Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Robotic Technology
Date:	11/28/00

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

Amendments to regulations are adopted pursuant to a petition for rule-making that requested a Board waiver of its requirement for a final check by the pharmacist if a drug is being dispensing by a robotic pharmacy system which assures accuracy of the final dispensing point through bar scanning technology. The regulations require approval of such a system by an informal conference committee of the Board based on an inspection of the system and on a quality assurance plan adopted by the pharmacy. Application and inspection fees are established to offset the costs of initial approval or review of a modified system.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On November 27, 2000, the Board of Pharmacy adopted final amendments to 18 VAC 110-20-10 et seq., Regulations Governing the Practice of Pharmacy, in order to implement robotic technology in hospital pharmacies.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

1. *To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*

3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*

4. *To establish schedules for renewals of registration, certification and licensure.*

5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*

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 and Chapter 25 of this title.*

7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*

8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*

9. *To take appropriate disciplinary action for violations of applicable law and regulations.*

10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.*

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*

12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.

Chapter 33 establishes the Board of Pharmacy and authorizes the Board to license and regulate pharmacies engaged in filling and dispensing prescription medications.

The Board of Pharmacy is mandated by **§ 54.1-3307** to regulate the practice of pharmacy, including the dispensing and distributing of drugs and devices. In the promulgation and enforcement of regulations, the Board is authorized to consider specific criteria as set forth in the Code.

§ 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.
The Board may collect and examine specimens of drugs, devices and cosmetics which are manufactured, stored or dispensed in this Commonwealth.

Chapter 34 establishes the Drug Control Act and authorizes the Board to ensure the safety and efficacy of the drugs prescribed and administered in the Commonwealth.

The Assistant Attorney General who provides counsel to the Board has certified that the Board has the authority to promulgate the amended regulations and that they do not conflict with existing state or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Amendments are adopted to ensure the protection for the health, safety and welfare of patients of hospitals or long term care facilities who depend on the protection and integrity of prescription drugs consistent with the Board's statutory mandate in Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*.

The petition for rule-making that precipitated the adoption of amendments to regulations requested a change or waiver in Board regulations that require the pharmacist to check each prescription dispensed for accuracy at the end of the process prior to it going to the patient (18 VAC 110-20-270 B). With use of the robot, the end of the process is checked by a bar code scanner which provides better accuracy than human checking. The points for inaccuracy in this system come in places other than the end. It could occur with the packaging of drugs in the bar-coded packages. According to information provided by Medical College of Virginia Hospitals, if the correct drug is placed in the packaging and bar-coded properly, then the robot will not make a mistake resulting in the incorrect drug being dispensed. MCV and other hospitals asked that the rules be amended to allow for pharmacist checking to occur at other points in the dispensing process where errors can occur and cause the wrong drug to be dispensed, rather than check each and every drug at the end of the process.

To ensure that the robotic system is performing accurately, the Board has required the submission of a quality assurance plan that will be reviewed by an informal conference committee prior to approval of a waiver. Only after the Board is satisfied that the plan provides the necessary safeguards and checks on the filling of unit dose carts by a robotic system will it approve a waiver of the requirement for the pharmacist to check each prescription before being delivered to the patient. As further protection, the Board has required that a pharmacist must review all data entry of prescription orders into the computer operating the system for accuracy and appropriateness of therapy and must also check all repackaged medication prior to loading into the system.

Proposed regulations authorize the board to withdraw approval of a waiver for failure to comply with the quality assurance plans to failure to meet other terms and conditions which were set in the initial approval. Further, the Board is authorized to conduct inspections of the systems at any time and is required to do so if modifications are made.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The Board has proposed a process and fee of approval of a robotic pharmacy system to make a determination on the acceptability of a system to be used in a pharmacy providing services to a hospital or long term care facility. Also, requirements are added to this chapter to provide a conditions by which a pharmacy may apply for the use of a robotic pharmacy system and continue to provide the safety and quality assurance for prescription drugs.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

ISSUE: Necessary safeguards to assure prescription accuracy in a robotic pharmacy system.

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Advantages and disadvantages to regulated entities

Some entities (hospital pharmacies) that requested amendments to regulations have already purchased a robotic pharmacy system. For them, these amendments would permit more efficient, less costly utilization of their systems if the Board is authorized to waive a time-consuming function that may only be performed by a licensed pharmacist. Through quality assurance plans adopted by the hospital or long term care facility, the safety of the drug being dispensed may be protected without a final check of each prescription before it leaves the pharmacy.

With the adoption of these regulations, other entities (pharmacies serving hospitals or long-term care facilities) may determine that it is more cost-effective to purchase some form of robotic system than it is to employ another pharmacist, a profession in high demand and short supply. The long-term savings and efficiency with the purchase of such a system would expect to offset some of the initial cost.

Advantages and disadvantages to the public

The incorporation of new technology into hospital pharmacies should improve services to the consumers through greater accuracy and speed. Since robotic systems are less labor-intensive, there should be increased efficiencies in the filling of unit dose carts for use on patient floors.

Advantages or disadvantages to the agency

There should be no particular advantage or disadvantage to the agency. Approval of robotic pharmacy systems will necessitate some additional work for staff and board members, but in most cases costs will be covered by fees charged to the applicants or to the pharmacy modifying a robotic system.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public hearing was held before the Board of Pharmacy at the Department of Health Professions in Richmond on October 10, 2000. No comment was presented at that time nor was any written or electronically submitted comment received.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

18 VAC 110-20-10. Definitions.

The proposed amendments define the terms "quality assurance plan" and "robotic pharmacy system" in order to provide clarity in the interpretation and enforcement of new regulations.

18 VAC 110-20-20. Fees.

The Board has proposed a new fee of $150 for board approval of a robotic pharmacy system. It is the minimal amount necessary to process an application and conduct an informal conference proceeding to make a determination on the acceptability of a system as it is being used in a pharmacy providing services to a hospital or long term care facility. Likewise, a fee of $150 has been established to cover the minimal expense to the board for an inspection of a new or modified robotic system.

18 VAC 110-20-425. Robotic Pharmacy System.

A new section is added to this chapter to provide a process and conditions by which a pharmacy may apply for the use of a robotic pharmacy system.

Subsection A specifies that a waiver of the requirement for a final check by the pharmacist may be granted if the system is utilized by a pharmacy providing services to a hospital or long term care facility that uses a unit dose dispensing system and provided the accuracy of the final prescription is determined by a quality assurance plan.

Subsection B specifies that the quality assurance plan must be submitted with the application and sets forth the minimum components of such a plan.

Subsection C specifies the process by which an informal conference committee of the board will review an application and determine approval or denial of a system. It further provides that the board may require an inspection of the system or withdraw approval of a waiver for failure to comply with the quality assurance plan or any other terms and conditions set by the board.

Subsection D provides for notification and board approval of any modification of a system.

Subsection E specifies that the pharmacist must review all data entry of prescription orders into the system for accuracy and appropriateness of therapy and shall check all repackaged medication prior to use in loading the system.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

The Board has reviewed the adopted regulations and concluded that the amendments have no effect on strengthening the authority and rights of parents, on economic self-sufficiency, on the marital commitment or on disposable family income.