Virginia Regulatory Town Hall

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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) citation** | 18VAC110-20-10 et seq. |
| **Regulation title** | Regulations Governing the Practice of Pharmacy |
| **Action title** | Modifications to requirements for hospital automated dispensing devices |
| **Date this document prepared** | 7/10/12 |

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 Board of Pharmacy received three petitions for rulemaking from hospital pharmacists requesting an amendment to the requirement for a monthly audit of automated dispensing devices (ADD) in 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. Rather than simply addressing the monthly audit provision, the Board determined that a review of the entire section was appropriate to allow more flexibility in the use of ADD's.

## 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.*

ADD – automated dispensing device

## 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:

***§ 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.*

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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 has adopted 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 and drug security.

## 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.)*

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The petitioners requested modifications to section 490 to change the requirement that automated dispensing devices must be manually 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. The proposed regulations reorganize requirements for use of ADD's in hospitals to clarify the process and also provide exceptions from certain audits for devices with technology that has the capability for monitoring, detection, reconciliation and analysis.

## 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 proposed changes are a significant advantage to pharmacists and the hospitals in which they work. If they are able to substitute electronic monitoring and reporting for manual procedures, the hours spent in compliance with current regulations can be redirected to tasks associated with patient care. The Board does not perceive any disadvantages or risks associated with substitution of manual audits and inspections with reconciliation software that can detect possible diversion.
2) There are no advantages or disadvantages to the agency; pharmacy inspections will continue to include records required for automated dispensing devices.
3) There are no other pertinent matters of interest.

## 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.*

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| **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 a one-time expense of less than $1,000 for promulgation of the amended rule. All notifications will be done electronically to minimize the cost. There are on-going expenditures for the agency related to changes in rules for automated dispensing devices. |
| **Projected cost of the *new regulations or changes to existing regulations* on localities.** | None |
| **Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.** | The entities that would be affected are hospital pharmacies that utilize automated dispensing devices. |
| **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 owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | Since the Board does not license pharmacies by type of practice, it is unknown how many hospital pharmacies and how many automated dispensing devices would be positively affected by the less restrictive regulation. |
| **All projected costs of the *new regulations or*** | There would no projected costs to the amended |

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| ***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.** | regulations which are intended to reduce the current staff time needed for audits. Hospitals would not be required to purchase any additional software but could take advantage of an exemption from monthly audits if they have access to software that analyzes ADD transactions. |
| **Beneficial impact the regulation is designed to produce.** | There would be a reduction in personnel costs for compliance with Board rules since software in most automated systems could be substituted for monthly manual audits. One hospital stated that the current process requires about 48 man-hours every month with little or no result. Software designed to identify transactions outside the norm allows for a focused audit or investigation of discrepancies. |

## 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.*

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

## 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. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of 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 proposed regulation.*

The agency has responded affirmatively to a petition for rulemaking from hospital pharmacists who requested the proposed changes as less stringent reporting/auditing requirements consistent with health and safety of prescription drugs in hospitals.

## Public comment

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

There were no comments on the NOIRA, but there were 15 comments from hospital pharmacists in full support of the changes recommended by the petition for rulemaking.

## 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 and family stability.

## 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.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

| Current section number | Current requirement | Proposed change, intent, rationale, and likely impact of proposed requirements |
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| 490 | Subsection A establishes that a hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460. | The section has been reorganized to make it easier for pharmacists to follow the steps that must be taken in the use of ADD's for dispensing and administration of controlled substances. |
| | Subsection B sets out the requirements for a | #1 of this subsection is identical to #8 in the |

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| | policy and procedure manual and for identification of users by access codes. | current section 490.<br>#2 of this subsection is identical to #7 in the current section 490, but authorizes the use of biometric identification or other coded identification that can eliminate sharing or theft of access codes. |
| | Subsection C describes the record for distribution of drugs from the pharmacy to be placed in the ADD. | The regulation is identical to #1 and #2 in the current section 490. |
| | Subsection D describes the record for distribution of drugs from the ADD | #1 of this subsection is identical to #3 of current section 490. The requirement for chronological filing if taken from current #9.<br>#2 is identical to #5 in the current section 490. |
| | Subsection E sets out the requirement for discrepancy reports. | This subsection is identical to #4 b of current section 490. |
| | Subsection F sets out the requirements for reviews and audits. | In the current regulation, the terms audit and review are used interchangeably. In fact, they are different processes, so the proposed regulations make a distinction about when an audit is necessary and appropriate.<br><br>Current regulations (#4 e) require a monthly *audit* for compliance with procedures for security and use of the ADD. Proposed regulations (F 1) specify a *review* of compliance, including procedures for termination of access codes when applicable.<br><br>In #2 of subsection F, the requirement for a monthly audit of distribution from the ADD is identical to #4 in current regulation with the following exceptions:<br>• The requirement for a discrepancy report is now in subsection E.<br>• A pharmacy that has a method for perpetually monitoring drugs dispensed from the pharmacy and loaded into the ADD <u>can limit</u> the audit to discrepancies or exceptions as identified by the monitoring method.<br><br>In #3 of subsection F, the requirement for a monthly audit of administration from the ADD is set forth. The current requirement for a monthly audit of administration records is amended by: 1) deleting the phrase "a sample" since the requirement is a review of "<u>all</u> Schedule II-V drugs administered for a |

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| | | time period of not less than 24 consecutive hours" (the term "sample" was confusing and not consistent with the regulation); 2) deletion of a requirement to check medical records as not necessary or practical; 3) an exemption from the audit requirements if reconciliation software can provide a monthly statistical analysis based on peer-to-peer comparisons for use and monitoring of overrides and unresolved discrepancies; and 4) a requirement for a focused audit of suspicious activity as identified by the report produced by the ADD software. |
| | Subsection G sets out requirements for monthly inspections of the devices | The requirement is identical to current #6 but the proposed regulations provide an exception from the need for a physical inspection if the device has the capability to perform certain functions electronically and automatically. For example, the ADD must monitor temperature ranges, use a machine readable product identifier, electronic tracking of expiration dates and electronic detection of opening and the identification of the person accessing the device. Since the vast majority of modern ADD's have such capability, the exception to a physical inspection is a significant savings in time and effort on the part of the pharmacists in a hospital. |
| | Subsection H sets out the requirements for maintenance of records associated with ADD's and their audits and reviews. | The amended regulations are virtually identical to current regulations except the requirement for signatures is changed to initials for ease of compliance. |