PRELIMINARY DETERMINATION
NOTICE OF INTENDED REGULATORY ACTION

DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF PHARMACY
18 VAC 110-20-10 et seq.

Regulations Governing the Practice of Pharmacy

A. Legal authority to promulgate the contemplated regulation.

The Board of Pharmacy is seeking to publish a Notice of Intended Regulatory Action in order to respond to a petition for rulemaking in concurrence with Public Participation Guidelines of the Board (18 VAC 110-10-10 et seq.).

18 VAC 110-10-50. Petition for rulemaking.

A. As provided in § 9-6.14:7.1. of the Code of Virginia, any person may petition the board to develop a new regulation or amend an existing regulation.

B. A petition shall include but need not be limited to the following:

1. The petitioner's name, mailing address, telephone number, and, if applicable, the organization represented in the petition.

2. The number and title of the regulation to be addressed.

3. A description of the regulatory problem or need to be addressed.

4. A recommended addition, deletion, or amendment to the regulation.

C. *The board shall receive, consider and respond to a petition within 180 days.*

D. *Nothing herein shall prohibit the board from receiving information from the public and proceeding on its own motion for rulemaking.*

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.

§ 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to ensure practitioner competency and to promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to effectively administer the regulatory system.

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

9. *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 (§ 9-6.14:1 et seq.). 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.*

B. Statement of potential issues to be addressed.

The issues involved in a potential regulatory change are best stated in a letter and the petition for rule-making that the Board of Pharmacy received from the Pharmacy Manager and Pharmacy Supervisor for the Medical College of Virginia hospitals and three other hospital systems in the Commonwealth that utilize robotics in the automated dispensing of prescription drugs. (See

attachment). In short, the petition requests a change in Board's regulations requiring the pharmacist to check each prescription dispensed for accuracy at the end of the process prior to it going to the patient.

With use of the robot, the end of the process is checked by a bar code scanner which is more accurate that a 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. If the correct drug is placed and bar-coded properly, then the robot will not make a mistake. MCV and other hospitals would like the rule amended to allow for pharmacist checking to occur at other points in the dispensing process where human error could occur and cause the wrong drug to be dispensed, rather than check each and every drug at the end of the process.

C. Statement setting forth the reasoning for the contemplated regulation.

Public participation guidelines of the Board (18 VAC 110-10-50) require it to "receive, consider and respond to a petition for rulemaking within 180 days. The Board is not required to proceed with the promulgation of regulations. However, in this case, the Board has concluded that there is validity to the issues raised by the petition and is seeking permission to publish a Notice of Intended Regulatory Action.

Since the ROBOT-Rx technology is used to actually fill the physicians' prescription orders for an individual patient in unit dose carts used on the floors of the hospital, there are requirements for pharmacist checking that go beyond those found in 18 VAC 110-20 490 for automated dispensing devices. In order to address the issues stated in the petition for rule-making, section **18 VAC 110-20-270. Dispensing of prescriptions; acts restricted to pharmacists; certification of completed prescriptions** would need to be amended. Specifically, subsection B 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 respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction."* In addition, section 420 A 8 d (requirements for unit dose dispensing systems) refers back to subsection B of section 270 and may also need to be amended.

D. Alternatives to be considered.

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. The petition for rule-making was filed and presented to the Regulation Committee of the Board at its meeting on March 11, 1999. The Committee agreed to pursue rule-making as it relates to the checking requirement when filling by use of an automated robot, and 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 robot process at MCV, would require promulgation through the normal process following Executive Order 25 (98) and the APA.

Alternatives to be considered would be for the pharmacist to have to continue to check each unit dose drawer filled which is very time consuming and not the best use of the pharmacist's time. This would make the purchase of such technology not very cost effective. Another alternative is to continue to use technicians to fill unit dose carts with pharmacists checking, which is less efficient and not as accurate, particularly in large hospitals. MCV and other hospitals would like the rule amended to allow for pharmacist checking to occur at other points in the dispensing process where human error could occur and cause the wrong drug to be dispensed, rather than check each and every drug at the end of the process.

In its petition, 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 set. It would also agree that the pharmacist continue to check all medication doses manually filled.

In its petition, MCV hospitals also provided a summary of regulations in other states where the ROBOT-Rx system is being utilized. The Board will consider the alternatives utilized in other states, which include a blanket waiver for a pharmacist checking in lieu of a continuous quality assurance check or a waiver issued to each hospital system on a case-by-case basis.

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 way 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 will seek to establish regulations that accommodate the development and implementation of new technology which will provide cost-savings in the health care system but will continue to protect the safety and efficacy of prescription drugs in the Commonwealth.