institute for Safe Medical Practices and a recent review of this practice by the Department of Justice. Because there was some concern that a regulatory action might constitute a restraint of trade, the Board voted to deny the petitioner's request but to refer the matter to the regulation committee for further consideration.

At its meeting on May 12, 2014, the Committee discussed additional information relating to prohibition on coupons, including language from other states and a press release from the U. S. Department of Justice, with a focus on whether a prohibition against incenting patients to transfer prescriptions could be construed as a restraint of trade. Ms. Juran reported that the executive director of Oregon indicated its language prohibits pharmacies from incenting the transferring of prescriptions, but allows the incenting of patients to retain their prescriptions at a single pharmacy such as through loyalty programs. Board counsel advised that the Oregon regulatory language did not appear to represent an uneasonable restraint of trade. The Committee reviewed a possible amendment to the unprofessional conduct section of regulation using language similar to Oregon and voted unanimously to recommend to the full board that it adopt a regulatory action regarding the use of coupons or other rewards to incentivize patients to transfer prescriptions.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

There is no alternative regulatory method.

Public comment

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

There was a comment period on the NOIRA from 11/16/15 to 12/16/15.

Commenter	Comment	Agency response
Tim Musselman for the Virginia Pharmacists Association	Encourages the Board to adopt strong regulations to eliminate dangerous incentives to transfer prescriptions. Such practices do not facilitate the goal of a concise medical home and complete medication records for review.	The Board concurs.
Lauren Caldas	Should ban transfer incentives. Incentivizing patients to change pharmacies multiple times based on coupon accumulation opens pharmacists to unsafe medication practices. Can lead to errors and unnecessary prescriptions.	The Board concurs.
Katie Clasen	Patient safety is jeopardized by incentivizing prescription transfers. Pharmacists can miss drug interactions and duplication of therapy. Transfers done solely for the sake of a coupon add a significant and unnecessary burden to an already heavy workload.	The Board concurs.
Brian Quigley, R.Ph.	Opposed to incentives to transfer prescriptions; pharmacists are here to protect the public by looking for drug interactions; adds another opportunity for prescription error.	The Board concurs.
Robert Rhodes, Pharmacist	This is one of the most dangerous things allowed in pharmacy. Encourages patients to poly-pharmacy; many prescriptions are not paid by insurance (because the store cost is cheaper) so there is no record of prescriptions with no real benefit. Sent a copy of an 2012 article from Oregon about the prohibition.	The Board concurs.

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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

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.