Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Pharmacy, Department of Health Professions
VAC Chapter Number:	18 VAC 110-20
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Robotic pharmacy systems
Date:	1-24-00

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments to regulations are proposed 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 proposed to offset the costs of initial approval or review of a modified system. Amendments are proposed 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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

18 VAC 110-20-10 et seq. Regulations Governing the Practice of Pharmacy was promulgated under the general authority of Title 54.1 of the Code of Virginia.

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 office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and / 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 proposed 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.

The purpose of the proposal is to amend regulations 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. The regulations are proposed 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 providing detail of the regulatory action's 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 110-20-421. 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.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

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

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 or 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.

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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget

activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board of Pharmacy must generate sufficient revenue to cover its expenditures from non-general funds, specifically the fees it charges to pharmacies seeking board approval of their robotic pharmacy system and their quality assurance plan as required by amended regulation. An application fee is adopted to overset the cost of processing an application, holding an informal conference. If the system is new and unknown to the board or it has been modified, a fee is assessed to cover the cost of conducting an inspection.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some costs (less than $2000) for mailings to the Public Participation Guidelines Mailing List, conducting a public hearing, and sending copies of final regulations to regulated entities. However, every effort will be made to incorporate those into anticipated mailings and board meetings already scheduled.

The agency will incur on-going costs for processing an application for approval of a robotic pharmacy system. Those costs include staff costs for sending and processing the application and for convening an informal conference committee to review the system and quality assurance plan and act on approval. The application fee is set at $150, which is the amount determined to minimally cover costs incurred, including per diem and travel expenses for two board members to conduct an informal conference. If the system is new and unfamiliar to the board or has been modified since the original approval, an inspection will also be required and a fee of $150 has been established to cover those costs. It is estimated that an inspection of a robotic pharmacy system and quality assurance plan will take from two to three hours at a cost of approximately $65/hour.

Projected cost on localities:

There is no projected costs to localities.

Description of entities that are likely to be affected by regulation:

While four hospital pharmacies signed the initial petition for rule-making, it is expected that there are others that will benefit from amended regulations. That number is not known at this time, but it is likely that pharmacies that handle a high volume of prescriptions (large hospitals, medical centers, or long-term care facilities) would benefit from some type of robotic pharmacy system. Since the board does not categorize licensed pharmacies by type, it is not known how many are hospital pharmacies or provide services to long-term care facilities.

Once amended regulations become effective, each licensed pharmacy will be required to submit an application describing the system and a quality assurance plan for approval by the board. With that process in place, the board will be able to track the types and numbers of systems being used in Virginia pharmacies.

Projected costs to the affected entities:

The 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 the initial cost.

Proposed amendments to regulations would not increase the cost of doing business for any licensed pharmacy but could have the effect of reducing costs over time. While there will be an initial application fee of $150 for board approval of a robotic pharmacy system, it is insignificant compared to the cost of the system and the expected cost-benefit and efficiency for the pharmacy.

Citizen input in development of regulation:

These amendments to regulations were initiated by a petition for rulemaking from the Directors of Pharmacy for the Medical College of Virginia, the University of Virginia Medical Center, the Winchester Medical Center and the Danville Regional Medical Center and from the McKesson MedManagement group. In the development of regulations through the Regulation Committee and the board, opportunities for citizen input were made available. The Board drafted regulations in consultation with persons who are knowledgeable about the robotic pharmacy systems. The Board expects the regulated entities affected by these regulations to have the ability to utilize technology does not anticipate any negative impact on the public.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

18 VAC 110-20-10. Definitions.

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18 VAC 110-20-20. Fees.

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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.

Alternatives

Please describe the specific 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.

A letter dated December 4, 1998 to the Executive Director of the Board described the robot system utilized at MCVH and other hospital systems in Virginia and requested an opinion about the applicability of certain requirements for a pharmacist to check the filling of prescription. Since current regulations are applicable to the use of a robotic system, the hospital was asked to submit a petition for rule-making in order to address the issue and proceed with promulgation of amendments. This petition for rule-making was filed and presented to the Regulation Committee of the Board at its meeting on March 11, 1999. A second petition from McKesson MedManagement for Columbia Richmond Hospitals was presented to the Committee at its May 5, 1999 meeting. After seeing a demonstration of the robotic filling system at MVCH Pharmacy, the Committee agreed to pursue rule-making as it relates to the checking requirement when filling by use of an automated robot. It was initially suggested that the Board might incorporate the issue of filling by robot into the promulgation of emergency regulations authorized by passage of House Bill 2461 (Chapter 750 of the 1999 Acts of the Assembly) relating to automated dispensing devices in hospitals. Subsequently, the Board concluded and Board counsel concurred that the changes necessary to strictly conform regulations to Chapter 750 could be promulgated under an exemption to the Administrative Process Act. Other amendments, such as those necessary to accommodate the robotic type

automation, would require promulgation through the normal process following Executive Order 25 (98) and the APA.

Since the robotic automation is used to actually fill prescription orders for individual hospital patients in unit dose carts, there are requirements for pharmacist checking that go beyond those found in 18 VAC 110-20 490 for other types of automated dispensing devices. In order to address the issues stated in the petition for rule-making, the Board needed to have the regulatory authority to grant a waiver to subsection B of 18 VAC 110-20-270, which requires that "after the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all re-spects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibil-ity for, the entire transaction."

One alternative to amending the rule was to continue to require the pharmacist to check each unit dose drawer filled. This is very time consuming and not the best use of the pharmacist's time. This would diminish the cost effectiveness and usefulness of such technology. Another alternative is to continue to use technicians to fill unit dose carts with pharmacists checking which is even less efficient, particularly in large hospitals, and not as accurate. MCV and other hospitals requested the rule 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 by the robot, rather than check each and every drug at the end of the process.

Prior to its meeting on May 6, 1999, the Regulation Committee accepted the invitation of MCV and met at the hospital to receive a briefing and demonstration of the use of the robotic filling system. With a first-hand view of the system, the board members have a better sense of the safeguards built into the technology and of the points at which error could occur. The Board has established regulations that accommodate the development and implementation of new technology and provide cost-savings in the health care system but continue to protect the safety and efficacy of prescription drugs in the Commonwealth.

To ensure that all necessary safeguards have been taken, the Board has proposed approval of a quality assurance plan for each robotic system in use. Rather than propose the specifics of a plan in regulation, the Board determined that it should establish the minimal components of a plan with the details to be determined by each pharmacy and to be approved by the Board. That will allow some flexibility for new generations of robotic pharmacy systems that are on the horizon. For example, in its proposed quality assurance plan, MCVH suggested a weekly quality control check of all of the doses filled by the robot with a daily check for three days if the robot fell below the standard. Provided no errors are made in earlier stages, the only error the robot makes in actually filling the medication drawers is occasionally picking up the wrong

quantity, not the wrong drug. Pharmacists continue to check all medication doses manually filled.

The Board examined the rules in other states where robotic systems are being utilized. Laws, regulations and guidance papers in states such as Oklahoma, Florida, Ohio, Nevada, and Texas were reviewed and certain portions adopted in the development of rules in Virginia. In addition, the Model Practice Act adopted by the National Boards of Pharmacy was reviewed for applicable definitions and requirements.

Finally, the Board reviewed the operational description of the ROBOT-Rx system, currently in use at several hospitals in Virginia, to determine its capabilities in assuring medication security, information confidentiality, inventory accountability, and quality control.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

The Notice of Intended Regulatory Action was published on September 27, 1999 and subsequently sent to the Public Participation Guidelines Mailing List of the Board; there was no comment received.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Prior to that adoption of proposed amendments, the Regulation Committee of the Board met in an open meeting to review the current regulations in light of regulations governing the practice of pharmacy. The clarity and reasonableness of the language that was adopted had the approval of the Assistant Attorney General who worked with the Regulation Committee in drafting regulatory language and of the board members who represent various types of pharmacy practice and the citizens of the Commonwealth. In addition, the Board sought the advice of the pharmacist-in-charge and an attorney representing the Virginia Hospital and Health Care Association to ensure that the language was clear and not problematic.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public Participation Guidelines of the Board of Pharmacy (18 VAC 110-10-10 et seq.) require a thorough review of regulations each biennium. Therefore, the Regulation Committee of the Board will review this set of regulations in 2002 and will bring any recommended amended regulations to the full board for consideration.

Finally, the Board receives public comment at each of its meetings and will consider any request for amendments. Petitions for rule-making also receive a response from the Board during the mandatory 180 days in accordance with its Public Participation Guidelines.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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 agency has reviewed the proposed regulation in relation to its impact on the institution of the family and family stability. There would be no effect of the proposal on the authority and rights of parents, economic self-sufficiency or the martial commitment. To the extent, the utilization of robotic pharmacy system may improve the efficiency of the prescription delivery system in large hospital systems, the proposal could serve to moderate the acceleration of health care costs. It is unlikely, however, that such efficiencies would have any direct benefit to disposable family income.