Virginia Regulatory Town Hall

Emergency 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:	

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

Amendments to regulation are required in order to comply with enactment clauses in Chapters 411, 632, 666 and 707 of the 2002 Acts of the Assembly requiring the Board to promulgate regulations within 280 days of enactment.

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. Regulations implement the changes in requirements for pharmacy practice to allow chart orders for hospice or home infusion patients, to permit different methods of keeping dispensing records and to allow for delivery of prescription drugs to alternative sites other than directly to the patient's residence. 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.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The legal authority to promulgate the emergency regulation is as follows:

The second enactment clauses of Chapters 411, 632, 666 and 707 state that: That the Board shall promulgate regulations to implement the provisions of this act within 280 days of its enactment."
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 "emergency situation" which exists is specified in § 2.2-4011 of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law.

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-4011

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

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 emergency 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 require emergency regulations and mandate 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, informing the board of the source of the drugs, 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.

While the emergency 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.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

There was no alternative to changes in the regulation as they were mandated by statute. The legislation was necessary to avoid having pharmacists engage in practices that are less than optimal or in pharmacists violating the law in order to engage in best practices. While the Board could conceivably handle some of the requests for changes in the Drug Control Act as pilot programs, the issues are too basic and widely applicable for a pilot program to be necessary. These changes are much more universally needed by pharmacists to necessitate a pilot program and should be available to all pharmacies and all consumers.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the 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 determined that there is no potential impact on the family or on family stability as a result of this regulation. There should be no increase or decrease in disposable family income.