Virginia Regulatory Town Hall

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Proposed Regulation
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	2/26/13

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.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The proposed regulation provides that, except in an emergency, a pharmacy cannot require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours must be allowed to take a 30-minute break.

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.

PBM = pharmacy benefits manager
DUR = drug utilization review

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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

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.

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.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The proposed regulation provides that, except in an emergency, a pharmacy cannot require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at

least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours must be allowed to take a 30-minute break.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) The primary advantage to the public would be greater assurance of safety in prescription medications dispensed by pharmacists who are not overly-fatigued from excessive hours of work without any break. Pharmacists would have the option of continuing with a patient beyond the prescribed hours or remaining on duty if a replacement pharmacist is not available, so patients would not be neglected. There are no disadvantages to the public.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

There are no applicable federal requirements.

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/agency 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**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the 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 requirements creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	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 or entities for necessary functions of regulation. There would be no additional expenses relating to promulgation of the amended rule. All notifications will be done electronically and a public hearing will be held in conjunction with a scheduled Board meeting. There are no on-going expenditures for the agency related to rules for pharmacy working conditions.
Projected cost of the *new regulations or changes to existing regulations* on localities.	There is no projected cost on localities.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	Pharmacies that hold a permit to operate in Virginia may be affected if they currently require pharmacists to work longer than 12 continuous hours or do not permit a break after six continuous hours of work.
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 (i) is independently	There are currently 1768 permitted pharmacies in Virginia. Most are owned by national chain drug stores and would not be considered small businesses. Of those that would be small

owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	businesses, it is likely that only a few would be affected by the restriction on hours of work.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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 projected costs for changes to the regulations. It is a matter of scheduling for the hours of operation.
Beneficial impact the regulation is designed to produce.	The beneficial impact may be less stressful situations in which a pharmacist may be prone to commit an error in reviewing or dispensing a prescribed medication.

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.

The purpose of the proposed 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. The action is the result of a petition for rulemaking by a pharmacist and was strongly supported in comment on the petition. 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.

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.

Regulatory flexibility analysis

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.

The agency has not identified alternative regulatory methods consistent with health and safety.

Public comment

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

Commenter	Comment	Agency response
John Crowder, pharmacist	Hours of work are not the only cause for workplace stress and accuracy; workload and distractions have increased dramatically. Not confident that additional Board regulation will resolve situation in which the PBM's and mega-chains defacto set the rules.	The Board appreciates the comment and agrees that the proposed rule would only address one aspect of the problem.
Lori Burgess, PharmD	Supports the proposal; some colleagues work in stressful situations & need a break	Board concurs with the comment.
Amber Darr, PharmD	Supports the proposal; should have an additional 15-minute break for shifts longer than 6 hours. Needed to minimize errors.	Board concurs with the comment, but did not add the additional requirement for a 15-minute break.
Otto Wachsmann, pharmacist	Bigger problem are the false DUR messages sent by Pharmacy Benefits Managers and e-scripts, etc. with incomplete information. Board should create regulations to eliminate or reduce these unnecessary distractions from outside forces that kill workflow. If licensee feels the work environment is unsafe, he should file a complaint to Board. Not necessary to mandate breaks for all pharmacies.	While the Board understands the problem of distractions and limitations from outside forces, it only has regulatory authority over pharmacists and pharmacies. Pharmacists may not recognize the work environment is unsafe until an error is made and a patient is harmed. Additionally, staff pharmacists are reluctant to file a complaint against their employer for fear of retribution and/or loss of a job.
Ken Lenviel, pharmacist	Retail pharmacist in a chain drug store and on my feet for 13 hours a day. Supports a 12-hour day and a 30-minute break as I definitely see fatigue playing a	Board concurs with the comment

	role in dispensing errors	
Myra Clements, retired pharmacist	Pharmacists need a break from during a 8-hour shift; it is challenging mentally and physically	Board concurs with the comment
F. W. Richards	Do not want the Board setting number of hours of work or breaks. An employee pharmacist should be able to contact Board if working conditions are abusive or dangerous & could contribute to mistakes; then Board could inspect & take action.	Pharmacists may not recognize the work environment is unsafe until an error is made and a patient is harmed. Additionally, staff pharmacists are reluctant to file a complaint against their employer for fear of retribution and/or loss of a job. If there are no standards for working conditions, the Board would have no basis for disciplinary action.
Bronwyn Burnham, pharmacist	Supports the proposed regulation; retail environment requires access to customers for 12-14 hours a day. Would reduce fatigue and improve overall work performance.	Board concurs with the comment.
David Halla	Not in favor of more regulations. Board members should be pharmacists in the trenches each day to know how to fix things.	The Board acknowledges that the proposed regulations will not fix the reduction in the gross margin.
Nat'l. Association of Chain Drug Stores, Jill McCormack	Every pharmacy environment is unique; management needs flexibility to evaluate the needs of each pharmacy & determine staffing. Regulations should be permissive, allowing pharmacists the option to set the work day schedule to meet patient needs.	Proposed regulations are drafted as permissive for the pharmacist who chooses to work a different schedule different
Kaiser Permanente, Soumi Saha	Agrees that lengthy work hours with no scheduled breaks may contribute to fatigue and a lapse in concentration which may lead to medication errors. Pharmacists at Kaiser may not be scheduled for more than 10.5 hours and have scheduled breaks. Parameters need to be flexible in case of emergencies.	Proposed regulations provide exceptions for emergency situations (replacement pharmacist cannot get to the pharmacy, etc.)
Virginia Pharmacists Association, Timothy Musselman	Prescription volumes continue to rise & demands with limited time are becoming the norm; pharmacists can face 12-14 shifts with no ability to take a break. Urges Board to allow flexibility in work environments when pharmacists may need to extend a shift for good reason.	Proposed regulations do allow such flexibility.
EPIC pharmacies, Hunter Jamerson	Proposed action does not take into account varying work environments and causes for prescription error. Pharmacists may need to extend a shift for continuity of care or to accommodate personal needs. Concerned about the statutory authority to regulate hours of service.	Proposed regulations allow pharmacists to meet the needs of patients or their own personal schedules. The Board has the authority to regulate the practice of pharmacy and pharmacists to ensure the safety and integrity of prescription drugs in the Commonwealth.
Craig Parrish Director, VDH Division of Pharmacy Services	Supports the premise that after a certain number of hours of continuous work, pharmacists will experience mental and physical fatigue to make them more prone to dispensing errors. Is concerned about	The regulations provide an exception for emergency situations.

	VDH ability to respond to public health emergencies.	

Family impact

Please assess the 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. 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.

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
110	Sets out requirements for pharmacies and the pharmacists in charge of permitted pharmacies	Subsection B is added to provide that: *Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.* Staff has identified 12 other states that currently have regulations aimed at relieving pharmacist workload. The regulation adopted is similar to neighboring state, especially in North Carolina. There is no evidence that the restriction on requiring a pharmacist to work longer than 12 continuous hours has created a hardship on pharmacies or patients in that state. Some pharmacists who commented on the petition for rulemaking asked the Board for rules on such subjects as availability of ancillary help and prohibition on mandatory corporate production metrics/quotas for filling prescriptions or immunizations. The Board chose to focus on the work hours and break time as the most reasonable and least intrusive regulation to improve pharmacist working conditions and increase the margin of safety for prescriptions.