



Virginia Board of Pharmacy Law Update

VPhA Annual Convention
August 5, 2009

Elizabeth Scott (Scotti) Russell
Executive Director
Board of Pharmacy



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- Brandon K. Yi, Vice Chair
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Program Objectives

- Provide brief overview of periodic regulatory review process
- Review amended regulatory changes to become effective September 2, 2009
- Explain ability to apply to participate in prescription drug donation program
- Provide brief update on the status of the Prescription Monitoring Program subsequent to possible security breach



Periodic Regulatory Review



Overview of Status

1. Identified potentially problematic regulations (could not address statutes) via public comment and Board committee in 2005 and 2006.
2. Created Notice of Intended Regulatory Action (NOIRA)- list of all identified regulations.
3. NOIRA was published 8/6/2007, public comment was accepted until 9/5/2007.



4. Proposed regulation amendments developed and Board adopted December 2007.
5. Underwent administrative review, published and 60 day public comment period was accepted until December 12, 2008.
6. Board summarized and responded to public comment. Several changes were made, primarily clarification. Board adopted final regulations March 10, 2009.
7. Underwent administrative review again, published, and will become effective September 2, 2009.



Regulatory Changes Effective September 2, 2009



18VAC110-20-10 Definitions

- Simply added a few definitions to help clarify existing regulations or adopted changes.



18VAC110-20-10 Definitions 18VAC110-20-20 Fees

- A few changes made to support existing regulations or adopted changes.



18VAC110-20-30 Requirements for pharmacy practical experience

- Conforms regulation to more current ACPE standards.
- Allows experience to be gained after completing equivalence of 2 semesters of pharmacy school, instead of first professional year.
- Still requires 1500 hours, but removes requirement to gain 300 hours outside the school of pharmacy practical experience program.



18VAC110-20-30 Requirements for pharmacy practical experience, cont.

- Continues requirement that maximum credit to be given per week is 50 hours, but now also states that credit will not be given for less than an average of 20 hours per week averaged over a month.



18VAC110-20-40 Procedure for Gaining Practical Experience

- Formalizes Board policies, previously in guidance documents, regarding certain qualifications for pharmacy intern registration and assigned expiration date of such registration.
- Removes requirement that only one pharmacy intern shall be supervised during the same time period.
- Requires pharmacy intern to notify Board in writing of any change in address of record within 14 days of change.



Department of Health Professions

18VAC110-20-50 Curriculum and approved schools of pharmacy

- Removed outdated information.

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Department of Health Professions

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Clarifies requirement that applicant may not sit for any examination until completed all other licensing requirements to include education and practical experience requirements.
- Increases time period for retaking law examination, if failed. Currently must wait 5 days. Will be increased to 30 days.

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Department of Health Professions

18VAC110-20-60, cont.

- Formalizes requirements for requesting ADA accommodations which was formerly in guidance document.

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Department of Health Professions

18VAC110-20-70 Requirements for foreign-trained applicants

- Formalizes requirements for foreign graduates, previously in guidance document, which states that FPGECE must first be obtained prior to meeting eligibility for pharmacy intern registration to gain practical experience in Virginia. Testing requirements remain the same.

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Department of Health Professions

18VAC110-20-80 Renewal and reinstatement of license

- Previously required pharmacist to *immediately* notify Board in writing of any change in address of record. Now states that notification must be made within 14 days of change.
- Clarifies that electronic notification and updating information through Board's web-based application or other approved means is acceptable.

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Department of Health Professions

18VAC110-20-90 Requirements for continuing education

- Previously required pharmacist to maintain original CE certificates for 2 years. Will be changed to 3 years.

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18VAC110-20-100 Approval of continuing education requirements

- Removes requirement for *evidence of pre and post test* for a Board-approved CE program. Will now only require evidence of post assessment.
- Will now assign expiration date to Board-approved program.
- Changes retention date for maintaining program records.
- Requires Board notification of dates when live programs will be given.



18VAC110-20-102 Criteria for approval for pharmacy technician training programs

- Removes requirement that instructor must have an unrestricted license, but clarifies that it must not be suspended or revoked in any jurisdiction.
- Requires a program director.
- Requires program to provide certificate of completion to participants and provide verification of completion upon Board request.



18VAC110-20-102 Criteria for approval for pharmacy technician training programs *cont.*

- Requires substantive changes to program, director, instructors, etc. to be reported to Board within 14 days of change.
- Assigns program expiration date and must be renewed every 2 years. (will assist in ensuring that current information is being taught)



18VAC110-20-104 Address of record, maintenance of certificate

- Previously required pharmacy technicians to notify Board *within 30 days* of any change to address of record. Will be changed to within 14 days.
- Requires pharmacy technicians to maintain current registration certificate at his principal place of practice. If no principal place, then at any pharmacy where he practices or his address of record.



18VAC110-20-110 Pharmacy permits generally

- Continues to require outgoing PIC to immediately return pharmacy permit to Board, but must now indicate on permit effective date on which he ceased to be PIC.
- Removes requirement for outgoing PIC to take accurate inventory of Schedule II-V drugs, but states that outgoing PIC must be afforded opportunity to take such inventory, unless owner submits written notice to Board showing good cause as to why opportunity should not be allowed.



18VAC110-20-110 Pharmacy permits generally

- Formalizes Board policy that only one pharmacy permit shall be issued to the same designated prescription department space and that a pharmacy may not obtain a different type of Board license, e.g., manufacturer, wholesale distributor, for the same designated prescription department space.
- States the Board will no longer issue a pharmacy permit to operate from private residence or dwelling.



18VAC110-20-111 Pharmacy technicians

- In addition to a pharmacy maintaining documentation of a pharmacy technician trainee being currently enrolled in a Board-approved pharmacy technician training program, pharmacy must now also maintain start date for each trainee.



18VAC110-20-120 Special or limited-use pharmacy permits

- Formalizes allowances, which were previously stated in guidance document, for a special-use pharmacy located in or providing services to a free clinic.



18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Formalizes that upon a pharmacy closing or going out of business, prescription records for prescriptions with active refills must now be transferred to a pharmacy where a patient may have access for obtaining refills or transferring the prescription to another pharmacy.



18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Formalizes Board policy, previously stated in guidance document, that a new pharmacy may not stock drugs earlier than 2 weeks prior to the designated opening date. Once stocked, pharmacist shall be present on daily basis to ensure safety and integrity.
- Board must be notified of any change to opening date and pharmacist must remain on site on daily basis.



18VAC110-20-180 Security System

- Requires capability of sending alarm signal to monitoring entity when breached even if communication line is inoperable.
- Alarms approved prior to November 4, 1993 do not need to meet this requirement, unless a structural change is made, alarm system is changed, prescription dept is closed while rest of pharmacy open, or a breaking and loss occurs.
 - If breaking and loss occurs, then shall upgrade alarm and file remodel application within 14 days of breaking.



18VAC110-20-180 Security System

- If a pharmacy that is open 24 hours wishes to reduce its hours or close, it must now submit a remodel application to the Board and install an alarm system, prior to closing, that meets all security system requirements.
- Previously it must have been installed within 72 hours of closing.



Department of Health Professions

18VAC110-20-190 Prescription department enclosures; access to prescription department

- Removed certain enclosure requirements and now simply require that the enclosure be capable of being locked in a secure manner any time pharmacist is on duty but not present in prescription department and that the enclosure be locked and alarmed at all times when pharmacist not on duty.
- Requirement that enclosure must protect drugs from unauthorized entry and pilferage at all times remains in place.

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Department of Health Professions

18VAC110-20-190 Prescription department enclosures; access to prescription department

- Will allow persons authorized by PIC or pharmacist on duty to possess key to prescription dept when pharmacist is on duty. Such key, however, shall not allow entry when pharmacist is not on duty, i.e. "day lock"
- Clarifies that each pharmacist on duty shall be responsible for security of pharmacy, including effective controls against theft or diversion.

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Department of Health Professions

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Clarifies that drugs awaiting delivery that are placed in a secured area outside of the prescription department must not be accessible to the public.

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Department of Health Professions

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records

- Requires all pharmacies to maintain a perpetual inventory as newly defined in 18VAC110-20-10 for all Schedule II drugs with reconciliation at least monthly.
- Electronic monitoring that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

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Department of Health Professions

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records

- Requires invoices of Schedule VI drugs to be maintained, but may be stored electronically.

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Department of Health Professions

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- Removes pharmacist to pharmacy technician ratio, however, §54.1-3320 still requires 1:4 ratio.
- Also, a pharmacist to determine number of pharmacy interns and pharmacy technician trainees he can safely and competently supervise at one time.

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Department of Health Professions

18VAC110-20-270 Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians

- If pharmacist determines from a prescriber or by other means, including use of his professional judgment, that presents prescription is a forgery, then pharmacy shall not return prescription to person presenting it.
- Shall be maintained for 30 days before destroying it.
- May be given to law enforcement investigating forgery.

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Department of Health Professions

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Clarifies that allowances for faxing prescriptions for hospice patients includes patients in a home hospice.
- Clarifies that the faxing of Schedule II prescriptions is allowable for long term care facilities (nursing homes and assisted living), not just nursing homes.

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Department of Health Professions

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Allows a pharmacy to dispense when forwarded a written prescription (signed by the prescriber) by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions, and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

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Department of Health Professions

18VAC110-20-286 Chart orders for outpatients

- Formalizes allowance, as previously stated in guidance document, for community pharmacies to dispense from chart orders under certain conditions.
- DEA caution for Schedule II-V prescriptions

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Department of Health Professions

18VAC110-20-320 Refilling of Schedule III through VI prescriptions

- Clarifies that the timing of dispensing a refill shall be within reasonable conformity with directions for use and allows for early refills provided the pharmacist documents a valid reason for the necessity of the early refill.
- This regulation was never intended to allow for dispensing a drug that is different from the one prescribed, i.e., Rx written for Zoloft 50mg and pharmacist wants to dispense (2) Zoloft 25mg.

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Department of Health Professions

18VAC110-20-340 Packaging standards for dispensed prescriptions

- Formalizes labeling requirements, as previously stated in guidance document, for compliance packaging that is comprised of a series of individual containers or pockets labeled with the specific date and time when the contents of that container are to be taken, and which may contain more than one different drug.

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Department of Health Professions

18VAC110-20-350 Special packaging

- Removes requirement for pharmacy to post sign that nonspecial packaging may be requested.
- Removes requirement to obtain and maintain a written signed release of such request.
- Refer to § 54.1-3427 regarding exemption from civil liability *if* recipient signs a release covering a period of time or a single delivery. Release must provide that the recipient releases the pharmacist from civil liability for not using the safety closure container, unless the pharmacist acted with willful and wanton disregard of safety.

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Department of Health Professions

18VAC110-20-355 Pharmacy repackaging of drug, records required; labeling requirements

- Requires the bin filling record for automated counting devices to be maintained for one year from date of filling.
- Such filling record must now include the expiration dates of all lots placed in the bin, the date of filling, and pharmacist's initials verifying the accuracy of the process.

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Department of Health Professions

18VAC110-20-355 Pharmacy repackaging of drug, records required; labeling requirements

- Formalizes requirement for returning drugs to stock which was previously explained in a guidance document.

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Department of Health Professions

18VAC110-20-391 Prescription blanks

- Formalizes requirement, previously found in guidance document, for providing prescription blanks to prescribers.

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Department of Health Professions

18VAC110-20-425 Robotic pharmacy systems

- Removes requirement for a hospital to apply for approval of a robotic pharmacy system for dispensing unit dose drugs and simply allows this type of technology pursuant to Board regulation.

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Department of Health Professions

18VAC110-20-520 Drugs in long-term care facilities

- By changing the word "drugs" to "prescription drugs", it now permits the stocking of over-the-counter drugs in a long term care facility.

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Department of Health Professions

18VAC110-20-535 Repackaging of already dispensed prescriptions

- Previously allowed in guidance document.
- Formalizes allowance for provider pharmacy for LTC facility to repackage a resident's prescription drugs dispensed by another pharmacy into the unit-dose or compliance packaging system used by the long-term care facility to assist in maintaining a uniform or more accurate system of administration.

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Department of Health Professions

18VAC110-20-536 Prescription drugs sent outside the facility

- Also, previously allowed in guidance document.
- States that the provider pharmacy shall assure that residents who leave a LTC facility for short periods of time or are discharged and who are allowed to take dispensed prescription medications with them, do so only in appropriate packaging, properly labeled for outpatient use.

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Department of Health Professions

18VAC110-20-536 Prescription drugs sent outside the facility, cont.

- Pharmacies providing medication to residents in compliance packaging consistent with 18VAC110-20-340 B, shall assure that if the facility separates and sends only the individual containers needed during the time the resident is away without the main package label, that the resident is also given a copy of the main package label or other appropriate documentation that contains the complete labeling information on the main package label.

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Department of Health Professions

18VAC110-20-540 Emergency drug kit

- Formalizes provision, previously stated in guidance document, that only a licensed nurse, pharmacist, or prescriber may access and administer a drug taken from an emergency drug kit provided to a LTC facility.

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Department of Health Professions

18VAC110-20-550 Stat drug box

- Formalizes provision, previously stated in guidance document, that only a licensed nurse, pharmacist, or prescriber may access and administer a drug taken from stat drug box provided to a LTC facility.
- Requires a valid order or lawful order prior to removing drug from box.

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Department of Health Professions

18VAC110-20-590 Drugs in correctional facilities

- Allows a correctional facility, as now defined in 18VAC110-20-10, to send the pharmacy a copy of the drug administration record, or other form showing substantially the same information, when returning unused or discontinued drugs.
- Previously required the actual drug administration record to be sent to the pharmacy.

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18VAC110-20-590 Drugs in correctional facilities

- Clarifies that vaccines may be floor-stocked at a medical clinic or surgery center that is part of a correctional facility staffed by one or more prescribers during the hours of operation when the clinic obtains a controlled substances registration.



Prescription Drug Donation Program



§54.1-3411.1 Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions

- Emergency regulations became effective 4/10/09 for a prescription drug donation program for accepting qualifying unused previously dispensed prescription drugs for the purpose of re-dispensing such drugs to indigent patients, either through hospitals, or through clinics organized in whole or in part for the delivery of health care services to the indigent.



18VAC110-20-750 Eligible drugs

- Drugs may be accepted by a registered drug donation site if:
 1. Official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, as set forth in § 54.1-3411.1, subdivision A2;
 2. The drugs bear an expiration date that is not less than 90 days from the date the drug is donated; and
 3. The drugs have not been adulterated or misbranded.



18VAC110-20-750 Eligible drugs, cont.

- Drugs that do **NOT** qualify for donation:
 1. Schedule II-V controlled substances or any other drug, if such return is inconsistent with federal law;
 2. Drugs determined to be hazardous for donation based on the pharmacist's professional judgment, experience, knowledge, or available reference materials;
 3. Drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and
 4. Drugs that have been previously compounded.



18VAC110-20-750 Eligible drugs, cont.

- Any pharmacy wishing to participate in a donation program shall submit the form [Registration For A Pharmacy To Be A Collection Site For Donated Drugs](#) found on the Board's website under Forms and Applications.
- No fee.
- Board will post names of participating pharmacies on its website for consumer use.



Prescription Drug Donation Program

- Participating pharmacy may either redispense qualifying drugs directly to a qualifying patient or may transfer drugs to another pharmacy registered to participate such as a free clinic pharmacy for this pharmacy to then redispense the drug directly to the patient.
- The pharmacy re-dispensing donated drugs shall not charge for cost of donated drugs, but may charge a dispensing or administrative fee for each such drug re-dispensed, consistent with provisions of subdivision 10 of § 54.1-3301.

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Prescription Drug Donation Program

- Complete regulations regarding process may currently be found on Board's website under Laws and Regulations, Emergency Regulations.

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Potential Breach of Security of PMP

- On April 30, 2009, DHP recognized an unauthorized message posted on the PMP website.
- DHP immediately shut down all computer systems to protect the security of its data.
- State authorities including VITA and law enforcement were notified.
- At the time of system shut-down, all DHP data had been properly backed up.
- Back up files had been properly secured.

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Current Situation of PMP

- Ongoing forensics investigation being conducted by VITA Commonwealth Security & Northrop Grumman with support from DHP, and in coordination with law enforcement.
- Information regarding steps citizens may take to safeguard against identity theft has been posted on DHP's website.
- Notification letters sent to some patients and registered users with numbers that *may* have been SSN's.
- "Best practices" information sent to pharmacy organizations for further distribution.
- Federal and State criminal investigation is still ongoing.

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Prescription Monitoring Program Status

- Data collection never ceased and was not affected by breach.
- Processing of manual requests began June 26, 2009—processed backlog of requests—new requests now being accepted via fax.
- New software and hardware are being tested and expected to be available in August 2009.
- New software will provide:
 - 24/7 access via internet
 - Response in 1-3 minutes for most requests (internet only)
 - New report format to provide more information on each Rx

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Board of Pharmacy website

www.dhp.virginia.gov/pharmacy

pharmbd@dhp.virginia.gov

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Department of Health Professions

Questions??

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