Virginia Regulatory Town Hall

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# Notice of Intended Regulatory Action (NOIRA) Agency Background Document

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| **Agency name** | Board of Pharmacy, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation** | 18VAC110-20-10 et seq. |
| **Regulation title** | Regulations Governing the Practice of Pharmacy |
| **Action title** | Modifications to requirements for automated dispensing devices |
| **Date this document prepared** | 9/23/11 |

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 Board of Pharmacy received three petitions for rulemaking from hospital pharmacists requesting an amendment to #5 of section 490 in Chapter 20, which provides requirements for automated devices for dispensing and administration of drugs. The petitioners requested less burdensome requirements for verification of storage, location, expiration dates, drug security and validity of access codes.

While the Board agreed that the petition was reasonable and the specific requirements in #5 may need to be modified for consistency with current technology, it concluded that all of section 490 should be examined for possible amendments that would ensure drug security and integrity but would make compliance less burdensome.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations:

***§ 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.*

As one of the petitioners stated, automation has been designed and updated to improve drug storage, security and safety, while streamlining work processes and increasing efficiencies. Advancements in technology can accommodate verification requirements that currently require manual processes. The Board will consider changes to the process and/or parameters to decrease the amount of time required to comply with monthly audits. Certain software that analyses automated dispensing machine transactions could substitute for some of the manual reconciliation process. Hospitals report that the software reports can more quickly and efficiently identify possible diversions from the machines. Taking advantage of technology to replace some of the manual processes appears to be advisable for public health and safety because it could allow pharmacists to spend more time focused on patient care and still continue to protect against diversion.

## Substance

*Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

The petitioners requested modifications to #5 of section 490 to change the requirement that automated dispensing devices must be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates the security of drugs and validity of access codes. Devices with technology that has certain capabilities would not require the same manual verification in a monthly inspection. However, the pharmacy would conduct a focused review on overrides or transactions that are outside the norm.

In addition to consideration of changes recommended by the petitioners, the Committee will review all of section 490 for less burdensome alternatives or clarifications consistent with current technology and public safety.

## 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.*

To be responsive to the petitions for rulemaking and the need to review the requirements for less burdensome options, there are no alternatives other that regulatory action.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

The agency/board is seeking comments on the intended regulatory action to replace the emergency regulations with permanent regulations, including but not limited to 1) ideas to assist in the development of a 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/board 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) 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 send them to Elaine Yeatts at the 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 or by posting on the Regulatory Townhall at www.townhall.virginia.gov . Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period on the Notice of Intended Regulatory Action.

At the conclusion of the NOIRA comment, the Board will adopt proposed regulations. A public meeting will be held and notice of the meeting will be found in the Calendar of Events section of the Virginia Register of Regulations after Executive Branch review and approval to open the regulation for 60 days of public comment. Both oral and written comments may be submitted at that time.

## Participatory approach

*Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.*

The Board will utilize the participatory approach as members of the Regulation Committee will review section 490 on automated dispensing devices, since its membership includes persons with expertise in hospital pharmacy systems. Additionally, pharmacy staff of the Board have expertise in automated devices and will be able to offer advice in the process. The Virginia Society of Hospital Pharmacies will be invited to attend and participate in the development of regulatory language, and public comment will be encouraged as the Committee considers 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.*

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