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# Proposed Regulation
# Agency Background Document

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| **Agency name** | Board of Pharmacy, Department of Health Professions |
| **Virginia Administrative Code (VAC) Chapter citation(s)** | 18VAC110-20 |
| **VAC Chapter title(s)** | Regulations Governing the Practice of Pharmacy |
| **Action title** | Pharmacy working conditions |
| **Date this document prepared** | December 6, 2023 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

## Brief Summary

*Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

Chapter 628 of the 2022 Acts of Assembly required that the Board of Pharmacy adopt emergency regulations related to work environments for pharmacy personnel that protect the health, safety, and welfare of patients. The Board has amended a section of Chapter 20 and added a new section to address the issues raised by Chapter 628 of the 2022 Acts of Assembly.

## Acronyms and Definitions

*Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.*

PIC = pharmacist in charge

## Mandate and Impetus

*Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*

Chapter 628 of the 2022 Acts of Assembly required that the Board of Pharmacy adopt emergency regulations related to work environments for pharmacy personnel that protect the health, safety, and welfare of patients. Enactment 2 of the legislation required that such emergency regulations be effective within 280 days of enactment. Although the General Assembly determined that this legislation required emergency regulations, rather than the Board, the emergency is likely related to concern for the safety of pharmacists, pharmacy staff, and patients given the current healthcare climate and increased workloads for pharmacists and other pharmacy personnel.

## Legal Basis

*Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.*

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Virginia Code § 54.1-3307(A) requires the Board to "regulate the practice of pharmacy." That subsection explicitly requires such regulations to include criteria for "[m]aintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia" (Va. Code § 54.1-3307(A)(4)) and "[s]uch other factors as may be relevant to, and consistent with, the public health and safety." (Va. Code § 54.1-3307(A)(9).

Chapter 628 of the 2022 Acts of Assembly directed the Board to promulgate emergency regulations related to pharmacy working conditions.

## Purpose

*Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.*

The purpose of the emergency regulations is to safeguard the health, safety, and welfare of patients by ensuring safe working environments exist for pharmacists and pharmacy personnel, ensuring a pharmacist's authority and control over the practice of pharmacy is not usurped by the pharmacy permit holder, and ensuring proper breaks are provided for pharmacists while protecting patient safety.

## Substance

*Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.*

In general, the substantive provisions: (i) ensure that the decisions of the pharmacist are not overridden by the pharmacy permit holder, including staffing decisions and the decision of whether pharmacy staff can safely provide vaccines at a given time; (ii) ensure that pharmacy permit holders provide sufficient staffing levels to avoid interference with a pharmacist's ability to practice with reasonable competence and safety; (iii) ensure that a pharmacist and pharmacy personnel are provided with proper and functioning equipment; (iv) ensure pharmacists and pharmacy staff are not burdened with external factors that may inhibit the ability to provide services to the public; (v) ensure staff are properly trained to provide the services they are tasked with; (vi) ensure pharmacists are provided appropriate breaks while maintaining drug stock integrity and providing required consultation services to the public; (vii) ensure pharmacists are provided adequate time to perform professional duties; and (viii) provide a reporting mechanism for staffing concerns.

## Issues

*Identify the issues associated with the regulatory change, 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, include a specific statement to that effect.*

1) The primary advantages to the public are provision of pharmacy services in a safe and efficient manner. There are no disadvantages to the public.
2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth and the directive included in Chapter 628 of the 2022 Acts of Assembly. The Board is authorized under § 54.1-2400 "[t]o 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 . . . 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 promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

## Requirements More Restrictive than Federal

*Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.*

There are no applicable federal requirements.

## Agencies, Localities, and Other Entities Particularly Affected

*Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

Other State Agencies Particularly Affected – none

Localities Particularly Affected – none

Other Entities Particularly Affected – none

## Economic Impact

*Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.*

**Impact on State Agencies**

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| *For your agency*: projected costs, savings, fees, or revenues resulting from the regulatory change, including:<br>a) fund source / fund detail;<br>b) delineation of one-time versus on-going expenditures; and<br>c) whether any costs or revenue loss can be absorbed within existing resources. | There are no expected costs, savings, fees, or revenues to the agency from this regulatory change. |
| *For other state agencies*: projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures. | There are no expected costs, savings, fees, or revenues to other state agencies from this regulatory change. |
| *For all agencies:* Benefits the regulatory change is designed to produce. | There is no benefit to state agencies. |

**Impact on Localities**

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.*

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| Projected costs, savings, fees, or revenues resulting from the regulatory change. | There are no expected costs, savings, fees or revenues to localities from this regulatory change. |
| Benefits the regulatory change is designed to produce. | There are no expected benefits to localities from this regulatory change. |

**Impact on Other Entities**

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.*

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect. | The entities that will be affected are owners of pharmacies, including chain pharmacies. The individuals that will be affected or impacted are pharmacists and pharmacy technicians. |
| Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated, and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | The agency has no estimate of the number of corporations or other entities which may be affected, since many hold more than one pharmacy permit. However, as of September 30, 2023, there were 1,751 permitted pharmacies in the Commonwealth. As of the same date, there were 16,606 licensed pharmacists and 13,310 registered pharmacy technicians in the Commonwealth. |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:<br>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br>c) fees;<br>d) purchases of equipment or services; and<br>e) time required to comply with the requirements. | Record keeping and administrative costs associated with these regulations should be minimal. The Board has provided a form for reporting workplace safety issues. The costs involved to print and/or keep such form in paper copies would be negligible. Businesses may also elect to save the forms electronically, further limiting the cost.<br><br>The proposed regulations do not require any business to hire employees, but employers that inadequately staffed pharmacy locations as a business practice may incur additional staffing costs. Those costs are related to complying with basic standards of care, however, not complying with regulation, and should not be included. |
| Benefits the regulatory change is designed to produce. | The regulatory change is not intended to provide any monetary benefit to stakeholders. |

## Alternatives to Regulation

*Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.*

Chapter 628 of the 2022 Acts of Assembly requires the Board to promulgate regulations. There are no alternatives to regulatory action.

## Regulatory Flexibility Analysis

*Consistent with § 2.2-4007.1 B of the Code of Virginia, 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. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.*

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The Board has analyzed the issues surrounding pharmacy working conditions, pharmacist and pharmacy technician burnout, and danger to patients and the public as a result of these issues for years. The Board reviewed methods used by other states in addressing working conditions and involved stakeholders in the drafting of the original guidance surrounding pharmacy working conditions in Virginia. The resulting regulations are necessary to protect the public while ensuring employers of pharmacists and pharmacy technicians assume responsibility for the conditions of permitted pharmacies.

## Periodic Review and Small Business Impact Review Report of Findings

*If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.*

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Not applicable.

## Public Comment

*Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.*

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| Commenter | Comment | Agency response |
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| Virginia Association of Chain Drug Stores, via letter | Requests that "uninterrupted" be stricken from new language added to 18VAC110-20-110(B) so that pharmacists can supervise pharmacy technicians and other staff while on break. | Making such a change to enable a pharmacy to require a pharmacist to keep working while on break defeats the purpose of the regulations and the enacting legislation. HB1324 requires the Board to promulgate regulations "stating standards for |

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| | | uninterrupted rest periods and meal breaks for pharmacy personnel." Additionally, the ability to continue supervision of pharmacy technicians or pharmacy interns while the pharmacist is on break is covered in 113(B)(5)(b). |
| | Requests amendment to 18VAC110-20-110(C) to state that a PIC or pharmacist control all clinical aspects of the practice of pharmacy. | This change would conflict with statutory law, and this regulatory language has been in place since at least September 2005. Virginia Code § 54.1-3434 requires that an application for a pharmacy permit "shall be . . . signed by a pharmacist who will be in full and actual charge of the pharmacy." Under the same statute, if an owner is not a pharmacist, the owner "shall not abridge the authority of the [PIC] to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations." Finally, § 54.1-3434 states that the pharmacy permit "shall be issued only to the pharmacist who signs the application as the [PIC] and as such assumes the full responsibilities for the legal operation of the pharmacy." (Emphasis added.) Thus, applicable statutory language does not limit required supervision to "clinical" aspects. The Board has no jurisdiction to make such a change. |
| | Requests that Board consider that permit holders are responsible for federal and state compliance but may not be able to control such compliance if PICs are in control of the pharmacy workspace. | Permit holders and PICs must work collaboratively. As stated previously, Virginia Code § 54.1-3434 gives PICs significant responsibility over the operation of the pharmacy. Yet, under Virginia Code § 54.1-3316(13), the Board may discipline a permit holder for endangering the health and welfare of the public. Pharmacy permit holders should consult with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of care. Permit holders should ensure that their decisions are not overriding the control of the PIC or other pharmacist on duty and, via consultation with pharmacy staff, that permit holders are providing a working environment for all pharmacy personnel that protects the health, safety, and welfare of patients. |
| | Requests that 18VAC110-20-113(C) state that the permit holder may not override the PIC on clinical aspects of pharmacy and, additionally, that 113(C) limit any | Any such limitation on PIC decisions conflicts with Virginia Code § 54.1-3434 as noted above. Allowing a PIC to refuse to issue vaccines only when one immunizer is on duty (which would include pharmacy interns and |

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| | PIC decision not to offer vaccines to circumstances when one immunizer is on duty (rather than one pharmacist as included in the emergency language).<br><br>Comment also presented other questions related to application of the regulatory language. | pharmacy technicians) would limit the PIC's supervision of the pharmacy under Virginia Code § 54.1-3434 in a manner the Board does not agree with. Additionally, an immunizer that is not a pharmacist must work under the supervision of a pharmacist and cannot operate independently. A pharmacist has the authority to determine that the pharmacist cannot provide such supervision of an immunizer while providing patient care.<br><br>The Board may address these issues in a guidance document if it believes it is necessary. |
| Kaiser Permanente, via letter | Expressed concern regarding the language in 18VAC110-20-113(B)(3) which states that permit holders shall "[a]void the introduction of external factors, such as productivity or production quotas or other programs, to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public." The letter describes benchmarking tools used as objective measures to monitor logistical functions and to lessen risk and improve quality of care, among other uses. The letter requests that, if the language remains, that the Board allow use of production quotas or programs that support objective observations and fair comparisons. | The Board deliberately included the language "to the extent that [the external factors] interfere with the pharmacist's ability to provide appropriate professional services to the public" to address this issue. HB1324 also contained this language. The Board recognizes that objective metrics can be useful tools to assist in provision of healthcare services to the public. The regulatory language is intended to address permit holders imposing external factors on pharmacists and pharmacy technicians to the extent that the external factors interfere with the provision of services to the public. Therefore, the Board believes this is adequately addressed in the emergency language. |
| Jeenu Phillip, on behalf of Walgreens, via Town Hall | Comment requests that, in this action, the Board eliminate the 4:1 technician ratio, eliminate the 2-year experience requirement to serve as a PIC, eliminate unannounced inspections of pharmacies, allow support staff in the pharmacy to perform duties they are currently not able to, and amend remote verification standards.<br><br>Requested to amend 113(A) to change "[a] permit holder's decisions shall not override the control of the PIC or other pharmacist on duty" to "[a] permit holder shall work in collaboration with the PIC or other pharmacist on duty." | Actions which are outside of the scope of the legislation cannot appropriately be addressed in these regulations, even if a tangential relationship exists between those suggestions and pharmacy working conditions. Additionally, eliminating unannounced inspections in favor of only scheduled inspections presents a danger to the public in that bad actors can falsify or manipulate records prior to a scheduled inspection.<br><br>This request conflicts with the broad responsibility given to the PIC under Virginia Code § 54.1-3434. The language as presented in the emergency regulation appropriately reflects the responsibility of the PIC under § 54.1-3434. |

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| | Requested to amend 113(B)(1) and (B)(4) to add the language "[a]long with the PIC," thereby making the requirements in (B)(1) and (B)(4) the responsibility of the PIC and the permit holder. | This request would shift the burden for providing adequate staff to the PIC, which is not the intent of the enacting legislation or the emergency regulations. |
| | Comment additionally addresses issues which are business decisions within pharmacy operations. The comment requests an addition to 113(C) which would add requirements to the pharmacist prior to ceasing patient care due to staffing issues. | Regulating business decisions within pharmacies would be overly prescriptive and limiting to businesses. Additionally, imposing more requirements on pharmacists who are attempting to protect patient safety by ceasing care when understaffed could exacerbate the potential patient harm issue. |
| | Requests that the Board define "quotas" and "metrics" within the regulation and issue guidance on the proper use of quotas and metrics. | The Board declines to define quotas and metrics in this action. Doing so would limit the Board's authority, as some providers use different terminology for quotas and metrics, yet the concept is the same. Additionally, the Board does not intend to issue guidance on how permit holders should use quotas and metrics. HB1324 and the Board's proposed regulations only impact quotas and metrics when those actions interfere with the ability to provide appropriate professional services. |
| | Stated concerns about the 48-hour response time in 113(D) due to weekends or holidays. Requests 72-hour response time to account for these factors. | 48 hours is the standard timeframe for producing documentation for inspection by the Board from the time at which the inspector requests documentation. For example, in 18VAC110-20-240, records in off-site storage "shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent." |
| | Requested the ability to submit form electronically. | The Board has addressed this issue by modifying the regulatory language to allow permit holders to develop a form provided that form contains all information required in the form developed by the Board. |
| | Requests amendment to 113(D)(2) to state that the PIC or pharmacist on duty "shall communicate their concerns directly to their immediate supervisor or permit holder. If these concerns go unresolved or need immediate escalation, they may report directly to the Board." | This request creates a new requirement that the PIC or pharmacist on duty must perform when that individual believes staffing concerns are endangering the welfare of the public. The current language does not include this requirement for the PIC or pharmacist on duty and the Board declines to include such a requirement. Additionally, this |

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| | | suggestion appears to limit when a PIC or pharmacist on duty may bring safety issues to the Board. There is no such limitation in current law, nor does the Board have jurisdiction to impose such a limitation. |
| 57 comments via Town Hall | Commenters stated support for the regulations and the Board action. | The Board appreciates the support. |
| Pharmacist with Giant Food Pharmacy | Requests that the employer of the PIC be added to 18VAC110-20-113(A) and (B), or a corporate employer may hold the PIC liable for those sections although the PIC has no control over those issues.<br><br>Commenter states that employer has threatened legal action against any PIC who removes a pharmacy permit upon leaving. The commenter requests that the PIC be allowed to notify the Board in writing of the PIC leaving the position rather than surrendering the pharmacy permit.<br><br>Requested that any staffing form submitted by a PIC to the permit holder pursuant to 113(D) be sent to the Board as well. | 18VAC110-20-113(A) and (B) state requirements for the *permit holder*. While the PIC's name is on the permit, the owner of the pharmacy is considered the permit holder. The permit holder, not the PIC, is therefore responsible for those actions. Including the PIC's employer in those provisions would be redundant.<br><br>Existing statutory law (Va. Code § 54.1-3434) requires that the PIC surrender the pharmacy permit to the Board upon the PIC leaving the position. The Board cannot enact regulatory language which conflicts with the Code.<br><br>The Board should not receive a copy of every staffing form submitted by a PIC to a permit holder. The receipt of such a staffing report would constitute a filed complaint that must be processed administratively and formally investigated by the Board. That would significantly increase workload for Board staff for issues that can be resolved internally rather than initiating a Board investigative process. |
| 26 comments via Town Hall | Commenters state that regulations are not law and request changes that the Board has no jurisdiction to regulate or are outside of this regulatory action, which is in response to specific legislation. Those requests include: more pay for pharmacists and pharmacy staff; imposing regulations which require physical inspection for enforcement on nonresident pharmacies; regulation of pharmacy benefit managers; expansion of the pharmacist-to-technician ratio; regulation of remote processing; removal of the 2-year practice requirement for a licensee to act as PIC; stop performing unannounced inspections of pharmacies and | The regulations promulgated by the Board are enforceable laws of the Commonwealth.<br><br>Actions which are outside of the scope of the legislation cannot appropriately be addressed in these regulations, even if a tangential relationship exists between those suggestions and pharmacy working conditions. Additionally, some suggestions, such as the Board no longer performing unscheduled inspections and only perform scheduled inspections, would negatively impact public health and safety, and would allow bad actors to ensure regulatory violations were addressed only during inspection. Finally, the Board does not have jurisdiction over several issues raised by the commenters, such as salary. |

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| | move to scheduled inspections only; requests to change portions of regulations which are not part of this regulatory action; and eliminate or limit pharmacists answering phone calls. | The Board does recognize the frustration evident in many of these comments related to the pharmacy system in Virginia and is sensitive to the effect these issues have on access to care, particularly reimbursement issues. |
| 7 comments via Town Hall | Several commenters requested amendments to require that a pharmacist never works alone. | This change would be overly restrictive and would negatively impact certain practice settings, such as overnight hospital pharmacies or any pharmacist brought in from on-call status. Additionally, 113(B)(1) is intended to ensure adequate personnel are scheduled to work. |
| VSHP via Town Hall<br><br>Josh Crawford via Town Hall<br><br>Natalie Nguyen via Town Hall<br><br>Ian Orensky via Town Hall | Requests clarification of on-call pharmacists and requests an exemption for residents. Specifically, several commenters have asked whether a pharmacist acting as "on-call" for 12 hours is considered working during that time or considered working only when activated from on-call status. This can particularly impact residents. | The standard definition of "work" does not include "on-call" situations. The Board did not intend for these regulations to apply to on-call situations. Work done by a pharmacist while on-call may constitute an "emergency" and would not be subject to this. If a pharmacist is brought in from on-call status repeatedly, that may constitute a staffing issue that should be addressed by the permit holder. |
| | Requests that any use of the term "prescriptions" in the regulations be defined to include "medication orders" to ensure compliance in hospital setting. | Virginia Code § 54.1-3401 defines "prescription" as "an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies." This broad definition does not exclude medication orders. |
| Virginia Pharmacy Association via Town Hall | Recommends amending 18VAC110-20-113(C) to include prohibition of direct or indirect disciplinary action or retaliation against a PIC or pharmacist on duty who exercises appropriate control over pharmacy operations. | This prohibition on retaliation is included in 113(D)(3). Any exercise of the pharmacist's authority under 113(C) would constitute a staffing concern, thereby activating the provisions of 113(D). Therefore, the Board declines to add a similar or identical provision to 113(C) because the issue is addressed in 113(D). |
| CVS Health, via Town Hall | Requests that the staffing issues form be available in electronic form. | The Board has addressed this issue by modifying the regulatory language to allow permit holders to develop a form provided that form contains all information required in the form developed by the Board. |
| 9 comments via Town Hall | Commenters state that pharmacies are not complying with the emergency regulations. | The emergency regulations became effective on October 23, 2023, the same day the comment forum opened. The Board will continue to provide information and education to pharmacy stakeholders, |

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| | | including licensed pharmacists, regarding the emergency regulations and the steps each party needs to take to ensure that the Board is aware of problems. |
| 5 comments via Town Hall | General comments that do not support or oppose the regulation, but state that the Board has no power to enforce the regulations, that they will remain unenforceable, or that the current situation will not change. | The Board is able and capable of enforcing its regulations. The Board will provide information and education to pharmacy stakeholders, including licensed pharmacists, regarding the emergency regulations and the steps each party needs to take to ensure that the Board is aware of problems. |
| 104 comments posted to Town Hall from the same IP address within minutes | These comments likely originated from one source or only a few sources posting from the same location. The comments generally supported working conditions regulations but also listed problems with the practice of pharmacy in general. | The Board appreciates support for the regulations. |

*Note: Many comments covered a range of issues and were addressed in multiple areas of this table. Those comments may be counted in more than one place.*

## Public Participation

*Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.*

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of the background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at https://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. In order to be considered, comments must be received by 11:59 pm 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 (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

## Detail of Changes

*List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.*

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*If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between the existing VAC Chapter(s) and the proposed regulation. If the existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.*

**Table 1: Changes to Existing VAC Chapter(s)**

| Current chapter-section number | New chapter-section number, if applicable | Current requirements in VAC | Change, intent, rationale, and likely impact of new requirements |
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| 20-110 | | Pharmacy permit holders cannot require a pharmacist to work longer than 12 continuous hours except in an emergency. Pharmacists working longer than six continuous hours must be provided a 30-minute break. | Under the amendments, a pharmacist may volunteer to work longer than 12 continuous hours. Additionally, the amendments require that breaks be provided consistent with 18VAC110-20-113(B)(5).<br><br>The amendments will permit pharmacists to volunteer for longer shifts but keeps the prohibition on permit holders requiring that pharmacists work more than 12 continuous hours. Additionally, the amendments refer back to the new section 20-113 to ensure breaks are provided appropriately. |
| | 20-113 | N/A | Subsection A requires that the pharmacy permit holder protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other staff to ensure services are safely provided. Subsection A prohibits the permit holder from overriding the control and decision-making of the PIC or pharmacist on duty regarding appropriate working environments. The rationale and likely impact of this provision is to guarantee that the decisions of the PIC or pharmacist on duty is not superseded by the permit holder at the expense of the safety of the public.<br><br>Subsection B lists the minimum requirements for a permit holder to provide a safe pharmacy working environment. Those include: (i) sufficient staffing and appropriate management of staffing levels; (ii) provision of sufficient tools and equipment, and minimization of |

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| | | | distractions to ensure a safe workflow for a pharmacist to practice; (iii) avoidance of external factors, such as production quotas; (iv) ensuring staff are sufficiently trained to perform assigned tasks and work with appropriate supervision; (v) provision of uninterrupted rest periods for pharmacists; (vi) provision of adequate time for pharmacists to complete professional duties; and (vii) assurance that pharmacy technicians do not perform duties restricted to pharmacists.<br><br>The intent and rationale behind these provisions is creation of a baseline for safe working conditions for pharmacists and pharmacy staff, with the further intent of ensuring the pharmacist and pharmacy staff are able to provide services safely to the public. These minimum requirements address the subjects included in Chapter 628 of the 2022 Acts of Assembly.<br><br>Subdivision (B)(5) additionally provides specific requirements for pharmacist break periods. The pharmacy may close during a pharmacist's break period based on the professional judgment of the pharmacist on duty as long as the pharmacy has complied with public notice requirements contained in Va. Code § 54.1-3434 and 18VAC110-20-135. If the pharmacy does not close during a pharmacist's break, the pharmacist must ensure security of drugs in the pharmacy by remaining in the pharmacy department or on the premises. Additionally, the pharmacist must determine if pharmacy technicians or pharmacy interns on staff may continue to perform duties while the pharmacist is on break. Subsection (B)(5)(c) contains responsibilities regarding patient counseling required by Va. Code § 54.1-3319 is provided immediately following the pharmacist's break. The rationale behind these amendments is to provide options and minimum requirements for pharmacist break periods, including options for the pharmacy closing or remaining open during the pharmacist break period.<br><br>Subsection C states that a permit holder shall not override the control of the |

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| | | | pharmacist on duty regarding any aspects of the practice of pharmacy. Although this is implied in other provisions of regulation and statute, this provision is meant to state the obvious and specifically prohibit encroaching on a pharmacist's professional responsibilities.<br><br>Subsection D provides a mechanism for internally reporting and recording staffing issues and resolving reported issues. Subsection D further prohibits workplace discipline against pharmacists or other pharmacy staff for good faith reporting of staffing concerns. The intent behind these provisions is to provide requirements for internal reports of staffing concerns and documentation of those concerns. The amendments additionally intend to require that a permit holder provide any staffing concern forms provided by staff to the permit holder to Board inspectors. |

**Table 3: Changes to the Emergency Regulation**

| Emergency chapter-section number | New chapter-section number, if applicable | Current <u>emergency</u> requirement | Change, intent, rationale, and likely impact of new or changed requirements since emergency stage |
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| 113 | N/A | Subsection C states that "[a] pharmacy permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy . . ." | Subsection C is changed to refer to "any aspects of the practice of pharmacy" for accuracy and clarity. |
| | | Subsection D requires staffing requests or concerns to be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the Board. | Subsection D is changed to clarify that staffing requests or concerns described in section 113 are the subject of D. Additionally, a change was made to allow permit holders to use a form which contains identical information to the form developed by the Board to allow permit holders to use internal electronic forms as long as those forms contain the information in the Board-developed form. |
| | | D 1 requires that executed staffing forms maintained in the pharmacy must be produced for inspection by the Board. | D 1 is changed to clarify that executed staffing forms maintained in the pharmacy must be produced for inspection by the board within 48 hours of request, consistent with E 3. |

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| | | D 3 states that good faith reports of staffing concerns or notification of staffing issues to the PIC or pharmacist on duty cannot result in workplace discipline against the reporting staff member. | D 3 is changed to clarify that good faith notification of staffing concerns to the PIC, pharmacist on duty, or the Board cannot result in workplace discipline against the reporting staff member. |