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Final Regulation Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Safe working conditions
Date this document prepared	6/29/16

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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 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 and must be 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.

N/A

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On June 14, 2016, the Board of Pharmacy amended 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

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. 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.

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 the new substantive provisions, the substantive changes to existing sections, or both.

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 and must allow 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 there are 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) A competitive impact analysis was performed by the Director of the Department of Health Professions. Under the powers and duties of health regulatory boards, the Board is authorized under § 54.1-2400 to “*promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.*” Chapter 33 of Title 54.1 specifies that “*the Board's regulations shall include criteria for: ...*
 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.*”

Therefore, the amendment limiting the time an employer can require a pharmacist to work without any break is consistent with the Board’s statutory responsibility for the safety and integrity 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 quality pharmaceutical services.

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.

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.

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.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

There was one change made since the proposed stage. The Board amended the rule to clarify the intent by specifying that a pharmacist cannot be required to work longer than 12 continuous hours, except in an emergency, and must be given at least six hours of off-time between consecutive shifts. The proposed regulation could be interpreted to mean that a pharmacist could be required to work an unlimited number of hours as long as he/she was given at least six hours off between shifts. That interpretation would be contrary to the intent of this action, so the Board clarified the rule.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Robert Rhodes	Public safety is the duty of the Board; it is a proven fact that long hours and reduced help can contribute to errors and cause harm to the patients. There should be at least 8 hours between 10/12 hour shifts.	The Board concurred with the comment, but did not amend the proposal to require an 8-hour break between shifts.
T. Barksdale	Pharmacies that operate for 12 or more hours should be required to close the prescription department for 30 minutes to 1 hour.	The Board understands the comment and the need for some pharmacies to close the prescription department to allow breaks, but did not choose to amend the proposal. Whether to close the prescription department for a lunch break is more of a business decision left up to the pharmacy.
Anonymous, Pharm D. candidate	Allowing a 30 minute break probably doesn't work unless there is a floater pharmacist available.	The Board understands the comment but cannot require a pharmacy to hire a floater pharmacist.
Wendy Klein, M.D.	Strongly supports the proposed regulation; will increase productivity by reducing fatigue and improving concentration. Should be the rule for all but especially for a field that demands intense attention to detail.	The Board concurs.
Anonymous, Pharm D. candidate	The 30 –minute break isn't workable unless pharmacist can leave the prescription dept. shocking to see how many pharmacists are not eating and standing for 12 hours.	The Board understands the comment and the need for some pharmacies to close the prescription department to allow breaks, but did not choose to amend the proposal.
Ifeanyi Ogbonna, Pharm D. student	Working 12 hour shifts may affect pharmacist's performance and indirectly affect service to patients.	The Board concurs.
2016 Pharm D	Problem is pharmacists not being allowed breaks; need to require pharmacy to halt production for 30 minutes for patient safety.	The Board understands the comment and the need for some pharmacies to close the prescription department to allow breaks, but did not choose to amend the proposal.
Tiffany Johnson, pharmacist	Proposal needs to reduce mental and physical fatigue; with a break more confidence in public safety.	The Board concurs.
Drug Topics Anonymous	All levels of management live on metrics only.	The comment does not specifically address the regulation.
Drug Topics Anonymous	Wrote about generally hostile working conditions for pharmacists.	The comment does not specifically address the regulation
Drug Topics Anonymous	Described working conditions as being detrimental to patient safety – only allowed 15 minute breaks at most.	The Board concurs.
Drug Topics Anonymous	Described working conditions as being corporate bullying.	The comment does not specifically address the regulation
Drug Topics Anonymous	Described working conditions and unfair labor practices.	The comment does not specifically address the regulation

Concerned pharmacist	Corporate pharmacy set up dispensing time metrics that put patients at risk at the same time demanding more in patient counseling, immunizations, etc. Older pharmacists face termination if they don't comply.	The comment does not specifically address the regulation
Concerned pharmacist	Need the Board to require breaks for patient safety because without it, corporate pharmacy will not implement.	The Board concurs.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

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	<p>Subsection B is added to provide that:</p> <p>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 and shall allow] 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.</p> <p><i>Staff has identified at least 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.</i></p> <p><i>The Board amended the rule to clarify the intent by specifying that a pharmacist cannot be required to work longer than 12 continuous hours, except in an emergency, and must be given at least six hours of off-time between consecutive shifts. The proposed regulation could be interpreted to mean that a pharmacist could be required to work an unlimited number of hours as long as he/she was</i></p>

		<p><i>given at least six hours off between shifts. That interpretation would be contrary to the intent of this action, so the Board clarified the rule.</i></p>
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