Form: TH-01



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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	18 VAC 110-20
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Time limit on refills of Schedule VI prescriptions
Document preparation date	

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the Virginia Register Form, Style, and Procedure Manual (http://legis.state.va.us/codecomm/register/download/styl8 95.rtf).

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.

Board meeting – The Board of Pharmacy met Tuesday, November 25. It considered a petition for rulemaking to reduce the time limit for refills on Schedule VI prescriptions from 2 years to 1 year. The request was made by a pharmacist because third-party insurance companies all require that prescriptions be renewed annually in order to be reimbursed. Approximately 85% of all prescriptions are covered by Medicaid or some other third-party. The Board voted to go forward with a NOIRA. For over 85%, (closer to 95% with the passage of the Medicare bill) of prescriptions, the disparity between Virginia law and what insurance carriers require causes confusion on the part of patients as to why they believe they may have refills remaining, but the pharmacy cannot refill the prescription. It also causes increased workload on the pharmacist having to call the prescriber and obtain a new prescription, as well as take time to explain the problem to the confused patient. VPhA is supportive of this petition. There is some concern that this may result in an increased cost to the private pay patient who may be required to see the physician annually rather than biennially to get the prescription renewed. However, in actual practice, the physician can verbally approve a new prescription for another year without necessitating an office visit, which is what usually happens now.

Legal basis

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Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, 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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board 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 (§ <u>54.1-100</u> et seq.) and Chapter 25 (§ <u>54.1-2500</u> et seq.) of this title. ...

Substance

Please detail any changes that will be proposed. 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. Include the specific reasons why the regulation is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

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.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

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There is no potential impact of the proposed regulatory action on the institution of the family or on family stability.

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