COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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Tentative Agenda of Regulation Committee Meeting
Periodic Regulatory Review, Inducements for Transferring Prescriptions

January 5, 2016

1PM

TOPIC	PAGES
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• Approval of Agenda	
Call for Public Comment	
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*Regulation packets available at
http://www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm

Adjourn

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date: December 2, 2015

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Periodic Regulation Review

Staff's Suggested Amendments - DRAFT

2nd Meeting, January 5, 2016

18VAC110-20-240

- Consider adding language from GD 110-16 regarding inventories into regulation

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

A. Each pharmacy shall maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. *The perpetual inventory shall accurately indicate the physical count of each Schedule II drug on-hand at the time of the inventory. When conducting the monthly reconciliation an explanation for any difference between the physical count and the theoretical count must be noted in the inventory record.* Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.

3. All executed order forms, prescriptions, and inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to Schedule II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and he is unable

to determine the exact kind and quantity of the drug loss. Dispensers, researchers, and reverse distributors may otherwise perform the inventory in a manner consistent with federal allowances, as listed in 21 CFR 1304.11, which require a physical count of drugs in Schedules I and II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules. Nothing shall prohibit a person from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

~~5~~6. Invoices or other records showing receipts of Schedule VI drugs shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

~~6~~7. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard-copy prescription for those patients listed in subdivision 1 of this subsection.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

18VAC110-20-270

- Consider moving allowance for drop boxes in GD 110-32 into regulation

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians; *use of drop boxes.*

A. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.

C. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the

responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

D. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

E. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

F. An on-hold prescription shall be entered into the automated data processing system, if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

G. A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box must be located in a visible area within the permitted facility and must be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. At no time shall a patient be allowed to leave containers to be refilled which contain drug.

18VAC110-20-275

- Discuss delivery of CII-VI drugs to a central desk at other facilities, e.g., ALFs, hotels, places of employment, etc.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

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h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

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18VAC110-20-276, 18VAC110-20-280, 18VAC110-20-285

- Clarify that signature must be manual for written prescriptions unless electronically transmitted (currently in GD 110-35)
- Clarify that written and oral prescriptions shall include quantity or duration of order by which pharmacist can calculate authorized quantity (currently in GD 110-35)
- Do we need to clarify whether a chart order in a LTCF requires a quantity or duration? (no draft language provided)
- Is there value to 18VAC110-20-280 A,1,C or should it be removed?

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

A. Unless otherwise prohibited by federal law, prescription orders for Schedule III through VI drugs may be transmitted to pharmacies by facsimile device (FAX) upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's *manual* signature~~.~~ *, quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.*

3. An authorized agent, as defined in §54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

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c. Forwarding a written prescription 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.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with §54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's *manual* signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's *manual* signature or agent's name, and date of authorization.

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

A. Unless otherwise prohibited by law, an electronic prescription may be transmitted from the prescriber or an authorized agent as defined in § 54.1-3408.01 C of the Code of Virginia directly to the dispensing pharmacy. Electronic prescriptions of Schedule II-V controlled substances shall comply with any security or other requirements of federal law. All electronic prescriptions shall also comply with all security requirements of state

law related to privacy of protected health information. *Electronic prescriptions shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.*

B. A pharmacy receiving an electronic prescription shall maintain such prescription record in accordance with 18VAC110-20-250 A.

C. An electronic prescription shall be transmitted only to the pharmacy of the patient's choice.

18VAC110-20-276 Prescription Requirements

In addition to the requirements in §54.1-3408.01 for a written prescription or oral prescription, such prescriptions shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature or agent's name.

18VAC110-20-290

- Add language from GD 110-41, allowable changes to a CII prescription

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in §54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, he shall make a reasonable effort to determine that the oral authorization came from a practitioner using his phone number as listed in the telephone directory or other good-faith efforts to ensure his identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person, by mail postmarked within the seven-day period, or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to him. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law, or the prescriber's signature.

18VAC110-20-330

- Consider requiring prescription labels to include drug expiration date

18VAC110-20-330. Labeling of prescription as to content and quantity.

Unless otherwise directed by the prescribing practitioner, any drug dispensed pursuant to a prescription shall bear on the label of the container, in addition to other requirements of §§54.1-3410 and 54.1-3463 of the Code of Virginia, the following information:

1. The drug name and strength, when strength is applicable:

a. For any drug product possessing a single active ingredient, the generic name of the drug shall be included on the label.

b. If a generic drug is dispensed when a prescription is written for a brand name drug, the label shall contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed.

c. The requirements of subdivisions 1 a and b of this section shall not apply to drugs dispensed to patients of a hospital or long term care facility where all drugs are administered by persons licensed to administer.

2. The number of dosage units or, if liquid, the number of milliliters dispensed.

3. The expiration date of the drug.

18VAC110-20-490

- Consider streamlining requirements for use of ADDs in hospitals
- Consider clarifying that drugs for emergency use may include drugs required for first doses
- Consider clarifying drugs stored for emergency purposes not restricted to quantities for emergency box

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug

name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports.

A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records from each device per month for possible diversion by fraudulent charting. The review shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections.

Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-550

- Consider clarifying that facility may possess multiple stat-drug boxes; must contents be uniform between boxes?

18VAC110-20-550. Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. *The provider pharmacist in consultation with the medical and nursing staff of the long-term care facility shall determine the number of stat-drug boxes a facility may possess at any given time.* A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient

18VAC110-20-555

- Consider streamline ADD requirements for nursing homes
- Consider clarifying that drugs for emergency use may include drugs required for first doses
- Consider clarifying drugs stored for emergency purposes not restricted to quantities for emergency box

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have on-line communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system.

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has on-line access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

4. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

5. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; nursing home; and a unique identifier for the specific device receiving drugs; and initials of pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

6. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

7. At the time of loading, the delivery record for all Schedule II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

8. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

9. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

10. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

11. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

12. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

13. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained off site or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-425

- Consider streamlining robotic pharmacy system regs (no copy or draft language provided)

18VAC110-20-425. Robotic pharmacy systems.

Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be

maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and shall include at a minimum, procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. Maintaining quality assurance reports.

5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all doses or compliance packages and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.

c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.

d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.

9. All unanticipated downtime shall be immediately reported to the board.

10. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Commonwealth of Virginia

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-50-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date: July 16, 2015

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Regulations Governing Wholesale Distributor, Manufacturer, and Warehousers

18VAC110-50-40

- Consider requiring back-up alarm similar to pharmacies

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer or warehouser shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be operable, centrally-monitored, ~~and~~ have an auxiliary source of power., *and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.*

4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, or warehouser, and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

18VAC110-50-60

- Consider expanding ability to issue limited-use for other entities, e.g., brokers, which engage in wholesale distribution or manufacturing but do not stock drugs

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license, *nonresident wholesale distributor registration, restricted or nonrestricted manufacturer permit* to entities that do not engage in the wholesale distribution of prescription drugs except medical gases *or entities that engage in wholesale distribution or manufacturing but do not stock drugs* and may waive certain requirements of regulation based on the limited nature of such distribution. *The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.*

18VAC110-50-70

- Consider placing language from GD 110-34 regarding SSN or control number into regulation

110-34 - **Manufacturer and Wholesale Distributor Licensure Guidance**

The holder of a New Drug Application or Abbreviated new Drug Application located in Virginia, regardless of whether it physically receives, stores or ships prescription drugs into the Commonwealth is deemed to be engaged in the practice of manufacturing and therefore must obtain a non-restricted manufacturer permit, prior to engaging in business in Virginia.

A non-resident wholesale distributor does not need to obtain a Virginia Controlled Substances Registration in order to distribute Schedule II-V controlled substances. This registration is required for a licensed wholesale distributor or manufacturer located within Virginia that possesses Schedule II-V controlled substances.

To comply with the requirements for submission of a social security number or control number as required in Regulation 18VAC110-50-70, the following individuals shall provide a social security number or control number:

- the person serving as the responsible party, and;
- the individual owner or sole proprietor, or;
- each partner, or corporate officer and director, who is specifically responsible for the operations of the facility listed on the application.

18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee;

3. The federal employer identification number of the applicant or licensee;

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility;

(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.

(4) The name, federal employer identification number, and state of incorporation of the parent company.

d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;

e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;

5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and

9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

18VAC110-50-80

- Consider requiring federal criminal history record check, not limited to Virginia Central Criminal Records Exchange

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A criminal history record check through the Central Criminal Records Exchange; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. Requiring any employee who has access to prescription drugs to attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs.

3. Maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. Maintaining proper security, storage and shipping conditions for all prescription drugs.

5. Maintaining all required records.

E. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record.

COMMONWEALTH of VIRGINIA

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December 10, 2015

Bill Irvin, R.Ph.
Director, Pharmacy Regulatory Affairs
13 Commerce Avenue
Londonderry, NH 03053

Dear Mr. Irvin:

The Virginia Board of Pharmacy would like to thank you for submission of a petition for rule-making on behalf of Omnicare to amend regulations to allow a pharmacy providing services to a long term care facility to provide prescription information of Schedule VI drugs to a "back-up" pharmacy. In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on December 28, 2015. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until January 27, 2016.

Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016, and you will be informed of the Board's decision on your request after that meeting.

Again, the Board appreciates your interest in amending the regulations governing the practice of pharmacy.

Very truly yours,

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

cc: Elaine J. Yeatts
Agency Regulatory Coordinator

MOTION:

Mr. Adams moved to recommend to the full board that it consider requiring the printed name and signature when documentation is required within Regulation 18VAC110-20-500. (Motion died for lack of a second.)

CQI REGULATION:

The Committee discussed the proposed replacement regulations for continuous quality improvement programs. Ms. Juran reported that she had spoken with R. Brent Rawlings who submitted public comment on behalf of the Virginia Hospital and Healthcare Association during the last public comment period. Mr. Rawlings stated his clients had not expressed specific concerns regarding the proposed replacement regulations, however, he was slightly concerned that once the dispensing error is reported to a patient safety organization that it cannot be used to defend a possible lawsuit. He acknowledged to Ms. Juran that not requiring the submission of a dispensing error to a patient safety organization may not be consistent with the intent of the statute. Ms. Thornbury later questioned the intent of the proposed definition for "dispensing error" and whether an error that was corrected prior to the patient receiving it but after the pharmacist's final verification should be treated as a dispensing error. The consensus of the Committee was that such a "near miss" should be treated as a dispensing error since the error was not found during the pharmacist's final verification process.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend the proposed definition of "dispensing error" in Regulation 18VAC110-20-10 by adding "regardless of whether the patient received the drug" following the phrase "after the final verification by the pharmacist" and to adopt the proposed CQI regulations as amended. (motion by Thornbury, second by Adams)

PHARMACY COUPONS:

The Committee discussed the information contained in the agenda packet with a focus on whether a prohibition against incenting patients to transfer prescriptions could be construed as a restraint of trade. Ms. Juran reported that New York is currently defending a law suit for its current prohibitions against incenting patients. She also stated that the executive director of Oregon indicated its language prohibits pharmacies from incenting the transferring of prescriptions, but allows the incenting of patients to retain their prescriptions at a single pharmacy such as through loyalty programs. Board counsel stated that he did not believe Oregon's language could be construed as a restraint of trade. The Committee reviewed a proposed amendment to unprofessional conduct found in Regulation 18VAC110-20-25 that staff prepared using language similar to Oregon.

MOTION:

The Committee voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action regarding the use of coupons to incent patients to transfer prescriptions. (motion by Adams, second by Munden)

LEGISLATIVE PROPOSALS:

- WHOLESALE

* Handout reviewed by Regulation Committee on 5/12/14

§ 54.1-3316. Refusal; revocation; suspension and denial.

The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;

2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;

3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;

4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;

5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;

6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;

7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;

8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;

9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;

10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;

11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;

12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;

13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or

14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

(1972, c. 798, § 54-524.22:1; 1976, c. 614; 1977, c. 86; 1982, c. 401; 1988, c. 765; 1992, c. 868; 1994, c. 296; 2007, c. 662.)

* Proposed amendment drafted by staff for Regulation Committee on 5/12/14

From *Regulations Governing the Practice of Pharmacy*, February 12, 2014

18VAC110-20-25. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing; or

11. Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not limited to, incenting or inducing the transfer of a prescription absent professional rationale.

Responses from Select States regarding Use of Pharmacy Coupons:

Oregon – per Oregon executive director
-appears able to avoid any trade issues by still allowing the use of coupons, etc to incent the person to stay with an outlet (i.e. loyalty programs) vs incenting them to switch
-no challenges to rule as of yet
-allowed businesses about 6 months to clear their advertising pipelines

855-041-1170
Grounds for Discipline
The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:
(1) Unprofessional conduct as defined in OAR 855-006-0005;
(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:
(a) Is false, fraudulent, deceptive, or misleading; or
(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.
(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:
(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.
(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.
(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:
(A) Drug Utilization Review;
(B) Immunization;
(C) Counseling;
(D) Verification of the accuracy of a prescription; and
(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.
(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.
(5) Incenting or inducing the transfer of a prescription absent professional rationale.
Stat. Auth: ORS 689.151, 689.155(2), 689.205, 689.225(4)
Stats. Implemented: ORS 689.155
Hist.: BP 2-2012, f. & cert. ef 6-12-12; Renumbered from 855-041-0016, BP 7-2012, f. & cert. ef. 12-17-12

New Jersey
-does not allow incentives to patients to transfer prescriptions, except as outlined below:
From N.J.S.A. 45:14-65 (26)(e) Refusal of application for examination, suspension, revocation of certificate; procedure.

e. The distribution of premiums or rebates of any kind whatsoever in connection with the sale of drugs and medications provided, however, that trading stamps and similar devices shall not be considered to be rebates for the

purposes of this act and provided further that discounts, premiums and rebates may be provided in connection with the sale of drugs and medications to any person who is 60 years of age or older.

New York

- Currently involved in federal law suit for its current prohibition.

Iowa

- Attempted to pass an administrative rule which prohibited pharmacy coupons for Rx transfers about 14 years ago, but was unsuccessful. The Board has not made another attempt based on advice from their AG's office that it may be a restraint of trade.

- Reconsideration of a fast-track regulation on EMS:

The Regulation Committee recommended that the board adopt the proposed changes to the EMS regulations and requested that they be fast-tracked. The amendments to the regulation would allow for an EMS agency to conduct a 1 for 1 exchange for schedule VI drugs or devices. Ms. Juran suggested a change in the language on page 60 under section 6, line 4, to add the wording "by the pharmacy".

MOTION:

The Board voted unanimously to adopt the change that was suggested by Ms. Juran to add the wording "by the pharmacy" on page 60, section 6, line 4. (motion by Stelly, second by Warriner)

Battalion Chief Jennie Collins with Prince William County Department of Fire and Rescue and Sam Dahl, Director of the Northern Virginia EMS Council requested that the Board consider suggested language on page 58 under 18VAC 110-20-500, section A, number 2 to add the wording "theft and loss" after "and aid in detection". Also, changes were suggested on page 61 under section B to add at the end of the sentence "provided that the schedule II, III, IV and V drugs are in a separate, sealed container".

MOTION:

The Board voted unanimously to adopt the amended language on page 58 that adds the wording "theft or loss" and on page 60 that adds "provided that the schedule II, III, IV and V drugs are in a separate, sealed container". (motion by Shinaberry, second by Warriner)

MOTION:

The Board voted unanimously to adopt the proposed regulations for EMS agencies as fast-track regulations as recommended by the Regulation committee and amended by the board. (motion by Stelly, second by Rhodes)

- Adoption of NOIRA prohibiting the offering of incentives or inducements to transfer prescriptions:

Ms. Yeatts reminded the members of the petition for rule-making that was submitted by Daniel Colpo requesting that the Board amend regulations in order to prohibit the offering of incentives or inducements that would entice patients to transfer their prescriptions. The board had denied the petition for rulemaking at the March 2014 full board meeting, but referred the matter to the Regulation Committee for further consideration.

MOTION:

The Board voted unanimously to adopt a Notice of Intended Regulatory Action (NORIA), as recommended by the Regulation Committee, that would prohibit the offering of incentives or inducements to transfer prescriptions. (motion by

Shinaberry, second by Adams)

Virginia Regulatory Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	Unprofessional conduct to induce or incentivize a patient to transfer prescriptions
Date this document prepared	6/5/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the regulatory action is to amend section 25, which sets out the practices that constitute unprofessional conduct and may be grounds for disciplinary action pursuant to § 54.1-3316. The new provision would prohibit advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing a patient to transfer a prescription absent professional rationale by use of coupons, rebates, etc. The action responds to a petition for rulemaking from a Virginia pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy 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 authority to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

In 2012, the U. S. Department of Justice resolved allegations against Walgreens Pharmacy with a $7.9 million payment because the chain offered beneficiaries of government health care programs (Medicare, Medicaid, TRICARE, etc.) inducements that are prohibited by law to transfer prescriptions to Walgreen pharmacies. Quotes from federal law enforcement illustrate the need to enact such a prohibition in Virginia. The U. S. Attorney for the Eastern District of Michigan said, "Continuity with a pharmacist is important to detect problems with dosages and drugs interactions. Patients should make decisions based on legitimate health care needs, not on inducements like gift cards." The Inspector General for the Department of Health and Human Services, said, "Violating Federal health care laws, as Walgreens allegedly did by offering incentives for new business, cannot be tolerated."

As the Virginia Pharmacists Association stated in its letter of support for a regulatory change, "Transfer coupons and other transfer incentives fragment the medication records of patients which leads to inaccuracies in the mediation records and is detrimental to patient care." The Board has determined that there is a need to propose a regulation to protect the health, safety and welfare of the citizens who count on Virginia pharmacies for accuracy and integrity in filling prescriptions.

Substance

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Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The proposed regulation would make it unprofessional conduct to offer inducements or incentives, such as coupons or gift cards, for a patient to transfer a prescription, absent any professional rationale for such transfer. Customer rewards or affinity cards that encourage loyalty to a pharmacy would not be considered unprofessional.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

At its meeting on March 26, 2014, the Board considered the petition for rulemaking submitted by Daniel Colpo to prohibit pharmacies from incentivizing patients through pharmacy coupons to transfer prescriptions from one pharmacy to another. The petitioner indicated in the petition that he believes this promotion leads to medication safety concerns through incomplete drug utilization review and profile data and transcription errors. Several board members expressed concern for the practice and referenced the position of concern from the Institute for Safe Medical Practices and a recent review of this practice by the Department of Justice. Because there was some concern that a regulatory action might constitute a restraint of trade, the Board voted to deny the petitioner's request but to refer the matter to the regulation committee for further consideration.

At its meeting on May 12, 2014, the Committee discussed additional information relating to prohibition on coupons, including language from other states and a press release from the U. S. Department of Justice, with a focus on whether a prohibition against incenting patients to transfer prescriptions could be construed as a restraint of trade. Ms. Juran reported that New York is currently defending a law suit for its current prohibition against pharmacy coupons. She also stated that the executive director of Oregon indicated its language prohibits pharmacies from incenting the transferring of prescriptions, but allows the incenting of patients to retain their prescriptions at a single pharmacy such as through loyalty programs. Board counsel advised that the Oregon regulatory language did not appear to represent a restraint of trade. The Committee reviewed a possible amendment to the unprofessional conduct section of regulation using language similar to Oregon and voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action regarding the use of coupons to incent patients to transfer prescriptions.

Public participation

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in

§ 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or at elaine.yeatts@dhp.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (**http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi**). Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.

There is no impact on the family.