Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) 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	Unprofessional conduct to induce or incentivize a patient to transfer prescriptions
Date this document prepared	6/5/14

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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended 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 § 45.1-3316. 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.

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 to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 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 detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

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 New York is currently defending a law suit for its current prohibition against pharmacy coupons. She also stated 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 a 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 Notice of Intended Regulatory Action regarding the use of coupons to incent patients to transfer prescriptions.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action 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 (**http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi**). Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed 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.