



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Richmond, Virginia 23230

(804) 367-4456 (Tel)
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Tentative Agenda of Meeting

December 10, 2008

9:00AM

TOPIC

PAGE(S)

Call to Order: David Kozera, Chairman

- Welcome and Introductions
- Reading of emergency evacuation script
- Approval of Agenda
- Approval of previous Board meeting minutes: 1-29
 - September 3, 2008, Board meeting
 - September 3, 2008, Panel, Formal Hearings
 - September 10, 2008, Telephone Conference Call
 - September 24, 2008, Special Conference Committee
 - September 25, 2008, Telephone Conference Call
 - September 29, 2008, Panel, Formal Hearing
 - November 13, 2008, Regulation Committee

Public Hearing: Proposed amendments to 18 VAC 110-20-10 et seq. 30-73

Call for public comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

DHP Report: Sandra Whitley Ryals, Director

Legislation update:

- VSHP proposal-Bobby Ison 74

Regulations: Elaine Yeatts

- Update on regulation processes
- Adopt proposed regulations on expiration dates 75-79
- Adopt proposed regulations defining unprofessional conduct 80-84

Miscellaneous:

- Interpretation of 54.1-3434.1 with respect to PIC for non-resident pharmacies 85-87
- Request for approval of ExCPT examination 88-95
- Set 2009 Meeting Calendar

Reports:

- Report on Board of Health Professions-Jennifer H. Edwards
- Executive Director's Report-Scotti Russell
 - January 1, 2009, new contractor for pharmacy technician examination
 - NABP News
 - November e-newsletter
 - Renewal update
 - report on disciplinary program-Cathy Reiniers-Day

Consideration of consent orders (if any)

Adjourn

***The Board will have a working lunch at approximately 12 noon.**

There will be an informal conference at the adjournment of the Board meeting to consider a pilot application. Committee: Dave Kozera, Chair, and Bobby Ison.

(DRAFT/UNAPPROVED)

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

September 3, 2008
Second Floor
Conference Room 4

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9 a.m.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Willie Brown
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Sandra Whitley Ryals, Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant (business portion)
Elizabeth Revere, Disciplinary Program Specialist (disciplinary portion)

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

APPROVAL OF AGENDA: Mr. Kozera announced that a possible summary suspension will be considered following the formal hearing.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the June 4, 2008 Board Meeting; June 4, 2008 Panel Formal Hearings; June 17, 2008 Ad Hoc Committee-Drug Donation; June 19, 2008 ICC-Robotic Pharmacy System; June 25, 2008 SCC; July 1, 2008 TCC; July 17, 2008 SCC; July 23, 2008 Ad Hoc Committee-Drug Donation; July 31, 2008 SCC; and August 14, 2008 TCC. There were several technical corrections to the minutes of the June 4, 2008 Board Meeting.

Motion: **The Board voted unanimously to approve the minutes as presented and amended by the Board. (motion by Beckner, second by Edwards)**

PUBLIC COMMENTS:

There were no public comments.

REPORT, DHP DIRECTOR

Sandra Whitley Ryals, Director, reported on the Virginia Performs measures. She stated that Visual Research had developed a new method of measuring the department's outcomes with respect to its performance measures, and the Board was provided with fourth quarter statistics on the new measures. The 250-day goal for dispensation of patient care cases has been divided into three separate measures to better reflect the progress being made. The measures are clearance rate, age of pending caseload, and time to disposition. She stated that while there is still work to do, there has been significant progress in achieving the goal of closure of 90% patient care cases within 250 days.

Ms. Ryals stated that with the worsening revenue projections for the state, all agencies were being required to submit plans for 5, 10, and 15 percent cuts in budget. Although DHP is a non-general fund agency, it is also being asked to submit reduction plans. More details about budget cuts are expected to be released in December.

She also reported on upcoming legislation submissions for inclusion in the administration package. Ms. Ryals stated that while it is difficult for her to turn down requests of boards for legislative proposal submissions, she has been directed by the Secretary to only submit proposals deemed essential and that fit the Governor's initiatives. She stated that for this reason, and because of significant concerns expressed by interested parties, the two proposals from the Board of Pharmacy, CQI and mandatory reporting, are not included in her submissions this year. She stated that she is moving forward with a proposal for collection of fees to cover the costs of disciplinary processes, which is not without controversy, but it is an effort to assess some program costs to those persons who have had disciplinary proceedings. Florida uses this user fee approach to recoup costs. She stated that other proposals going forward were the result of other internal committees seeking more efficient and cost-effective ways of doing business, and looking at non-performing and non-government activities. She should be able to report more about the legislative proposals in December.

LEGISLATION UPDATE:

Ms. Russell stated that the opposition on the two legislative proposals was primarily from the National Association of Chain Drug Stores. The issue with the CQI proposal related to concerns about required disclosure of work product in civil proceedings. Ms. Russell stated that currently there did not appear to be a way to address these concerns in state law to the satisfaction of NACDS. She stated over the next year, the proposed regulations to

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implement the federal Patient Safety Act may become effective and would have been vetted by the various organizations. There are some protections from disclosure for voluntary reporting provided in these regulations. Once these regulations become effective, there may not be a need for a state requirement, or if there still is, there may be a better way to structure the requirement for CQI to use the federal protections. She stated that the objections to the mandatory reporting of impairment or other grounds for suspension of a license were varied, but included concern about persons being reported by persons not qualified to make determinations of impairment or incompetence. Based on NACDS comments, staff looked at changing the proposal to voluntary reporting with some protection from civil liability, but ultimately it was decided this initiative, particularly if changed from mandatory to voluntary, was not essential to agency operations.

Gerard Dabney joined the meeting at approximately 10 a.m.

REGULATION UPDATE:

Ms. Yeatts provided the Board with an update of ongoing regulatory processes. She stated that the proposed package resulting from regulation review is currently in the Governor's office awaiting approval to publish, as are the packages for emergency regulations for expiration date changes and fast-track regulations for changes to nuclear pharmacy regulations.

- Emergency Regulations for a Drug Donation Program

The Board reviewed draft regulations included in the agenda package that were developed by the ad hoc committee for establishing a drug donation program. The Board made an amendment to 18 VAC 110-20-750 B 4 to eliminate a need for a further definition of "restricted distribution system". It corrected the numbering in 18 VAC 110-20-770. Also, a change was made to 18 VAC 110-20-780 B to tie any dispensing fee directly to the allowable fee in § 54.1-3301, subsection 10 rather than tie the fee to the Medicaid dispensing fee directly. Ms. Russell stated that the Virginia Association of Free Clinics may be seeking a change to that section of law this next session, to increase what can be charged for a dispensing fee for manufacturer donated drugs as the current language does not cover costs.

Motion:

The Board voted unanimously to adopt as emergency regulations, the draft regulations in the agenda package as amended by the Board, and publish a NOIRA for the replacement of emergency regulations. (motion by Ison, second by Brown)

- Exempt PPG Regulations

Ms. Yeatts explained that the Department of Planning and Budget had developed standard regulations for public participation

guidelines and was requiring all agencies to adopt them. She stated that she had worked closely with DPB staff in the development and as a result, the standard regulations are not that different from the current PPG regulations. There is the ability for a Regulatory Advisory Panel under the new regulations, but this is not new for the Board, as it has frequently used such entities in developing regulations.

Motion:

The Board voted unanimously to adopt the exempt PPG regulations, 18 VAC 110-11 and repeal the existing PPG regulations, 18 VAC 110-10. (motion by Stredler, second by Yi)

- Consider proposing regulations for defining unprofessional conduct

The Board reviewed draft of proposed regulations that would define unprofessional conduct included in the agenda package.

Motion:

Mr. Beckner moved to adopt the draft presented as proposed regulations, with a second by Mr. Ross. The Chairman called for discussion.

The Board members had a number of questions concerning the wording of the draft document. Ms. Yeatts explained that a number of Boards had such regulations and that some of these were similar, some specific to pharmacy. Ms. Russell stated that staff had tried to include the types of activities for which the Department had received complaints in the past, but for which the Board has no authority to take actions, such as physical assault on a patient by a pharmacist, speaking of confidential information loudly enough where it was overheard by others, and using patient identifying information to initiate a personal relationship. Ms. Abernathy had a concern that one of the definitions could be construed to mean that a pharmacist's refusal to dispense a prescription could fit. Board members expressed concerns that the provisions were too broad and could capture activities not problematic. Mr. Casway explained that many grounds for disciplinary action were purposely broad, because if too narrowly drawn, then it would be impossible to make findings of a violation in many cases in which the Board would want to take action. Ms. Russell stated that the Board could defer any action on this matter until the next meeting, have the regulation committee meet and possibly accept public comment, and have a recommendation for the Board in December.

Motion:

The Board voted unanimously to table the original motion, defer this matter until December, and refer it first to the regulation committee for further review and recommendation. (motion by Yi, second by Beckner)

GUIDANCE DOCUMENT
110-25

Ms. Russell advised the Board that there had been a recent suspension of a physician's license by the Board of Medicine who had specialized in pain management. The Board had received numerous inquiries that the existing guidance document did not answer questions related to whether pharmacists could fill new prescriptions in these circumstances. The existing document only addresses refills. Ms. Russell stated that because most of the inquiries were related to Schedule II-IV controlled substances, she also checked with DEA as to its policy with respect to physicians no longer in practice. A representative of DEA stated that DEA's policy was consistent with the Board's guidance document, and could be extended to new prescriptions, but asked that there be an additional sentence advising pharmacists to more closely scrutinize these prescriptions before filling or refilling for validity when the prescriber had been suspended or revoked for violations related to prescribing. The Board reviewed draft changes to the guidance document as presented in the agenda package.

Motion:

The Board voted unanimously to approve the amended guidance document as presented. (motion by Beckner, second by Stredler)

GUIDANCE DOCUMENT
110-36

The Board reviewed a request sent by the Virginia Hospital and Healthcare Association asking for further delay, until March 2009, in requiring compliance with USP Chapter 797 standards for sterile compounding. The request suggested that the Board could grant waivers to hospitals under the provisions of 18 VAC 110-20-120. Ms. Russell stated that the waiver provision is not appropriate in this case because the requirement is in statute, not regulation, and the Board does not have the authority to waive a requirement of statute. Additionally, a hospital pharmacy would most likely not qualify for a waiver under this section because it would not meet the criteria to be a limited-use pharmacy. The Board discussed the fact that it had already delayed enforcement of the physical requirements of Chapter 797 at least three times since 2004, the most recent being the last board meeting with the delay until October 2008. There were no motions in this matter, but the Board asked Ms. Russell to respond to the request, addressing the concerns, and restating the Board's decision of June 2008.

BHP REPORT

Ms. Edwards reported that the Board of Health Professions had not met since the last Board of Pharmacy meeting, so she had no report at this time.

EXECUTIVE DIRECTOR'S
REPORT

Ms. Russell stated that after a competitive bidding process, the contract for the pharmacy technician examination had been awarded to Schroeder Measurement Technologies, Inc. (SMT).

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The committee that evaluated the proposals included herself, Mr. Yi, Mr. Kozera and Ms. Juran. She stated that the current vendor, ICPT, would continue administering the examination until December 31, 2008, and SMT would pick up administration on January 1, 2009. She advised that the examination committee would be reviewing the job analysis for this examination at some point after the new vendor takes over the process.

DISCIPLINARY REPORT

Ms. Reiniers-Day presented the Board's disciplinary caseload report as of September 2, 2008, and stated for patient care cases only there were 23 cases at the enforcement level, 38 cases at the probable cause level, 8 cases at the APD level, 7 cases at the informal conference level, 4 cases at the formal hearing level and 15 cases at the pending closure level. For all BOP cases, there were 57 cases at the enforcement level, 91 cases at the probable cause level, 7 cases at the informal conference level, 5 cases at the formal hearing level and 11 cases at the APD level.

LICENSING REPORT

Ms. Juran reported that the Board issued 946 additional licenses since the last full Board meeting on June 4, 2008. Of those licenses issued, 312 were for pharmacists, 14 for pharmacies, 507 for pharmacy technicians and 17 for physicians selling controlled substances. Ms. Juran also reported that the Board's Web site now includes a link to NABP's Web site regarding buying medicine online. This link provides information on obtaining drugs from internet pharmacies and lists the names of internet pharmacies which NABP recommends, does not recommend, or has reviewed. Additionally, the Board has included instructions for obtaining a pharmacist license through examination or reciprocity in a more prominent location on its homepage. Lastly, Ms. Juran stated that in August 2008, an informal conference committee approved a robotic pharmacy system for Virginia Hospital Center Arlington Pharmacy. It was approved for three years from the date of implementation; however, the Board has not yet been informed of the specific date for implementation.

FORMAL HEARING

RICHARD B. LAKES
Pharmacist
License Number:
0202-004156

A formal hearing in the matter of Richard B. Lakes was held to discuss his petition for reinstatement of his pharmacist license that was mandatorily suspended on March 30, 2007, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy in Virginia.

William Clay Garrett, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Lakes appeared and was not represented by counsel.

Vicki Fox, DHP Senior Investigator, testified on behalf of the Commonwealth.

Richard B. Lakes testified on his own behalf.

Mr. Yi stated that he works for Giant Pharmacy, had not supervised Mr. Lakes and could make a fair and impartial decision in this matter. There were no objections from Mr. Lakes or the remaining board members.

Closed Meeting:

Mr. Stredler moved, and 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 in the matter of Richard B. Lakes. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell, Caroline Juran and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene:

Mr. Stredler moved, and 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 closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Stredler moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Garrett, amended by the Board and read by Mr. Casway (Attachment #1).

Mr. Beckner moved, and the Board voted seven in favor of the motion, two opposed the motion, and one abstention, for the reinstatement of Mr. Lakes' license. The motion failed as three-quarters of the Board's vote is required for the motion to pass. (Attachment #1).

Mr. Dabney departed at approximately 3:30 p.m.

SUMMARY SUSPENSION:

Closed meeting:

Mr. Stredler moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Elizabeth Revere, Howard Casway, Wayne Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

MARK MANERS
Pharmacy Technician
Registration Number:
0230-004353

Wayne Halbleib, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Reconvene:

Mr. Stredler moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Beckner moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Mark Maners poses a substantial danger to the public; and therefore, the registration of Mark Maners to practice as a pharmacy technician be summarily suspended and that a Consent Order be offered to Mr. Maners for the indefinite suspension of his registration in lieu of a hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 3:45 p.m.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Board Chairman

Date



**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

Wednesday, September 3, 2008
Second Floor
Board Room 4

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 3:45 p.m.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: Gill Abernathy
John O. Beckner
Willie Brown
Jennifer H. Edwards
Bobby Ison
Leo H. Ross
Michael E. Stradler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

QUORUM: With nine members of the Board present, a quorum to constitute a panel was established.

JAREN C. OUTLAW
Registration # 0230-004831 A formal hearing was held in the matter of Jaren C. Outlaw to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Ms. Outlaw was not present at the hearing. The Panel proceeded in Ms. Outlaw's absence as the Notice of Formal Hearing dated August 11, 2008, was mailed to Ms. Outlaw's legal address of record, both regular and certified mail. Mr. Kozera ruled that adequate notice was provided to Ms. Outlaw and the hearing proceeded in her absence.

Wayne Halblieb, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Kristin R. Parsley, Loss Prevention Manager, Rite Aid Pharmacy, and Nan Dunaway, DHP Pharmacy Inspector, appeared and testified on behalf of the Commonwealth.

Closed Meeting:

Mr. Stredler moved, and the Panel voted 9-0, to convene a closed meeting pursuant to Section 2.2-3711(A)(27) of the Code of Virginia for the purpose to reach a decision in the matter of Jaren C. Outlaw. Additionally, he moved that Scotti Russell, Cathy M. Reiniers-Day and Howard Casway attend the closed meeting.

Reconvene:

Mr. Stredler moved, and the Panel voted 9-0, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Yi moved, and the Panel voted 9-0, to adopt the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the Panel and read by Mr. Casway (Attachment 1).

Mr. Yi moved, and the Panel voted 9-0, that Ms. Outlaw's registration be revoked.

MEMBERS ABSENT:

Mr. Kozera and Mr. Brown departed at 4:45 p.m.

With seven Board Members remaining a quorum to constitute a panel was established.

PRESIDING:

Michael E. Stredler, Vice Chair

LESLIE M. ROBERTSON
Registration # 0230-003645

A formal hearing was held in the matter of Leslie M. Robertson following the summary suspension of her pharmacy technician registration on May 23, 2008, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Robertson was not present at the hearing. The Panel proceeded in Ms. Robertson's absence as the Notice of Formal Hearing dated May 23, 2008, was mailed to Ms. Robertson's legal address of record, both regular and

certified mail. Mr. Stredler ruled that adequate notice was provided to Ms. Robertson and the hearing proceeded in her absence.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mr. Egan.

DECISION:

Mr. Beckner moved, and the Panel voted 7-0, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann, and read by Mr. Casway. (Attachment #2)

Mr. Beckner moved, and the Panel voted 7-0, that Ms. Robertson's pharmacy technician registration be revoked.

ADJOURN:

With all business concluded, the meeting adjourned at 5:10 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

Michael E. Stredler, Vice Chair

Date

Attachment 1
Board of Pharmacy
Formal Hearings - Panel
September 3, 2008

Jaren C. Outlaw

Findings of Fact:

- Jaren C. Outlaw holds registration number 0230-004831 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia. Said registration shall expire on December 31, 2008.
- Based upon representations of Wayne T. Halbleib, Assistant Attorney General, and Commonwealth's Exhibits Nos. 1 & 2, the Notice of Formal Hearing and Statement of Particulars, and the Affidavit of Mailing, the presiding officer ruled there was adequate notice and the panel of the Board proceeded with the hearing in Ms. Outlaw's absence.
- Jaren C. Outlaw diverted quantities of controlled substances for distribution and personal and unauthorized use. Specifically, by her own admission, between September, 2006, and February, 2008, during the course of her employment as a pharmacy technician at Rite Aid Pharmacy #11267, Virginia Beach, Virginia, (formerly Eckerd Pharmacy #8336 until June 2007,) she diverted approximately 3,765 tablets of various controlled substances, including hydrocodone/APAP (Schedule III), Ambien (zolpidem tartrate, Schedule IV), alprazolam (Schedule IV), and Restoril (temazepam, Schedule IV). In addition, by her own admission, Ms. Outlaw obtained the drugs for her illegal use and distribution to her mother and to her brother, for his unlawful use and distribution.

Conclusions of Law:

- Finding of Fact #3 constitutes a violation of § 54.1-3316(9) of the Code.

Sanction:

- The registration of Jaren C. Outlaw be, and hereby is, REVOKED.

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Attachment 2
Board of Pharmacy
Formal Hearings - Panel
September 3, 2008

Leslie Robertson

Findings of Fact :

- Leslie M. Robertson holds registration number 0230-003645 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia that was summarily suspended on May 13, 2008.
- Based upon representations of James E. Schliessmann, Assistant Attorney General, and Commonwealth's Exhibits Nos. 1-3, the Notice of Formal Hearing and Statement of Particulars, the Order of Summary Suspension and the Affidavit of Mailing, the presiding officer ruled there was adequate notice and the panel of the Board proceeded with the hearing in Ms. Robertson's absence.
- Leslie M. Robertson diverted quantities of controlled substances for unauthorized use. Specifically, by her own admission, during the course of Ms. Robertson's employment as a pharmacy technician at CVS/pharmacy #3544 and CVS/pharmacy #7565, Rocky Mount, Virginia, she diverted approximately sixty (60) full bottles of hydrocodone/APAP 10/650 (Schedule III) and fifty (50) full bottles of hydrocodone/APAP 10/500 (Schedule III). Each bottle contained 100 dosage units. As a result, her employment was terminated.

Conclusions of Law:

- Finding of Fact No. 3 constitutes a violation of § 54.1-3316(1), (5), (9) and (13) [formerly § 54.1-3322(6)] of the Code between April 2006 and June 30, 2007, and § 54.1-3316(1), (5), (9) and (13) of the Code (effective July 1, 2007) between July 1, 2007 and April 3, 2008.

Sanction:

- The registration of Leslie M. Robertson be, and hereby is, REVOKED.

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**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, September 10, 2008

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: After an attempt to schedule a regular meeting failed, pursuant to § 54.1-2408.1 of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:35 a.m., on September 10, 2008, to consider the summary suspension of the registration of Bridgett S. Bassett to practice as a pharmacy technician.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: Gill Abernathy
Willie Brown
Bobby Ison
Leo Ross
Michael E. Stredler
Brandon Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Discipline Program Specialist
Howard Casway, Senior Assistant Attorney General
Wayne Halbleib, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With seven members participating and three members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

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BRIDGETT S. BASSETT
Registration #0230-011357

Mr. Halbleib presented a summary of the evidence in this case.

Decision:

Mr. Yi moved, and the Board voted 7-0 in favor of the motion, that with the evidence presented, the practice as a pharmacy technician by Bridgett S. Bassett poses a substantial danger to the public; and therefore, that the registration of Bridgett S. Bassett, to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Bassett for the revocation of her registration in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 8:45a.m.

Elizabeth M. Revere
Discipline Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Michael E. Stredler, Vice Chairman

Date

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**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE**

Wednesday, September 24, 2008
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.

PRESIDING: Brandon Yi, Committee Chairman

MEMBERS PRESENT: Bobby Ison

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

JESSICA LARGE
Registration #0230-008988
Jessica Large appeared with individuals from Rx Services, Carmen Trent, pharmacist; William Deane, pharmacist-in-charge, and William Hancock, Omnicare Area Director, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 9, 2008 Notice.

Closed Meeting: Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Jessica Large. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.

Reconvene: Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision: After consideration of the evidence and statements concerning the allegations, Mr. Ison moved, and the

Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 1.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Ms. Large unless a written request to the Board for a formal hearing on the allegations made against her is received from Ms. Large within such time. If service of the Order is made by mail, three additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

CARMEN TRENT
License #0202-207085

Carmen Trent appeared with individuals from Rx Services, Jessica Large, pharmacy technician; William Deane, pharmacist-in-charge; and William Hancock, Omicare Area Director, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 9, 2008 Notice.

Closed Meeting:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Carmen Trent. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 2.

As provided by law, this decision shall become a final

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Order thirty days after service of such Order on Ms. Trent unless a written request to the Board for a formal hearing on the allegations made against her is received from Ms. Trent within such time. If service of the Order is made by mail, three additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

SEAN CHAMPNEY
Registration #0230-011656

Sean Champney appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the August 19, 2008 Notice.

Closed Meeting:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Sean Champney. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, to offer a Consent Order to Mr. Champney adopting findings of fact and conclusions of law for the indefinite suspension of his registration. Further, the suspension shall be stayed once he enters into a Recovery Monitoring Contract with the Health Practitioners' Intervention Program and Mr. Champney be placed on Terms and conditions.

(This Consent Order shall be effective upon endorsement by Mr. Champney and the Board of the findings of fact, conclusions of law, and terms of the Consent Order.)

16

FAISAL M. KHAN
License #0202-206664

Faisal M. Khan appeared with Charles Witthoefft, his attorney; and Donna Whitney; and Heleen Anderson-Grant, HPIP Case Managers; to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 29, 2008 Notice.

Closed Meeting:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Faisal M. Khan. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and their presence would aid the Committee in its deliberations.

Reconvene:

Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

After consideration of the evidence and statements concerning the allegations, Mr. Ison moved, and the Committee voted 2-0 in favor of the motion, that the Committee make the findings of fact, conclusions of law and sanctions as stated in Attachment 3.

As provided by law, this decision shall become a final Order thirty days after service of such Order on Mr. Khan unless a written request to the Board for a formal hearing on the allegations made against him is received from Mr. Khan within such time. If service of the Order is made by mail, three additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 4:40 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Brandon Yi, Chair

Date

Attachment 1
Minutes - Board of Pharmacy
Special Conference Committee
September 24, 2008

Jessica Large

Findings of Fact and Conclusions of Law:

- Jessica M. Large holds registration number 0230-008988 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia.
- Ms. Large violated § 54.1-3316(1) and (7) and § 54.1-3462(A)(1) of the Code in that, during the course of Ms. Large's employment as a pharmacy technician at RX Services, Williamson Drug Company, Inc., Abingdon, Virginia, on December 26, 2007, she prepared a prescription with Thorazine 100mg tablets (chlorpromazine HCL, Schedule VI) instead of the prescribed 10mg tablets. The cassette was mislabeled as containing 10mg tablets. After taking the medication for one day, the patient was hospitalized for a Thorazine overdose.

Sanction

- It is hereby ORDERED that Jessica M. Large shall successfully complete two (2) hours of continuing pharmacy education in the subject of medication errors.

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Attachment 2
Minutes - Board of Pharmacy
Special Conference Committee
September 24, 2008

Carmen Trent

Findings of Fact and Conclusions of Law:

- Carmen M. Trent holds license number 0202-207085 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- Ms. Trent violated § 54.1-3316(1) and (7), § 54.1-3320(A)(1) and (6), and § 54.1-3462(A)(1) of the Code, and 18 VAC 110-20-270(C) of the Board of Pharmacy Regulations, in that during the course of Ms. Trent's employment as a pharmacist at RX Services, Williamson Drug Company, Inc., Abingdon, Virginia, on December 26, 2007, she dispensed a prescription with Thorazine 100mg tablets (chlorpromazine HCL, Schedule VI) instead of the prescribed 10mg tablets. The cassette was mislabeled as containing 10mg tablets. After taking the medication for one day, the patient was hospitalized for a Thorazine overdose.
- Ms. Trent stated to the Committee that, at the time of the above error, the verification of accuracy of prescriptions did not include a visual confirmation of the drug to be dispensed and the prescribed drug. Since that time, the accuracy verification process has been changed to require a visual verification and a bar code scan to ensure that the proper drug is dispensed.

Sanction

- It is hereby ORDERED that Carmen M. Trent shall successfully complete four (4) hours of continuing pharmacy education in the subject of medication errors.

w

Attachment 3
Minutes - Board of Pharmacy
Special Conference Committee
September 24, 2008

Faisal M. Khan

Findings of Fact and Conclusions of Law:

- Faisal M. Khan holds license number 0202-206664 issued by the Board to practice pharmacy in the Commonwealth of Virginia.
- Mr. Khan violated § 54.1-3316(6) and (7) and § 54.1-3303(A) of the Code, and 18 VAC 110-20-270(C) of the Board of Pharmacy Regulations, in that between December 2007, and January 2, 2008, he forged at least two prescriptions for Percocet (oxycodone, Schedule II) for his personal and unauthorized use.
- Mr. Khan violated § 54.1-3316(4) of the Code in that he may be unsafe to practice pharmacy due to substance abuse, for which he is currently undergoing treatment.
- Mr. Khan signed a Participation Contract and then a Recovery Monitoring Contract with the Health Practitioners' Intervention Program ("HPIP") on January 7, 2008, and May 3, 2008, respectively.
- Mr. Khan successfully attended the William J. Farley Center at Williamsburg Place, Williamsburg, Virginia between January and April 2008.
- Donna Whitney, Mr. Khan's first HPIP case manager, stated to the Committee that Mr. Khan's contract requires that he undergo thirty-six (36) random drug screens a year, and that he has had negative results for the twelve (12) screens he has had thus far.
- Mr. Khan stated to the Committee that he has a sponsor and is currently working on step 4 of a 12-step program. Additionally, he stated that he is not currently practicing as a pharmacist
- Both Ms. Whitney and his current HPIP case manager, Heleen Anderson-Grant, are supportive of Mr. Khan retaining his license, but have not yet discussed his return to the practice of pharmacy.

Sanction

- It is hereby ORDERED that Faisal M. Khan's pharmacist license be placed on PROBATION with the following terms and conditions:
 - The period of probation shall begin on the date that this Order is entered and shall continue INDEFINITELY. Mr. Khan may petition the Board to end his probation after he has been successfully discharged from HPIP.
 - Mr. Khan shall comply with all terms and conditions for the period specified by HPIP.
 - Any violation of the terms and conditions of HPIP or any of the terms and conditions stated in this Order shall be reason for revoking the license of Mr. Khan, and an administrative proceeding shall be held to decide whether Mr. Khan's license shall be revoked. Mr. Khan shall be noticed to appear at an administrative hearing at such time as the Board is notified that:
 - Mr. Khan is not in compliance with the terms and conditions specified by HPIP;
 - Mr. Khan's participation in HPIP has been terminated;
 - There is a pending investigation or unresolved allegation against Mr. Khan involving a violation of law, regulation, or any term or condition of this Order.
 - Mr. Khan shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code.

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**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Thursday, September 25, 2008

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy was held at 8:40 a.m., on September 25, 2008, to consider the settlement proposals for two matters currently before the Board.

PRESIDING: Michael E. Stredler, Vice Chairman

MEMBERS PRESENT: Gill Abernathy
John Beckner
Willie Brown
Jennifer Edwards
Leo Ross

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
William Clay Garrett, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

REBECCA GLOVER
License Number 0202-004710
Mr. Garrett presented a Consent Order to the Board for consideration in lieu of proceeding to a formal hearing regarding this matter.

Decision: Mr. Brown moved, and the Panel voted 6-0 to accept the amended Consent Order and authorized Ms. Russell to sign the Consent Order upon receipt of the original document.

LEWIS J. BLACKBURN
License Number 0202-006343
Mr. Garrett presented a Consent Order to the Board for consideration in lieu of proceeding to a formal hearing regarding this matter.

Decision: Mr. Beckner moved, and the Panel voted 6-0 to accept the amended Consent Order and authorized Ms. Russell to sign



the Consent Order upon receipt of the original document.

ADJOURN:

With all business concluded, the conference call adjourned at 8:50a.m.

Elizabeth M. Revere
Disciplinary Program Specialist

Cathy M. Reiniers-Day
Deputy Executive Director

Michael E. Stredler, Vice Chairman

Date

**DRAFT/UNAPPROVED
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD**

Monday, September 29, 2008
Second Floor
Board Room 1

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:45 a.m.

PRESIDING: Michael E. Stredler, Vice Chairman

MEMBERS PRESENT: John O. Beckner
Willie Brown
Leo H. Ross
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Elizabeth M. Revere, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

QUORUM: With five members of the Board present, a panel was established.

KEVIN O. RIVERA
Registration # 0230-009415

A formal hearing was held in the matter of Kevin O. Rivera to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Mr. Rivera was not present at the hearing. The Panel proceeded in Mr. Rivera's absence as the Notice of Formal Hearing dated August 29, 2008, was mailed to Mr. Rivera's legal address of record, both regular and certified mail. Mr. Stredler ruled that adequate notice was provided to Mr. Rivera and the hearing proceeded in his absence.

James Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Decision: Mr. Beckner moved, and the Panel voted 5-0, to adopt the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and amended by the Panel. (Attachment 1).

Mr. Yi moved, and the Panel voted 5-0, that Mr. Rivera's registration be revoked.

ADJOURN: With all business concluded, the meeting adjourned at 10:55 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Michael E. Stredler, Vice Chair

Date

25

Attachment 1
Board of Pharmacy
Formal Hearings – Panel
September 29, 2008

Kevin O. Rivera

Findings of Fact:

- Kevin O. Rivera holds registration number 0230-009415 issued by the Board to practice as a pharmacy technician in the Commonwealth of Virginia that was summarily suspended on August 29, 2008.
- Based upon representations of James E. Schliessmann, Assistant Attorney General, and Commonwealth's Exhibits Nos. 1-3; i.e., the notice of formal hearing and statement of particulars, the order of summary suspension and the affidavit of mailing, the presiding officer ruled there was adequate notice and the panel of the Board proceeded with the hearing in Mr. Rivera's absence.
- During the course of Mr. Rivera's employment as a pharmacy technician at CVS/Pharmacy #1832, Dale City, Virginia, between July 2007, and June 12, 2008, by his own admission, he diverted approximately 11,310 tablets of Schedule III and IV controlled substances including hydrocodone/APAP 10/500, hydrocodone/APAP 10/325, alprazolam 0.5mg, alprazolam 1mg, diazepam 5mg, and lorazepam 1mg, reportedly for the use of another person.

Conclusions of Law:

- The Board finds that Finding of Fact No. # 3 constitutes a violation of § 54.1-3316(1), (5), (9) and (13) of the Code.

Sanction:

- It is hereby ORDERED that the registration of Kevin O. Rivera be, and hereby is, REVOKED.

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(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING**

November 13, 2008
Second Floor
Conference Center

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 10AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT: John O. Beckner
Jennifer H. Edwards
Bobby Ison

MEMBERS ABSENT: Leo Ross

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Regulatory Analyst, DHP

PUBLIC COMMENTS: No public comments were given at this time.

**DRAFT REGULATIONS
DEFINING
UNPROFESSIONAL
CONDUCT:** The committee reviewed a previous draft of regulations defining unprofessional conduct that had been prepared by staff and reviewed by the full Board at the September 3, 2008 meeting. The Board had begun editing the draft, but had then referred the matter to the Regulation Committee for additional discussion and comment. Staff had made some edits from the original draft based on discussions at the September meeting. Additionally, staff had sent the revised draft to the Virginia Pharmacists Association (VPhA), Virginia Association of Chain Drug Stores (VACDS), and the Virginia Society Health-Systems Pharmacists (VSHP) and solicited feedback. All three organizations responded that they had no issues with the draft. Tim Musselman with VPhA suggested that the wording in #7 of the draft might be written to ensure that "known" dispensing error meant a dispensing error "known to the licensee". The Committee discussed this wording at length, but considered that it was worded clearly enough, since a pharmacist could not take any action if he did not know about an error.

The committee reviewed the entire draft and made a number of edits with a final document to be presented to the full Board on December 10, 2008. (Attachment 1)

ADJOURN: With all business concluded, the meeting adjourned at noon.

Elizabeth Scott Russell
Executive Director

David C. Kozera, Chairman

Date

DRAFT UNDER REVIEW

BOARD OF PHARMACY
Standards of conduct

18VAC110-20-25. Unprofessional conduct.

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

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

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

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

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

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

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

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

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

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

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

DRAFT

PROPOSED REGULATION, ADOPTED 12/12/2007

1 Project 753 - NOIRA

2 BOARD OF PHARMACY

3 Periodic review

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PROPOSED REGULATION, ADOPTED 12/12/2007

67 Project 753 - NOIRA

68

BOARD OF PHARMACY

69

Periodic review

70

71 18VAC110-20-10. Definitions.

72 In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the
73 following words and terms when used in this chapter shall have the following meanings, unless the
74 context clearly indicates otherwise:

75 "ACPE" means the Accreditation Council for Pharmacy Education.

76 "Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the
77 purchase or transfer of all or substantially all of the assets of the entity or of any corporation that
78 owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in
79 partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock
80 of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning
81 the entity, except that this shall not apply to any corporation the voting stock of which is actively
82 traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a
83 corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the
84 entity, with another business or corporation.

85 "Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed
86 prescriptions on behalf of and for further delivery or administration to a patient.

87 "Aseptic processing" means the technique involving procedures designed to preclude
88 contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

89 "Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or
90 dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded
91 as defined in §§54.1-3461 and 54.1-3462 of the Code of Virginia.

92 "Board" means the Virginia Board of Pharmacy.

93 "CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

94 "CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact
95 hours.

96 "Chart order" means a lawful order for a drug or device entered on the chart or in a medical
97 record of a patient by a prescriber or his designated agent.

98 "Class 100 environment" means an atmospheric environment which contains less than 100
99 particles, 0.5 microns in diameter, per cubic foot of air.

100 "Closed system transfer" means the movement of sterile products from one container to another
101 in which the container-closure system and transfer devices remain intact throughout the entire
102 transfer process, compromised only by the penetration of a sterile, pyrogen-free needle or cannula
103 through a designated stopper or port to effect transfer, withdrawal, or delivery, to include the
104 withdrawal of a sterile solution from an ampul in a class 100 environment.

105 "Compliance packaging" means packaging for dispensed drugs which is comprised of a series of
106 containers for solid oral dosage forms and which is designed to assist the user in administering or
107 self-administering the drugs in accordance with directions for use.

108 "Contact hour" means the amount of credit awarded for 60 minutes of participation in and
109 successful completion of a continuing education program.

110 "Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other
111 facility in which persons are incarcerated by government officials.

112 "Cytotoxic drug" means a drug which has the capability of killing living cells.

113 "DEA" means the United States Drug Enforcement Administration.

114 "Electronic transmission prescription" is any prescription, other than an oral or written
115 prescription or a prescription transmitted by facsimile machine, that is electronically transmitted from

116 a practitioner authorized to prescribe directly to a pharmacy without interception or intervention from
117 a third party, or from one pharmacy to another pharmacy.

118 "Expiration date" means that date placed on a drug package by the manufacturer or repacker
119 beyond which the product may not be dispensed or used.

120 "Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an
121 electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a
122 hard copy form.

123 "FDA" means the United States Food and Drug Administration.

124 "Floor stock" means a supply of drugs that have been distributed for the purpose of general
125 administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

126 "Foreign school of pharmacy" means a school outside the United States and its territories
127 offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in
128 duration resulting in a degree that qualifies a person to practice pharmacy in that country.

129 "Forgery" means a prescription that was falsely created, falsely signed, or altered.

130 "FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency
131 Committee of NABP which certifies that the holder of such certificate has passed the Foreign
132 Pharmacy Equivalency Examination and a credential review of foreign training to establish
133 educational equivalency to board approved schools of pharmacy, and has passed approved
134 examinations establishing proficiency in English.

135 "Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-
136 National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

137 "Hermetic container" means a container that is impervious to air or any other gas under the
138 ordinary or customary conditions of handling, shipment, storage, and distribution.

139 "Home infusion pharmacy" means a pharmacy which compounds solutions for direct parenteral
140 administration to a patient in a private residence, long-term care facility or hospice setting.

141 "Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of
142 Virginia or as defined in regulations by the Virginia Department of Health.

143 "Inactive license" means a license which is registered with the Commonwealth but does not
144 entitle the licensee to practice, the holder of which is not required to submit documentation of CE
145 necessary to hold an active license.

146 "Light-resistant container" means a container that protects the contents from the effects of light
147 by virtue of the specific properties of the material of which it is composed, including any coating
148 applied to it. Alternatively, a clear and colorless or a translucent container may be made light
149 resistant by means of an opaque covering, in which case the label of the container bears a
150 statement that the opaque covering is needed until the contents have been used. Where a
151 monograph directs protection from light, storage in a light-resistant container is intended.

152 "Long-term care facility" means a nursing home, retirement care, mental care or other facility or
153 institution which provides extended health care to resident patients.

154 "NABP" means the National Association of Boards of Pharmacy.

155 "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

156 "On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy
157 and is available as needed.

158 "Open-system transfer" means the combining of products in a nonsealed reservoir before filling
159 or when a solution passes through the atmosphere during a transfer operation.

160 "Permitted physician" means a physician who is licensed pursuant to §54.1-3304 of the Code of
161 Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably
162 available.

163 "Perpetual inventory" means an ongoing system for recording quantities of drugs received,
164 dispensed or otherwise distributed, and drugs on hand by a pharmacy.

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

169 "Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to
170 provide for continuity of pharmacy services or lawful access to patient prescription records or other
171 required patient records for the purpose of continued pharmacy services to patients.

172 "Pharmacy technician trainee" means a person who is currently enrolled in an approved
173 pharmacy technician training program and is performing duties restricted to pharmacy technicians
174 for the purpose of obtaining practical experience in accordance with §54.1-3321 D.

175 "PIC" means the pharmacist-in-charge of a permitted pharmacy.

176 "Practice location" means any location in which a prescriber evaluates or treats a patient.

177 "Prescription department" means any contiguous or noncontiguous areas used for the
178 compounding, dispensing and storage of all Schedule II through VI drugs and devices and any
179 Schedule I investigational drugs.

180 "PTCB" means the Pharmacy Technician Certification Board, co-founded by the American
181 Pharmaceutical Association and the American Society of Health System Pharmacists, as the
182 national organization for voluntary examination and certification of pharmacy technicians.

183 "Quality assurance plan" means a plan approved by the board for continuous ongoing
184 monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy
185 function or system.

186 "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable
187 nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit
188 or radionuclide generator that is intended to be used in the preparation of any such substance, but
189 does not include drugs such as carbon-containing compounds or potassium-containing salts that
190 include trace quantities of naturally occurring radionuclides. The term also includes any biological
191 product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

192 "Repackaged drug" means any drug removed from the manufacturer's original package and
193 placed in different packaging.

194 "Robotic pharmacy system" means a mechanical system controlled by a computer that performs
195 operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of
196 medications, and collects, controls, and maintains all transaction information.

197 "Safety closure container" means a container which meets the requirements of the federal
198 Poison Prevention Packaging Act of 1970 (15 USC §§1471-1476), i.e., in testing such containers,
199 that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a
200 five-minute period and that 80% fail in another five minutes after a demonstration of how to open it
201 and that 90% of a test group of 100 adults must be able to open and close the container.

202 "Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted
203 pharmacy of a hospital but at the location designated on the pharmacy permit.

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

209 "Special use permit" means a permit issued to conduct a pharmacy of a special scope of service
210 that varies in any way from the provisions of any board regulation.

211 "Sterile pharmaceutical product" means a dosage form free from living microorganisms.

212 "Storage temperature" means those specific directions stated in some monographs with respect
213 to the temperatures at which pharmaceutical articles shall be stored, where it is considered that
214 storage at a lower or higher temperature may produce undesirable results. The conditions are
215 defined by the following terms:

216 1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in
217 which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a
218 cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and
219 14°F).

220 2. "Room temperature" means the temperature prevailing in a working area.

221 3. "Controlled room temperature" is a temperature maintained thermostatically that
222 encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that
223 results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for
224 excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals,
225 and warehouses.

226 4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

227 5. "Excessive heat" means any temperature above 40°C (104°F).

228 6. "Protection from freezing" means where, in addition to the risk of breakage of the container,
229 freezing subjects a product to loss of strength or potency, or to the destructive alteration of its
230 characteristics, the container label bears an appropriate instruction to protect the product from
231 freezing.

232 7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

233 "Terminally ill" means a patient with a terminal condition as defined in §54.1-2982 of the Code of
234 Virginia.

235 "Tight container" means a container that protects the contents from contamination by extraneous
236 liquids, solids, or vapors, from loss of the drug, and from efflorescence, deliquescence, or
237 evaporation under the ordinary or customary conditions of handling, shipment, storage, and
238 distribution, and is capable of tight reclosure. Where a tight container is specified, it may be replaced
239 by a hermetic container for a single dose of a drug and physical tests to determine whether
240 standards are met shall be as currently specified in United States Pharmacopeia-National
241 Formulary.

242 "Unit dose container" means a container that is a single-unit container, as defined in United
243 States Pharmacopeia-National Formulary, for articles intended for administration by other than the
244 parenteral route as a single dose, direct from the container.

245 "Unit dose package" means a container that contains a particular dose ordered for a patient.

246 "Unit dose system" means a system in which multiple drugs in unit dose packaging are
247 dispensed in a single container, such as a medication drawer or bin, labeled only with patient name
248 and location. Directions for administration are not provided by the pharmacy on the drug packaging
249 or container but are obtained by the person administering directly from a prescriber's order or
250 medication administration record.

251 "USP-NF" means the United States Pharmacopeia-National Formulary.

252 "Well-closed container" means a container that protects the contents from extraneous solids and
253 from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and
254 distribution.

255 **18VAC110-20-20. Fees.**

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

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

259 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. Medical equipment supplier permit \$180
- 7. Humane society permit \$20
- 8. Nonresident pharmacy \$270
- 9. Controlled substances registrations (~~Between November 2, 2005, and December 31, 2006, the application fee for a controlled substance registration shall be \$50~~) \$90
- ~~10. Robotic pharmacy system approval \$150~~
- ~~11. 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.

- ~~12-11. Approval of a pharmacy technician training program \$150~~
- ~~13-12. Approval of a continuing education program \$100~~

260 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. Medical equipment supplier permit \$180
- 7. Humane society permit \$20
- 8. Nonresident pharmacy \$270
- 9. Controlled substances registrations \$90
- 10. Innovative program continued approval based on board order not to exceed \$200 per approval period.
- 11. Approval of a pharmacy technician training program \$75 every two years

261 E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew
262 an expired license within one year of the expiration date or within two years in the case of a
263 pharmacy technician training program. In addition, engaging in activities requiring a license, permit,
264 or registration after the expiration date of such license, permit, or registration shall be grounds for
265 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. Medical equipment supplier permit \$60
- 7. Humane society permit \$5



8. Nonresident pharmacy	\$90
9. Controlled substances registrations	\$30
10. <u>Approval of a pharmacy technician training program</u>	<u>\$15</u>

266 F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration
 267 more than one year after the expiration date, or more than two years after the expiration date in the
 268 case of a pharmacy technician training program, shall submit an application for reinstatement with
 269 any required fees. Reinstatement is at the discretion of the board and, except for reinstatement
 270 following license revocation or suspension, may be granted by the executive director of the board
 271 upon completion of an application and payment of any required fees.

272

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. Medical equipment supplier permit	\$210
d. Humane society permit	\$30
e. Nonresident pharmacy	\$115
f. Controlled substances registration	\$180
g. <u>Approval of a pharmacy technician training program</u>	<u>\$75</u>

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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

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H. Miscellaneous fees.

1. Duplicate wall certificate	\$25
2. Returned check	\$35

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~~I. For the annual renewal due on or before December 31, 2006, the following fees shall be imposed for a license, permit or registration:~~

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1. Pharmacist active license	\$50
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2.	Pharmacist inactive license	\$25
3.	Pharmacy technician registration	\$15
4.	Pharmacy permit	\$210
5.	Physician permit to practice pharmacy	\$210
6.	Medical equipment supplier permit	\$140
7.	Humane society permit	\$20
8.	Nonresident pharmacy	\$210
9.	Controlled substances registrations	\$50

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Part II

Licensure Requirements for Pharmacists

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

A. Each applicant for licensure as a pharmacist ~~by examination shall have gained practical experience in the practice of pharmacy, to include no less than 300 hours in the area of prescription compounding and dispensing within a pharmacy as set forth in this section and 18 VAC 110-20-40.~~

B. An applicant ~~who graduated from an approved school of pharmacy after January 1, 2003 shall accumulate for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience, of which at least 300 hours shall be gained outside of a school of pharmacy practical experience program. For purposes of this regulation, credit will not be given for more than 50 hours in any one week. Applicants who graduated from an approved school of pharmacy prior to January 1, 2003 shall have gained at least 1,000 hours of practical experience.~~

C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.

~~C.D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program required shall only be gained after successful completion of the first professional year equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.~~

D. ~~Practical experience gained in a school of pharmacy which has a program designed to provide the applicant with practical experience in all phases of pharmacy practice and which program is approved by the American Council on Pharmaceutical Education will be accepted by the board for the time period during which the student is actually enrolled. The applicant will be required to gain any additional experience outside the school program as needed to meet the requirements of subsections A and B of this section.~~

E. In accordance with §54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.

18VAC110-20-40. Procedure for gaining practical experience.

A. ~~Each pharmacy student or graduate of an approved school of pharmacy who desires to gain practical experience in a pharmacy within the Commonwealth shall~~ person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall also apply to students any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

316 1. The applicant shall be enrolled in, and have started course work, in a professional degree
317 program of a board-approved school of pharmacy. Such registration is only valid while the student
318 is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the
319 requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration
320 to cover the estimated time period for the student to complete the school program and pass the
321 required examinations. If the student is no longer enrolled in the school program, takes a voluntary
322 break from the program, or is otherwise not actively participating in the school program, except for
323 regularly scheduled school breaks, the registration is no longer valid and shall be returned to the
324 board immediately;

325 2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a
326 foreign school of pharmacy, has established educational equivalency and proficiency in English by
327 obtaining the FPGEC certificate, and desires to gain required practical experience required for
328 licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of
329 current employment, or an employment start date within 90 days, in a pharmacy in Virginia with
330 approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated
331 time period needed to obtain the required practical experience hours and take the required
332 examinations to become licensed as a pharmacist;

333 3. The applicant has already gained the required practical experience, but is an otherwise
334 qualified applicant awaiting examination for licensure. A three-month expiration date shall be
335 assigned to allow the applicant time to take required examinations; or

336 4. The applicant is an applicant for reactivation or reinstatement of a previously-issued
337 pharmacist license and is meeting board requirements for re-licensure. An expiration date shall be
338 assigned to reasonably cover the period of time necessary to meet the board requirements.

339 C. For documented, good cause shown, the executive director of the board may extend the
340 expiration date of the intern registration upon submission of an application form approved by the
341 board and payment of the initial application fee.

342 B-D. The applicant A pharmacy intern shall be supervised by a pharmacist who holds an a
343 current, unrestricted license and assumes full responsibility for the training, supervision and conduct
344 of the intern. The supervising pharmacist shall not supervise more than one pharmacy intern during
345 the same time period.

346 E-E. The intern registration of a pharmacy student shall be valid only while the student is
347 enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the
348 board upon failure to be enrolled.

349 D-F. Practical experience gained within any other state must be registered with and certified by
350 the board of that state in order to be accepted or certified by this board. In the event that a state
351 does not use internships to gain practical experience in pharmacy but relies on the pharmacy school
352 to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of
353 experience gained in the United States may be accepted in lieu of board certification.

354 E-G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved
355 by the board, which shall be filed prior to or with the application for examination for licensure.

356 F-H. An applicant for licensure by endorsement may provide verification acceptable to the board
357 of practical experience hours worked as a pharmacist in another state within the United States in lieu
358 of pre-licensure intern hours in order to meet the practical experience requirement

359 I. A pharmacy intern shall notify the board in writing of any change in address of record within 14
360 days of such change.

361 **18VAC110-20-50. Curriculum and approved schools of pharmacy.**

362 A. The following minimum educational requirements for the specified periods shall be recognized
363 by the board for the purpose of licensure.

364 1. On and after June 1, 1928, but before June 1, 1936, the applicant for licensure shall have
365 been graduated from a three-year course of study with a pharmacy graduate or pharmacy college
366 degree in pharmacy awarded.

367 2. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have
368 been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy
369 awarded.

370 3.2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at
371 least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of
372 Pharmacy degree awarded.

373 B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have
374 been granted the first professional degree from a program of a school of pharmacy which meets the
375 requirements of §54.1-3312 of the Code of Virginia.

376 **18VAC110-20-60. Content of the examination and grades required; limitation on admittance to**
377 **examination.**

378 A. Prior to admission to any examination required for licensure, the applicant shall have met all
379 other requirements to include education and practical experience requirements, but in no case shall
380 the applicant be admitted if grounds exist to deny licensure under §54.1-3316 of the Code of
381 Virginia.

382 B. The applicant shall achieve a passing score as determined by the board on the licensure
383 examination which is approved by the board and which shall consist of an integrated examination of
384 pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are
385 necessary to assure that the candidate possesses the necessary knowledge and skills to practice
386 pharmacy.

387 ~~C. The applicant shall also achieve a passing score as determined by the board on an~~
388 ~~examination which tests the candidate's knowledge of federal and state laws related to pharmacy~~
389 ~~practice.~~

390 ~~D. When an applicant for licensure by examination fails to meet the passing requirements of the~~
391 ~~board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to~~
392 ~~the examination until he has completed an additional 1,000 hours of practical experience as a~~
393 ~~pharmacy intern as set forth in 18VAC110-20-40.~~

394 D. The applicant shall also achieve a passing score as determined by the board on an
395 examination which tests the candidate's knowledge of federal and state laws related to pharmacy
396 practice.

397 E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a
398 period of 30 days.

399 F. If an applicant requests a testing accommodation for either examination based on a physical
400 or mental impairment that substantially limits one or more major life activities, subject to the
401 Americans with Disabilities Act, the board may approve a reasonable accommodation that does not
402 compromise the security or integrity of the examination.

403 1. Supporting documentation shall be provided by the applicant to include the following to be
404 considered for review:

- 405 a. A letter of request from the candidate that specifies the testing accommodation requested;
406 b. A written report of an evaluation (educational, psychological, or physical) within the
407 preceding two years from a qualified professional which states a diagnosis of the disability,
408 describes the disability, recommends specific accommodations, and provides justification
409 that the accommodation is appropriate and necessary for the diagnosed disability. If the
410 comprehensive evaluation was done more than two years ago and the condition is one that
411 is not subject to change, the original evaluation report may be submitted along with a current
412 letter from the qualified professional stating that there has been no change in the condition
413 since the time of the evaluation; and
414 c. A written statement from the appropriate person at the applicant's school of pharmacy
415 which describes any testing accommodations made while the student was enrolled, if
416 applicable.

417 2. The applicant will be notified in writing of the decision. If the request for accommodation is
418 granted, the approval information will be forwarded to the examination contractor and the form of the
419 accommodation will be coordinated with the contractor.

420 **18VAC110-20-70. Requirements for foreign-trained applicants.**

421 A. Applicants for licensure who were trained in foreign schools of pharmacy shall ~~meet the~~
422 ~~following additional requirements~~ obtain the FPGEC certificate prior to being allowed to take the
423 ~~examinations required by 18VAC110-20-60:~~ register as a pharmacy intern and gain required
424 practical experience in Virginia.

425 ~~1. Obtain verification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) of~~
426 ~~the National Association of Boards of Pharmacy (NABP) that the applicant is a graduate of a foreign~~
427 ~~school of pharmacy.~~

428 ~~2. Complete and receive a score acceptable to the board on the Foreign Pharmacy Graduate~~
429 ~~Equivalency Examination (FPGEE).~~

430 ~~3. Complete and receive a score acceptable to the board on the Test of English as a Foreign~~
431 ~~Language (TOEFL) or on the TOEFL iBT, the Internet-based tests of listening, reading, speaking~~
432 ~~and writing.~~

433 ~~4. Complete the Test of Spoken English (TSE) or the TOEFL iBT as given by the Educational~~
434 ~~Testing Service with a score acceptable to the board.~~

435 ~~5.B. Fulfill~~ After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern
436 registration and shall fulfill the requirements for practical experience ~~as prescribed~~ set forth in
437 18VAC110-20-30 A, B and E and 18VAC110-20-40 A, B, D, E and F ~~before being admitted to~~
438 ~~examinations required by 18VAC110-20-60.~~

439 ~~B.C. Applicants for licensure who were trained in foreign schools of pharmacy shall also~~
440 ~~complete and achieve passing scores on the examinations as prescribed~~ set forth in 18VAC110-20-
441 60 before being licensed as a pharmacist.

442 **18VAC110-20-80. Renewal and reinstatement of license.**

443 A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date
444 by the submission of a renewal fee, renewal form, and statement of compliance with continuing
445 education requirements.

446 B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license
447 until December 31 of the following year.

448 C. A pharmacist who fails to renew his license by the expiration date may renew his license at
449 any time within one year of its expiration by submission of the renewal fee and late fee, renewal
450 form, and statement of compliance with continuing education requirements.

451 D. A pharmacist who fails to renew his license for more than one year following expiration and
452 who wishes to reinstate such license shall submit an application for reinstatement, pay the current
453 renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing
454 education requirements. Reinstatement is at the discretion of the board and may be granted by the
455 executive director of the board provided no grounds exist to deny said reinstatement.

456 E. A pharmacist who has been registered as inactive for more than one year must apply for
457 reinstatement, submit documentation showing compliance with continuing education requirements,
458 and pay the current year active renewal fee in order to resume active licensure.

459 F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an
460 inactive license, who has allowed his license to lapse, or who has had his license suspended or
461 revoked must submit evidence of completion of CEU's or hours equal to the requirements for the
462 number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

463 G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for
464 more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and
465 receive a passing score on the board-approved law examination and furnish acceptable
466 documentation of one of the following:

467 1. Active pharmacy practice within the past five years as a properly licensed pharmacist in
468 another state; or

469 2. Practical experience as a pharmacy intern registered with the board of at least 160 hours
470 within six months immediately prior to being reinstated.

471 H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall
472 constitute grounds for disciplinary action by the board.

473 I. It shall be the duty and responsibility of each licensee to inform the board of his current
474 address. A licensee shall immediately notify the board within 14 days in writing or electronically of
475 any change of an address of record. Properly updating address of record directly through the
476 board's web-based application or other approved means shall constitute lawful notification. All
477 notices required by law or by these rules and regulations are deemed to be legally given when
478 mailed to the address given of record and shall not relieve the licensee of the obligation to comply.

479 **18VAC110-20-90. Requirements for continuing education.**

480 A. ~~On and after December 31, 1993,~~ a A pharmacist shall be required to have completed a
481 minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved
482 program for each annual renewal of licensure. CEUs or hours in excess of the number required for
483 renewal may not be transferred or credited to another year.

484 B. A pharmacy education program approved for continuing pharmacy education is:

485 1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);

486 2. One that is approved as a Category I Continuing Medical Education (CME) course, the
487 primary focus of which is pharmacy, pharmacology or drug therapy; or

488 3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.

489 C. The board may grant an extension pursuant to ~~§54.1-3314 E~~ §54.1-3314.1 E of the Code of
490 Virginia. Any subsequent extension shall be granted only for good cause shown.

491 D. Pharmacists are required to attest to compliance with CE requirements in a manner approved
492 by the board at the time of their annual license renewal. Following each renewal period, the board
493 may conduct an audit of the immediate past two years' CE documents to verify compliance with
494 requirements. Pharmacists are required to maintain, for ~~two~~ three years following renewal, the
495 original certificates documenting successful completion of CE, showing date and title of the CE
496 program or activity, the number of CEU's or contact hours awarded, and a certifying signature or
497 other certification of the approved provider. Pharmacists selected for audit must provide these
498 original documents to the board by the deadline date specified by the board in the audit notice.

499 **18VAC110-20-100. Approval of continuing education programs.**

500 A. The board will approve without application or further review any program offered by an ACPE-
501 approved provider and will accept for credit certificates bearing the official ACPE logo and program
502 number.

503 B. The board may approve an individual CE program under the following provisions:

504 1. An approved individual program is a course, activity, or lecture which includes subject matter
505 related to the competency of the practice of pharmacy and which has been approved for CE credit
506 by the board.

507 2. In order to receive approval for an individual program, the sponsor or provider must ~~make~~
508 application apply prior to the program offering on a form provided by the board. The information
509 which must be provided shall include but not be limited to: name of provider, location, date and time
510 of program, charges to participants, description of program content and objectives, credentials of
511 speaker or author, method of delivery, evaluation procedure, evidence of a ~~pre~~ and post test
512 assessment, credits requested, mechanism for recordkeeping, and any such information as the
513 board deems necessary to assure quality and compliance.

514 3. The sponsor ~~making application applying~~ for board approval of an individual program must
515 pay a fee as required in 18VAC110-20-20 C 18.

516 4. The board shall notify the provider or sponsor within 60 days following the receipt of a
517 completed application of approval or disapproval of a program and the number of credits which may
518 be awarded. The board shall also assign an expiration date for approval of the program not to
519 exceed two years from the date of approval.

520 5. The provider of an approved program shall provide to each participant who completes the
521 required hours and passes the post test a certification with the name of the provider, name of the
522 participant, description of course and method of delivery, number of hours credited, date of
523 completion, and program identification number.

524 6. The provider of an approved program shall maintain all records on that program, its
525 participants, and hours awarded for a period of ~~three~~ five years and shall make those records
526 available to the board upon request.

527 7. The board shall periodically review and monitor programs. The provider of a CE program shall
528 waive registration fees for a representative of the board for that purpose.

529 8. Any changes in the information previously provided about an approved program or provider
530 must be submitted or the board may withdraw its approval. If a provider wants to give a live program
531 more than once, all program dates must either be submitted on the original application or provided to
532 the board in subsequent correspondence at least five days prior to giving the program.

533 Part III

534 Requirements For Pharmacy Technician Registration

535 **18VAC110-20-101. Application for registration as a pharmacy technician.**

536 A. Any person wishing to apply for registration as a pharmacy technician shall submit the
537 application fee and an application on a form approved by the board.

538 B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the
539 following:

- 540 1. Satisfactory completion of an approved training program, and
- 541 2. A passing score on a board-approved examination.

542 C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence
543 of current PTCB certification.

544 D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no
545 more than nine months without becoming registered as a pharmacy technician.

546 **18VAC110-20-102. Criteria for approval for training programs.**

547 A. Any person wishing to apply for approval of a pharmacy technician training program shall
548 submit the application fee and an application on a form approved by the board and meet the criteria
549 established in this section.

550 B. The curriculum of a training program for pharmacy technicians shall include instruction in
551 applicable, current laws and regulations and in the tasks that may be performed by a pharmacy
552 technician to include the following or any other task restricted to pharmacy technicians in regulation:

- 553 1. The entry of prescription information and drug history into a data system or other
554 recordkeeping system;
- 555 2. The preparation of prescription labels or patient information;
- 556 3. The removal of the drug to be dispensed from inventory;
- 557 4. The counting, measuring, or compounding of the drug to be dispensed;
- 558 5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
- 559 6. The stocking or loading of automated dispensing devices or other devices used in the
560 dispensing process; and
- 561 7. The acceptance of refill authorization from a prescriber or his authorized agent provided there
562 is no change to the original prescription.

563 C. ~~Instructors~~ Each program shall have a program director who shall be either (i) a pharmacist
564 with a current unrestricted license in any jurisdiction and who is not currently suspended or revoked

565 in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of
566 experience performing technician tasks who holds a current unrestricted registration in Virginia or a
567 current PTCB certification and who is not currently suspended or revoked as a pharmacy technician
568 in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program
569 director.

570 D. Instructors for the core components listed in paragraph B of this section shall meet the
571 requirements for the program director listed in paragraph C of this section. The program director
572 may serve as an instructor.

573 D.E. The length of the program shall be sufficient to prepare a program participant to sit for the
574 board-approved examination and demonstrate entry-level competency.

575 E.F. The program shall maintain records of program participants either on-site or at another
576 location where the records are readily retrievable upon request for inspection. A program shall
577 provide a certificate of completion to participants who successfully complete the program and
578 provide verification of completion of the program for a participant upon request by the board.
579 Records shall be maintained for two years from date of completion or termination of program.

580 G. The program shall report within 14 days any substantive change in the program to include a
581 change in program name, program director, instructors, name of institution or business if applicable,
582 address, program content, length of program, or location of records.

583 H. A pharmacy technician training program approval expires after two years, after which the
584 program may apply for renewal. For continued approval, the program shall submit the renewal
585 application, renewal fee, and a self-evaluation report on a form provided by the board at the time of
586 renewal notification. Renewal of a program's approval is at the discretion of the board, and the
587 decision to renew shall be based on documentation of continued compliance with the criteria set
588 forth in this section.

589 **18VAC110-20-103. Examination.**

590 A. The board shall approve one or more examinations to test entry-level competency for
591 pharmacy technicians. In order to be approved, a competency examination shall be developed in
592 accordance with and meet the recognized acceptable test measurement standards of the Joint
593 Technical Standards for Education and Psychological Testing (American Psychological Association,
594 current edition), and shall be administered by an independent third party.

595 B. The board may contract with an examination service for the development and administration
596 of a competency examination.

597 C. The board shall determine the minimum passing standard on the competency examination.

598 D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in
599 accordance with the provisions of 18VAC110-20-60 F.

600 **18VAC110-20-104. Address of record; maintenance of certificate.**

601 A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his
602 current address. A pharmacy technician shall notify the board in writing or electronically of any
603 change of an address of record within 30 14 days. Properly updating address of record directly
604 through the board's web-based application or other approved means shall constitute lawful
605 notification. All notices required by law or by these rules and regulations are deemed to be legally
606 given when mailed to the address given of record and shall not relieve the registrant of the obligation
607 to comply.

608 B. A pharmacy technician shall maintain his current registration certificate at his principal place
609 of practice, available for inspection upon request. A pharmacy technician who does not have a
610 principal place of practice may maintain it at any pharmacy in which he practices or his address of
611 record.

612 **18VAC110-20-106. Requirements for continued competency.**

613 A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five
614 contact hours of approved continuing education for each annual renewal of registration. Hours in
615 excess of the number required for renewal may not be transferred or credited to another year.

616 B. An approved continuing education program shall meet the requirements as set forth in
617 subsection B of 48VAC110-20-90 18VAC110-20-100.

618 C. Upon written request of a pharmacy technician, the board may grant an extension of up to
619 one year in order for the pharmacy technician to fulfill the continuing education requirements for the
620 period of time in question. The granting of an extension shall not relieve the pharmacy technician
621 from complying with current year requirements. Any subsequent extension shall be granted for good
622 cause shown.

623 D. Original certificates showing successful completion of continuing education programs shall be
624 maintained by the pharmacy technician for a period of ~~two~~ three years following the renewal of his
625 registration. The pharmacy technician shall provide such original certificates to the board upon
626 request in a manner to be determined by the board.

627 Part IV

628 Pharmacies

629 **18VAC110-20-110. Pharmacy permits generally.**

630 A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more
631 than two pharmacies.

632 B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the
633 practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty
634 shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the
635 pharmacy permit.

636 C. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC,
637 he shall take ~~a complete and accurate inventory of all Schedule II through V controlled substances~~
638 ~~on hand and~~ shall immediately return the pharmacy permit to the board indicating the effective date
639 on which he ceased to be PIC.

640 D. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take
641 a complete and accurate inventory of all Schedule II through V controlled substances on hand on the
642 date he ceases to be PIC, unless the owner submits written notice to the board showing good cause
643 as to why this opportunity should not be allowed.

644 E. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no
645 longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than
646 30 days shall be responsible for notifying the board, returning the permit, and taking the required
647 inventory. For unanticipated absences by the PIC, which exceed 15 days with no known return date
648 within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

649 D. F. An application for a permit designating the new PIC shall be filed with the required fee
650 within 14 days of the original date of resignation or termination of the PIC on a form provided by the
651 board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline
652 unless the board receives a request for an extension prior to the deadline. The executive director for
653 the board may grant an extension for up to an additional 14 days for good cause shown.

654 G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same
655 designated prescription department space. A pharmacy shall not engage in any other activity
656 requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of
657 the same designated prescription department space.

658 H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and
659 local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a
660 private dwelling or residence after (effective date of this subsection).

661 **18VAC110-20-111. Pharmacy technicians.**

662 A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific
663 training program and manual for training pharmacy technicians to work at that pharmacy. The
664 program shall include training consistent with that specific pharmacy practice to include, but not be
665 limited to, training in proper use of site-specific computer programs and equipment, proper use of

666 other equipment used at the pharmacy in performing technician duties, and pharmacy calculations
667 consistent with the duties at that pharmacy.

668 B. Every pharmacy shall maintain documentation of successful completion of the site specific
669 training program for each pharmacy technician for the duration of the employment and for a period
670 of two years from date of termination of employment. Documentation for currently employed
671 pharmacy technicians shall be maintained on site or at another location where the records are
672 readily retrievable upon request for inspection. After employment is terminated, such documentation
673 may be maintained at an off-site location where it is retrievable upon request.

674 C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician
675 training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to
676 conduct tasks restricted to pharmacy technicians for no more than nine months without that person
677 becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101.
678 Every pharmacy using such a person shall have documentation on site and available for inspection
679 showing that the person is currently enrolled in an approved training program and the start date for
680 each pharmacy technician in training.

681 **18VAC110-20-120. Special or limited-use pharmacy permits.**

682 A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when
683 the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or
684 unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based
685 on special conditions of use requested by the applicant and imposed by the board in cases where
686 certain requirements of regulations may be waived. The following conditions shall apply:

687 1. The application shall list the regulatory requirements for which a waiver is requested and a
688 brief explanation as to why each requirement should not apply to that practice.

689 2. A policy and procedure manual detailing the type and method of operation, hours of operation,
690 schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing
691 pharmacist control must accompany the application.

692 3. The issuance and continuation of such permits shall be subject to continuing compliance with
693 the conditions set forth by the board.

694 B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer
695 pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the
696 board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the
697 following conditions:

698 1. The access is only for the purpose of repairing or upgrading essential equipment or for the
699 purpose of securing a delivered drug order in the pharmacy.

700 2. The PIC shall be notified prior to each entry and give permission for the designated, specific
701 individuals to enter.

702 3. If entry is by a non-pharmacist, two persons must enter together, one of whom must be an
703 employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician
704 assistant. Both persons must remain in the pharmacy the entire time that access is required.

705 4. The key or other means of unlocking the pharmacy and the alarm access code shall be
706 maintained in a secure location within the facility in a sealed envelope or other container with the
707 name of the "sealing" pharmacist written across the seal. If a non-pharmacist accesses the
708 pharmacy, this means of access may be used, and the licensed health professional, as set forth in
709 paragraph B 3 of this section, is responsible for resealing the means of access and writing his name
710 across the seal. The PIC shall ensure that the alarm access code is changed within 48 hours. In
711 lieu of the pharmacist's signature across a seal, the executive director for the board may approve
712 other methods of securing the emergency access to the prescription department.

713 5. A log must be maintained of each non-pharmacist entry showing date and time of entry,
714 names of the two persons entering, purpose for entry, and notation that permission was granted by
715 the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for
716 one year.

717 **18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.**

718 A. At least 14 days prior to the date a pharmacy closes in accordance with §54.1-3434.01 of the
719 Code of Virginia or goes out of business, the owner shall notify the board. The proposed disposition
720 of all Schedule II through VI drugs, prescription dispensing records, patient information records, and
721 other required records shall be reported to the board. If the pharmacy drug stock and records are to
722 be transferred to another licensee, the owner shall inform the board of the name and address of the
723 licensee to whom the drugs and records are being transferred and the date of transfer. Prescription
724 records for prescriptions with active refills shall be transferred to another pharmacy where a patient
725 may obtain access for the purpose of obtaining refills either at that location or in accordance with the
726 transfer provisions of 18 VAC 110-20-360.

727 B. Exceptions to the public notice as required in §54.1-3434.01 of the Code of Virginia and the
728 notice required in subsection A of this section shall be approved by the board and may include
729 sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction,
730 bankruptcy, or other emergency circumstances. If the pharmacy is not able to meet the notification
731 requirements of §54.1-3434.01, the owner shall ensure that the board and public are properly
732 notified as soon as he knows of the closure and shall disclose the emergency circumstances
733 preventing the notification within the required deadlines.

734 C. In the event of an exception to the notice as required in §54.1-3434.01 of the Code of Virginia
735 and in subsection A of this section, the PIC or owner shall provide notice as far in advance of closing
736 as allowed by the circumstances.

737 D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall
738 notify the board of the pending change.

739 1. Upon any change in ownership of an existing pharmacy, the prescription dispensing records
740 for the two years immediately preceding the date of change of ownership and other required patient
741 information shall be provided to the new owners on the date of change of ownership in substantially
742 the same format as previously used immediately prior to the transfer to provide continuity of
743 pharmacy services.

744 2. The previous owner shall be held responsible for assuring the proper and lawful transfer of
745 records on the date of the transfer.

746 3. The format of the prescription dispensing records which are transferred to a new owner shall
747 comply with the requirements of Chapter 34 (§54.1-3400 et seq.) of Title 54.1 of the Code of
748 Virginia, and this chapter. Failure to comply with this chapter during a change in ownership shall be
749 deemed to be a closing of the existing pharmacy for which the existing pharmacy owner shall be
750 required to provide notice to the board and public in accordance with §54.1-3434.01 of the Code of
751 Virginia and subsection A of this section.

752 **18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.**

753 A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing
754 pharmacy, change the location of an existing pharmacy, move the location or make structural
755 changes to an existing prescription department, or make changes to a previously approved security
756 system shall file an application with the board.

757 B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to
758 anyone for purposes other than for continuity of pharmacy services at substantially the same level
759 offered by the previous owner or for the necessary transfer of prescription records, the owner of the
760 pharmacy acquiring the records shall disclose such information in writing to each patient 14 days
761 prior to the acquisition. Such release of prescription records shall be allowed only to the extent
762 authorized by §32.1-127.1:03 of the Code of Virginia.

763 C. The proposed location or structural changes shall be inspected by an authorized agent of the
764 board prior to issuance of a permit.

765 1. Pharmacy permit applications which indicate a requested inspection date, or requests which
766 are received after the application is filed, shall be honored provided a 14-day notice is allowed prior
767 to the requested inspection date.

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

770 3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150,
771 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

772 4. If an applicant substantially fails to meet the requirements for issuance of a permit and a
773 reinspection is required, or if the applicant is not ready for the inspection on the established date and
774 fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall
775 pay a reinspection fee as specified in 18VAC110-20-20 prior to a reinspection being conducted.

776 D. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until
777 approval is granted by the inspector or board staff.

778 E. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior
779 to the designated opening date. Once prescription drugs have been placed in the pharmacy, a
780 pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there
781 is a change in the designated opening date, the pharmacy shall notify the board office, and a
782 pharmacist shall continue to be on-site on a daily basis.

783 **18VAC110-20-180. Security system.**

784 A. A device for the detection of breaking shall be installed in each prescription department of
785 each pharmacy. The installation and the device shall be based on accepted burglar alarm industry
786 standards, and shall be subject to the following conditions:

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

789 2. The device shall be monitored in accordance with accepted industry standards, maintained in
790 operating order, and shall have an auxiliary source of power, and shall be capable of sending an
791 alarm signal to the monitoring entity when breached if the communication line is not operational.

792 3. The device shall fully protect the prescription department and shall be capable of detecting
793 breaking by any means when activated.

794 4. Access to the alarm system for the prescription department area of the pharmacy shall be
795 restricted to the pharmacists working at the pharmacy, except for access by other persons in
796 accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the
797 prescription department is closed for business.

798 B. Exceptions to provisions in this section:

799 5.1. This regulation shall not apply to pharmacies which have been granted a permit Alarm
800 systems approved prior to November 4, 1993 will be deemed to meet the requirements of
801 subsection A 1, 2, and 3, provided that a previously approved security alarm system is in place, that
802 no structural changes are made in the prescription department, that no changes are made in the
803 security system, that the prescription department is not closed while the rest of the business remains
804 open, and provided further that a breaking and loss of drugs does not occur. If a breaking with a
805 loss of drugs occurs, the pharmacy shall immediately upgrade the alarm to meet the current
806 standards and shall file an application with the board in accordance with 18VAC110-20-140 A.

807 6.2. If the prescription department was located in a business with extended hours prior to
808 November 4, 1993, and had met the special security requirements by having a floor to ceiling
809 enclosure, a separately activated alarm system shall not be required.

810 7.3. This section shall not apply to pharmacies which are open and staffed by pharmacists 24
811 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or
812 owner must immediately notify the board, file an application in accordance with 18VAC110-20-140
813 A, and have installed within 72 hours prior to closing, a security system which meets the
814 requirements of subdivisions 1 through 4 of this section.

815 **18VAC110-20-190. Prescription department enclosures; access to prescription department.**

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

48

818 1. The enclosure shall be constructed in such a manner that it protects the ~~controlled drug stock~~
819 prescription drugs from unauthorized entry and from pilferage at all times whether or not a
820 pharmacist is on duty.

821 2. The enclosure shall be of sufficient height as to prevent a person from reaching over to gain
822 access to the drugs locked and alarmed at all times when a pharmacist is not on duty.

823 3. ~~Entrances to the enclosed area must have a door with no more than a six-inch gap from the~~
824 ~~floor and which is at least as high as the adjacent structure. The requirement for a maximum six-inch~~
825 ~~gap shall not apply to those pharmacies in existence prior to February 3, 1999, with the exception of~~
826 ~~any pharmacy which experiences a related diversion or theft. The enclosure shall be capable of~~
827 ~~being locked in a secure manner, at any time the pharmacist on duty is not present in the~~
828 ~~prescription department.~~

829 4. ~~Doors to the area must have locking devices which will prevent unauthorized entry in the~~
830 ~~absence of the pharmacist.~~

831 B. ~~The door keys or other means of entry into a locked prescription department, and the alarm~~
832 ~~access code to the dispensing areas shall be subject to the following requirements:~~

833 1. ~~Only restricted to pharmacists practicing at the pharmacy and authorized by the PIC shall be~~
834 ~~in possession of any keys to or other means of opening the locking device on the door to such~~
835 ~~enclosure, or to the alarm access code. with the following exceptions:~~

836 2.1. ~~The PIC or a pharmacist on duty, for emergency access, may place a key or other means of~~
837 ~~opening the locking device unlocking the prescription department and the alarm access code in a~~
838 ~~sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault~~
839 ~~or other secured place within the pharmacy or other secured place. This key or code means of~~
840 ~~emergency access shall only be used to allow entrance to the prescription department by other~~
841 ~~pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of~~
842 ~~the pharmacist's signature across a seal, the executive director for the board may approve other~~
843 ~~methods of securing the emergency keys or access codes to the prescription department.~~

844 2. ~~Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or~~
845 ~~pharmacist on duty may possess a key or other means of entry into a locked prescription~~
846 ~~department only when a pharmacist is on duty. Such key or other means of entry shall not allow~~
847 ~~entry when a pharmacist is not on duty.~~

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

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

857 1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular
858 prescription department hours;

859 2. Alternate pharmacist coverage cannot immediately be obtained;

860 3. The technician is accompanied by a member of the pharmacy's management or
861 administration; and

862 4. All requirements of subsection E of this section are met.

863 E. Requirements for entry into the prescription department in the absence of a pharmacist.

864 1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are
865 followed.

866 2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal
867 permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and
868 use the emergency key or other access and alarm access code and enter the pharmacy.