

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

December 12, 2012
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:16 AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Cynthia Warriner

MEMBERS ABSENT: Pratt P. Stelly
Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

QUORUM: With eight members present, a quorum was established.

APPROVAL OF AGENDA: With no changes to the agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the October 1, 2012 (Full Board Meeting), October 24, 2012 (Special Conference Committee and Informal Conference Committee), November 6, 2012 (Special Conference Committee and Informal Conference Committee), November 20, 2012 (Telephone Conference Call), November 28, 2012 (Informal Conference Committee for Innovative Pilot Programs), and November 29, 2012 (Panel Formal Hearing). There was a suggestion to add the list of standing committees to page 7 of the October 1, 2012 full board meeting minutes under the "Scheduling of 2013 dates for full board meetings".

MOTION: **The Board voted unanimously to approve the minutes as amended. (motion by Warriner, second by Allen)**

PUBLIC COMMENTS:

There were no public comments offered at this time.

DHP DIRECTOR'S REPORT:

Dr. Cane discussed with the Board the three legislative proposals that will be included in the Governor's package. The first one proposes to eliminate the Psychiatric Advisory Board since it has never had a need to meet. The second proposes a prohibition for a Department of Health Professional licensee from being able to practice on a suspended or revoked license pending appeal of the board's order. The third proposes placing the anabolic steroids prostanazol and methasterone into Schedule III of the Drug Control Act to conform to recent federal scheduling action.

Dr. Cane attended the Milbank Conference, along with state legislators and agency heads, to discuss how to reduce the abuse of prescription drugs. The Southwest Drug Abuse Summit was held November 14th in Wytheville, Virginia. Dr. Cane and Ralph Orr, Director of the Prescription Monitoring Program, attended. In January, Virginia's working committees associated with the National Governors Association policy grant efforts to reduce prescription drug abuse will meet. Arne Owens, Chief Deputy Director of the Department of Health Professions, will preside as Chair and work directly with Caroline Juran and Ralph Orr.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated the emergency regulations for continuous quality improvement programs (CQI) went into effect on October 1, 2012 and that they will expire in one year but may be extended for an additional six months after expiration. The proposed regulations for CQI to replace the emergency regulations will be presented during the meeting to the Board for adoption. The comment period for the notice of intended regulatory action (NOIRA) addressing the hours of continuous work by pharmacists closed on October 10, 2012. The proposed regulations for pharmacist working conditions (hours of continuous work by pharmacists) was drafted by the Regulation Committee at the December 11, 2012 meeting, and will be presented to the Board for adoption. The adopted regulations for administrative fees for duplicate licenses and verifications are currently at the Secretary's Office. Three sets of proposed regulations will be included in the Governor's fast-track regulatory reform initiative because they are less restrictive or burdensome: on-hold prescriptions; automated dispensing devices; and run-dry requirement for automated counting devices.

- Adoption of proposed regulations for CQI to replace emergency regulations:

Ms. Shinaberry discussed the Regulation Committee's recommendation for the proposed CQI regulations to replace the emergency regulations.

MOTION:

The Board voted unanimously to adopt the proposed continuous quality improvement program (CQI) regulations as moved by the Regulation Committee. (second by Adams)

- Adoption of proposed regulations for working conditions of pharmacists:

Ms. Shinaberry stated the Regulation Committee's recommendation to adopt proposed regulations regarding working conditions of pharmacists. Specifically, the committee recommended adding a new section B to Regulation 18VAC110-20-110 which states: "Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30 minute break." There was discussion regarding whether regulatory action was needed or if a stepwise approach beginning with Board guidance was more appropriate. The term "emergency" as used in the proposed regulation was also discussed. It was agreed that staff sickness or inclement weather could constitute an "emergency".

MOTION:

The Board voted to adopt the proposed regulations regarding working conditions of pharmacists as recommended by the Regulation Committee. (second by Adams; opposed by Warriner, Allen, and Kozera)

- Adoption of fast-track regulations resulting from Governor's regulatory reform initiative:

Ms. Yeatts presented the Board for its consideration staff recommendations to amend certain regulations as part of the Governor's regulatory reform initiative. Because the amendments would create less restrictive regulations with likely no opposition, they could move forward as fast-track regulations. Suggested amendments were made to *Regulations for Practitioners of the Healing Arts to Sell Controlled Substances* (Attachment A), *Regulations for Collaborative Practice Agreements* (Attachment B), and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen* (Attachment C). Suggested changes to the *Regulations Governing the Practice of Pharmacy* will be presented at the March 2013 full board meeting.

Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

- 18VAC110-30-20 – amendment suggested to conform language to Code
- 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130 – amendments suggested for consistency with regulations for pharmacies and to recognize allowances which are currently approved under a limited-use license

MOTION:

The Board voted unanimously to adopt the Regulation Committee's recommendation for proposed fast-track regulatory amendments of *Regulations for Practitioners of the Healing Arts to Sell Controlled Substances* (18VAC110-30-20, 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130) as presented by staff.

Regulations for Collaborative Practice Agreements

- 18VAC110-40-10- consistent with the definition of “collaborative agreement” in §54.1-3300, a definition of “alternate practitioner” is suggested to clarify that a licensed nurse practitioner or physician assistant who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy, or podiatry may participate in a collaborative practice agreement

MOTION:

The Board voted unanimously to adopt the Regulation Committee’s recommendation for proposed fast-track regulatory amendments of *Regulations for Collaborative Practice Agreements* (18VAC110-40-10 and 18VAC110-40-20) as presented by staff.

Regulations Governing Wholesale Distributors, Manufacturers, and Warehouseurs

- 18VAC110-50-70 – amendment suggested to clarify who must provide a social security number or control number as currently indicated in Guidance Document 110-34
- 18VAC110-50-40 and 18VAC110-50-80 – amendments to clarify intent of regulations

MOTION:

The Board voted unanimously to adopt the Regulation Committee’s recommendation for proposed fast-track regulatory amendments of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehouseurs* (18VAC110-50-40, 18VAC110-50-70, and 18VAC110-50-80) as presented by staff.

UPDATE ON ACTION ITEMS:

- Discussion of “authorized generics”

Ms. Juran gave an overview of the research that she obtained at the Board’s request during the October 1, 2012 full board meeting concerning “authorized generics”. While surveying states to determine how they address authorized generics, she was provided an excerpt from a newsletter posted by the Kentucky Board of Pharmacy which referenced the preface of the FDA Orange Book which states, “Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder’s drug product even if the application holder’s drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder’s drug product are considered to have the same code as the application holder.” Thus, it appears FDA considers authorized generics to be therapeutically equivalent to branded products.

MOTION:

The Board voted unanimously to adopt a guidance document that deems “authorized generics” as being therapeutically equivalent to branded products as stated in the 32nd edition of the FDA Orange Book and have staff reference this information in the next

newsletter. (motion by Warriner, second by Shinaberry)

ADDITION TO AGENDA:

The Board approved an additional item to the agenda, ethics training offered by Board counsel, after the consideration of consent orders.

MISCELLANEOUS:

- Update on actions taken regarding pharmacies performing sterile compounding, staff request for additional guidance:

Ms. Juran gave the Board an update of actions taken by staff since the October 1, 2012 full board meeting to address recent concerns for sterile compounding pharmacies located in Virginia or registered with the Board as non-resident pharmacies. The nonresident pharmacy registration held by the New England Compounding Center (NECC) was mandatorily suspended on October 5, 2012. Staff had numerous communications with FDA, CDC, and VDH state epidemiologists to receive updates on NECC and Ameridose, posted updates on board's website, and responded to numerous media inquiries. Board staff worked collaboratively with the Enforcement Division to identify pharmacies located in Virginia that perform sterile compounding and increased efforts to perform routine inspections of these pharmacies. Ms. Juran reminded the members that it has been a longstanding policy to perform routine unannounced pharmacy inspections approximately every two years. Additionally, in an effort to identify the nonresident pharmacies that are shipping compounded sterile products (CSP) into Virginia, staff mailed on November 27, 2012, with the Chairman's approval, a written request to all nonresident pharmacies registered in Virginia. The request seeks confirmation if the pharmacy is shipping CSP into Virginia and requires submission of documents indicating compliance with sterile compounding standards listed in USP Chapter 797. The Chairman will appoint an ad hoc committee of the Board to assist staff in reviewing the submitted documents. A submission deadline of December 28, 2012 was provided. Staff also recently responded to two Congressional committee requests sent to all boards of pharmacy to determine each state's oversight on sterile compounding. Ms. Juran reported that she and Mr. Casway will attend a 50 state intergovernmental meeting hosted by the FDA on December 19, 2012 in Silver Spring, MD. Staff has reviewed the number of pharmacy inspectors currently employed and has received approval to hire one additional pharmacy inspector. A second hiring request for board staff will be submitted as well for consideration. All state hiring requests must be approved by the Chief of Staff. Staff is recommending the Board review Guidance Document 110-9 to determine if any deficiencies related to sterile compounding should be revised since they were implemented over a year ago. Staff obtained a free 42-module of continuing education for staff and members regarding USP standards. Staff has been and will continue to stay abreast of NABP's efforts to address sterile compounding. Many of NABP's efforts were determined at the recently held Executive Officer Forum which Ms. Juran attended.

- Consideration of possible legislative amendments regarding licensure and renewal process of non-

Staff is aware that legislators and/or stakeholders may be contemplating legislation to address sterile compounding concerns. Staff provided members with possible statutory amendments which could be considered by legislators and sought a reaction from the members. The Board also

resident pharmacies and
compounding:

received public comment from several practicing pharmacists on the issue of sterile compounding. Cheri Garvin with Leesburg Pharmacy stated that states should continue to regulate compounding, but that uniform national standards such as PCAB accreditation are necessary. She indicated that a myriad of drugs are compounded for office-use and therefore, did not support elimination of compounding for office-use. She expressed concern for non-resident pharmacies that appear to ship compounded drugs for resale when Virginia law prohibits it.

Baylor Rice from South River Compounding Pharmacy addressed the Board stating that the compounding pharmacies in Virginia have not had any major issues and that he believes the legislation that is currently in place is adequate. Mr. Rice serves as a board member for the International Academy of Compounding Pharmacists and suggested the members reference its position paper. Mr. Rice and Ms. Garvin indicated they would be willing to assist the board as necessary. Sonny Currin representing Rx3 Compounding Pharmacy discussed his concerns and expressed value for the positive service that compounding pharmacies offer patients. He expressed concern for non-resident pharmacies that ship CSP into Virginia for office-use.

In discussing whether possible legislative amendments are necessary, the Board expressed some concern for eliminating the ability to compound for office-use since this may impact patient access to needed drugs and further review of the subject would be warranted. There was positive feedback for holding nonresident pharmacies to similar standards as resident pharmacies by requiring a current inspection report to be taken within the last 6 months prior to the issuance of a nonresident pharmacy registration, a requirement for submission of a current inspection report from nonresident pharmacies upon renewal in even years with the report having been taken within the last 2 years, and clarification that inspection reports for nonresident pharmacies shall indicate compliance with USP 797 standards. Additionally, there was positive feedback for requiring all healthcare professionals who perform sterile compounding to comply with USP standards.

- Adoption of amendments to guidance document 110-9

Mr. Johnson gave the Board an overview of the proposed amendments made to Guidance Document 110-9 that refers to inspection deficiencies. The changes made to the Guidance Document reflected primarily around sterile compounding.

MOTION:

The Board voted unanimously to adopt the proposed amendments to Major deficiency 20 with additional changes made to the wording under section 20a by omitting “checking” and adding “final verification” and to section 20b by omitting “checking” and adding “final verification”. (motion by Rhodes, second by Allen)

MOTION:

The Board voted unanimously to adopt the proposed amendment to Major deficiency 21 to increase the monetary penalty to \$10,000. (motion by Munden, second by Allen)

MOTION:

The Board voted unanimously to adopt the proposed amendments to

Major deficiencies 22 and 23 and added the wording to Major 22 under conditions "Review 2 most recent reports". (motion by Allen, second by Munden)

MOTION: The Board voted unanimously to adopt the proposed amendments to Major deficiencies 25, 25a, 25b, and 25c. (motion by Adams, second by Rhodes)

MOTION: The Board voted unanimously to adopt the proposed amendments to Major deficiencies 26 and 26a. (motion by Allen, second by Adams)

MOTION: The Board voted unanimously to adopt the proposed amendments to Major deficiency 33. (motion by Munden, second by Rhodes)

MOTION: The Board voted unanimously to adopt the proposed amendments to Minor deficiencies 30 and 30a, and adding under law/regulation citations "54.1-3410.2". (motion by Rhodes, second by Adams)

MOTION: The Board voted unanimously to adopt the proposed amendments to Minor deficiencies 31 and 32. (motion by Munden, second by Allen)

REPORTS:

- Report on Board of Health Professions:

Mr. Rhodes gave an update to the Board regarding previous and upcoming meetings with the Board of Health Professions. The full board met on October 2, 2012. It was reported that the Perfusionist study is moving forward and the next step is for the Committee to receive public comment on the profession. The Pharmacy Scope of Practice & Team Delivery study is being continued in deference to the General Assembly's action on potential legislation under development by the Virginia Pharmacist Association and Medical Society of Virginia. The Committee was not privy to specific language under consideration at that time. A request to regulate medical assistants has been sent back to the Regulatory Research Committee to obtain additional information regarding the study. BHP staff will be coordinating on the development of a draft website for DHP dedicated to providing information relative to military service member, military spouses, and veterans. There will be information on relevant statutes and licensure requirements and links to the key Commonwealth websites for services and information relating to educational, training, employment, and other issues of significance. The Regulatory Research Committee met on October 2, 2012 and Dr. Carter reported that the Board of Pharmacy' comments were positive concerning the recommendations for collaborative practice put forward by the Virginia Pharmacists Association (VPhA) in response to the Committee's review. The Committee agreed that the Pharmacy Scope of Practice & Team Delivery study should continue after the General Assembly has had the opportunity to address the anticipated 2013 legislation. BHP staff will continue to prepare information on the pharmacy technician scope of practice for presentation at the next meeting scheduled for February 5, 2013. The Regulatory Research Committee held a public hearing on perfusionists on December 3, 2012.

- Report on Licensure Program:

Mr. Johnson reported that the Board issued 1,047 licenses and registrations for the period of September 1, 2012 through November 30, 2012, including 148 pharmacists, 299 pharmacy interns, and 457 pharmacy technicians. Inspectors conducted 251 facility inspections including 72 routine inspections of pharmacies: 23 resulted in no deficiency, 9 with deficiencies, and 40 with deficiencies and a consent order. One innovative (pilot) program for the utilization of the InstyMeds automated dispensing device in an immediate care center was approved by an informal conference committee.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of March 12, 2012; June 8, 2012; September 28, 2012; and December 11, 2012. For the final date, open cases are 72 at the investigation stage; 66 at the probable cause stage; 11 at the administrative proceedings division stage; 15 at the informal stage; three at the formal stage; and 39 at the pending closure stage.

- Executive Director's Report:

Ms. Juran presented the members with the Board's revenue and expenditures summary report and asked if they would like a copy provided to them at each board meeting. She stated that the Board's expenses are relatively steady and that it has been in good financial standing for several years. She reported that Leo Ross, former Board member, attended the International Pharmaceutical Federation Centennial Congress in Amsterdam in October. Board members Cynthia Warriner, Crady Adams, Ellen Shinaberry and Robbie Rhodes attended the NABP District 1&2 meeting in SkyTop, Pennsylvania with Ms. Juran in mid-October. There was much discussion at the meeting regarding collaborative practice agreements and possible expansion of pharmacist allowances under these agreements. An informative presentation was given by the Assistant Surgeon General of the U.S., Scott Giberson, who is also a pharmacist. District II discussed the bylaws associated with becoming a 501c and passed a resolution that NABP needs to encourage state boards to require accreditation of pharmacies that perform sterile compounding. Another resolution discussed was to prohibit pharmacies acting as a wholesale distributor under the 5% allowance, except for emergencies since this appears to be creating gray market concerns. Ms. Juran also attended the first Tri-Regulator meeting in Washington, DC, which is a meeting of the NABP, National Council of State Boards of Nursing, and the Federation of State Medical Boards.

**CONSIDERATION OF
CONSENT ORDERS:
MOTION FOR CLOSED
MEETING:**

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Howard Casway, Sammy Johnson and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Allen, second by Adams)

**MOTION TO CERTIFY THE
PURPOSE OF THE CLOSED
MEETING:**

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Allen, second by Adams)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Brian Burns, Pharmacy Technician (motion by Warriner, second by Munden)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of William Wimbish, Jr. , Pharmacist (motion by Warriner, second by Allen)

**REPORT FROM
ENFORCEMENT DIVISION:**

Faye Lemon, Director of the Enforcement Division, updated the Board on the inspection process, and what procedures were taking place for inspecting pharmacies performing sterile compounding in Virginia. Ms. Lemon reported there are currently three full time pharmacists, one part-time pharmacist, and that interviews for the Northern Virginia pharmacy inspector will be taking place this Friday. Ms. Lemon is also anticipating a fifth pharmacy inspector to be hired in the near future who will serve as a floater inspector to assist with all regions, primarily Northern Virginia.

**PRESENTATION BY BOARD
COUNCIL REGARDING
BOARD MEMBER ETHICS:**

Howard Casway, Board Council, reviewed with the Board a power-point presentation of possible conflicts of interests that the members could have while serving on the Board and situations to avoid.

ADJOURN:

With all business concluded, the meeting adjourned at 3:32 pm.

David C. Kozera, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

Commonwealth of Virginia



VIRGINIA BOARD OF PHARMACY

REGULATIONS

FOR

PRACTITIONERS OF THE HEALING ARTS

TO SELL CONTROLLED SUBSTANCES

Title of Regulations: 18 VAC 110-30-10 et seq.

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

STAFF RECOMMENDATIONS

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Project 3497 – Fast-track (Reg Reform)

BOARD OF PHARMACY

Regulatory review changes

Part II

Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice ~~medicine~~ shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and

2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than ~~6040~~ square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing, ~~and record-keeping~~ Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area.

The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided ~~the portion of the office used exclusively for controlled substances storage and preparation~~ is at least ~~60~~40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18VAC110-30-130. Selling area enclosures.

A. The controlled substance selling and storage area of the licensee shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be ~~construed~~ constructed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty;
2. ~~The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances;~~
3. ~~Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions; and~~
4. ~~Doors to the area must have locking devices which will prevent entry in the absence of the licensee.~~

2. The enclosure shall be locked and alarmed at all times when the licensee is not on duty.

3. The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area.

B. The door keys or other means of entry and alarm access code to the selling and storage area shall be subject to the following requirements restricted to the licensee with the following exceptions:

~~1. Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure~~ Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty; and

~~2. The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs; and~~

~~3. The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee for emergency access. In lieu of the licensee's signature across a seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.~~

C. The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.

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

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.
2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.
3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.
2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;
2. Alternate pharmacist coverage cannot immediately be obtained;
3. The technician is accompanied by a member of the pharmacy's management or administration; and
4. All requirements of subsection E of this section are met.

Commonwealth of Virginia



**Virginia Board of Pharmacy
Virginia Board of Medicine**

**REGULATIONS
FOR
COLLABORATIVE PRACTICE
AGREEMENTS**

Title of Regulations: 18 VAC 110-40-10 et seq.

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

Staff recommendations

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18VAC110-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Agreement" means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of §54.1-3300.1 of the Code of Virginia.

"Alternate practitioner" means a doctor of medicine, osteopathy, or podiatry or a licensed nurse practitioner or physician assistant with an active license to practice in Virginia who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy or podiatry to participate in a collaborative agreement.

"Committee" means an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members of the Board of Medicine.

"Pharmacist" means a pharmacist who holds an active license to practice pharmacy from the Virginia Board of Pharmacy.

"Practitioner" means, ~~notwithstanding the definition in §54.1-3401 of the Code of Virginia,~~ a doctor of medicine, osteopathy, or podiatry or an alternate practitioners who writes the order and is directly and ultimately responsible for the care of a patient being treated under an agreement and who holds an active license to practice ~~from the Virginia Board of Medicine.~~

18VAC110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner of medicine, osteopathy, or podiatry involved directly in patient care and a pharmacist involved directly in patient care. The Within the collaborative agreement, the practitioner may designate alternate practitioners, and the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.
2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.
3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

18VAC110-40-30. Approval of protocols outside the standard of care.

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***

STAFF RECOMMENDATIONS

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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.

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.

Part II. Wholesale Distributors.

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 listed on the application, 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 listed on the application;
 - (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. 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. ~~A sworn statement or affirmation~~ 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.

Virginia Board of Pharmacy

Wholesale Distributor Licensure Guidance

An entity located outside Virginia that does not physically possess and ship prescription drugs into Virginia does not need to register with the Virginia Board of Pharmacy as a non-resident wholesale distributor. Likewise, an entity located within Virginia that does not physically possess and ship prescription drugs within Virginia does not need to obtain a license from the Virginia Board of Pharmacy as a wholesale distributor. If, for example, a manufacturer or distributor uses a third-party to physically house and distribute prescription drugs into or within Virginia, that third-party is required to hold the wholesale distributor license and that party's name must be on any invoice as the distributor.

Additionally, 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 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.*