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
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Safe working conditions
Date this document prepared	June 19, 2012

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 planned regulatory action is to address a petition for rulemaking requesting amendments that will specify a limitation of excessive hours of work without any breaks for pharmacists. Regulation is necessary to prevent, to the extent possible, prescription errors due to fatigue and lack of concentration by pharmacists in the important task of assuring the accuracy and integrity of controlled substances. The action is the result of a petition for rulemaking by a pharmacist and was strongly supported in comment on the petition.

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 statutory authority for the Board of Pharmacy to regulate the practice of pharmacy including regulations pertaining to the safety and integrity of drugs 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.

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.

While the Board is not aware of studies documenting the error rate for pharmacists working extensive hours continuously, every pharmacist who spoke to the Board and members of the Board are aware that fatigue and lack of concentration can and do lead to errors in filling, reviewing for drug interactions and dispensing prescription drugs. For other professions who rely on mental acuity, such as airline pilots, there is a limitation on continuous hours of work. Therefore, the Board believes it is essential for public health and safety that some reasonable limitation be instituted on continuous hours of work without any breaks for pharmacists in Virginia.

The primary issue that must be resolved in the development of regulations is the extent to which an exception to the 12-hour rule will be allowed. All agreed that there must be an exception for an emergency situation in order to keep a pharmacist on duty, but some want a pharmacist to be able to opt out of the 12-hour rule. Whether that would defeat the purpose of the regulatory restriction is an issue for further discussion by the Board.

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 Board has not determined the specific language to be proposed, but the Regulation Committee recommended a limitation of 12 hours for a pharmacist to be on duty dispensing prescriptions and a requirement that there be a 30 minute uninterrupted break for at least 6 hours of work plus an additional 15 minute break thereafter. There may be a limitation of 12 hours within a 24-hour period or no more than 60 hours over a five-day work period. The Board would include an exception for emergencies (i.e.; when a replacement pharmacist does not report for work) or for imminent patient need (i.e.; when the pharmacist must complete an urgent prescription).

There are similar provisions in neighboring states, and the Board has requested information be obtained about requirements in all states. In North Carolina, a permit holder cannot require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than 6 continuous hours per work day must be allowed during that time period to take a 30-minute meal break and one additional 15-minute break.

In West Virginia, no pharmacist can work more than 12 hours within a 24-hour period without at least 8 hours off duty within the 24 hours, except in a case of emergency when a pharmacist calls off work. The pharmacist on duty may work more than 12 hours in order to keep the pharmacy open. The pharmacists must document and make available to the Board the date and the amount of time worked beyond the 12 hour limit along with the reason for the extended work hours. Other states with similar regulations include: AL, FL, MN, MA, MO, NJ, OK, TN; and Texas has similar requirements in a policy statement.

The Pharmacy Alliance, a national organization of pharmacists dedicated to better working conditions, strongly supports the limitation on work hours and mandatory breaks as one of a number of issues that it believes constitute workplace safety violations. The Board has taken the comments and requests of the Alliance under advisement but did not expand the specific focus of the petition to include other workplace issues.

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.

Since there are no specific requirements in regulation for safe working conditions for pharmacists, the only alternative is the promulgation of an amendment through the regulatory process.

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 to Elaine Yeatts at 9960 Mayland Drive, Henrico, VA 23233; by fax to (804) 527-4434 or by email to 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.

The Board will utilize the participatory approach as members of the Regulation Committee has reviewed the petition for rulemaking and heard significant comment from the public about working conditions in pharmacies. Public participation was encouraged and evident in discussions of the issues during the Committee and Board meetings at which this item was on the agenda. Public comment was encouraged as the Board considers necessary and appropriate changes to the regulation.

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 of the proposed regulatory action on the institution of the family.