

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

September 13, 2005  
Fifth Floor  
Conference Room 2

Department of Health Professions  
6603 West Broad Street  
Richmond, Virginia 23230

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- CALL TO ORDER:** A meeting of the Board of Pharmacy was called to order at 9:10 a.m.
- PRESIDING:** Leo H. Ross, Chairman
- MEMBERS PRESENT:** Gill B. Abernathy  
Toni Aust  
John O. Beckner  
Willie Brown  
Michelle R. Easton  
Bobby Ison  
David C. Kozera  
Diane Langhorst (arrived 9:32)
- MEMBERS ABSENT:** Mark A. Oley
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
Caroline D. Juran, Deputy Executive Director  
Elaine J. Yeatts, Senior Regulatory Analyst  
Howard M. Casway, Senior Assistant Attorney General  
Donna M. Lee, Administrative Assistant
- QUORUM:** With eight members of the Board present, a quorum was established.
- Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2. She also reminded everyone to turn off cell phones during the meeting.
- WELCOME:** Mr. Ross welcomed David Kozera as a new Board member and Caroline D. Juran as the new Deputy Executive Director replacing Ralph Orr.
- APPROVAL OF MINUTES:** Mr. Ross called for changes or corrections to the minutes of June 7, 2005. Hearing no changes, the minutes were approved as presented.
- PUBLIC COMMENTS:** No public comments were received at this time.
- APPROVAL OF AGENDA:** The revised agenda was approved as presented.
- UPDATE ON REGULATION** Ms. Yeatts reviewed with the Board the status of ongoing

**PROCESSES:**

regulatory processes for the Board of Pharmacy. (Attachment 1) She also stated that the proposed wholesale distributor regulations have been approved for publication and that there will be a public hearing on the amendments to Chapters 20 and 50 at the next board meeting on December 1, 2005. Ms. Yeatts stated that a collaborative practice committee meeting will be scheduled soon.

**ADOPTION OF FINAL REGULATIONS ON TWO-YEAR TO ONE-YEAR REFILL AUTHORIZATION DEFAULT LIMIT FOR SCHEDULE VI PRESCRIPTIONS:**

The Board was advised that there had been no public comment received either written or at the public hearing during the comment period on the proposed amendment to regulations to change the refill limitation on Schedule VI prescriptions from two years to a one-year default. Ms. Abernathy moved, and the Board voted unanimously, to adopt the final regulations on two-year to one-year refill authorization default limit for Schedule VI prescriptions. (Attachment 2)

**ADOPTION OF FINAL REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES:**

Ms. Yeatts stated that there was a periodic review of the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances in order to update the regulations for consistency with recent changes in pharmacy law, regulations, and current pharmacy practices. No public comments were received on the proposed regulations during the public comment period. Ms. Aust moved, and the Board voted unanimously, to adopt the final regulations for Practitioners of the Healing Arts to Sell Controlled Substances. (Attachment 3)

**DISCUSSED NABP CHANGES IN REQUIREMENTS FOR LANGUAGE PROFICIENCY TESTS FOR FOREIGN GRADUATES AND NEEDED AMENDMENTS TO GUIDANCE DOCUMENT 110-17 AND REGULATIONS 18VAC110-20-70:**

Ms. Russell informed the Board that NABP had announced a modification of the language requirements for the Foreign Pharmacy Graduate Equivalency Certificate (FPGEC) (Agenda pgs. 120-123, Attachment 9). Over the next year the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English will be phased out and replaced by Internet Based TOEFL (iBT). The internet-based TOEFL will measure the four language skills of reading, writing, listening and speaking. Effective September 24, 2005, candidates will be able to submit TOEFL (iBT) scores in place of the old TOEFL and TSE scores. The TSE examination will continue to be administered until June 2006. During the transition period, either minimal acceptable TOEFL iBT scores or the combination of minimal acceptable TOEFL/TSE scores will meet the language requirements for FPGEC. Effective June 2006, only the minimal acceptable TOEFL iBT scores will meet the language requirements of the FPGEC Certification.

The Board inquired about the minimal acceptable scores in the past as compared to the new scores and also as to whether or not the old testing procedure will still be acceptable. Ms. Russell explained to the Board that the new scores were developed by an expert committee and were consistent with the passing scores on

the TOEFL and TSE. She stated that the old tests will be phased out and no longer available, but that the board may still receive scores from the old tests for some time by candidates who had already taken them and passed, but were waiting to meet other requirements before submitting an application. Additionally, there may be reciprocity candidates with scores on the older tests.

Ms. Russell stated that in order to accept the new TOEFL iBT, changes would need to be made to Guidance Document 110-17 and that the Board would need to also change its regulations. Ms. Yeatts stated and Mr. Casway concurred that the Board could likely use the fast-track regulation process to make the needed amendments to 18VAC110-20-70, which outlines the requirements for foreign-trained applicants. It was explained to the Board that the fast-track regulation process allows the Board to make non-controversial changes to regulations, and it eliminates the NOIRA and can eliminate the final regulation process. If there are not ten or more objections, the regulations become effective at the end of the public comment period.

Mr. Beckner moved, and the Board voted unanimously, to adopt the modification to examination requirements as stated in 18VAC110-20-70 and to proceed with the fast-track regulation process. (Attachment 4)

Ms. Abernathy moved, and the Board voted unanimously, to adopt Guidance Document 110-17 as amended with the passing scores on the TOEFL iBT, Writing 24, Speaking 26, Listening 18, and Reading 21. (Attachment 5)

**REVIEWED REVENUE  
AND EXPENDITURE  
ANALYSIS AND NEED FOR  
A FEE REDUCTION:**

Ms. Yeatts explained to the Board that it has a revenue surplus exceeding 10% and, after staff analysis, it is recommended that the Board adopt a reduction for one year of renewal fees due on or before December 31, 2005. She stated that a permanent reduction is not recommended as the Board's expenditures are now exceeding revenue currently being collected and will eventually reduce the current surplus. If necessary to further reduce the surplus, a second reduction could be adopted at the end of the next fiscal year. She further stated that this is an exempt regulation in accordance with the Administrative Process Act and that if the fee reduction is adopted by the Board, it would become effective in 30 days. The fee reduction would only apply to renewals for the upcoming renewal cycle.

The Board inquired as to date of the last fee reduction, how the fee reduction would be disseminated to the licensees, and whether this was a mandatory reduction. Ms. Russell stated that the last fee

reduction was in 1994. She further stated that licensees will be notified of the revised fee because it will be printed on the renewal notices when they are mailed. The system will only accept the new fee and a refund will be issued if there is an overpayment. She explained that this is a mandatory reduction, that the Board is required by law, § 54.1-113, to reduce fees if at the close of a biennium, its revenues exceed its expenditures by more than 10% which is the case currently.

Mr. Beckner moved, and the Board voted unanimously, to adopt the exempt regulation for a one-time fee reduction as proposed by staff. (Attachment 6)

Several Board members inquired as to whether it would be appropriate to reduce the pharmacy technician fee from \$15 to \$5. The Board was advised that other comparable professions such as certified nurse aides and medical technicians pay a fee of \$50, and a concern was expressed as to whether or not a \$5 fee would pay for the cost of printing and postage of the renewals. It was mentioned to the Board that some pharmacies pay the renewal fee for pharmacy technicians. Ms. Russell stated to the Board that there is a significant cost of regulating pharmacy technicians, that there have been a number of investigations conducted, which have led to formal hearings which are very costly to conduct a \$5 fee would not sufficiently fund the program.

No motion was made to further reduce the pharmacy technician renewal fee.

**REVIEWED THE AG  
ADVISORY OPINION  
PERTAINING TO THE  
CONFLICT OF INTEREST  
ACT AND THE  
PROCUREMENT ACT  
RELATING TO  
REIMBURSEMENT OF  
BOARD MEMBERS:**

Mr. Casway addressed the Board regarding the advisory opinion provided by the Attorney General's Office as it pertains to the Conflict of Interest Act and the Procurement Act relating to reimbursement of Board members. (Agenda pgs. 114-119, Attachment 9). Mr. Casway informed the Board that the Attorney General's Office has the authority to render opinions regarding applicability of law. The opinion is advisory and state agencies are bound by it. He explained that in most instances Board members are reimbursed for per diem and allowable travel expenses and that would not cause any problems. He provided an example that Board members may vote to contract with a paid examiner to conduct testing on behalf of the Board. If there are arrangements for employment with that specific contracting agency after the Board member leaves the Board, there could be a possible conflict of interest. Mr. Casway advised the Board that if there is ever a question about whether something could possibly be a conflict of interest, they should contact him or Ms. Russell to seek advice. He also reminded the Board that a person who violates the Conflict of Interest Act can be criminally prosecuted.

**REQUIREMENT FOR CSR  
FOR COMMUNITY  
SERVICE BOARDS AS  
ALTERNATE DELIVERY  
SITES:**

Ms. Russell informed the Board that back in the 1970's the Board granted approval to the Aftercare Pharmacy to deliver filled prescriptions for mentally disabled patients to the appropriate Community Service Boards (CSB) clinic rather than to the address of the client, even though the Board did not have clear legal authority to grant this procedure. She further stated to the Board that she could not find the minutes where the Board approved this process, but she was aware that it has been a practice that has been going on for some time. Ms. Russell stated that in August 2004, the Board did promulgate regulations to authorize alternate delivery sites for filled prescriptions and there are currently regulations that allow for filled prescriptions to be delivered to another pharmacy, a physician who holds a license with the Board of Pharmacy to dispense drugs, or to another entity that holds a controlled substances registration (CSR) for this purpose.

The Board became aware of the fact that the CSB sites did not have a controlled substances registration when a recent inspection was conducted at a pharmacy that dispensed medications to a CSB. Ms. Russell stated that prior to the inspection, she had conversations with the PIC of Hiram Davis Medical Center Pharmacy where the aftercare pharmacy operation is currently housed about the new requirements for the CSBs to have CSRs. Since the recent inspection she has had several conversations with Michele Thomas of the Department of Mental Health, Mental Retardation and Substance Abuse Services to resolve this issue, and she informed Ms. Thomas that each CSB would need to possess a controlled substance registration if they are going to continue to maintain filled prescriptions at their sites.

Michele Thomas, Clinical Pharmacy Services Manager, with DMHMRSAS; Kirk Morton, Medication Access Team Leader, with RBHA, VACSB and VACPN; and Nancy Cook, Acting Director of Pharmacy, with Hiram Davis Medical Center, all addressed the Board on behalf of the current procedure that is being conducted by the CSB.

Mr. Morton inquired as to the reason for the needed change with the current process and he also expressed concerns about paying the \$90 fee for each location. He informed the Board that the language about administering medications does not apply to the CSB because they only deliver the prescriptions to the clients. He also stated that this would be a fundamental change and would like to discuss the matter further before a final decision is made by the Board. Ms. Thomas requested that the Board reduce the \$90 registration fee for fear that the high cost may create a financial hardship for the CSB locations. She, also, requested that the \$50

renewal fee reduction be extended to include initial applications for the CSBs. Ms. Cook informed the Board that the aftercare pharmacy operation has done an excellent job in monitoring the prescription delivery and that the current procedure is a good one. She, also, requested that the renewal fee for 2005 be waived if the new procedure is effective immediately.

Ms. Russell explained that any license issued after October 1<sup>st</sup>, automatically has an expiration date of December 31, 2006. She stated the Board could agree to reduce the initial licensing fee from \$90 to \$50. Inspections of the facilities would then be conducted, to include the storage area of the drugs, alarm system, and other requirements. The aftercare pharmacy operation would need to meet the requirements and responsibilities of the regulations related to using alternate delivery locations. In response to Mr. Morton's question concerning the need for this change, Ms. Russell stated that there is now a specific law and regulation authorizing alternate delivery sites, but that the sites had to be licensed with the Board of Pharmacy in some way. Ms. Russell stated that the registration requirement in law cannot be waived. She stated that she would be happy to assist the CSBs during the process of coming into compliance. She stated that CSBs were probably already in compliance with most of the requirements of regulation other than having the CSR, with the possible exception of an alarm system.

Mr. Morton stated that there may be approximately 140 clinics that receive aftercare prescriptions, that some CSBs have more than one associated clinic.

Ms. Langhorst mentioned that she has worked in two CSB clinics for the last 12 years and that she is in favor of them having to obtain a controlled substance registration. However, she had concerns about the administrative paperwork that would be involved and how that would be handled because it would take some time to submit to the Board. Ms. Aust asked if all 140 sites would need to be inspected. Ms. Russell replied that inspections would need to be conducted at each site that receives filled prescriptions.

There was a question as to impact on the department for conducting the inspections. Sammy Johnson, Deputy Director of Enforcement for DHP, stated that there may be some initial burden because of the number of inspections, but once the registrations are issued the facilities would be incorporated into the routine two-year inspection program, and that 70 additional inspections per year would not create a need for additional personnel.

There was some discussion about eliminating the fee entirely for CSBs or permanently reducing the fee for CSBs. Mr. Casway stated that reducing a fee is within the Board's discretion but reminded the Board that there are other similar state agencies and other non-profit organizations that are required to pay the full fees that may be aggrieved if a fee reduction is allowed only for CSB locations. He stated that the Board cannot reduce fees for a certain group absent regulations. He stated that the Board could create a new category, for example, CSRs for all alternate delivery sites via the fast-track regulation process, or do a one-time fee reduction across the board for all initial controlled substances registration applicants.

Ms. Yeatts stated that the Board could propose to reduce the \$90 fee to a \$50 fee for the initial application fee for controlled substances registration and that could be added under subsection "C" of the exempt regulation for fee reduction that has already been approved by the Board.

Mr. Brown moved, and the Board voted unanimously, to amend the approved exempt regulation for fee reduction under subsection "C" to reduce the initial application fee for a controlled substance registration from \$90 to \$50 for applications received by the Board prior to December 31, 2006.

Mr. Beckner moved, and the Board voted unanimously, that the controlled substances registration applications for CSBs acting as alternate delivery sites should be received by the Board on or before December 31, 2005.

Ms. Thomas asked if the CSBs could continue to operate as alternate delivery sites until the registrations have been issued. Mr. Casway advised that they could continue to operate until registered with the understanding that applications for registration will be submitted by the end of the year. Ms. Thomas will be notifying the CSBs of this requirement. Ms. Russell stated that she would assist in wording a notice to be sent.

**DISCUSSED ADOPTION OF  
GUIDANCE DOCUMENT  
110-39 RELATED TO  
EXAMINATION  
ACCOMMODATIONS  
UNDER ADA:**

The Board was informed that requests for testing accommodations under the ADA are usually honored if they are reasonable. Ms. Russell stated that recently the Board has had candidates not providing adequate documentation to request accommodations so she prepared a draft guidance document that can be distributed to people once they make a request. She said typically they are requests for extra time to take the exam. Requests for readers are not allowed. Board staff will review the documentation and grant or deny the request.

Ms. Easton expressed concerns about guideline #2 and the third bullet that talks about a written statement from the college of pharmacy that the person attended describing any testing accommodations made while the student was enrolled. She said it may be difficult to get a statement from the school if the candidate did not go through the 504 accommodation process at school or the need for the accommodation may have occurred after graduation. She stated she would like to recommend that the words "if applicable" be added at the end of the sentence.

Mr. Casway said the Board makes the determination as to what documentation a candidate must submit in order to request an ADA accommodation.

Mr. Beckner moved, and the Board voted unanimously, to adopt Guidance Document 110-39 with the amendment suggested by Ms. Easton. (Attachment 7)

**REPORT OF BOARD OF  
HEALTH PROFESSIONS:**

Ms. Easton presented the minutes from July 14, 2005 Board of Health Professions meeting. She stated that it was announced that the Prescription Monitoring Program was now in effect statewide and that the Sanction Reference Study was completed for the Board of Pharmacy. Ms. Easton also announced that at the end of this year she will no longer meet the requirements to serve on the Board of Health Professions as a Board of Pharmacy representative. She stated if any Board member would like to be named to the Board of Health Professions, to let either her or Ms. Russell know and their name would be submitted to the appropriate parties.

**EXECUTIVE DIRECTOR'S  
REPORT:**

• **HURRICANE KATRINA-  
EXECUTIVE ORDERS:**

Ms. Russell stated that each Board member was e-mailed the Governor's Executive Order 97. Ms. Russell stated that because of that order, a Department of Health Professions Order outlining the procedures for handling prescriptions for individuals displaced by the effects of Hurricane Katrina was posted on the Board's website, VPhA distributed it to their contact list, and the Health Department sent it to their emergency contact information list.

Ms. Russell stated that Executive Order 97 was being amended to permit the Board to allow temporary licensure, provided that the applicants meet the criteria for licensure in Virginia and the Board receives verification that their license had not been disciplined by another state. NABP will provide an expedited procedure for pharmacists who want to assist in Hurricane Katrina efforts and they had a one day turnaround process. For pharmacists who were

displaced by Katrina seeking employment in other states, NABP will put them in the queue for complete application processing, but could provide some information to the Board within a few hours as to current license status and status of disciplinary information in their system, which is up-to-date for Louisiana. The pharmacy boards in all three affected hurricane states are still operational and information could be received from each board. All applicants for Virginia would have to take the law examination. A pharmacist could probably be licensed within one to two weeks.

- **METHAMPHETAMINE  
EXECUTIVE  
DIRECTIVE:**

Executive Directive 8 relates to curbing methamphetamine manufacture by restricting access to precursors. An Order will be issued by the Commissioner of Health by September 15<sup>th</sup> with details of restrictions on ephedrine and pseudoephedrine sales. The Order will become effective October 1, 2005. Once the order is available, it will be sent out by e-mail to the emergency contact information list and also posted it on the website.

- **BYLAW CHANGE**

Ms. Russell stated to the Board that when the Governor declares a disaster or state of emergency, the Board has the authority to waive provisions of Chapter 33, 34, and its regulations, but this authority has not been delegated. Because of the extreme difficulty in assembling a quorum of the Board in a timely manner to deal with an emergency, Ms. Russell proposed that the Board's bylaws be amended to delegate this authority to the Chairman.

Ms. Abernathy moved, and the Board voted unanimously, to amend the bylaws to delegate this authority to the Chairman, or the Vice Chairman in the absence of the Chairman. (Attachment 8)

Ms. Russell informed the Board that Ralph Orr will be working full time as the Program Manager for the Prescription Monitoring Program since it is now statewide. She stated that he has been a great asset to the Board of Pharmacy. She stated that Caroline Juran, who replaces Mr. Orr, had most recently been employed by Westminster-Canterbury and also had previous employment experience in community pharmacy practice.

- **NABP DISTRICT II,  
OCTOBER 20-22,  
WASHINGTON, DC**

Ms. Russell notified the Board that the NABP District II meeting will be held in Washington, DC on October 20-22. She instructed any Board member who would like to attend to let her know so that she can submit travel requests for approval. She stated that Ms. Juran will be attending. Ms. Aust, Mr. Ison and Mr. Kozera indicated that they would like to attend.

**NEW BUSINESS:**

Mr. Ison requested that the Board further consider a motion pertaining to the fee reduction for pharmacy technicians. Mr. Ison

moved that a one-time reduction in the renewal fee for pharmacy technician should be granted so that the renewal fee can be reduced to \$10.

The Chairman called for discussion. Ms. Yeatts stated that in future years the fee may need to be increased as expenditures rise, and it would be more difficult to raise it back to more than the \$25 if the one-time reduction is more than half the current fee. Mr. Beckner stated that the Board should be careful not to devalue the technician registration and expressed concerns as to whether the lower fee would even cover the cost of the registration. Ms. Russell stated that a \$10 fee would probably not cover costs.

After discussion the Chairman called for the vote on the motion. The Board voted 3 to 6 against the motion. The motion failed.

**ADVICE FROM BOARD  
COUNSEL ON  
CONDUCTING INFORMAL  
CONFERENCES:**

Mr. Casway gave a presentation to the Board on the informal conference process and how an informal conference should be conducted.

Ms. Langhorst left the Board meeting at 1:00. Mr. Beckner left the Board meeting at 1:43.

**ADJOURN:**

With all business concluded, the meeting adjourned at 2:10 p.m.

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Elizabeth Scott Russell  
Executive Director

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Donna M. Lee  
Administrative Assistant

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Leo H. Ross, Board Chair

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Date

**BOARD OF PHARMACY - REGULATORY ACTIONS**  
**September 2005**

<b>NAME OF ACTION</b>	<b>Refills of Schedule VI</b>	<b>Off-site DUR &amp; data entry</b>	<b>Wholesale distributors – Chapters 20 &amp; 50</b>	<b>Periodic Review Physician Selling Drugs – Chap. 30</b>	<b>Periodic Review Collaborative Practice Chapter 40</b>	<b>Pedigree – wholesale distribution</b>
<b>BOARD ADOPTS PRE-NOIRA</b>	11/25/03	6/8/04	6/8/04	6/8/04	Comment 4/18/05 to 5/18 /05	6/7/05
<b>PRE-NOIRA submitted</b>	1/8/04	6/9/04	6/9/04	8/27/04		6/9/05
<b>DPB approves</b>	1/23/04	6/23/04	6/23/04	9/9/04		6/23/05
<b>SHHR approves</b>	3/30/04	6/29/04	7/1/04	9/16/04		6/28/05
<b>GOV. approves</b>	n/a	7/12/04	7/12/04	n/a		6/29/05
<b>NOIRA published; (Comment period)</b>	5/3/04 Comment ends 6/2/04	8/9/04 Comment ends 9/8/04	8/9/04 Comment ends 9/8/04	11/1/04 Comment ends 12/1/04		7/25/05 Comment ends 8/24/05
<b>Board adopts proposed reg</b>	6/8/04 Readopt 12/10/04	9/15/04	12/10/04 & 3/1/05	12/10/04		
<b>SUBMIT for review</b>	12/13/04	10/4/04	4/15/05	12/21/04		
<b>DPB approves</b>	1/26/05	11/7/04	8/1/05	3/31/05		
<b>SHHR approves</b>	2/1/05	12/3/04	8/2/05	4/7/05		
<b>GOV. approves</b>	5/2/05	12/6/04	8/30/05	5/16/05		
<b>PUBLISH PROP</b>	5/30/05	1/10/05	10/3/05	6/13/05		
<b>Public Hearing</b>	6/7/05	1/20/05	12/1/05	6/22/05		
<b>Comment Period ends</b>	7/29/05	3/11/05 & 5/18/05	12/2/05	8/12/05		
<b>BOARD ADOPTS FINAL REG</b>	9/13/05	6/7/05		9/13/05		

**Board of Pharmacy Minutes  
September 13, 2005  
Attachment 1**

<b>DPB approves</b>	9/15/05	7/8/05		9/15/05		
<b>SHHR approves</b>		7/11/05				
<b>GOV. approves</b>		7/19/05				
<b>Publication of final</b>		8/8/05				
<b>REG IN EFFECT</b>		9/7/05				

**Final Regulation – Regulations Governing the Practice of Pharmacy**

**Change to one year refill on S VI**

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

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with [§54.1-3412](#) and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

a. Each partial dispensing is recorded in the same manner as a refilling;

b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

c. No dispensing occurs after six months after the date on which the prescription order was issued.

B. A prescription for a drug listed in Schedule VI shall be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in §54.1-3410 C or subdivision 4 of [§54.1-3411](#) of the Code of Virginia.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than ~~two years~~ one year after the date on which it was issued, unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

C. As an alternative to all manual recordkeeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18VAC110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription drugs dispensed.

D. Authorized refills of all prescription drugs may only be dispensed in reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment.

# Virginia Administrative Code

## CHAPTER 30

### REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

#### Part I

#### Definitions and Fees

#### **18VAC110-30-10. Definitions.**

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

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" means a doctor of medicine, ~~osteopathy~~ osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

**18VAC110-30-15. Fees.**

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Fee for initial license for a practitioner of the healing arts to sell controlled substances.

1. The application fee for initial licensure shall be ~~\$200~~ 240.

2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be \$500.

C. Renewal of license for a practitioner of the healing arts to sell controlled substances.

1. The annual fee for renewal of an active license shall be \$90.

~~2. The annual fee for renewal of an inactive license shall be \$45.~~

3. The late fee for renewal of a license within ~~60 days~~ one year after the expiration date is \$30 in addition to the annual renewal fee.

4. The ~~delinquent~~ fee for reinstatement of a ~~lapsed~~ license expired for more than one year is ~~\$70~~ in addition to all unpaid renewal fees shall be \$210.

D. The fee for reinspection of any facility shall be \$150.

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 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;

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

~~3. Application for a limited use license is contingent on the practitioner selling only controlled substances which have been received prepackaged in ready to dispense quantities and containers needing only the addition of required labeling.~~

**18VAC110-30-30. Renewal of license.**

A. A license so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license by payment of these fees for ~~60~~ one year days from the date of expiration.

C. Failure to renew the license to sell within ~~60 days~~ one year following expiration shall cause the license to lapse. The selling of controlled substances with a lapsed license shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf ~~upon submission of a reinstatement application, payment of all unpaid renewal fees, and the delinquent fee~~ provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a license that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted unless another practitioner at the same location has held an active license to sell controlled substances during that period. A practitioner seeking reinstatement shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license is unlawful and shall constitute grounds for disciplinary action by the board.

**18VAC110-30-35. Inactive status. Repealed**

~~A. A licensee who intends to cease selling controlled substances may take inactive status. An inactive license may be reactivated by applying to the board for reactivation and paying any unpaid portion of the current renewal fee for an active license.~~

~~B. A licensee with inactive status shall not engage in the sale of controlled substances. Engaging in the sale of controlled substances with an inactive license shall constitute grounds for disciplinary action by the board.~~

**18VAC110-30-40. Acts to be performed by the licensee.**

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. ~~Only one person who is not a licensee may be present in the storage and selling area at any given time for the purpose of assisting the licensee in the preparation, packaging and labeling of a controlled substance.~~ A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth § 54.1-3321 of the Code of Virginia, provided such person is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

a. The entry of prescription information and drug history into a data system or other recordkeeping system;

b. The preparation of prescription labels or patient information;

c. The removal of the drug to be dispensed from inventory;

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

e. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and

2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

**18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.**

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on an ~~inactive~~ expired status ~~or may be surrendered.~~

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license pursuant to this section may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

Part III

Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

**18VAC110-30-80. Inspection and notice required.**

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for licenses which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a license and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

~~E~~ F. No license shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the ~~board or its authorized agent~~ the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

**18VAC110-30-110. Minimum equipment.**

The licensee shall be responsible for maintaining the following equipment in the designated area:

1. A current dispensing information reference source, either hard copy or electronic;
2. A refrigerator with a monitoring thermometer, located in the selling area, if any controlled substances requiring refrigeration are maintained;
3. ~~A current copy of the Virginia Drug Control Act and board regulations;~~
4. ~~A current copy of the Virginia Voluntary Formulary;~~

~~5 3. A laminar flow hood~~ Equipment consistent with requirements of §54.1-3410.2 of the Code of Virginia and USP-NF standards, if sterile products are to be prepared;~~and~~

~~6 4. Prescription balances, sensitive to 15 milligrams, and weights or an electronic scale, if the licensee is engaged in extemporaneous compounding~~ dispensing activities that require the weighing of components; ~~and~~

5. Other equipment, supplies, and references consistent with the practitioner's scope of practice and with the public safety.

**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 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.

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:

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;
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. 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.

**18VAC110-30-150. Expired controlled substances; security.**

Any controlled substance which has exceeded the expiration date shall not be dispensed or sold and shall be separated from the stock used for selling and may but shall be maintained in a designated the selling and storage area with the unexpired stock prior to the disposal of the expired controlled substances.

Part IV

Written Prescription and Record Keeping Standards

**18VAC110-30-170. Sign and written prescription requirements.**

~~A. The licensee shall provide the patient with a written prescription whether or not he intends to sell the controlled substance to the patient.~~

~~B~~ A. The licensee shall conspicuously display a sign in the public area of the office and in each patient examination room advising patients of their right to choose where they have their prescriptions filled.

~~C~~ B. The licensee ~~after delivery of the written prescription to the patient shall, in each case,~~ advise the patient of their right to obtain the controlled substance from him or from a pharmacy.

C. If the patient chooses to obtain the controlled substance from a pharmacy, the licensee shall either provide the patient with a written prescription or transmit the prescription orally, electronically or by fax to a pharmacy of his choice.

- D. If the patient chooses to purchase the controlled substance from the licensee, the licensee shall either:
1. Have the patient sign the written prescription shall be returned and return it to the licensee and signed by the patient. If the licensee chooses to use the hard copy prescription as his record of sale, he shall record all information and file as required by 18VAC110-30-190. If the licensee chooses to record the sale in book form or maintain it in an automated data system, he shall mark the prescription void, file chronologically, and maintain for a period of two years; or
  2. In lieu of a written prescription, have the patient sign a separate waiver form to be maintained for at least two years with the dispensing records according to date of dispensing. The waiver form may not be kept in the patient's chart.

**18VAC110-30-180. Manner of maintaining inventory records for licensees selling controlled substances.**

Each licensee shall maintain the inventories and records of controlled substances as follows:

1. Inventories and records of all controlled substances listed in Schedule II shall be maintained separately from all other records of the licensee;
2. Inventories and records of controlled substances listed in Schedules III, IV and V may be maintained separately or with records of Schedule VI controlled substances but shall not be maintained with other records of the licensee;
3. All records of Schedule II through V controlled substances shall be maintained at the same location as the stock of controlled substances to which the records pertain except that records maintained in an off-site database shall be retrieved and made available for inspection within 48 hours of a request by the board or an authorized agent;
4. In the event that an inventory is taken as the result of a theft of controlled substances pursuant to §54.1-3404 of the Drug Control Act of the Code of Virginia, the inventory shall be used as the opening

inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date; and

5. 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.

5 6. All records required by this section shall be filed chronologically.

**18VAC110-30-190. Manner of maintaining records for Schedule II through VI controlled substances sold.**

A. A hard copy prescription shall be placed on file for every new prescription dispensed and be maintained for two years from date of last refill. All prescriptions shall be filed chronologically from date of initial dispensing. In lieu of a hard copy prescription, a licensee may have an alternative record of all drugs sold maintained for two years from date of dispensing or of refilling an order. Such record shall be in chronological order by date of initial dispensing with refills listed with initial dispensing information or by date of dispensing.

B. The hard copy prescription or records of sale for Schedule II controlled substances shall be maintained as follows:

1. They shall be maintained separately from other records; and
2. They shall be maintained in chronological order and shall show the selling date, a number which identifies the sale, the name and address of the patient, the name and strength of the controlled substance, the initials of the licensee, and the quantity sold.

B.C. The hard copy prescription or records of sale for Schedule III through V controlled substances shall be maintained as follows:

1. They shall be maintained in the manner set forth in subsection A of this section; and

2. The hard copy prescription or records of sale for Schedule III through V controlled substances may be maintained separately from other selling records or may be maintained with selling records for Schedule VI controlled substances provided the Schedule III through V controlled substance records are readily retrievable from the selling records for Schedule VI controlled substances. The records shall be deemed readily retrievable if a red "C" is placed uniformly on the record entry line for each Schedule III through V controlled substance sold. However, if the licensee employs an automated data processing system or other electronic recordkeeping system for prescriptions that 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 record with a red "C" is waived.

**18VAC110-30-200. Automated data processing records of sale.**

A. An automated data processing system may be used for the storage and retrieval of the sale of controlled substances instead of manual recordkeeping requirements, subject to the following conditions:

1. Any computerized system shall also provide retrieval via computer monitor display or printout of the sale of all controlled substances during the past two years, the listing to be in chronological order and shall include all information required by the manual method;
2. If the system provides a printout of each day's selling activity, the printout shall be verified, dated and signed by the licensee. The licensee shall verify that the data indicated is correct and then sign the document in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). In place of such printout, the licensee shall maintain a bound log book, or separate file, in which the licensee shall sign a statement each day, in the manner previously described, attesting to the fact that the selling information entered into the computer that day under his initials has been reviewed by him and is correct as shown; and

~~3. A hard copy prescription shall be placed on file chronologically and maintained for a period of two years.~~

B. Any computerized system shall have the capability of producing a printout of any selling data which the practitioner is responsible for maintaining under the Drug Control Act and such printout shall be provided within 48 hours of a request of an authorized agent.

## Part V

### Packaging, Repackaging and Label Standards

#### **18VAC110-30-210. Repackaging of controlled substances; records required; labeling requirements.**

A. A licensee repackaging controlled substances shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the controlled substances repackaged, strength, if any, quantity prepared, initials of the licensee supervising the process, the assigned control number, or the manufacturer's or distributor's name and control number, and an expiration date.

B. The controlled substance name, strength, if any, the assigned control number, or the manufacturer's or distributor's name and control number, and an appropriate expiration date determined by the licensee in accordance with USP-NF guidelines shall appear on any subsequently repackaged or reconstituted units as follows: .

- ~~1. If U.S.P. N.F. Class B or better packaging material is used for oral unit dose packages, an expiration date not to exceed six months or the expiration date shown on the original manufacturing bulk containers, whichever is less, shall appear on the repackaged units;~~
- ~~2. If it can be documented that the repackaged unit has a stability greater than six months, an appropriate expiration date may be assigned; and~~
- ~~3. If U.S.P. N.F. Class C or less packaging material is used for oral, solid medication, an expiration date not to exceed 30 days shall appear on the repackaged units.~~

#### **18VAC110-30-220. Labeling of prescription as to content and quantity.**

Any controlled substances sold by a licensee shall bear on the label of the container, in addition to other requirements, the following information:

1. The name and address of the practitioner and the name of the patient;
2. The date of the dispensing;
3. 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 ~~in accordance with §32.1-87 A of the Code of Virginia~~, the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed; and
4. The number of dosage units or, if liquid, the number of millimeters dispensed.

**18VAC110-30-240. Special packaging.**

A. Each controlled substance sold to a person in a household shall be sold in special packaging, except when otherwise requested by the purchaser, or when such controlled substance is exempted from such requirements promulgated pursuant to the Poison Prevention Packaging Act of 1970, 15 USC §§1471-1476.

B. Each licensee may have a sign posted near the compounding and selling area advising the patients that nonspecial packaging may be requested.

C. If nonspecial packaging is requested, a ~~signed~~ release of such request shall be obtained ~~pursuant to §54.1-3427 of the Code of Virginia~~ from the patient or the patient's authorized agent and maintained for two years from the date of dispensing.

Part VI

Patient's Choice of Supplier, Purchase of Drugs, and Return of Controlled Substances

**18VAC110-30-260. Returning of controlled substances.**

Controlled substances shall not be accepted for return or exchange by any licensee for resale after such controlled substances have been taken from the premises where sold, unless such controlled substances are in the manufacturer's original sealed container or in a unit-dose container which meets the U.S.P.-N.F. Class A or Class B container requirement, have ~~not~~ been stored under conditions in which official compendium storage requirements can be assured ~~whereby they may have become contaminated~~, and provided such return or exchange is consistent with federal law and regulation.

Part VII

Grounds for Disciplinary Action

**18VAC110-30-270. Grounds for disciplinary action.**

In addition to those grounds listed in §54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, ~~osteopathy~~ osteopathic medicine or podiatry suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice ~~medicine~~ in the Commonwealth of Virginia.

## Fast-Track Regulation

### *Modification to examination requirements*

#### **18VAC110-20-70. Requirements for foreign-trained applicants.**

A. Applicants for licensure who were trained in foreign schools of pharmacy shall meet the following additional requirements prior to being allowed to take the examinations required by 18VAC110-20-60:

1. Obtain verification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy (NABP) that the applicant is a graduate of a foreign school of pharmacy.
2. Complete and receive a score acceptable to the board on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).
3. Complete and receive a score acceptable to the board on the Test of English as a Foreign Language (TOEFL) or on the TOEFL iBT, the Internet Based tests of listening, reading, speaking and writing.
4. Complete the Test of Spoken English (TSE) or the TOEFL iBT as given by the Educational Testing Service with a score acceptable to the board.

§ 4. Fulfill the requirements for practical experience as prescribed in 18 VAC110-20-30 A, B and E of and 18VAC110-20-40 A, B, D, E and F.

B. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations as prescribed in 18VAC110-20-60.

## INSTRUCTIONS FOR GRADUATES OF FOREIGN SCHOOLS OF PHARMACY

If you are applying for licensure in Virginia as a pharmacist, at least 30 days before the desired examination date, you must submit the required fee with the following:

**1. A completed application.**

- a. An "Application for Licensure As a Pharmacist by Examination" if you are applying for initial licensure by examination. You may omit the college affidavit section on page 3.
- b. An application of the National Association of Boards of Pharmacy titled "Official Application for Transfer of Pharmaceutic License", if you are applying to have your pharmacist's license transferred from another state in which you are already licensed as a pharmacist (Licensure by Endorsement).

**2. Affidavits showing evidence of at least 1500 hours\* practical experience gained within the United States.**

- a. At least 300 of the 1500 required hours must be in the area of prescription compounding and dispensing.
- b. Credit will not be given for more than 50 hours in any one week.
- c. The applicant shall be supervised by a pharmacist who holds an unrestricted pharmacist license, and the supervising pharmacist may only supervise one intern during a time period.

**Prior to gaining practical experience in Virginia for credit, you must register with this Board as a "Pharmacy Intern". Practical experience gained in another state must be certified by that state's board of pharmacy.**

**3. Verification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of the National Association of Boards of Pharmacy (NABP) of the following:**

- a. that you are a graduate of a foreign school of pharmacy;
- b. your score on the Foreign Pharmacy Graduate Equivalency Examination (FPGEE). A scaled score of at least 75 is acceptable to the Board; and
- c. your score on the written and oral communication ability tests of the English language as follows:
  - the Internet Based Test of English as a Foreign Language (TOEFL iBT). The following is the minimum passing score for each component: Writing 24, Speaking 26, Listening 18, and Reading 21.

**or**

- your scores on both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE). A score of at least 550 for the paper TOEFL or 213 for the computer-based TOEFL and a score of at least 50 for the TSE is acceptable to the Board.

\* *Persons who graduated from a school of pharmacy before January 1, 2003 are only required to obtain 1000 hours practical experience within the United States.*

\*\* *The TOEFL iBT, or the TSE and TOEFL, scores may be sent directly from the Educational Testing Service (ETS) as an alternative to direct verification by NABP. **The Board's test code number for ETS is 9938.** Originals or copies of score certificates sent to the Board by the applicant will not be accepted.*

Revised 9/24/2005

**Board of Pharmacy  
Exempt Regulation  
Fee Reduction**

**18VAC110-20-20. Fees.**

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees

1. Pharmacist license \$180

2. Pharmacy intern registration \$15

3. Pharmacy technician registration \$25

4. Pharmacy permit \$270

5. Permitted physician licensed to dispense drugs \$270

6. Nonrestricted manufacturer permit \$270

7. Restricted manufacturer permit \$180

8. Wholesale distributor license \$270

9. Warehouser permit \$270

10. Medical equipment supplier permit \$180

11. Humane society permit \$20

12. Non-resident pharmacy \$270

13. Non-resident wholesale distributor \$270

14. Controlled substances registrations \$90

(Between November 2, 2005 and December 31, 2006, the application fee for a controlled substance registration shall be \$50)

15. Robotic pharmacy system approval \$150

16. Innovative program approval \$250

If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.

17. Approval of a pharmacy technician training program \$150

18. Approval of a continuing education program \$100

D. Annual renewal fees:

1. Pharmacist active license           \$90
2. Pharmacist inactive license       \$45
3. Pharmacy technician registration   \$25
4. Pharmacy permit   \$270
5. Physician permit to practice pharmacy   \$270
6. Nonrestricted manufacturer permit \$270
7. Restricted manufacturer permit   \$180
8. Wholesale distributor license       \$270
9. Warehouser permit \$270
10. Medical equipment supplier permit   \$180
11. Humane society permit   \$20

- 12. Non-resident pharmacy \$270
  
- 13. Non-resident wholesale distributor \$270
  
- 14. Controlled substances registrations \$90
  
- 15. Innovative program continued approval based on board order not to exceed \$200 per approval period

***E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.***

- 1. Pharmacist license \$30
  
- 2. Pharmacist inactive license \$15
  
- 3. Pharmacy technician registration \$10
  
- 4. Pharmacy permit \$90
  
- 5. Physician permit to practice pharmacy \$90
  
- 6. Nonrestricted manufacturer permit \$90

- 7. Restricted manufacturer permit \$60
- 8. Wholesale distributor license \$90
- 9. Warehouser permit \$90
- 10. Medical equipment supplier permit \$60
- 11. Humane society permit \$5
- 12. Non-resident pharmacy \$90
- 13. Non-resident wholesale distributor \$90
- 14. Controlled substances registrations \$30

***F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.***

1. Pharmacist license \$210
  
2. Pharmacist license after revocation or suspension \$500
  
3. Pharmacy technician registration \$35
  
4. Pharmacy technician registration after revocation or suspension \$125
  
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:
  - a. Pharmacy permit \$240
  
  - b. Physician permit to practice pharmacy \$240
  
  - c. Nonrestricted manufacturer permit \$240
  
  - d. Restricted manufacturer permit \$ 210
  
  - e. Wholesale distributor license \$240
  
  - f. Warehouse permit \$240

g. Medical equipment supplier permit \$210

h. Humane society permit \$30

i. Non-resident pharmacy \$115

j. Non-resident wholesale distributor \$115

k. Controlled substances registration \$180

***G. Application for change or inspection fees for facilities or other entities***

1. Change of pharmacist-in-charge \$50

2. Change of ownership for any facility \$50

3. Inspection for remodeling or change of location for any facility \$150

4. Reinspection of any facility \$150

5. Board-required inspection for a robotic pharmacy system \$150

6. Board-required inspection of an innovative program location \$150

7. Change of pharmacist responsible for an approved innovative program \$25

*H. Miscellaneous fees*

1. Duplicate wall certificate \$25

2. Returned check \$25

I. For the annual renewal due on or before December 31, 2005, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license \$50

2. Pharmacist inactive license \$25

3. Pharmacy technician registration \$15

4. Pharmacy permit \$210

5. Physician permit to practice pharmacy \$210

6. Nonrestricted manufacturer permit \$210

7. Restricted manufacturer permit \$140

8. Wholesale distributor license \$210

9. Warehouser permit \$210

10. Medical equipment supplier permit \$140

11. Humane society permit \$20

12. Non-resident pharmacy \$210

13. Non-resident wholesale distributor \$210

14. Controlled substances registrations \$50

Guidance Document 110-39

Guidelines for Requests for NAPLEX and Virginia Drug Law Examination Accommodations

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1. Only physical or mental impairments that substantially limit one or more major life activities are considered disabilities subject to protection of the American with Disabilities Act.
2. Supporting documentation must include the following to be considered for review:
  - Letter of request from the candidate that specifies the testing accommodation requested
  - A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional which (a.) states a diagnosis of the disability, and describes the disability and recommends specific accommodations, and (b.) provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation.
  - A written statement from the appropriate person with the college of pharmacy which describes any testing accommodations made while the student was enrolled, if applicable.
3. If the request for accommodation is granted, the information will be forwarded to either NABP (NAPLEX) or Thompson Prometric (law examination).
4. Candidates will also be notified in writing of the decision.

## **BYLAWS OF THE VIRGINIA BOARD OF PHARMACY**

### **ARTICLE I: GENERAL**

The organizational year for the Board shall be from July 1<sup>st</sup> through June 30<sup>th</sup>. At the last meeting before July 1, the Board shall elect from its members a Chair and a Vice Chair. The term of office shall be one year and shall begin on July 1. A person shall not serve as Chair or Vice Chair for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

### **ARTICLE II: OFFICERS OF THE BOARD**

1. The officers of the Board shall be the Chair and the Vice-Chair
2. The Chair presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The Chair shall appoint all committees unless otherwise ordered by the Board.
3. The Vice-Chair shall act as Chair in the absence of the Chair.
4. In the absence, or inability to serve, of both the Chair and Vice-Chair, the Chair shall appoint another board member to preside at the meeting and/or formal administrative hearing.
5. The Executive Director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

### **ARTICLE III: ORDER OF BUSINESS MEETINGS**

The order of business shall be as follows:

1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.
2. Approval of Agenda
3. Public comment received
4. Approval of Minutes

5. **The remainder of the agenda shall be established by the Executive Director in consultation with the Chair.**

**ARTICLE IV: COMMITTEES**

- A. There shall be the following standing committees:

Special Conference Committees

Examination Committee

Item Review Committee

Regulation Committee

Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The Chair may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chair shall appoint committees as needed to expedite the adjudication of cases. These committees may also function as informal conference committees if a case involves a permit.
2. Examination Committee. This committee shall consist of four board members and the Executive Director. The Examination Committee shall meet as required to maintain the integrity, defensibility and current status of the Drug Law Examination. Additionally, the Board delegates to this Committee the approval of the Drug Law Examination for the purpose of licensure.
3. Item Review Committee. This committee shall consist of at least seven pharmacists holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of writing new items for the Drug Law Examination item bank.
4. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board's Public Participation Guidelines and any Executive Order of the Governor, and any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

5. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and robotic pharmacy systems and any matters related to such programs.

B. Ad Hoc Committees.

The Chair shall also name such other committees as may be deemed necessary.

**C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.**

#### **ARTICLE V: GENERAL DELEGATION OF AUTHORITY**

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.

**2. The Board delegates to the Executive Director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.**

3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.

4. The Board delegates to the Department of Health Professions' inspectors the authority to issue Compliance Notices upon completion of an inspection, and the Board delegates to the Executive Director the authority to issue letters regarding reported deficiencies to the facilities or licensee.

5. The Board delegates to the Executive Director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

6. The Board delegates to the Executive Director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

7. The Board delegates to the Executive Director, in consultation with the Chair, the review and approval of applications for special or limited use pharmacy permits. If the Executive Director and Chair do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.

8. The Board delegates to the Executive Director, in consultation with the Chair, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the Executive Director and the Chair not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.

9. The Board delegates to the Executive Director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the Executive Director in consultation with the Chair. Should the Executive Director and Chair not reach agreement, the matter shall be referred to a special conference committee.
10. The Board delegates to the Chair, the authority to represent the Board in instances where Board “consultation” or “review” may be requested, but where a vote of the Board is not required and a meeting is not feasible.
11. The Board delegates the approval of continuing education programs to the Executive Director in consultation with one member of the Board.
12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with §54.1-2408.1, to the Executive Director or Deputy Executive Director-Discipline. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with §54.1-2400 (13), to the Executive Director or Deputy Executive Director-Discipline. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the Executive Director or Deputy Executive Director-Discipline.
13. The Board delegates to the Chairman, or the Vice Chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with §54.1-3307.3.

#### **ARTICLE VI: AMENDMENTS**

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board

meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date:	July 1, 1997
Revised:	October 9, 1997
	August 17, 1999
	June 13, 2001
	September 15, 2004
	June 7, 2005
	September 13, 2005

**LIST OF DOCUMENTS CONTAINED IN ATTACHMENT 9**  
**(Copies can be obtained by contacting the Board)**

<u>DOCUMENT</u>	<u>AGENDA PAGES</u>
Letter from NABP about TOEFL/TSE Scores	120-123
AG Advisory Opinion	114-119