Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Board of Pharmacy/Department of Health Professions
VAC Chapter Number:	18 VAC 110-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Pharmacy
Action Title:	Changes in pharmacy practice
Date:	10/3/2002

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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 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.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board the authority to promulgate regulations to 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:*
> *…*
> *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 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) 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 by letter that the Board 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 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 proposed 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 providing detail of the regulatory action's changes.

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 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.

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.

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 must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(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 one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a

public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

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

The entities that are likely to be affected by these regulations would be licensed pharmacists, permitted pharmacies and physicians who may choose to obtain a controlled substance registration in order to maintain a stock of donated drugs to be provided to his patients through a free clinic.

Estimate of number of entities to be affected:

There are 7807 active pharmacists and 1497 pharmacies that hold a Virginia license. Though not all will be affected by changes in rules on chart orders, alternative delivery sites, or indigent pharmacy programs, most of the retail pharmacies will benefit from the less restrictive requirement for record-keeping on refills. There is no way to predict the number of practitioners who would seek a controlled substance registration to maintain a stock of donated drugs, but the number is expected to be very small.

Projected costs to the affected entities:

The current cost for a controlled substance registration is $20. There are no other compliance cost.

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 110-20-240. 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 proposed 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.

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.

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.

As a result of comment on the NOIRA, there were several changes in section 730 from the language published in the emergency regulation. The Virginia Association of Free Clinics objected to language in subsection A requiring the practitioner to inform the Board of the sources of donated drugs. The rationale for the requirement in the emergency regulation was that pharmacies are prohibited by state and federal law from acquiring drugs from an unlicensed source; there was no such prohibition for these practitioners in free clinics. There was concern that unregulated or expired drugs could be donated and dispensed to the detriment of patients. The Board agreed that patients at free clinics need the same protection against dangerous or inefficacious drugs as other consumers. To accommodate the concern about burdensome reporting by free clinics, the Board adopted a requirement (now in subsection B) that the practitioner in a free clinic may only accept drugs from an entity or practitioner who holds a current active license or permit from the board, authorizing the dispensing or distribution of drugs. Thus, the practitioner in a free clinic is held to the same standard as a pharmacy.

The second concern expressed by the free clinics centered on the requirement for free clinics to have a written procedure for monthly inventory for the removal of expired drugs. Their argument was that the requirement exceeded what is required of a pharmacy. In fact, pharmacies are prohibited from keeping expired drugs in stock and are required to remove such drugs and store them separately for return or destruction. Since drugs expire on a monthly basis, pharmacies must have a plan to check all drugs in stock monthly in order to remain in compliance. In response to comment, the Board amended subsection C to specify that an expired drug cannot be dispensed and to make the practitioner responsible for maintaining and complying with a written procedure for reviewing inventory and removing expired stock. The requirement for a monthly inventory review is eliminated, but a practitioner at a free clinic is going to have to develop a written procedure to ensure that expired stock is not co-mingled with current drugs.

Finally, the free clinics objected to the requirement that the prescription label contain the patient's address; that exceeds the requirement for a prescription dispensed by a pharmacy. The Board agreed that the requirement was unnecessary and should not have been included in the emergency regulation. It was removed in the proposed regulation in subsection E.

With the passage this legislation, the Board was mandated to promulgate regulations implementing provisions of the law within 280 days. It adopted emergency regulations and now proposes these amendments to replace them with permanent regulations prior to July 18, 2003.

Public Comment

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

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received August 12, 2002 until September 11, 2002. During the 30-day comment period, there were two comments were received from members of the public. The first was an email from Mark Cruise with the Virginia Association

of Free Clinics. He raised three objections to language in the emergency regulation, which were addressed in the adoption of proposed regulations (see discussion under "Alternatives").
The second comment was from the National Association of Chain Drug Stores. They objected to the deletion of language in section 400 about the return or exchange of drugs being consistent with federal law and regulation. They preferred that language to remain in the regulation to alert the regulation reader that federal law must be consulted. In response, the Board noted that a new section of the Code of Virginia (§ 54.1-3411.1 A 2) now clearly provides any return or exchange must be consistent with federal law. Proposed regulations in section 400 require a drug to be returned or exchange in accordance with all the provisions of § 54.1-3411.1, including consistency with federal law. Therefore, no change in the emergency regulation was necessary in the adoption of proposed regulations.

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.

Members of the Board met in open session to work on the emergency regulations and the proposed regulations. The public has been invited to comment during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

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 require the Board to review regulations each biennium or as required by Executive Order. These regulations will be reviewed again during the 2005-06 fiscal year.

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 proposed 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.