Form: TH- 03

11Virginia 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:	Changes in pharmacy practice
Date:	

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Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed.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or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed.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 regulation are required in order to comply with Chapters 411, 632, 666 and 707 of the 2002 Acts of the Assembly.

Regulations are necessary to implement the changes in requirements for pharmacy practice, pursuant to Chapter 632 to allow chart orders for hospice or home infusion, to permit different methods of keeping dispensing records and to allow for delivery of prescription drugs to alternative sites. Statutory revisions in Chapters 411, 666 and 707 require amendments to allow a nursing home to donate unused drugs or a physician to dispense donated drugs provided basic requirements for security, storage, labeling and recordkeeping have been observed to protect the safety, integrity and efficacy of the drugs.

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.

There were no changes made in the text since proposed regulations were published.

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 April 29, 2003, the Board of Pharmacy adopted final amendments to regulations, 18 VAC 110-20-10 et seq. in order to implement provisions of Chapters 632, 411, 666 and 707 of the 2002 General Assembly. The final amendments replace emergency regulations that expire on July 18, 2003.

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

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.

The specific legal mandates to promulgate amended regulations are found in Chapters 411, 632, 666 and 707 of the 2002 Acts of the Assembly.

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0411

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0632

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0666

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0707

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the amended 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 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.

The objective of the statutory revisions in Chapter 632 was to facilitate current pharmacy practice by providing more appropriate methods of practice and eliminating unnecessary barriers to best care and efficiencies in practice. The objective of the statutory revisions in Chapters 411, 666 and 707 was to expand the availability of drugs to indigent patients by allowing a nursing home to donate unused drugs or a physician to dispense donated drugs provided basic requirements for security, storage, labeling and recordkeeping have been observed to protect the safety, integrity and accountability of the drugs.

While the amended regulations will expand the practice of pharmacy to address certain problems with patient access to prescription drugs and to accommodate newer technologies, they also contain requirements that address issues of drug security and integrity to ensure that the health and safety of the public is not compromised.

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.

Chapter 411 updates several statutes affecting the practice of pharmacy to conform to current practice to: 1) expand the use of "chart orders" which may contain more than one prescription order to hospice patients and patients receiving home infusion, 2) allow pharmacies to use a combination of computer and manual records when necessary to maintain accurate records of dispensing, and 3) allow for delivery of prescriptions to locations other than directly to the patient pursuant to regulations of the Board. The specific sections being amended are as follows:

18 VAC 110-20-240. Manner of maintaining records, prescriptions, inventory records.
18 VAC 110-20-430. Chart orders (repealed)
The current language limits the use of chart orders containing multiple prescription orders to hospital and nursing home patients. Pharmacies which serve hospice patients and home infusion patients have a need for the use of chart orders as prescriptions, because of the nature of the illnesses involved and the complexity of the drug therapy. Hospice patients usually receive a "kit" in addition to regularly administered drugs for use in end stages of the disease or in emergencies. The "kit" is put together by the provider pharmacy and contains one to two doses of a number of drugs. A pharmacy now must receive a separate prescription for each individual drug to be placed in the "kit". The drugs for the kit are standardized and on a list with standard instructions for use. Additionally, many of these orders are either originally written upon discharge from a hospital on a chart order or are written as standing orders on a multiple prescription format. In order for these pharmacies to receive a separate prescription on a separate form for each drug order, someone will have to transcribe them onto prescription blanks for the prescriber's signature, introducing an opportunity for error from possible incorrect transcription, accidental deletion of one of the drugs from the multiple order or the list, and from the additional workload on the health care practitioners involved.

18 VAC 110-20-255. Other dispensing records.
18 VAC 110-20-320. Refilling of Schedule III through VI prescriptions.
Current language allows a pharmacist to record dispensing data either manually on the prescription itself or in a data processing system. Because in current practice, often more than one pharmacist is involved in the dispensing process, some data systems do not accommodate more than one pharmacist's initials. Partially filling a prescription also creates a problem with recordkeeping. The Board has a need for accurate recording of which pharmacist is responsible for a prescription transaction and has had problems in handling disciplinary actions where the initials in the data system were not always indicative of the pharmacist who ultimately checked the prescription. The change in statute with the proposed regulation to implement the provisions would correct this problem by allowing for an alternative system for recording dispensing information.

18 VAC 110-20-275. Delivery of dispensed prescriptions.

Current law defines the term "dispense" to mean the delivery of the drug to the ultimate user. Based on this definition, the Board has prevented the use of intermediate delivery locations or "drop stations" where a pharmacy delivers a group of prescriptions to a central location for subsequent pick-up by patients. The Board has received numerous requests from various entities over the past five or more years to allow intermediate delivery locations for different situations. The Board has proposed regulations that provide consistent, reasonable controls as are necessary to ensure security and proper storage of the stock of delivered drugs until patient pickup, protect patient confidentiality, minimize the risk of mix-ups with handing out the drugs, and require records to ensure accountability. A pharmacy that delivers to an alternative site or entity is required to have a written agreement for the delivery procedures and maintain a policy and procedure manual that sets out the method employed by the pharmacy for compliance with record-keeping, counseling, storage, and confidentiality requirements. Only a person or entity which holds a license, permit, or registration with the Board either as a pharmacy, a physician who is licensed to dispense, or a controlled substances registration for this purpose may act as an alternative delivery location.

Chapter 632 permits nursing homes to enter into voluntary agreements with pharmacists to return any drugs that are no longer necessary for their residents in order that the pharmacy may dispense such drugs to the indigent, free of charge, subject to certain restrictions. The drugs must be in the manufacturers' original sealed containers or sealed individual dose or unit dose packaging and the return must comply with federal law. Only an authorized person can accomplish the physical transfer, consent must be obtained from the relevant patient or his authorized representative for return of the medication, the expiration date remains, all identifying data relating to the patient for whom the drug was dispensed must be removed, inventories must accompany the transferred drugs, and outdated drugs cannot be transferred and must be destroyed according to the Board's regulations. The pharmacist-in-charge at the participating pharmacy will be responsible for determining the suitability of the drug for re-dispensing. This law does not authorize donation of prescriptions dispensed to persons eligible for coverage under Title XIX or Title XXI of the Social Security Act. To implement the program, the Board is requires to promulgate regulations as follows:

18 VAC 110-20-400. Returning of drugs and devices.

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.

Section 400 is amended to conform this section of regulations related to return of drugs and devices for resale to the new provisions of § 54.1-3411.1 and to remove any duplicative language. A written agreement between a pharmacy and a nursing home must be maintained as well as a current policy and procedure manual that outlines the method of tracking and delivery from the nursing home to the pharmacy, the procedure for determining the suitability and integrity of drugs for re-dispensing and a procedure for assigning a beyond-use date on re-dispensed drugs.

Section 530 is amended to include provisions of Chapter 632 in the pharmacy's responsibility to long term care facilities in the re-dispensing of donated drugs to the indigent.

Chapters 666 and 707 are identical (HB 687 and SB 145). They provide two exceptions from the requirements for the practice of pharmacy for practitioners of medicine or osteopathy relating to obtaining prescription drugs without charge for indigent patients, i.e., through pharmaceutical manufacturers' indigent programs and through donations from other entities. Practitioners who participate in pharmaceutical manufacturers' indigent programs in which the manufacturer donates a stock bottle of the prescription drug that is to be dispensed to an indigent patient are provided authority to dispense such drugs. The current labeling and packaging standards in the Drug Control Act will apply (non-child resistant packaging may be requested by the patient or ordered by the prescriber) and the drug cannot be used for any other purpose, unless the manufacturer authorizes dispensing to another indigent patient. Practitioners may, in lieu of dispensing directly to the patient, transfer the stock bottle to a pharmacy participating in the indigent program. The participating practitioner and the pharmacy are prohibited from charging the patient a fee for the medication. A reasonable dispensing or administrative fee to offset the cost of dispensing may be charged, not to exceed the comparable allowable fee reimbursed by the Virginia Medicaid program; however, if the patient is unable to pay the dispensing or administrative fee, this fee must be waived. In addition, practitioners of medicine or osteopathy are authorized to provide controlled substances to their own patients in free clinics without charge when the drugs have been donated by an entity other than a pharmaceutical manufacturer. The practitioner must first obtain a controlled substances registration and will be required to comply with the existing labeling and packaging requirements. Enactment clauses required emergency regulations and mandated that the Board of Pharmacy assist free clinics in resolving issues relating to the practice of pharmacy and the Drug Control Act. To implement the provisions of the Acts, the Board has adopted a new section of regulation, section 730.

18 VAC 110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

Section 730 sets forth the requirements for the practitioner who provides donated drugs in a free clinic to include acquisition of a controlled substance registration, a requirement that the drugs be donated by an entity that holds a license or permit from the Board of Pharmacy, compliance with packaging, labeling, recordkeeping and storage and security requirements. The practitioner may enter into an agreement with a pharmacy for dispensing, delivery and maintenance all or part of the donated stock of drugs segregated from the regular inventory.

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.

The primary advantages to the public of implementing the amended regulations are as follows: a) pharmacies will have the ability to fill chart orders for hospice or home infusion patients, rather than requiring individual prescriptions for multiple medications; b) with proper controls, prescriptions can be delivered to an alternative site rather than to the patient (such as a student

health clinic); c) unused drugs from nursing homes may be donated to a free clinic for re-dispensing; and c) donated drugs may be more accessible to indigent patients.

There are no disadvantages to the public as all amendments are intended to provide better access to prescription drugs, update the methods for record-keeping, and facilitate the safe storage and provision of drugs to indigent patients. Essential requirements for patient safety and the integrity and security of prescription drugs have been incorporated into the amended regulations.

There are no advantages or disadvantages to the agency; the amended regulations do not impose a new responsibility on the Board. Since the number of practitioners who may apply for a controlled substance registration in order to dispense donated drugs to their patients in a free clinic is expected to be very small, it does not involve additional cost or staff time.

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.

Proposed regulations were published in the Virginia Register of Regulations on February 11, 2003. Public comment was requested for a 60-day period ending April 11, 2003.

A Public Hearing before the Board of Pharmacy was held on February 19, 2003 at which no public comment was 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 110-20-240. Manner of maintaining records, prescriptions, inventory records.
A new subsection C is added to specify amended rules for chart orders to include hospice and home infusion patients as well as hospital and long-term care.

18 VAC 110-20-255. Other dispensing records.
A new section on dispensing records is added to conform requirements to the amended § 54.1-3412 which permits an alternative record-keeping system as set forth in the pharmacy's policy and procedure manual.

18 VAC 110-20-275. Delivery of dispensed prescriptions.
A new section is added to require a pharmacy that delivers to an alternative site or entity (only than the patient) to have a written agreement for the delivery procedures and maintain a policy and procedure manual that sets out the method employed by the pharmacy for compliance with

record-keeping, counseling, storage, and confidentiality requirements. Only a person or entity which holds a license, permit, or registration with the Board either as a pharmacy, a physician who is licensed to dispense, or a controlled substances registration for this purpose may act as an alternative delivery location.

18 VAC 110-20-320. Refilling of Schedule III through VI prescriptions.
The amended regulation will implement the statutory provisions to allow for an alternative system for recording dispensing information in accordance with § 54.1-3412 and section 255 as amended.

18 VAC 110-20-400. Returning of drugs and devices.
Amendments conform this section of regulations related to return of drugs and devices for resale to the new provisions of § 54.1-3411.1 and remove any duplicative language. A written agreement between a pharmacy and a nursing home must be maintained as well as a current policy and procedure manual that outlines the method of tracking and delivery from the nursing home to the pharmacy, the procedure for determining the suitability and integrity of drugs for re-dispensing and a procedure for assigning a beyond-use date on re-dispensed drugs.

18 VAC 110-20-430. Chart orders (repealed)
This section (currently found in the part on regulations for hospital pharmacies) is repealed and replaced by subsection C of section 240 (see above).

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.
Section 530 is amended to include provisions on the pharmacy's responsibility to long term care facilities in the re-dispensing of donated drugs to the indigent.

18 VAC 110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.
Section 730 is added to set forth the requirements for the practitioner who provides donated drugs in a free clinic to include acquisition of a controlled substance registration, a requirement for the practitioner to only accept donated drugs from an entity or practitioner who holds a license or permit from the Board, compliance with packaging, labeling, recordkeeping and storage and security requirements and a prohibition on dispensing expired drugs. The practitioner may enter into an agreement with a pharmacy for dispensing, delivery and maintenance all or part of the donated stock of drugs segregated from the regular inventory.

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 amended regulatory action would not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, strengthen or erode the marital commitment or increase or decrease disposable family income.