REGISTRAR'S SUBMISSION PACKAGE

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

Analysis of Adopted Amendments to Regulation

1. Basis of Regulation:

Title 54.1, Chapter 24, Chapter 33, and Chapter 34 of the Code of Virginia provide the basis for these regulations.

Chapter 24 establishes the general powers and duties of health regulatory boards including the power to establish qualifications for licensure and responsibility to promulgate regulations.

Chapter 33 establishes the Board of Pharmacy and authorizes the Board to regulate the practice of pharmacy consistent with public health and safety.

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

2. Statement of Purpose:

The purpose of the proposed is to amend regulations pursuant to changes in the Code of Virginia made in Chapters 470 and 490 of the 1998 General Assembly which required the Board to promulgate regulations for continuation of pharmacy services and appropriate transfer of records in a pharmacy closing or acquisition and also for the issuance of controlled substance registration to entities which may need to stock quantities of scheduled drugs. The regulations are proposed for the protection for the health, safety and welfare of the public and for the protection and integrity of prescription drugs consistent with the Board's statutory mandate in Chapter 33 of Title 54.1 of the *Code of Virginia.*

3. Substance of Regulations:

18 VAC 110-20-10. Definitions.

The proposed regulations would add definitions for "Acquisition" and "Pharmacy closing" in compliance with amendments to §§ 54.1-3434 and 54.1-3434.01, which require the Board to promulgate regulations providing for such definitions of those terms.

18 VAC 110-20-135. Change of hours in an existing pharmacy.

This section is added to comply with new language in § 54.1-3434, which requires notification to the Board of any change lasting more than one week and which also requires the Board to promulgate regulations to provide for exception to this prior notification. The proposed exceptions for notification are an emergency beyond the control of the pharmacist-in-charge and an expansion of the current pharmacy hours.

18 VAC 110-20-140. New pharmacies, acquisitions, and changes to existing pharmacies.

The amendments add "acquisitions" in the title and a provision requiring disclosure to each patient if prescription records are to be accessible for purposes other than the continuity of services or for the necessary transfer of the records to the new owner.

XVI. Controlled Substance Registration for other Persons or Entities.
18 VAC 110-20-690 et seq.

Pursuant to provisions of Chapter 490 of the 1998 Acts of the Assembly, the Board is adding a new section to this chapter to allow persons or entities that maintain or intend to maintain a supply of Schedule II through VI controlled substances to obtain a controlled substance registration from the Board. In doing so, the Board is establishing regulations "related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping."

4. Issues of the Regulations

ISSUE 1: Need for additional definitions.

Definitions of "acquisition" and "pharmacy closing" are required by statute (§§ 54.1-3434 and 54.1-3434.1). The Board determined the definition of an "acquisition" to be similar to the statutory definition of "change of ownership" in § 54.1-3401. For a definition of a "pharmacy closing", the emphasis is placed on any situation in which the pharmacy ceases or fails to provide continuity of pharmacy services or fails to provide patient access to prescription records for the purposes of such continuity.

Advantages and disadvantages

There are no disadvantages for the public which remains protected in their use of pharmacy services. Explicit definitions of "acquistion" and "pharmacy closing" will help to protect the public from transactions which effectively shut down access by the public to prescription records and will also provide clear guidance as to requirements of law and regulation for entities who are engaged in the acquisition of an existing pharmacy.

ISSUE 2: Rules for change of hours of a pharmacy.

Chapter 470 of the 1998 General Assembly amended § 54.1-3434 to provide that a pharmacy must list its hours of operation in the pharmacy permit application and required that they notify the Board of any change in those hours lasting more than one week. It further required the Board to promulgate rules for exceptions to the requirement for a 14-day notice prior to a change.

In adopting a proposed regulation, the Board determined that there may be emergency circumstances beyond the control of the pharmacist in charge and so specified that the owner is responsible for notifying the Board as soon as he knows of the change and for disclosing the emergency circumstance that prevented a 14-day notice to the Board and the public. The proposed rule will also make an exception to the notification requirement for a pharmacy which is expanding its current hours of operation. Current law requires a 14-day notice for a pharmacy which is closing to allow patients the opportunity to access and transfer their prescriptions. The change in statute was a acknowledgement that an extended change in hours without notice to the public could have the same detrimental effect on patient access as a pharmacy closing.

In the development of this proposed amendment, the Board considered listing the circumstances which may be beyond the control of the pharmacist, such as fire, flood, natural disaster, material destruction, eviction, bankruptcy, death or illness. Instead, the Board has adopted a more generic requirement for the "emergency circumstance" to determine when the pharmacy hours must be changed without notice. Acknowledging that the pharmacist in charge may not have the authority to make such a decision, the Board determined that the owner should be responsible for immediate notification to the Board and for justification for the change.

Advantages and disadvantages

The intent of this proposed regulation is to protect the consuming public from an abrupt diminution or discontinuation of pharmacy hours which would interrupt patients' ability to get prescriptions filled in a timely manner or deny them access to their prescription records. The advantage of the proposed regulation to the public is the implementation of the notice requirement with the provision for an exception in case of emergency circumstances or for an expansion of hours which is advantageous to the consumer.

There are no disadvantages to the public which is better protected from situations in which pharmacy services might be severely curtailed. The pharmacy and its owner are protected by the provision for an exception to the 14-day notice requirement in an emergency.

ISSUE 3: Requirements for accessibility of patient records in the acquisition of an existing pharmacy.

Proposed regulations are intended to address the problems which occurred for patients in the disruption of pharmacy services when a large number of pharmacies owned by one chain were

acquired by another. Amendments to the Code in § 54.1-3434.01 specify that prescription dispensing records and other patient records shall be transferred to the new owner in a manner to ensure the "confidentiality, integrity, and security of the pharmacy's prescription dispensing records" and that there should be "continuity of pharmacy services at substantially the same level as that offered by the precious owner."

Since the Code is very specific about the transfer of patient records and the continuity of prescription service to the patient, the regulations proposed by the Board specify that if the records are to be accessible for any purpose other than for the continuity of services or the necessary transfer of records to the new owner, the pharmacy acquiring the records must disclose such information in writing to each patient 14 days prior to the acquisition.

Advantage or disadvantages

There are definite advantages to the public, which is better protected by requiring a pharmacy acquiring prescription records to disclose in writing if those records are going to be made accessible for any purpose other than continuity of services. In addition, any release of records could only be made in accordance with requirements in the Code for disclosure of patient records which attempts to protect confidentiality of patient records.

ISSUE 4: Requirements necessary in order to issue a controlled substance registration to certain entities.

There are an increasing number of entities that need to maintain a stock of controlled substances but in which there is no pharmacy on premises or no single practitioner who will assume total responsibility for the drugs under his registration with the Drug Enforcement Administration. Some examples of these settings include: a) out-patient surgery centers where large quantities of controlled substances are shared by a number of surgeons, anesthesiologists or nurse anesthetists with no in-house pharmacy or practitioner maintaining oversight; b) nursing homes with a more acutely ill population and a need for ready access to drugs for emergencies and first doses; c) small hospitals which contract with an outside pharmacy for pharmacy services; and d) more technically advanced EMS agencies with trained personnel and protocols calling for rapid drug intervention to prevent mortality and reduce morbidity. The U. S. Drug Enforcement Administration (DEA) is requiring that these sites be registered, and these regulations will enable to Board to issue these entities a controlled substance registration which will in turn enable them to obtain a "mid-level" DEA registration. These "mid-level" entities will be registered with a responsible person who has continuity on-site, but who is under the general supervision of a pharmacist or a medical practitioner with a DEA registration.

In promulgating regulations, the Board considered which of its regulations related to drug storage, security and recordkeeping would be essential for the maintenance of controlled substances at one of these "mid-level" registrants. Entities such as EMS agencies may have a high turnover of personnel with relatively basic levels of medical training; there must be

safeguards against diversion or improper storage to protect the efficacy of the drug supply and the public from illegal use and abuse of prescription drugs.

There are an increasing number of entities with a need for Schedule VI drugs, some of which also have abuse potential. Without a controlled substance registration or an on-site pharmacy, there is no authority for these entities to possess any controlled substances, including Schedule VI, and no authority for a manufacturer or wholesale distributor to provide drugs to those sites. There have also been requests from researchers who only need to work with Schedule VI drugs but who were unable to order the drugs with a controlled substance registration. These regulations will permit the Board to issue a CSR to an entity that can meet the requirements for safe storage and security from diversion.

Advantage and disadvantages

The intent of these regulations and of the '98 legislation which was submitted by the Governor was to enable certain entities to obtain a controlled substance registration which would allow them to secure a DEA number as a "mid-level" provider. In some out-patient surgery centers or small hospitals, the practitioner whose DEA number is being used to order and stock the drugs is only a member of the medical staff who is rotates on-site to do surgery or see patients. To have the security and efficacy of those drugs under his DEA registration places an unnecessary burden and responsibility on that one practitioner. With these proposed regulations, these entities will have the ability to transfer control of the drug supply to someone on-site under the general supervision of a medical director. For a small hospital without an in-house pharmacy, these regulations will enable it to get a DEA number and to order and have a floor stock of drugs.

The Board is aware that some EMS agencies are having difficulty with the exchange box program under which a hospital takes responsibility for stocking and refilling the box that contains the drugs the agency needs in responding to emergencies. With these regulations, the EMS agency would be able to obtain a CSR, be registered with the DEA, and order their own drugs under general supervision of a medical practitioner.

There are no disadvantages to the regulations, which clearly spell out the requirements for supervision of controlled substance registrants, for storage and security and for record-keeping. The regulations were developed in consultation with the advice of the U. S. Drug Enforcement Administration, the Office of Emergency Medical Services, and practitioners.

5. Estimated Fiscal Impact of the Regulations

I. Fiscal Impact Prepared by the Agency:

Number of entities affected by this regulation:

Licensed pharmacists	7520
Pharmacies	1556

There are approximately 7250 licensed pharmacists and 1556 licensed pharmacies which would potentially be involved in compliance with these regulations. In fact, only a small percentage of those pharmacies are closed or acquired each year, and that number is not predictable.
The number of entities, such as outpatient surgery centers, that will apply for a controlled substance registration under new regulations in Part XVI is not known. There are 730 emergency medical services (EMS) agencies, including volunteer rescue squads. In addition, we estimate that there are at least 300-400 other types of entities, such as out-patient surgery centers that would seek a controlled substance registration under these regulations.

Projected cost to the agency:

The agency will incur some costs (less than $3000) 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.

Projected costs to the affected entities:

There would be no additional costs for compliance with these regulations for pharmacies which are involved in a closing or an acquisition. The intent of the amendments to Chapter 34 of Title 54.1 of the *Code of Virginia* and these regulations is to clearly specify the requirements for a closing or acquisition for the continuity of services to patients in order to prevent a situation in which a pharmacy owner might be the subject of a disciplinary proceeding resulting in a substantial fine.

For those entities which may seek a controlled substance registration from the Board, the annual cost would be $20.

Citizen input in development of regulation:

In the development of regulations, the Board made every effort to include citizen input from those engaged in the practice of pharmacy in the communities, in hospitals or other settings, from associations affiliated with the practice, and from businesses providing technology for pharmacies and practitioners. Consequently, the Board drafted regulations with a consideration for any fiscal impact on licensees, especially small businesses, and does not anticipate a negative impact on the entities affected by regulation or on the public.

Localities affected:

There are no localities affected by these regulations in the Commonwealth.

II. Fiscal Impact Prepared by the Department of Planning and Budget: (Attached)

III. Agency Response:

The Board does not agree with the estimated economic impact of the Department in which it is stated that "the proposed regulation also requires pharmacies to provide 14-day advance notification to the Board and the public, of any change in operating hours lasting more than one week." **The notification requirement is clearly and specifically statutory (§ 54.1-3434),** not a requirement initiated by the proposed regulation.

The proposed regulation provides that notice shall be given to the public and to the Board **in accordance with § 54.1-3434**. The purpose of the regulation is to provide for exceptions to the requirement, if the change is necessitated by emergency circumstances or the change will result in an expansion of pharmacy hours.

The Board would agree that "the requirement is intended to protect consumers from an abrupt reduction in pharmacy hours which could interrupt patients' ability to get vital prescriptions filled in a timely manner or deny them access to their prescription records." (DHP analysis) However, it is a requirement imposed by the Code of Virginia as amended by Chapter 490 of the 1998 Acts of the Assembly, not a requirement imposed by the Board as a result of the proposed regulation.